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Life Sciences

UK – Law and Practice

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Contributed by Arnold & Porter LLP ***Authors:*** Lincoln Tsang, Adela Williams, Jackie Mulryne, Ewan Townsend

Law and Practice

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UK LAW AND PRACTICE

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Arnold & Porter LLP's transatlantic life sciences practice provides globally integrated counselling to pharmaceutical, biotechnology, medical device and diagnostic companies, individual scientist entrepreneurs, emerging growth companies, trade associations, investors, non-profit institutions, and universities around the world. Its lawyers advise on the full spectrum of regulatory, transactional and litigation matters. Areas of expertise include global compliance programs, patent procurement, regulatory issues, commercial agreements, internal and government investigations and patent and commercial litigation. The authors would like to acknowledge the contributions of Ian Dodds-Smith, Anna Buscall, Richard Dickinson, Tom Fox, Kathleen Harris, Silvia Valverde, Libby Amos, Louise Strom and Hannah Kerr-Peterson.

Authors

Lincoln Tsang partner, is a former senior regulator, and advises clients in pharmaceuticals, biotechnology, medical devices, in vitro diagnostic devices, cosmetics, and food with particular emphasis on the intersection of the law and public policy. He represents clients on highly technical and precedent-setting regulatory, compliance and enforcement matters. By ministerial appointment, Lincoln Tsang has served as a Commissioner for the British Pharmacopoeia where he chairs the Commissions Biological and Biotechnology Specialist Group and co-chairs the Nomenclature Committee.

Adela Williams, partner, specialises in pricing and reimbursement issues, including all stages of health technology appraisals by the National Institute for Health and Clinical Excellence (NICE), Scottish Medicines Consortium, and the All Wales Medicines Strategy Group. She frequently represents clients at NICE appeal hearings and has acted on behalf of the manufacturer company in two of the three applications for judicial review which have been brought against NICE in the Administrative Court.

Jackie Mulryne, counsel, advises clients in the life sciences, medical devices, cosmetics and foods sectors, and has a broad practice providing regulatory compliance and public policy advice. She advises on UK and EU law, and is highly experienced on a wide range of regulatory issues that arise throughout the product life cycle for both medicinal products and medical devices. In particular, she advises on public and administrative law cases brought before the UK and European courts, arising from the decisions of regulatory bodies in the EU (EMA and Commission) and UK (MHRA and NICE).

Ewan Townsend, counsel, specialises in transactional and regulatory work in the life sciences sector. He has experience in drafting and negotiating a wide range of complex, high value agreements, such as licences and collaboration agreements, manufacture and supply agreements, technology transfers and clinical trial agreements. He is uniquely placed in his ability to advise on the regulatory issues that arise in the context of those transactions, particularly in relation to marketing authorisations, manufacturing and distribution, pricing, advertising and promotion, freedom of information and data protection.

1. Regulatory Framework

1.1 Legislation and Regulation

The regulation of medicinal products in the UK derives from EU legislation, principally Directive 2001/83/EC (the "Directive") and Regulation (EC) 726/2004 (the "EU Regulation"). The key UK legislation is the Human Medicines Regulations 2012 (SI 2012/1916) (the "Human Medicines Regulations").

The Human Medicines Regulations define a medicinal product as follows:

- "any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
- any substance or combination of substances that may be used by or administered to human beings with a view to—
  - (a) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or
  - (b) making a medical diagnosis."

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Medical devices in the EU are currently regulated by three directives (the "Medical Device Directives"):

- Council Directive 93/42/EEC on Medical Devices ("MDD");
- Council Directive 90/385/EEC on Active Implantable Medical Devices ("AIMDD"); and
- Council Directive 98/79/EC on In Vitro Diagnostic Medical Devices ("IVDMD").

The MMD is applicable to all medical devices, which are defined as "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means." This includes items such as heart valves, hip replacements, contact lenses, bandages, inhalers and certain software apps.

The AIMDD concerns active medical devices, meaning any medical device that relies on a source of energy or power, other than that directly generated by the human body or gravity, which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, which is intended to remain there after the procedure. This includes devices such as pacemakers, insulin pumps and cochlear implants.

The IVDMD concerns any medical devices that is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens. This includes items such as pregnancy tests, blood glucose meters and HIV tests.

Before they could take effect, the Medical Device Directives required transposition into domestic law. In the UK, this was achieved by the Medical Devices Regulations 2002/618. As a result of the diverging interpretations, the EU framework has been applied somewhat inconsistently across the Member States. To address this, in September 2012 the European Commission presented two legislative proposals on medical and in-vitro diagnostic devices. This process culminated in two new directly applicable regulations being adopted 25 May 2017, namely:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (the "MDR"); and
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (the "IVDR").

The majority of the MDR and IVDR provisions will apply from 26 May 2020 and 26 May 2022, respectively. The information set out below is based on the UK's current legislation, except where stated otherwise.

1.2 Regulatory Bodies

The Medicines and Healthcare products Regulatory Agency ("MHRA") is an executive agency of the Department of Health, acting on behalf of the UK Licensing Authority, with the statutory responsibility to apply and enforce laws governing pharmaceuticals and medical devices in the UK. The MHRA is responsible for managing applications made through the national, mutual recognition or decentralised procedures. However, any applications for marketing authorisation that are submitted through the centralised procedure fall within the remit of the European Medicines Agency ("EMA"). The EMA advises the European Commission in relation to the supervision of medicinal products authorised in the EU, including those authorised through the centralised procedure.

Pricing and reimbursement matters fall primarily within the competence of the Department of Health.

Notified bodies are private organisations that have been designated by an EU Member State to assess whether manufacturers and their medical devices meet the requirements set out in the legislation. Manufacturers can apply to any notified body within the EU for certification. On receipt of an application, the notified body will conduct an assessment which, if successful, will result in the relevant certification being granted to the manufacturer. This certification allows manufacturers to place CE marks on their products, which in turn permits these products to be placed on the EU market.

In the UK, there are five notified bodies, namely:

- Amtac Certification Services Ltd;

- BSI Healthcare;
- Lloyd's Register Quality Assurance Ltd;
- SGS United Kingdom Ltd; and
- UL International (UK) Ltd.

The MHRA is responsible for ensuring that medical devices placed on the market and put into service in the UK meet the regulatory requirements. Accordingly, the MHRA does the following:

- assesses all allegations of non-compliance;
- monitors the activity of notified bodies that it has designated to assess the compliance of manufacturers;
- investigates medical devices as a result of adverse incident reports or intelligence that indicates a potential problem; and
- carries out proactive risk-based projects with other member states in Europe to identify emerging risks.

1.3 Challenging Decisions of Regulatory Bodies

Decisions of the MHRA can be challenged by way of judicial review in the Administrative Court, Queen's Bench Division.

In order to challenge a decision of the MHRA by judicial review, an application must be made promptly, and in any event within three months of the decision to be challenged; this is a strict deadline that cannot be extended by agreement between the parties. In order to bring a claim for judicial review, the applicants must be able to show a sufficient interest in the matter to which the application relates. This will be shown where a decision of the MHRA directly affects the legal rights of enterprises to market or deal in their products for example, refusal to grant marketing authorisation.

The court's permission is required to proceed with a claim for judicial review. The test for permission to be granted is whether there is an arguable case for judicial review that justifies full investigation of the substantive merits. An arguable case is considered to be one with a realistic prospect of success.

The court's function in judicial review is to assess the decision made by the regulator or public authority for legal error. The court cannot remake the decision or make factual determinations. The grounds for judicial review are evolving but can be summarised under four heads:

- Illegality – did the regulator/public authority misdirect itself in law, exercise a power wrongly, or improperly purport to exercise a power that it does not have?
- Irrationality – is the decision unreasonable, were irrelevant matters taken into account, were relevant matters not taken into account or was an error of fact made?
- Procedural unfairness – were relevant statutory procedures or principles of natural justice not properly observed?
- Legitimate expectation – where the regulator/public authority has set an expectation of how it will behave by its own actions and statements, was this expectation followed?

The judicial review rules and procedures apply equally to challenges concerning other products regulated by a public authority, such as food products.

1.4 Borderlines Between Pharmaceuticals and Other Life Sciences Products

The definition of a medicinal product is set out above. UK law reflects the non-cumulation principle under EU law, whereby products can ordinarily only be regulated as one type of product. The MHRA's Medicines Borderline Section is able to give advice on whether or not a product is likely to be classified as a medicinal product under UK law. Its 'Guidance Note 8' sets out factors that it will consider in determining whether a product should be classified as a medicinal product (rather than, for example, a medical device, cosmetic or food). The MHRA will take account of a range of factors, including:

- claims;
- presentation;
- primary intended purpose;
- pharmacological, immunological, or metabolic properties;
- similar products on the market;
- decisions of other Member States; and
- relevant ECJ/domestic court precedents.

Where doubt remains, the product in question will be classified as medicinal product.

To distinguish between medical devices and medicinal products, it is important to consider the intended purpose of the product, taking into account the way it is presented, and the method by which the principal intended action is achieved.

The principal intended action of a medical device is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions), whereas the principal action of a medicinal product is normally achieved by pharmacological, immunological or metabolic means. A substance administered for diagnostic purposes is also usually considered to be a medicinal product.

Cosmetic products are regulated by the Cosmetic Products Regulation (EC) 1223/2009, which is implemented in the UK through the Cosmetic Products Enforcement Regulations 2013/1478. The definition in the UK Regulations is the same as that in the EU Regulation and focuses on the location of use (the external parts of the body or the teeth) and the purpose – cleaning, perfuming, changing appearance, correcting body odours, protecting, or keeping in good

condition. However, such purposes must not be wholly for the purpose of treating or preventing disease.

Foods and foodstuffs are defined in Regulation (EC) 178/2002, which has direct effect in the UK. The classification of foods and foodstuffs will depend on a range of factors, including the scope of any claims made and the actual effect the product has on the body. For example, if a product has a significant pharmacological, immunological or metabolic action (or claims to do so), it is likely to be viewed as a medicinal product.

The MHRA's Borderline Section is able to issue determinations on whether a product falls within the definition of a medicinal product or a medical device. For food and cosmetics borderline cases, advice can be obtained from the Trading Standards Institute.

1.5 Functional Foods and Nutraceuticals

Functional foods and nutraceuticals must comply with general UK food laws. These are principally derived from EU law, and include:

- Regulation (EC) No 178/2002 (the General Food Law Regulation);
- Regulation (EU) No 1169/2011 (the Food Information Regulation); and
- Regulation (EC) No 1924/2006 (the Claims Regulation).

Where necessary, the UK has implemented the EU legislation by way of several legal instruments. The Food Safety Act 1990 (as amended) and the General Food Regulations 2004 make it an offence to falsely describe a food or provide misleading information regarding its nature, substance or quality. The UK Food Information Regulations 2014 put in place additional requirements concerning enforcement and claims.

Food supplements are regulated by the Food Supplements (England) Regulations 2003 as amended (and equivalent regulations in Scotland, Wales and Northern Ireland), which implement the EU Food Supplements Directive 2002/46.

1.6 Intermediate Categories

Since 20 July 2016, Regulation (EU) No. 609/2013 on foods for specific groups (the FSG Regulation) has regulated the labelling and advertising requirements for food intended for certain specific groups, and sets out specific rules for the following four categories of products:

- infant formula and follow-on formula;
- processed cereal-based food and baby food;
- food for special medical purposes; and
- total diet replacement for weight control.

Food that does not fall within one of these four categories will be subject only to the general food law requirements.

The UK Food for Specific Groups (Information and Compositional Requirements) (England) Regulations 2016 (SI 2016/6881) came into force on 20 July 2016. These implement the minimal requirements of the FSG Regulation and put provisions in place to enable the FSG Regulation to be enforced in the UK.

1.7 Different Categories

There are three categories or "legal classifications" of pharmaceutical products, which determine the level of control over supply. In part, classification rests on how much health professional input is needed to diagnose and treat the conditions for which the medicine might be used. The underlying principle for classifying medicines is to maximise timely access to effective medicines while minimising the risk of harm from inappropriate use.

The three legal classifications are as follows:

- prescription-only medicines (POM) – these have to be prescribed by a doctor or other authorised health professional and have to be dispensed from a pharmacy or from another specifically licensed place;
- pharmacy (also known as over the counter) (P) – this is an intermediate level of control, and products classified as such can be bought only from pharmacies and under a pharmacist's supervision; and
- general sales list (GSL) – these may be bought from general retail stores or vending machines.

As discussed above, there are three main types of medical devices:

- general medical devices;
- active implantable medical devices; and
- in vitro diagnostic medical devices (IVDs).

Medical devices are given a classification depending on the level of risk associated with their use. How a medical device is classified will depend on factors including the intended purpose of the device, how long it is intended to be in use and whether or not the device is invasive/surgically invasive, implantable or active, or contains a substance which in its own right is considered to be a medicinal substance.

General medical devices and active implantable devices fall within the following categories:

- Class I – generally regarded as low risk;
- Class IIa – generally regarded as medium risk;
- Class IIb – generally regarded as medium risk; and
- Class III – generally regarded as high risk.

All active implantable medical devices fall under the highest risk category (Class III).

In vitro diagnostic medical devices are currently categorised into four main groups, namely those which are:

- considered as general IVD medical devices;
- within the classifications stated in Annex II List A of the IVDMD;
- within the classifications stated in Annex II List B of the IVDMD; and
- for 'self-test' intended to be used by a person at home.

However, the classification of IVDs has been revamped under the IVDR which, as discussed above, will be applicable on 26 May 2022.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of medicinal products are regulated by the Clinical Trials Regulations 2004/1031, which implement Directive 2001/20/EC on the conduct of clinical trials (the "Clinical Trials Directive") in the UK. Clinical trials must be conducted in accordance with good clinical practice, as well as the terms of the protocol, clinical trial authorisation and the ethics committee approval. New legislation has not yet been proposed in anticipation of the application of the Clinical Trials Regulation 536/2014.

Clinical investigations for medical devices are regulated by the Medical Devices Regulations (SI 2002/618), which seek to implement Directive 93/42/EEC (the "Medical Devices Directive"), Directive 90/385/EEC (the "Active Implantable Medical Devices Directive") and Directive 98/79/EC (the "In Vitro Diagnostic Medical Devices Directive"), collectively, in the UK. Clinical investigations must be conducted in accordance with Annex X of the Medical Devices Directive, and any conditions imposed by the Secretary of State on the conduct of the trial. New legislation has not yet been proposed in anticipation of the application of the Medical Devices Regulations 2017/745/EU.

2.2 Procedure for Securing Authorisation

Applications for a clinical trial authorisation for a medicinal product are made to the MHRA. It is also necessary to obtain approval from an appropriate ethics committee. A clinical trial can only be started if the competent authorities have concluded that the anticipated therapeutic and public health benefits justify the risks.

After receipt of a valid request for an authorisation, the MHRA will conduct an initial assessment within 30 days. At this time, the MHRA will either accept the request for the clinical trial authorisation, accept the request subject to conditions, or not accept the request, and provide reasons for its decision.

The ethics committee will review certain documents relating to the trial, especially the trial protocol, the informed consent form, the suitability of the personnel, investigator and facilities, and the investigator's brochure. In doing so, the ethics committee will consider the recruitment, compensation and consent of the subjects who will be taking part in the trial. The ethics committee has 60 days in which to form a view on the clinical trial, and must then give a reasoned opinion to the applicant and the MHRA.

The MHRA must also be notified of clinical investigations for medical devices. A sponsor must notify the MHRA at least 60 days before starting the investigation. The MHRA will consider valid documentation, and assess the safety and performance of the device as well as the design of the clinical investigation to be carried out. A letter will be sent to the sponsor within 60 days with a decision (either an 'objection' or 'no objection') as to whether or not the proposed clinical investigation can be carried out.

An opinion of the ethics committee is also required, following a similar process as for medicinal products.

2.3 Public Availability of Databases

The UK Clinical Trials Regulations refer to the EU Clinical Trials Directive, and the obligations set out therein. In the UK, there no independent obligations are imposed on sponsors in relation to the publication of clinical trial data. Instead, the UK requirements refer to Article 11 of the Clinical Trials Directive, which states that Member States have an obligation to enter certain information about trials conducted in their territory onto the European EudraCT database, and are required to make some of that information public.

Similarly, the advertising code for the pharmaceutical industry published by the Association of the British Pharmaceutical Industry (the "ABPI") requires companies to disclose details of clinical trials in accordance with the IFPMA/EFPIA/PhRMA/JPMA's Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases, and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature.

There are no particular obligations relating to the publication of information on clinical investigations.

2.4 Restriction for Using Online Tools

There are no restrictions in relation to using online tools to support clinical trials or clinical investigations. However, all advertising of clinical trials and clinical investigations, and all materials provided or directed to subjects, will be

reviewed by the relevant ethics committee. There may also be a question as to whether any online tool or application may be considered to be a medical device in its own right, depending on its functionality.

2.5 Public or Sensitive Data

When first collected from clinical trial or clinical investigation subjects, data is considered as both personal and sensitive data (under the Data Protection Act 1998, or the corresponding "special category" data under the General Data Protection Regulation 2016 – "GDPR"), as it will concern health, and relates to an identified or identifiable natural person.

If the data is fully anonymised after the initial collection, so that the relevant subject is no longer identifiable or able to be linked to the data, the data may no longer be considered as personal and sensitive/special category data. However, the processes of anonymisation would need to be considered on a case-by-case basis; if the anonymisation is reversible, it may mean the data falls back within the personal and sensitive/special category data classification.

Subject to compliance with the guiding principles for lawful processing of personal data including data security, the resulting data can be transferred to a third party or affiliate, provided that the relevant individual has been informed of this and has provided their consent (where consent is being relied upon as a legal basis for the processing of the data according to a legitimate purpose and is not excessive). Contracts between the sending and recipient entities would need to contain provisions to reflect the GDPR requirements. The GDPR also requires certain criteria to be included in contracts between data controllers (the entities that determine the purposes and means of the personal data processing) and data processors (the entities that process personal data on behalf of data controllers).

If the personal data is intended to be transferred to a country outside of the European Economic Area, the relevant individuals would need to explicitly consent to this, or certain protective mechanisms would need to be put in place. Such mechanisms include the EU-US Privacy Shield or standard contractual clauses that have been approved by the European Commission, or binding corporate internal rules for data transfers within multinational companies.

2.6 Further Requirements

If consent is being relied upon as the legal basis for processing personal or sensitive data, individuals would need to explicitly consent to any processing connected to the database. Safeguards should be put in place to ensure security in authorised access so that the quality and integrity of the data are protected.

In accordance with the legislative principle of transparent processing, individuals would also need to be provided with certain information in relation to the database (such as their rights under the legislation and the potential recipients of their personal data). In addition, the personal data stored on the database would need to be kept up to date, accurate and secure, and kept no longer than necessary for the purposes of the particular processing activities or as required under applicable laws.

3. Marketing Authorities

3.1 Assessment Process and Criteria

Regulation 2 of the Human Medicines Regulations defines a medicinal product as follows:

- any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or
- any substance or combination of substances that may be used by or administered to human beings with a view to:

  (a) restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or
  (b) making a medical diagnosis.

Regulation 2(1) of the Medical Devices Regulations 2002 (SI 2002/618) (the "Medical Devices Regulations") defines a medical device as any instrument, apparatus, appliance, software, material or other article used alone or combined for humans to:

- diagnose, prevent, monitor, treat or alleviate disease;
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap;
- investigate, replace or modify the anatomy or a physiological process; or
- control conception.

To distinguish between medical devices and medicinal products, it is important to consider the intended purpose of the product, taking into account the way it is presented, and the method by which the principal intended action is achieved.

The principal intended action of a medical device is typically fulfilled by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions), whereas the principal action of a medicinal product is normally achieved by pharmacological, immunological or metabolic means. A medical device should not achieve its main intended action by pharmacological, immunological or metabolic means, although it can be assisted by these means.

Where the assessment is not straightforward or disagreement arises, the MHRA's Medicines Borderline Section is able to issue determinations on whether a product falls within the definition of a medicinal product or a medical device. Its 'Guidance Note 8' sets out factors that it will consider in determining whether or not a product should be classified as a medicinal product. The MHRA will take account of a range of factors, including:

- claims made about the product by the manufacturer or on the product information;
- the presentation;
- the primary intended purpose;
- the product's pharmacological, immunological or metabolic properties;
- the classification of similar products on the market;
- the decisions of other EU Member States on similar products; and
- relevant EU Court/domestic court precedents.

Where doubt remains, the product in question will be classified as a medicinal product.

3.2 Types of Marketing Authorisations

Medicinal Products

The Human Medicines Regulations implement EU law regarding the procedures and requirements to obtain a marketing authorisation ("MA"). The general rule is that a medicinal product may only be placed on the UK market if it has been granted an MA. Part 5 of the Human Medicines Regulations sets out the details and conditions for an application for grant of an MA in the UK. In practice, submissions of MA applications must be made to the MHRA, and those submissions that do not meet the relevant requirements will not be validated.

The MHRA may only grant the MA if it is satisfied of the following:

- the applicant has established the therapeutic efficacy of the product;
- the positive therapeutic effects of the product outweigh the associated risks;
- the application is fully compliant with the requirements of the Human Medicines Regulations; and
- the product's qualitative and quantitative composition is as described in the MA application.

In a "full" application" as per Article 8(3), this will usually require the submission of substantial laboratory, pre-clinical (animal) and clinical (from clinical trials in humans) data, known as a full dossier.

Biological medicinal products must meet the same quality, safety and efficacy criteria to obtain an MA as non-biological medicinal products. However, since biological medicinal products are especially sensitive to change in starting materials or manufacturing conditions, Annex I to EU Directive 2001/83/EC (the "Directive") sets out specific requirements applicable to biological medicinal products.

Certain types of application can use the abridged application procedure, whereby the application does not need to provide a full dossier of pre-clinical or clinical data but can cross-refer to data submitted for another medicinal product, known as the reference medicinal product. Abridged applications include the following:

- Generic application: if the new product meets the requirements for a generic product as defined in Article 10(2)b of the Directive, the application may be abridged to refer to the relevant data of a reference product whose data protection period has expired. Therefore, it can be authorised without its own clinical and pre-clinical data (regulation 51 of the Human Medicines Regulations).
- Hybrid application: a hybrid application complying with Article 10(3) of the Directive differs from a generic application in that the results of appropriate pre-clinical tests and clinical trials will be necessary in the following three circumstances: (i) where the strict definition of a generic medicinal product is not met; (ii) where the bioavailability studies cannot be used to demonstrate bioequivalence; and (iii) where there are changes in the product compared to the reference medicinal product (regulation 52).
- Biosimilar application: a biosimilar application complying with Article 10(4) of the Directive differs from a generic application due to differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product. As a result, appropriate pre-clinical tests and clinical trials will be necessary (regulation 53).
- Well-established use application: the new product may include an active substance that has a well-established medicinal use for a particular indication and an acceptable level of safety such that, consistent with Article 10a of the Directive, the applicant may submit published data demonstrating ten years of systematic use to support the safety and efficacy of the product (regulation 54).
- Informed consent application: consistent with Article 10c of the Directive, where a company provides its "informed consent" to rely upon the originator's dossier, a second company can get an exact copy of the MA (regulation 56).

Medical Devices

Before a medical device can be placed on the UK market, it must carry a European Conformity mark ("CE mark"). CE marking is applied by the manufacturer and means that the device meets the relevant regulatory requirements, known as the "essential requirements" contained in Annex I of the EU Medical Devices Directive 93/42/EEC (the "Medical Devices

Directive"), and, when used as intended, works properly and is acceptably safe. When a CE mark is applied to a product, the medical device can be freely marketed anywhere in the EEA without further control.

It is the manufacturer's responsibility to obtain and place the CE mark on the product. If the product is imported from outside the EEA, this responsibility falls to the importer within the EU.

General medical devices may be classified as Class I, Class IIa, Class IIb or Class III. However, it should be noted that, under the new Regulations, the classification rules for medical devices have been expanded (and completely overhauled for in vitro diagnostic devices). There are no grandfathering provisions, so all medical devices already on the market will need to be reassessed in accordance with the new requirements. The process for obtaining a CE mark, and whether this requires the involvement of a notified body, is discussed in the section on obtaining a CE mark below.

3.3 Period of Validity

Medicinal Products

MAs in the UK are valid for five years. However, a marketing authorisation ceases to be valid if the product is not placed on the market within three years of the date of authorisation (known as the "sunset" clause).

The renewal application should be submitted to the MHRA six months before expiry. The authorisation may be renewed on the basis of a re-evaluation of the risk-benefit balance. Once renewed, the MA will be valid for an unlimited period, unless there are justified pharmacovigilance-related grounds to proceed with one additional five-year renewal (regulation 65 of the Human Medicines Regulations).

The MHRA may revoke, vary or suspend a UK MA if any of the 11 conditions listed in regulation 68 of the Human Medicines Regulations is met. This list of conditions includes situations such as the MHRA believing that the product is harmful or that the positive therapeutic effects of the product do not outweigh its risks to the health of patients or of the public, or that the product's composition is not as described in the application for the MA or the material supplied with it.

Medical Devices

A CE mark is valid indefinitely and the underlying conformity assessment does not require renewal, unless the specifications of the device change.

The MHRA has the power to issue:

- restriction notices, in order to restrict the availability of a particular medical device or of devices of a particular class or description;
- prohibition notices, to ban the supply of any goods that are considered unsafe or that do not comply with the Medical Devices Regulations;
- notices to warn, which require a manufacturer to issue a warning at his own expense about any relevant goods that are considered unsafe;
- suspension notices, to suspend the supply of any goods for up to six months where it is suspected that a safety provision has been contravened;
- compliance notices, to formally outline perceived offences under the Medical Devices Regulations and request non-compliance to be corrected;
- forfeiture orders, for goods where there has been a contravention of a safety provision; and
- notices to obtain information, where the MHRA requires a person to furnish information or to produce records to help decide whether to serve, vary or revoke a prohibition notice or a notice to warn.

3.4 Procedure for Obtaining a Marketing Authorisation

Medicinal Products

Process for Obtaining Authorisation

If the applicant wants to market a medicine only in the UK, an application for a UK national MA must be made to the MHRA. Applicants who have an existing authorisation in another Member State can apply under the Mutual Recognition Procedure, describing the UK/MHRA as a Concerned Member State. There is also the option to start a decentralised procedure at EU level, with the UK/MHRA as Reference Member State or as a concerned Member State. All applications must follow the Common Technical Document ("CTD") format.

The procedure takes up to 210 days for decentralised and national procedures, or 90 days for a mutual recognition procedure, excluding the time taken to provide further information or if further data or explanations are required. If the UK is a Concerned Member State, the MHRA will issue a national licence for the product within 30 days of the close of the co-ordinated procedure.

The current fees range from GBP121,664 for a full application made through the DCP with the UK as RMS, to GBP2,564 for a second-wave mutual recognition application for an abridged application. Proof of payment should be included in the application.

Paediatric Population

The Paediatric Regulation 1901/2006 is directly applicable in the UK, so an applicant in the UK may be obliged to conduct paediatric clinical trials or obtain a waiver or deferral, as necessary, and to provide information regarding existing paediatric studies to the MHRA.

Variation
The Variations Regulation (EC) 1234/2008 is directly applicable in the UK.

Type IA variations can be implemented before the MA holder notifies the MHRA, as long as the MHRA is notified within 12 months. The MHRA will take up to 30 days to process the application. Type IAIN variations must be notified "immediately" – ie, within two weeks of the change being implemented.

Type IB variations must be approved before they are implemented. The MHRA will assess the application in up to 30 days, and the MAH will be given a further 30 days to respond to any requests for information.

Major type II variations must be approved before they are implemented. Once the MHRA has all the documents, it will take 30, 90 or 120 days to assess the application, depending on how urgent or complex the changes are, excluding time taken to answer questions.

Fees are up to GBP36,724 for an extended type II complex variation with the MHRA as the Reference Member State; there is no fee for a type IA variation.

Transfer
The transfer of a granted MA from one legal entity to another is referred to as "change of ownership" in the UK. The legal entity taking over the MA is required to submit an application for change of ownership together with a series of supporting documents (such as letters from the manufacturer(s) confirming that it is prepared to manufacture on behalf of the new MA holder). The application will contain all the necessary particulars of the future MA holder and the existing MA, and the new MA holder's declaration of having all the necessary means to comply with the obligations imposed on an MA holder. The application must be signed by the existing MA holder. It is not possible to transfer ownership of pending MAs.

The procedure for a change of ownership is governed by UK secondary legislation and is considered an administrative process. Applications for transfers of ownership attract a fee of GBP442 and take up to 42 days from the date of submission.

Medical Devices
Process for Obtaining Authorisation
In order to obtain a CE mark for a medical device, the manufacturer must follow one of four conformity assessment procedures, depending on the classification of the medical device. The process of conformity assessment is risk-based, having regard to the characteristics of the hazards associated with the device, in order to minimise harm to users.

The manufacturer must select the appropriate Conformity Assessment Procedure to obtain a CE mark for their medical device. For all classes of device, the manufacturer is required to provide a technical file, although the requirements for the technical file will depend upon the Conformity Assessment Procedure selected. As a general rule, the documentation should cover the design, manufacture and intended operation of the product.

The conformity assessment procedure determines whether a device meets all the general essential requirements and relevant design and construction essential requirements contained in Annex I of the Medical Devices Directive. Where available, relevant harmonised standards may be used to demonstrate how the requirements have been met. The Medical Devices Directive contains no specific requirement to undertake clinical testing, although this is required for certain conformity assessment procedures. However, under the new Regulations, the evidence required to demonstrate compliance with the general safety and performance requirements has greatly increased; in particular, clinical data is now required.

All but the very lowest risk devices must have a conformity assessment carried out by an independent certification body, called a notified body. A notified body ensures that manufacturers comply with the requirements, including reviewing clinical and scientific data, manufacturing processes and the quality management system. If they comply, the notified body will issue a CE certificate, which manufacturers can use to show that the device has passed the conformity assessment. Low risk Class I medical devices do not need to go through a conformity procedure with a notified body, but must be registered with the MHRA. For all devices, once the relevant assessment has been successfully completed (and the certificate received, as applicable), the manufacturer may place the CE mark on their medical device and put their device on the UK market.

Paediatric Population
There are no specific obligations to conduct studies of use of the medical device in children in order to obtain a CE mark.

Variation
If any specification, method of manufacture or intended use of a medical device is amended, it is the responsibility of the manufacturer to ensure that the relevant conformity assessment is updated so that the CE mark remains a true representation that the product is fit for purpose.

Transfer
If the ownership of a medical device is transferred to another party, the new party become the legal manufacturer and is responsible for the device's compliance with the CE mark. In cases where the medical device is registered with

the MHRA, the MHRA should be notified of the new ownership. There is a GBP100 fee for each change request, but it is possible to change more than one detail within each registration request.

3.5 Access to Unauthorised Products

Medicinal Products

The Human Medicines Regulations state that a person may not sell or supply – or offer to sell or supply – an unauthorised medicinal product, or a medicinal product otherwise than in accordance with the terms of an MA. However, consistent with Article 5(1) of the Directive, the UK allows an exception to this provision if:

- the medicinal product is supplied in response to an unsolicited order;
- the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;
- the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and
- a number of conditions set out in the Human Medicines Regulations are met, including that written records of the manufacture or assembly of the medicinal product are maintained and made available to the MHRA on request, and manufacture must be undertaken in accordance with an appropriate licence.

The supply of unlicensed products under these provisions is often called "named patient supply" in the UK, although the patient does not, in fact, have to be named by the doctor seeking supply of the unlicensed product.

The Human Medicines Regulations also set out other exemptions, for example where medicinal products other than prescription-only medicines are manufactured and assembled in accordance with the instructions from a healthcare professional, or where general sales list medicinal products are mixed. There are also exemptions in relation to advanced therapy medicinal products prepared on a non-routine basis, and for certain radiopharmaceuticals. An MA is also not required where supply is authorised by the MHRA on a temporary basis in response to a suspected or confirmed spread of agents that may cause harm to human beings, such as chemical agents or nuclear radiation. Unlicensed medicines can also be supplied in the context of clinical trials.

In 2014, the UK government launched the Early Access to Medicines Scheme ("EAMS"), a voluntary, non-statutory scheme that is intended to run in parallel with the above provisions. The scheme allows patients to access innovative unlicensed medicines earlier than the current MA procedures permit, but applies only to medicines that target life-threatening or seriously debilitating conditions for which there are no existing treatments, or where existing treatments are unsatisfactory. There must be sufficient quality, safety and efficacy data available to show that the risk-benefit profile of the product is positive, and that the medicine represents a significant advance in the treatment of an unmet need. Products will normally be eligible for an early access scientific opinion after Phase III clinical trials, although medicines with exceptional and compelling data may be eligible after Phase II.

Medical Devices

Devices that are custom-made for individual patients or intended for clinical investigation do not need a CE mark.

Custom-made medical devices are defined by regulation 5(1) of the Medical Devices Regulations as devices manufactured specifically in accordance with a duly qualified medical practitioner's written prescription that gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient. The manufacturer of a custom-made medical device must meet the requirements of the Medical Devices Regulations that relate to custom-made devices.

The MHRA may also approve exceptional use of a non-compliant device on humanitarian grounds under Regulation 12(5) of the Medical Devices Regulations. These devices do not need a CE mark. A manufacturer can apply to the MHRA to supply a medical device that does not comply with the law in order to protect a patient's health if there is no legitimate alternative available. The same provision may be made for custom-made devices that have not complied with the standard conformity assessment procedure.

3.6 Ongoing Obligations

Pharmacovigilance is defined here as the pharmacological science *relating to the detection, assessment, understanding and prevention of* adverse effects, *particularly long-term and short-term side effects of* medicines.

Technovigilance is defined here as the pharmacological science *relating to the detection, assessment, understanding and prevention of* adverse incidents, *particularly long-term and short-term side effects of* medical devices.

Medicinal Products

Ongoing Obligations

The marketing authorisation holder is responsible for the quality, efficacy and safety of the product throughout the product lifecycle. As part of this, the authorisation holder has an obligation to keep the dossier up-to-date as regards scientific and technical progress. In terms of pharmacovigilance, MA holders are required to operate and audit appropriate pharmacovigilance and risk management systems, to

monitor the safety of their products throughout the products' life cycle, and to detect any change in their risk-benefit balance. As part of their pharmacovigilance systems, MA holders must 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, record and report all suspected adverse reactions occurring in relation to their products, and submit periodic risk-benefit evaluation reports for their products. In addition, they must report any suspected falsified medicines entering the legitimate supply chain (see the section on falsified medicines below).

Post-Marketing Obligations
The MHRA may grant an MA subject to one or more conditions, including:

- to take certain measures for ensuring the safe use of the medicinal product and include them in the risk management plan;
- to comply with obligations on the recording or reporting of suspected adverse reactions that are stricter than the general requirements;
- any other conditions or restrictions with regard to the safe and effective use of the medicinal product; and
- to conduct post-authorisation efficacy studies or post-authorisation safety studies where concerns relating to some aspects of the efficacy or safety of the medicinal product are identified and can be resolved only after the medicinal product has been marketed.

The MA holder must incorporate any such condition into the risk management system for the product.

Medical Devices
Under the current Medical Devices Directive and implementing Human Medicines Regulations, limited post-marketing and vigilance obligations are placed on manufacturers within the legislation itself. However, guidance from the European Commission and international standards set out further detail, such as the details of the quality management system that should be in place to demonstrate compliance with the applicable requirements, and the details of the post-market surveillance that should be conducted, including monitoring and reporting adverse events, and taking appropriate corrective action. In the UK, the MHRA requires the manufacturer to monitor a medical device once it has been placed on the UK market, and to report any serious adverse incidents associated with the product to the MHRA.

The new Regulations place enhanced reactive and proactive post-market obligations on manufacturers. For example, the legislation now sets out specific requirements whereby, depending on the level of risk that the product poses, manufacturers may be required to do the following:

- establish and implement a post-market surveillance system in a manner proportionate to risk;
- develop a post-market surveillance plan;
- submit periodic safety update reports; and
- upon reporting serious incidents, implement field safety corrective action.

The Regulations also introduce greater visibility over the whole supply chain and requirements relating to the traceability of devices.

The Regulations also introduce enhanced obligations on post-market clinical follow-up, whereby the manufacturer must identify potential risks associated with the product as part of the post-market surveillance plan, and conduct post-market clinical follow-up to assess those risks.

3.7 Third-Party Access to Pending Applications

Medicinal Products
Requests for information about MAs and pending MAs may be submitted to the MHRA under the Freedom of Information Act 2000 ("FOIA").

The MHRA releases very little information in relation to pending MA applications. Whilst it will treat requests made under the FOIA on their own merits and in accordance with the legislation, the MHRA recognises pharmaceutical companies' commercial interests in limiting the disclosure of information relating to products they plan to bring to market.

Following the grant or refusal of an MA, the MHRA generally releases detailed information about the application and authorisation, both proactively via disclosures on its websites and also in response to third party information requests. FOIA provides mechanisms whereby personal data, confidential information and commercially sensitive information may be withheld or redacted from documents requested by third parties, and the MHRA typically allows MA holders to comment on any proposed redactions prior to their release. However, information will be considered commercially confidential in only limited situations where specific and actual evidence is provided to show how disclosure would undermine a company's commercial interests.

Medical Devices
The notified bodies registered in the UK (see the section on regulatory bodies detailed above) are private entities, so the access to information provisions that apply to public bodies do not apply. As such, the information pertaining to the device remains the property of the manufacturer, both before and after CE marking.

Once registered with the MHRA, a manufacturer's details will be added to the Public Access Database for Medical Device Registration. Records are listed by manufacturer and

device, and include contact details. Manufacturers of IVDs will not be published on this database, as the IVD Directive contains a confidentiality clause. Other information held by the MHRA could be requested under the FOIA, but will only be provided where no exceptions under the FOIA apply.

The European Database for Medical Devices, or Eudamed, contains data on medical devices that have been collected and entered by Competent Authorities and the European Commission. Eudamed includes data on the following:

- registration of manufacturers, authorised representatives and devices;
- certificates issued, modified, supplemented, suspended, withdrawn or refused;
- data obtained in accordance with the Medical Device Vigilance System; and
- clinical investigations.

Currently, Eudamed can only be accessed by the national Competent Authorities and the European Commission, but parts of the Eudamed database are to be made public under the new Regulations. For example, members of the public will be able to access key information on notified body certificates, suspension, withdrawal and restriction, as well as clinical investigation reports and summaries, and field safety notices.

3.8 Specific Rules for Online Platforms and/or Medical Apps

In the UK, standalone software and medical apps that meet the definition of a medical device (set out in the section on legislation and regulation above) will be regulated as medical devices and are required to be CE marked. Not all apps used in a healthcare setting will be medical devices: a case-by-case assessment is required considering the product's functionality as a whole. The key factor to determine whether standalone software or an app falls within the definition of "medical device" is whether its use has a medical purpose.

3.9 Existing Rules Against Illegal Medicines and/or Medical Devices

Medicinal Products

The Falsified Medicines Directive introduced a number of regulatory measures intended to prevent the entry of falsified medicines into the legal supply chain. These measures were transposed through amendments to the Human Medicines Regulations, which came into force in 2013, and include:

- registration requirements for all brokers of medicinal products as well as manufacturers, importers and distributors of APIs;
- increased obligations to verify that upstream suppliers of medicinal products and active substances are appropriately registered or authorised, and comply with the relevant requirements of GMP and good distribution practice ("GDP"); and
- increased controls over sales of medicines via the internet, including a requirement for pharmacies to register with the MHRA and display the EU common logo.

The Falsified Medicines Directive also provided a further requirement for prescription-only medicines to include certain safety features, including a seal on the outer packaging (to indicate whether the pack has been tampered with) and a unique identifier. Following the publication of delegated legislation, these new requirements will come into force in the UK in 2019.

Medical Devices

The MHRA has enforcement powers under the Medical Devices Regulations and the General Product Safety Regulations 2005 (SI 2005 No 1803). As part of this, the MHRA can investigate any business activity that is covered by these regulations, including falsification and illegal distribution of medical devices. To ensure that medical devices placed on the market and put into service in the UK meet these regulatory requirements, the MHRA assesses all allegations of non-compliance raised using a risk-based system, monitors the activity of notified bodies designated by the MHRA to assess the compliance of manufacturers, investigates medical devices as a result of adverse incident reports or intelligence indicating a potential problem, and carries out proactive risk-based projects with other Member States in Europe to identify emerging risks. These activities form part of the MHRA's market surveillance obligations under EU law and are intended to capture, amongst other things, falsified and legally non-compliant devices.

3.10 Available Border Measures

There are a number of options for using IP rights to tackle counterfeit pharmaceuticals and medical devices at the border, which are discussed under **10 IP Other Than Patent**, below. Counterfeit pharmaceuticals and medical devices can be detained by the UK customs authority – the UK Border Agency ("UKBA") – on entry into the UK. Under Regulation 608/2013 (the "Customs Regulation"), the holder of an intellectual property right ("IPR"), including a patent or a trade mark, can register its right with the UKBA and ask the UKBA to detain goods that are suspected of infringing that right.

4. Pricing and Reimbursement

4.1 Controlling Prices

Statutory controls on pharmaceutical pricing are set out in the National Health Service Act 2006 and subordinate legislation. Products that are not supplied through the National Health Service ("NHS") are not subject to price controls

although, in practice, over 90% of medicines are supplied through the NHS.

The Pharmaceutical Price Regulation Scheme 2014 ("PPRS") is a voluntary agreement negotiated between the Department of Health and the Association of the British Pharmaceutical Industry (ABPI), which controls prices of branded medicinal products indirectly by controlling profit on NHS business and by establishing a budget cap on the total expenditure by the NHS on branded health service medicines, with member companies making PPRS Payments to the Department of Health as quarterly rebates to cover excess expenditure.

Around 10% of companies are not members of the PPRS), and are regulated by the parallel Statutory Scheme, currently set out in the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 (as amended). The Statutory Scheme is applicable only to branded health service prescription only medicinal products. From 1 January 2014, it has imposed a mandatory 15% price reduction on the prices of all medicinal products that were on the UK market on 1 December 2013, with enforcement provisions if the price reductions are not met. However, new regulations (the Branded Health Service Medicines (Costs) Regulations 2018) will come into effect from 1 April 2018, which revise the Statutory Scheme to align it more closely with the PPRS and require scheme members to make rebate payments as a percentage of sales. In addition, however, the 2018 Regulations provide that the maximum price which may be charged for a medicinal product is the price at which that product was on sale for health service purposes on 1 December 2008 less 3.9%. Where a product was not on sale on 1 December 2008, it must be priced as directed by the Secretary of State.

In primary care, the price of some medicinal products is also indirectly controlled by the reimbursement price, as set out in the Drug Tariff (a monthly publication specifying the amounts to be paid to contractors for providing relevant services). These prices are calculated based on sales information provided by pharmacies, manufacturers and wholesalers. Where the Drug Tariff does not list a reimbursement price for a particular medicinal product (which is the situation for most originator products prior to patent expiry) or where a product is prescribed by its brand name, it will be reimbursed at the manufacturer's list price.

Medical devices will only be routinely dispensed in primary care through the NHS if they are included in the Drug Tariff. The Department of Health/NHS Business Services Authority ("NHSBSA") agrees the reimbursement price of the medical device with the device manufacturer at launch. The reimbursement price will principally be determined by comparing the device with similar products on the market and their respective prices. If there are no comparable devices or the applicant submits evidence to support a different price, the reimbursement price is determined by negotiation between the parties. The sale of any device not listed within the Drug Tariff is a matter for negotiation between the seller and the local NHS.

4.2 Regulations and Specific Procedures

New branded health services medicines that contain a new active substance and are supplied by PPRS member companies are subject to free pricing at launch, as are line extensions of such medicinal products where the application for regulatory approval is submitted within five years of the marketing authorisation for the original product being granted; however, the prices of such products must be notified to the Department of Health prior to launch. The price for all other branded products supplied by PPRS member companies must be agreed with the Department of Health, taking into account factors such as clinical need, the price of comparable products, total forecast sales and the likely effect on the NHS medicines bill.

New branded medicines supplied by Statutory Scheme members are priced at the direction of the Secretary of State, taking into account factors similar to those under the PPRS, including whether the product includes a new active substance. There is no formal system of international reference pricing, although the cost of the presentation in other markets is specifically listed as a relevant criterion to which the Secretary of State should have regard.

The prices of branded generic medicinal products are controlled in the same way as originator medicines, under either the PPRS or the Statutory Scheme.

Unbranded generic medicinal products may be priced at the discretion of the manufacturer, with the expectation that prices will be controlled by the effects of competition. To the extent that the price of any medicine not subject to a voluntary scheme is deemed to be excessive, the Secretary of State has power to issue a direction to limit the price, under the National Health Service Act 2006.

4.3 Initial Price Negotiation

All medicines validly prescribed on an NHS prescription may, in principle, be reimbursed from public funds, unless expressly excluded. Schedules 1 and 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 list a limited number of products that may not be prescribed at all by NHS prescribers in primary care (generally on the basis that they are perceived to have no clinical or therapeutic advantage over other cheaper medicines, or are borderline substances with no real clinical or therapeutic value), or may be prescribed in certain limited circumstances or to specified groups of pa-

tients, in which case the prescription must be appropriately endorsed by the relevant prescriber.

In primary care, patients receive medicines prescribed by their general practitioners from pharmacies in the community. They must pay a fixed price for NHS prescriptions, unless they fall within one of a number of exempt categories (for example, children, the elderly and persons suffering from certain chronic diseases). The current prescription charge is GBP8.80.

In relation to the reimbursement of medicinal products used in NHS hospitals, the Health and Social Care Act 2012 established the "national tariff" – a set of prices for defined items of care ("currencies"). Hospitals are paid by commissioners, based on procedures performed or care provided, with the cost of the procedure or care (including the costs of associated medicines and devices) fixed in the national tariff. Certain high-cost medicinal products and medical devices are reimbursed outside the tariff system, and enhanced payments may be made for certain patients.

4.4 Public Funds

When a medicinal product receives an MA, the NHS list price must be notified or agreed (as appropriate) with the Department of Health before it is supplied to the NHS. In principle, all such products may be reimbursed without further cost-benefit analysis.

However, in England most new medicines (and new indications for existing products) undergo health technology appraisal by the National Institute for Health and Care Excellence ("NICE"), which issues guidance to the NHS on the use of the particular medicinal product, based on an assessment of clinical effectiveness and cost-effectiveness relative to alternative therapies. NHS bodies in England are required by regulations to make funding available so that patients are able to access treatments recommended by NICE in technology appraisal guidance, generally from a date three months after the guidance is issued. In cases where the estimated budget impact associated with use of the technology exceeds GBP20 million in any of the first three years after launch, NHS England may ask NICE to delay the period for mandatory implementation.

NICE also assesses some medical devices and diagnostic tests through parallel procedures.

The All Wales Medicines Strategy Group ("AWMSG") issues guidance on new technologies immediately following launch, prior to NICE guidance being issued or where NICE will not be conducting an appraisal. In Scotland, the Scottish Medicines Consortium ("SMC") assesses all new medicines and new indications for existing medicines, and issues guidance close to the product launch. In Northern Ireland, the Department of Health, Social Services and Public Safety considers NICE guidance and reviews it for legal, policy and financial consequences only, before deciding on implementation.

4.5 Cost-Benefit Analysis

While in theory NHS prescribers may prescribe any product they consider to be clinically appropriate for their patients, in practice, NHS commissioners control which medicines may be prescribed through local or national formularies, the content of which is largely determined by the cost-effectiveness of individual products. Treatments recommended by NICE should be included automatically in NHS formularies in England. In contrast, products that are not recommended by NICE are generally not funded on a routine basis. An equivalent approach is taken to products recommended by AWMSG, SMC and the Northern Ireland Department of Health, Social Services and Public Safety in the devolved administrations.

In addition to NICE's recommendations (or those of AWMSG, SMC and the Northern Ireland Department of Health, Social Services and Public Safety), the following factors will be used to determine whether medicines are funded:

- any policy must comply with public procurement requirements;
- the criteria applied in developing the policy must comply with EU law, including the criteria notified to the Commission under the Transparency Directive;
- transparency and fairness require consultation with the holders of MAs directly affected by the application of the policy; and
- the policy must comply with public law principles that prohibit the adoption of inflexible policies, including the exclusion of all new medicines until they have been appraised by NICE, etc, which do not take into account the individual circumstances of a particular patient.

4.6 Regulation on the Prescribing Physicians and Dispensing Pharmacists

Community pharmacists purchase products from manufacturers or wholesalers and are reimbursed by the NHSBSA for the service they provide and the products they dispense at the rate specified in the Drug Tariff, or at the manufacturer's list price if no reimbursement price is set in the Drug Tariff. To the extent that the price paid by the pharmacist is less than that reimbursed by NHSBSA, the pharmacist makes a margin. The extent of the margin is monitored by NHSBSA, and clawbacks are imposed to ensure that pharmacy profits do not exceed defined limits.

There is no generic substitution in the UK, and the Medicines Act 1968 requires the particular product prescribed in

a prescription to be dispensed. However, in general, doctors are encouraged to prescribe products using their international non-proprietary name ("INN") and NHS prescribing systems convert prescriptions for a branded product to the INN, unless the doctor specifies otherwise. Where a product is prescribed by INN, the pharmacist may dispense any product that meets the specifications/INN described, and is likely to select the lowest-cost product.

5. Promotion and Advertising

5.1 Governing Rules

The promotion of pharmaceuticals in the UK is controlled by a combination of legislation and self-regulation by reference to national codes of practice.

The key legal provisions regarding the advertising of medicines are found in Part 14 of the Human Medicines Regulations, which are supplemented by guidance from the MHRA ("the Blue Guide"). Part 14 and the Blue Guide cover advertising aimed both at healthcare professionals ("HCPs") and at the general public. The Bribery Act 2010 overlaps with certain areas covered by the medicines advertising legislation to the extent that these are concerned with interactions between industry and HCPs and other decision makers.

There are different rules for the advertising of medicines to the public and advertising aimed at HCPs. Advertising to the public is permitted for medicines legally classified as Pharmacy Sale or General Sale List, while advertising for prescription-only medicines may only be targeted at "persons qualified to prescribe or supply" medicines.

The laws governing the promotion and advertising of medical devices are less detailed than those established for medicines. The Medical Devices Regulations 2002 implement the EU Medical Devices Directives and do not regulate advertising material per se, although they cover the issues of labelling, information to be supplied with medical devices and the CE mark. The advertising of medical devices is therefore governed by general consumer legislation such as the Sale of Goods Act 1979, the Consumer Protection from Unfair Trading Regulations 2008, the Business Protection from Misleading Marketing Regulations 2008 and the Bribery Act 2010.

The new EU Medical Devices Regulations (Regulation 2017/745, the "MDR" and Regulation 2017/746, the "IVDR") entered into force on 25 May 2017 but will not apply fully until after the transition period has ended, on 25 May 2020 and 2022 respectively. During the transition period, devices can be placed on the market under the current EU Medical Devices Directives, or the new EU Medical Devices Regulations (if they fully comply with the new EU Medical Devices Regulations). Article 7 of the new EU Medical Devices Regulations, which are directly effective in the UK, includes a new requirement concerning claims. In particular, when advertising a medical device, it is expressly prohibited to make claims that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

- ascribing functions and properties to the device that it does not have;
- creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
- failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; or
- suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

When placing devices on the market in the UK under the new EU Medical Device Regulations, Article 7 must be complied with in addition to the general consumer legislation outlined below.

5.2 Obtaining an Authorisation

Advance notification or authorisation of advertising of medicines and medical devices is not generally required; however, section 304 of the Regulations provides the MHRA with the power to issue a notice requiring any person concerned with the publication of advertisements relating to medicinal products to supply copies of advertisements prior to publication, and not to use those advertisements until they have been approved. It is a criminal offence to fail to comply with such a notice. Circumstances in which pre-use vetting may be required include the following:

- where a newly licensed product subject to intensive monitoring is placed on the market;
- where a product is reclassified – for example, from prescription-only to pharmacy; or
- where previous advertising for a product has breached the Regulations.

Pre-use vetting may also be requested as a result of a major new indication for use, or where there are safety concerns. In addition, the MHRA has committed to vet initial advertising for all new active substances.

The duration of the vetting is commonly two to three months, and does not normally extend for longer than six months. This period can be reduced or extended depending on the quality of the initial advertising material submitted and other relevant factors.

Companies are also able to seek guidance from the MHRA on proposed advertisements, or to request a meeting to discuss issues that arise during the vetting procedure.

From a self-regulatory system point of view, the Association of the British Pharmaceutical Industry Code of Practice (the "ABPI Code"), administered by the Prescription Medicines Code of Practice Authority ("PMCPA"), does not require any prior approval for the advertising of POMs but, again, guidance can be sought prior to publication. MHRA vetting does not guarantee compliance with the ABPI Code.

In the case of over-the-counter medicines, the Proprietary Association of Great Britain ("PAGB") Consumer Code requires prior approval. However, this requirement does not apply to advertisements aimed at persons qualified to prescribe or supply medicines, or their employers (caught by the PAGB Professional Code). The PAGB reviews all members' advertising to the public against their code of practice.

There are no authorisation or pre-notification requirements for the promotion and advertising of medical devices in the UK.

5.3 Self-Regulatory Body

The self-regulatory system for medicines is controlled by the above-mentioned ABPI Code and the PAGB codes, which apply to the advertising of prescription-only medicines and the advertising of over-the-counter medicines respectively. The activities of companies that do not agree to be subject to the self-regulatory regimes are controlled directly by the MHRA.

The Advertising Standards Authority ("ASA") administers the Committees of Advertising Practice Codes and has competence to hear complaints about advertising generally, including the advertising of medicines to the general public. The types of complaints the ASA normally reviews are those that fall outside the remit of the PMCPA or PAGB and, in particular, those concerning borderline products.

In practice, the majority of advertising complaints concerning medicines (including those made by HCPs) are dealt with under the self-regulatory system. There is a memorandum of understanding between the ABPI, PMCPA and the MHRA clarifying the relationship between the self-regulatory process and the enforcement function of the MHRA, and another memorandum of understanding between the ABPI, PMCPA and the Serious Fraud Office ("SFO") clarifying the synergies between these two complementary systems of control.

The SFO is responsible for enforcing the Bribery Act 2010 and, as a general matter, has endorsed the efforts of the MHRA and ABPI to control medicines advertising regarding those activities covered by the Human Medicines Regulations, the ABPI Code and the Bribery Act.

As the PMCPA is performing a general regulatory and public law function in relation to the advertising of medicines, its decisions have, in one case, been found to be subject to judicial review by the Administrative Court, but it is possible that another court would take a different view of the PMCPA's role.

The self-regulatory regime for the medical technology or devices sector is primarily controlled by the Association of British Healthcare Industries (ABHI) in accordance with the principles set out in its Code of Business Practice, which requires any advertising of medical devices to be accurate, balanced, fair, objective and unambiguous. The ABHI Code, along with the Eucomed Code of Ethical Business Practice, governs collaborations and other interactions between medical device manufacturers and HCPs.

5.4 Sanctions or Provisional Safety Measures

Under the statutory process, sections 304, 305 and 306 of the Human Medicines Regulations provide the MHRA with the power to issue notices prohibiting the publication of specified advertisements. The sanctions that may be determined if the advertising regulations are breached are detailed in the section on self-regulatory/state system sanctions below.

Since there is no specific regulation of the advertising of medical devices under UK law (as opposed to self-regulation, addressed below), the sanctions/provisional safety measures include only those set out in general consumer law, which also apply to medicines.

5.5 Enforcement by Competitors or by Third Parties/Bodies

In practice, the majority of advertising complaints are raised by competitors, but all competent bodies, the MHRA, the SFO and the ABPI can hear complaints from whatever source, including HCPs and other interested parties (including journalists and members of the public).

The MHRA and the SFO will routinely decline to investigate cases where they are aware that a self-regulatory body such as the PMCPA is investigating, but reserve their right to take action if serious public health concerns are raised (in the case of the MHRA) or if the complaint meets its criteria of serious fraud (in the case of the SFO), or if self-regulation fails in the sense that a company is a persistent and serious offender.

Competitors make complaints about medical devices to the ABHI. Complaints about advertising to consumers may be directed to the Advertising Standards Authority. The self-regulatory bodies prefer to resolve complaints informally,

with companies agreeing to correct their advertising voluntarily; prosecutions for advertising offences are rare.

Generally, it is unusual for competitors to take direct action through the courts. The unfair competition causes of action available in some Member States are not part of UK law; slander of goods and other tortious causes of action do exist, but often involve difficult issues of proof.

5.6 Sanctions Provided by the Self-Regulatory/ State System

Under the statutory system, a person contravening the Human Medicines Regulations faces a fine if the matter is dealt with by the Magistrates' Court. If the matter is dealt with by the Crown Court, imprisonment may be imposed for a period of up to two years on responsible individuals, in addition to or instead of a fine. The courts have discretion over the amount of the fine imposed.

Under the self-regulatory system, if a company is found in breach of the ABPI Code, the PMCPA may impose administrative charges of GBP3,500 per matter for pharmaceutical companies (both members and non-members of the ABPI), or GBP12,000 if the matter is unsuccessfully appealed. The PMCPA also has the power to suspend or expel a company from the ABPI, and to require an audit of a company's promotional procedures. The PAGB does not impose financial sanctions but has the power to expel a company from the association if it has failed to comply with the PAGB Code.

Under the statutory process, sections 304, 305 and 306 of the Human Medicines Regulations provide the MHRA with the power to issue notices prohibiting the publication of specified advertisements. In these cases, the MHRA notifies the company issuing the advertising that it is minded to consider such advertisement to be in breach of the Regulations, and the company has the right to make written representations to the Independent Review Panel for Advertising, which gives advice to the MHRA. If the MHRA issues a final notice determining that the advertisement is in breach, the company has no further right of appeal and will commit a criminal offence if it publishes the advertisement again. There are no specific time limits set out for the duration of the process but, in practice, it may take a few months from first notification to final MHRA determination.

For complaints submitted to the MHRA by competitors, the MHRA endeavours to complete its investigations within 30 days. This timeframe may be extended if the discussions with the respondent are detailed, or if the MHRA has taken formal legal action. Where appropriate, the MHRA may refer the complaint to one of the regulatory or self-regulatory bodies that deal with the advertising and promotion of medicines.

On the self-regulatory side, there are no time limits specified for the total duration of the process before the PMCPA, which can take from a few weeks to a few months where an appeal to the Appeal Board occurs. The PMCPA requires companies to engage in inter-company dialogue in advance of any complaint being accepted. In practice, some issues are resolved after a few weeks of inter-company dialogue. If the PMCPA finds that the advertising in question breached the ABPI Code, the respondent has five working days to provide an undertaking that the activity or use of the material will cease. The respondent has the option of appealing the decision but use of the promotional material or activity at issue must be suspended pending the final outcome.

Complaints under the PAGB Code are considered by the Complaints Committee and can be appealed to the Appeal Board. The PAGB has a complaints procedure in place for advertising to HCPs but not in respect of consumer advertising; instead, PAGB administers a vetting process for its members' consumer advertising material. If this material is the subject of complaint, the complaint is handled by the ASA.

In relation to medical devices, the ABHI operates a similar enforcement system to that of the ABPI and PMCPA, whereby member companies may ultimately be expelled from the ABHI. However, there is little practical experience with the operation of the ABHI complaints procedure, as there have only been approximately 30 complaints to date. None of these has gone through the entire complaints procedure, with cases being either settled through mediation or withdrawn before the full investigation is completed.

Complaints about consumer advertising of medicines or medical devices can also be submitted to the ASA. There are no set timelines for resolution of a complaint by the ASA, and the length of the process depends on the complexity of the issue at hand.

5.7 Restrictions Regarding Gifts and Sponsorships

All interactions with HCOs and HCPs must comply with the Bribery Act 2010, and particular care must be taken when transferring something of value to a healthcare organisation or HCP. The ABPI and ABHI Codes provide guidance on the standards that are expected of pharmaceutical and medical device companies in this respect.

As a general rule, gifts cannot be provided to HCPs or organisations. The prohibition includes inconsequential items such as mugs, calendars and even items for use with patients, such as surgical gloves and tissues. An exception exists for inexpensive notebooks and writing utensils that do not bear product branding and are provided by the company at scientific meetings (stationery for use at third-party events must bear no product or company branding); the total cost of all

such items provided to an individual attending a meeting must not exceed GBP6 excl. VAT. Exceptions also exist for other items – in particular, items intended to be provided to patients via HCPs as part of a patient support programme (the items must be inexpensive and directly benefit patient care) and certain items for HCPs containing educational or promotional material eg, memory sticks, promotional aids and textbooks.

Companies are also allowed to provide HCOs with medical and educational goods and services ("MEGS") that benefit the NHS and/or enhance/maintain patient care or are made for the purpose of supporting research. These are considered as donations, grants or benefits in kind. MEGS should not bear product branding but may bear a company name and, in any event, the involvement of the company must be made clear to any HCO or HCP receiving the MEGS.

There is no legal rule obliging disclosure of this information in the UK but members of the ABPI are obliged by the ABPI Code to disclose publicly certain transfers of value they make directly or indirectly to HCPs and HCOs located in Europe. Pharmaceutical companies who are not members of the ABPI may do so on a voluntary basis.

The transparency requirements under the ABPI Code are based on and broadly consistent with the EFPIA Disclosure Code 2014. The categories of information that must be disclosed are similar to those set out in the EFPIA Code and include the following:

- payments made via joint working arrangements;
- donations, grants and benefits in kind;
- research-related payments;
- sponsorship of attendance by HCPs and other relevant decision makers at meetings;
- fees and expenses paid to HCPs and other relevant decision makers, or to their employers, for consultancy services; and
- contributions towards the costs of meetings paid to HCOs.

Under the ABPI Code, transfers of value must be disclosed annually via the ABPI's central platform. A template available to download from the PMCPA's website must be used to disclose the data. Disclosure should take place within the first six months after the end of the calendar year in which the transfers of value were made.

The ABHI Code and the MedTech Europe Code of Business Practice set out transparency requirements applicable to interactions between medical technology companies and healthcare providers. Under the ABHI Code, direct sponsorship to individual HCPs is in the process of being phased out. From the end of the transitional period on 1 January 2019, member companies will not be able to provide financial or in-kind support directly to individual HCPs to cover the costs of their attendance at third-party organised educational events.

As of 1 January 2018, ABHI member companies are required to gather data regarding educational grants provided to HCOs, with a view to publicly disclosing them on 1 January 2019. The information to be disclosed will be the aggregate amount of all the grants provided to each healthcare organisation during the previous reporting year. It is anticipated that this information will be disclosed in the MedTech public platform currently being built for this purpose.

5.8 Most Common Issues

A high proportion of the complaints received by the MHRA in the past couple of years are about advertising to the public of botulinum toxin products and other prescription-only-medicines. The advertising material that was the subject of these complaints predominantly appeared on websites, but in the past few years the MHRA has seen an increase in the number of complaints about advertising on social media such as Facebook and Twitter. Another common issue encountered by the MHRA is some large supermarkets and other retailers not adhering to the MHRA guidelines on OTC sales of aspirin and paracetamol.

The subject of complaints under the ABPI Code is very varied and includes complaints by competitors and HCPs on misleading advertising, comparative advertisements, advertising of off-label and unlicensed medicines, inappropriate arrangements for advisory board meetings and other meetings involving HCPs, and the provision of MEGS by companies.

In relation to the advertising and promotion of medical devices, the most common complaint received by the ABHI to date concerns comparative claims made against another company's products. All these complaints have been resolved through mediation between the companies by the ABHI secretariat and the Complaints Panel Chairman.

5.9 Consumer Protection Rules

The advertising of both medicines and medical devices is governed by the general consumer legislation, including the Sale of Goods Act 1979 and the Consumer Protection from Unfair Trading Regulations 2008.

Advertisements for medicines and medical devices must also comply with general consumer protection self-regulatory instruments, namely the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code) and the UK Code of Broadcast Advertising (BCAP Code). These instruments are enforced by the Advertising Standards Authority (ASA). Both the CAP and BCAP Codes contain specific rules in relation to the advertising of health products.

Under UK law, misleading advertisements include those that contain false information or those where the overall presentation deceives or is likely to deceive the average consumer in relation to, for example, the availability, benefits, risks or composition of the product. An advertisement can also be considered misleading if it creates confusion with any products, trade marks, trade names or other distinguishing marks of a competitor.

6. Manufacturing

6.1 Manufacturing Plants Subject to an Authorisation

Pharmaceutical Products

A manufacturer licence issued by the MHRA is required in order to manufacture finished pharmaceutical products. Following submission of an application, the MHRA will perform an inspection of the designated manufacturing site to verify compliance with good manufacturing practices. Applications are generally processed within 90 working days, although timings can vary depending on how quickly an inspection can be carried out, subject to the availability of inspectors, and whether there are any deficiencies that the applicant is required to address before the MHRA can make a determination on the granting of a manufacturer's licence. The current fee for a standard manufacturer's licence is GBP3,143 plus a GBP2,655 inspection fee.

A manufacturer licence may be restricted to the manufacture and control of specific product types, such as sterile products. The MHRA is responsible for regulating the manufacturing site and relevant personnel (including the 'Qualified Person') located in the UK.

Once granted, the manufacturer receives a licence document setting out the specific terms of the licence. This licence remains in force until it is revoked by the MHRA or surrendered by the licence holder.

For facilities located outside of the EU/EEA where no mutual recognition agreement exists and where the MHRA acts as the Supervising Authority, a manufacturer's certificate of good manufacturing practice ("GMP") is issued for each inspected site.

Medical Devices

Manufacturers of medical devices are not required to obtain specific authorisation to manufacture. Depending on the classification of the medical device, its legal manufacturer may be required to register with the competent authority (the MHRA in the UK) or be assessed by a notified body in order to place the medical devices on the market in the UK.

7. Distribution

7.1 Establishments Engaged in Wholesale

Pharmaceutical Products

A wholesale distribution authorisation issued by the MHRA is required in order to engage in the sale, supply, offer for sale or supply of prescription-only, pharmacy, traditional herbal and general sales list medicines in the UK, or to import unlicensed medicinal products into the UK from countries inside the European Economic Area ("EEA"). Applicants for a new wholesale distribution authorisation or wholesale dealer licence should apply using the MHRA's online Process Licensing Portal. As with manufacturer licences, applications are generally processed within 90 working days. The current fee for a wholesale distribution authorisation is GBP1,803 plus a GBP1,936 inspection fee.

The facility involved in wholesale dealing is subject to inspection by the MHRA before a wholesale dealer licence is granted.

The site and relevant personnel (including the 'Responsible Person') must be located in the UK.

Once granted, the wholesaler receives a licence document certifying compliance with good distribution practice, detailing the types of products being handled for each inspected site. A wholesale distribution authorisation remains in force until it is revoked by the MHRA or surrendered by the authorisation holder.

Medical Devices

Distributors of medical devices are not required to obtain an authorisation to engage in wholesale trade.

7.2 Different Classifications

Medicinal products are classified within three categories:

- Prescription-Only Medicine (POM) – POM products must be prescribed by a doctor or other health professional, and must be dispensed from a pharmacy or other appropriately licensed premises;
- Pharmacy (P) – P products are available from pharmacies and subject to a pharmacist's supervision; and
- General Sales List (GSL) – GSL products may be bought from retail stores such as newsagents, supermarkets and vending machines.

8. Import and Export

8.1 Governing Rules

Importing and exporting medicinal products is governed by the Human Medicines Regulations, and importing medical devices is governed by the Medical Devices Regulations

2002. There are no specific rules regarding exporting medical devices.

8.2 Governmental Entities

HM Revenue and Customs is responsible for border control. The MHRA Enforcement Group is responsible for applying and enforcing the Human Medicines Regulations 2012 and the Medical Devices Regulations 2002.

8.3 Importer of Record

Imports are currently treated differently depending on whether the goods are being imported from countries within or outside the EU. Most goods imported from other EU countries are freely circulating on the EU single market and so can be imported with minimal customs control and no import duty or VAT to pay. Importers of goods from outside the EU must make an import declaration to customs, and will generally have to pay import duty and import VAT.

Businesses that are established in the EU, actively involved in customs operations and international trade and have an Economic Operator Registration and Identification (EORI) number can register with HM Revenue and Customs (HMRC) as Authorised Economic Operators (AEO). The scheme is not compulsory, but companies that meet the requirements can take advantage of simplified customs procedures for the security and safety of their imported goods in transit.

It should be noted that the designation of a particular entity as the importer of record for customs purposes will not be conclusive in determining who should hold any required import authorisations from a regulatory perspective.

8.4 Prior Authorisations

Pharmaceutical Products

Medicines authorised in the UK and another EU Member State may be parallel imported from that other Member State and marketed in the UK, provided the imported product has no therapeutic difference from the corresponding UK product.

Parallel importers must submit an application to the MHRA for a Parallel Import Licence prior to any importation. They must also hold a wholesale distribution authorisation covering importing, storage and sale of the relevant products. Any relabelling or repackaging activities will likely require a manufacturer licence.

Medicines that are unlicensed in the UK can be imported and used to meet the special clinical needs of a patient that cannot be met by a licensed medicine.

Importing unlicensed medicines from outside the EEA requires a manufacturer 'specials' licence, whilst importing an unlicensed human medicinal product from within the EEA requires a wholesale distribution authorisation. These licences must be valid for the import and handling of unlicensed medicinal products.

Importers should send the MHRA a completed notification of intent form 28 days prior to import. If the MHRA does not object within 28 days (on the basis of concerns about the product's safety or quality, if there is an equivalent licensed product available that will meet the special clinical needs of the individual patient or if there is no special clinical need for a patient to have the product), then the import may proceed. In the event of clinical emergencies, the MHRA is able to process import notifications within one working day.

There are no formal restrictions on an individual importing medicines into the UK, provided they are strictly for use by that person or a member of their immediate family. Consequently, no authorisation is required to aid personal importation. The MHRA considers personal use to involve up to a three-month supply for use by an individual or their immediate family or household, with no onward sale or supply.

Medical Devices

Importers of medical devices from outside the EU are not required to obtain an import authorisation, but will instead become legally responsible under the medical devices legislation for those devices. They may choose either to sell under the name of the manufacturer as its local authorised representative, or to sell on an 'own brand' basis (which will require agreement with the manufacturer ensuring the provision of technical documentation relating to the CE marking).

8.5 Non-Tariff Regulations and Restrictions

A common customs tariff is charged across all EU countries on goods imported from outside the EU. Details of specific tariff duties and measures are contained in the Integrated Tariff of the United Kingdom. The Tariff is used to determine the specific classification code of your goods, and to find out:

- any licensing requirements that apply;
- the rates of duty and import VAT that apply;
- any additional charges, such as anti-dumping duties; and
- any available preferential duty rates.

An importer or exporter is responsible for the correct tariff classification of goods. Goods and commodities are classified in order to identify what duties and controls apply, to make correct import and export declarations, and to make sure correct customs declarations and Intrastat returns are made.

HMRC has developed an online Trade Tariff tool to assist in product classification.

HMRC also applies Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff for the goods use. This complements HMRC classification guides for classifying pharmaceutical products for import and export, as well as those products that fall outside of the UK Trade Tariffs. Pharmaceutical products are classified in chapter 30 of the Tariff according to their nature, the way they are made up (for example, in measured doses like tablets or ampoules), and whether or not they are intended for retail sale.

8.6 Exportations of Intangibles

The UK imposes export controls on items that could be used for military purposes, torture or capital punishment, or for developing or manufacturing chemical, biological or nuclear weapons.

8.7 Control of Exports of Dual-Use Goods

The main legal basis for controls on exports of "dual-use items" is the EU Dual-Use Regulation 428/2009 (as amended), which is directly applicable in the UK. In addition to dual-use goods controlled by the EU Dual-Use Regulation, a number of dual-use items are listed in separate UK legislation. A consolidated list of strategic military and dual-use items that require export authorisation is published by the Department for International Trade and includes biological agents, toxins, genetically modified organisms, pathogens, toxic chemicals, and technology for the development or production of these materials.

8.8 Provisions on Trade/Regulatory Facilitation

The UK participates in the free trade arrangements of the EU and European Free Trade Association (EFTA), and is a member of the World Trade Organization (WTO).

8.9 Economic Sanctions

The UK's declared policy is to put sanctions and embargoes in place as political trade restrictions against target countries, with the aim of maintaining or restoring international peace and security. When a sanction or embargo is set, the UK follows international procedure to put it in place in British law. The UN Security Council imposes sanctions through Security Council Resolutions. The EU acts on these by adopting a Common Position and, where appropriate, an EU regulation directly applicable to member states is introduced. Where sanctions and embargo measures require more than administrative action to implement them, the UK introduces new or amends existing secondary licensing and enforcement legislation.

The most frequently applied measures are as follows:

- embargoes on exporting or supplying arms and associated technical assistance, training and financing;
- a ban on exporting equipment that might be used for internal repression;
- financial sanctions on individuals in government, government bodies and associated companies, or terrorist groups and individuals associated with those groups;
- travel bans on named individuals; and
- bans on imports of raw materials or goods from the sanctioned target.

Other measures may be applied according to individual circumstances.

9. Patents

9.1 Laws

Applicable Laws

UK patents are subject to the Patents Act 1977 as amended ("Patents Act"), as interpreted in a substantial body of case law. The UK is a common law jurisdiction with a binding system of precedent, so the UK courts are bound to follow earlier decisions on the interpretation and application of the Patents Act.

The UK is a signatory to the Patent Co-operation Treaty 1970 ("PCT") and the European Patent Convention 2000 ("EPC 2000"), which are implemented in the Patents Act. The PCT is administered by the World Intellectual Property Office, and most jurisdictions likely to be of interest to a patent applicant are signatories. The PCT provides a single route for filing an application in all of the contracting countries, but examination and grant are dealt with by national or regional patent offices. The EPC 2000 provides a single route for the examination and grant of a patent across all contracting European states via the European Patent Office, although once granted a European patent operates as a bundle of individual national patents.

The UK is also a signatory to the Unified Patent Court Agreement ("UPCA") which, together with the associated EU regulations establishing the Unitary Patent, provides for the grant and enforcement of a single unitary patent across all participating EU Member States. The UPCA (and consequential amendments to the Patents Act) will come into force once it has been ratified by the UK and Germany. However, the combination of Brexit and a constitutional challenge to the UPC Agreement in Germany has made it uncertain whether the UPCA will come into force in its current form, or at all. There is no clear timetable at present.

Finally, extensions of UK patents by supplementary protection certificates ("SPCs") and paediatric extensions are governed by EU law, as discussed further below.

Contributed by Arnold & Porter LLP ***Authors:*** Lincoln Tsang, Adela Williams, Jackie Mulryne, Ewan Townsend

Issues Arising
Pharmaceutical patents are frequently subject to validity challenges in the UK courts, particularly challenges to the validity of second medical use patents on the ground of obviousness and, increasingly in recent years, lack of plausibility (though the availability and scope of this ground is currently under consideration by the Supreme Court in Warner-Lambert v Mylan & Actavis). SPCs for pharmaceutical patents are also frequently challenged, and there is considerable uncertainty across Europe as to when an SPC is available and the scope and duration of protection. This uncertainty has led to a number of references from the UK courts to the Court of Justice of the European Union ("CJEU") on the correct interpretation of the SPC legislation.

Patentability Requirements
An invention (pharmaceutical or otherwise) is patentable if it is new, involves an inventive step, is capable of industrial application (a fairly low hurdle) and is not specifically excluded from patent protection (eg, methods of diagnosis and methods of treatment by surgery or therapy are excluded categories).

As in other European jurisdictions, UK law requires claims to a specific medical use of a pharmaceutical substance or composition to be drafted in a particular form. Historically, claims to a specific use of a known pharmaceutical could only be protected using the "Swiss-type" form: "the use of substance X for the manufacture of a medicament to treat indication Y". This form was used in order to avoid the prohibition on patenting methods of treatment. Following the revision of the Patents Act to implement the EPC 2000, such claims must now be in the form of "substance X for use in the treatment of indication Y". As the change in form was only implemented by the European Patent Office and the UK Intellectual Property Office in 2010, pharmaceutical patents currently in force may contain claims of either form, depending on the date of grant.

9.2 Patentable Subsequent Medical Uses

Second Medical Uses
Claims to second and subsequent medical uses are patentable as long as they fulfil the usual requirements of patentability, including novelty and non-obviousness, subject to the above-mentioned requirements regarding form of claim.

New Dosage Regimes and Patient Populations
Claims to new dosage regimens or to new or selected patient populations are patentable on the same basis.

Activities Constituting Infringement
The English courts considered the issues surrounding infringement of second medical use patents for the first time in the Warner-Lambert v Mylan & Actavis case concerning the drug pregabalin.

In relation to direct infringement (ie, disposal/offering to dispose/use/importation of a product obtained directly by means of the patented process), there remains a question mark over intention. Although technically obiter dicta (as the relevant claims of the patent were held to be invalid), the Court of Appeal considered that it was enough to infringe a "Swiss form" claim for the manufacturer to foresee the intentional use of the drug by the end user for the specified purpose, unless the manufacturer took all reasonable steps within his power to prevent that happening. On appeal to the Supreme Court, the generic manufacturers contend that infringement requires actual intention by the manufacturer that the product should be used for the specified purpose (ie, manufactured to be used for the treatment of indication Y). The Supreme Court hearing took place in February 2018 and judgment is likely in summer 2018..

In relation to indirect infringement, contrary to the view of the trial judge (Arnold J), the Court of Appeal considered that the process of preparing the composition can continue through any packaging step performed by the manufacturer, and includes the labelling step performed by the pharmacist. The Supreme Court may also provide clarity on this issue.

The English courts have not yet fully considered the question of final relief, although Arnold J opined that a traditional style of injunction (ie, infringer A shall not infringe patent B) may not be appropriate for a second medical use patent. In the Warner-Lambert case there was substantial discussion regarding interim remedies; most notably, the court ordered that NHS England should issue guidance to clinical commissioning groups and the NHSBSA that pharmacists should prescribe only the patentee's product for the patent-protected second medical use.

9.3 Mechanisms for Patent Term Extension

Patent term extensions in the UK are governed by EU Regulation 469/2009 (the "SPC Regulation") and Regulation 1901/2006 (the "Paediatric Regulation").

The SPC Regulation provides for a patent's term to be extended for a period equal to the period between the date of filing of the patent and the date of grant of the first authorisation to place the product on the market in the EU, less five years. The extension is subject to a maximum duration of five years. The Paediatric Regulation provides for an additional six-month extension of term if the patent holder completes an agreed Paediatric Investigation Plan to determine whether the product is safe for use in children.

Application of the Provisions
Only one SPC may be granted per product per patent holder, and the product must be "protected" by the patent in question in order for that patent's term to be extended. As mentioned above, there is considerable uncertainty as to the ap-

plication of the SPC Regulation, particularly in relation to combination products and where the patent claims adopt functional definitions or use Markush formulas to define products. This uncertainty has given rise to a large number of disputes in the UK courts, many of which resulted in the UK court referring questions of interpretation of the SPC Regulation to the CJEU, although the CJEU's answers have still not provided certainty.

Challenge to Extensions
Patent term extensions can be challenged by bringing an action for revocation of the SPC or paediatric extension in the UK court. Alternatively, the scope of an extension can be challenged by bringing an action for a declaration that a particular product does not fall within the scope of the extension, and so the patent (as extended) is not infringed.

9.4 Infringement

Infringement
Where a patent covers a pharmaceutical product or medical device, it is an infringing act to make, sell, offer to sell, use, import or keep the product or device in the UK. It is not an infringing act to make an offer to sell a product before patent expiry if the offer is to sell the product after patent expiry. It is also not an infringing act to merely apply for or obtain authorisation to sell a pharmaceutical product or medical device before patent expiry.

Where a patent covers a method for making a pharmaceutical product or medical device, it is an infringing act to use the patented method in the UK. It is also an infringing act to sell, offer to sell, use, import or keep a product "obtained directly" by means of the patented process. Whether a product has been "obtained directly" from a patented process is a question of fact in each case and has been the subject of a number of disputes in the UK.

It is also an (indirect) infringement to supply or offer to supply in the UK means relating to an essential element of the invention, for putting the invention into effect, if it is known (or should be 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.

Threats
It is possible to apply for an injunction restraining a party from infringing a patent on the basis of a threat of infringement, even if no actual infringement has occurred. There is no requirement for the infringement to be "imminent" in order for an injunction to be granted: the patent holder must only prove that there is a sufficiently strong probability that, in the absence of an injunction, the other party will infringe the patent.

9.5 Specific Defences to Patent Infringement

Defences
A number of general exemptions from patent infringement might apply to pharmaceutical products and medical devices, as follows:

- Acts carried out privately and for purposes which are not commercial are exempted from infringement.Acts carried out for experimental purposes relating to the subject matter of the invention are also not infringing, even if those acts are carried out for a commercial purpose.
- "Experimental purposes" include anything done in or for the purposes of a "medicinal product assessment", the latter term including work done in the UK for the purposes of obtaining an MA for a pharmaceutical product (whether generic or innovative) anywhere in the world. There is no equivalent express provision relating to medical devices.
- There is also a specific exemption from patent infringement for trials carried out in order to obtain an MA or comply with related regulatory requirements for a pharmaceutical product.

Compulsory Licences
A compulsory licence of a UK patent is available if, where the patented invention is a product, demand for that product is not being met on reasonable terms. A compulsory licence is also available if the patent holder's behaviour is causing the establishment or development of commercial or industrial activities in the UK to be unfairly prejudiced, or if the exploitation of an important technical advance of considerable economic significance is being hindered. These compulsory licence provisions are rarely asserted and are therefore of limited relevance in practice. However, there have been an increasing number of cases where the patentee does not seek an injunction on the basis that an appropriate royalty is agreed or awarded by the court for future infringement (ie, in effect a Court-imposed compulsory licence following a finding of infringement).

9.6 Bringing Proceedings for Patent Infringement

Bringing Proceedings
An action for infringement may be brought by the patent holder or by an exclusive licensee.

Available Remedies
The remedies available for infringement are an injunction to prevent future infringement, damages or, at the option of the patent holder, an account of the infringer's profits. The patent holder may also seek delivery up or destruction of all infringing articles in the possession or power of the infringer.

Procedure
An action for infringement can be brought in the Patents Court or in the Intellectual Property Enterprise Court ("IPEC"), both of which are part of the English High Court.

The IPEC is designed to deal with lower-value, less complex cases. There are two alternative procedures for making a claim in the IPEC. The IPEC multi-track has a limit on damages of up to GBP500,000, and costs are subject to a GBP50,000 cap. The small claims track is for claims with a value of up to GBP10,000, and costs orders are highly restricted.

Higher-value claims must be brought in the Patents Court. Depending on the parties' assessment of the technical complexity of the case, the case may be heard by a specialist patents judge.

An infringement action is commenced with the issue of a Claim Form and Particulars of Claim, outlining the patent holder's claim for infringement. The alleged infringer then submits its Defence and any Counterclaim, which may include a counterclaim for invalidity. If the alleged infringer raises a Counterclaim, then the patent holder will serve its own Defence. Parties may then Reply to any Defences.

Following the exchange of formal pleadings, the court will schedule a Case Management Conference to set the timetable for the action and the estimated trial date.

In a Patents Court action, the parties are typically required to give disclosure of all documents that support or undermine either party's case. Instead of giving disclosure in relation to infringement, the alleged infringer may submit a description of the product or process alleged to infringe. Disclosure relating to validity is typically limited to documents created in a four-year window around the priority date of the patent.

Expert evidence is typically exchanged before trial in written witness statements, and the experts are cross-examined on the content of these statements during the trial. If necessary, the parties may also provide evidence of experiments relating to infringement or validity, subject to a tightly controlled procedure.

The procedure in the IPEC is more streamlined in order to keep costs in proportion to the value of the claim, and the judge has wide case management powers to achieve this. Similar, but not identical, procedures are being trialled in the Patents Court which may provide something of a halfway-house.

Invalidity as a Defence
Invalidity is available as a defence to an infringement claim and is raised by way of a Counterclaim. If validity is challenged, the alleged infringer is required to serve Grounds of Invalidity setting out on what basis the patent is said to be invalid, including any prior art cited in support of a lack of novelty or obviousness attack.

9.7 Procedures Available to a Potential Generic Entrant

Procedures Available to Generic Entrant
A generic entrant who wishes to "clear the way" may start an action to revoke a patent or SPC that is a potential block to market entry – there are no standing requirements. Alternatively, or in addition, the generic entrant may start an action for a declaration that its proposed product does not infringe the patent or SPC.

Clearing the Way
There is no requirement on a generic entrant to "clear the way", and there is no patent linkage between the authorisation for a pharmaceutical product and the patent position. However, a generic entrant who does not "clear the way" is likely to be sued for infringement by the patent holder. If the patent holder can show that generic entry will cause irreparable harm, which has typically been accepted by the UK court, the patent holder can obtain an interim injunction preventing the generic entrant from launching its product.

Regulatory Authorisation and Patents
The authorisation procedure for pharmaceuticals and medical devices ordinarily have no regard to patent issues (unlike the position in the USA). An exception is that, although ordinarily a generic pharmaceutical will be approved after expiry of data protection, with the same SmPC as the originator's product, the authorities will allow the approval of a product without dosage forms and indications still protected by a patent at the time when the generic is approved for marketing (a so-called "skinny label").

10. IP Other Than Patent

10.1 Legislation and Procedures

A rights holder has a number of options for tackling counterfeit pharmaceuticals and medical devices.

Trade mark infringement can constitute a criminal offence under the UK Trade Marks Act 1994 ("Trade Marks Act"). The criminal sanctions under the Trade Marks Act are imprisonment for up to ten years, a fine, or both. Although it is possible to bring a private criminal prosecution against an infringer, criminal proceedings are more usually brought by the UK's Trading Standards Authorities or by the MHRA, which also has the power to bring criminal proceedings against counterfeiters under the Human Medicines Regulation 2012. The sanctions under the Regulations are imprisonment for up to two years and/or an unlimited fine, as well as administrative sanctions.

A trade mark holder can also bring a civil action for trade mark infringement under the Trade Marks Act. As with a patent infringement claim, a trade mark action can be

brought in the High Court, the IPEC or the IPEC small claims track, depending on the value and complexity of the claim. Civil proceedings may be appropriate when dealing with counterfeiting on a large scale, or where the rights holder wishes to take advantage of the procedural tools and remedies offered in civil proceedings (for example, search orders or injunctions).

Where the counterfeit product also infringes a patent, the patent holder can commence an action for patent infringement, as discussed above. However, for counterfeit products, a trade mark infringement action may be more straightforward.

Counterfeit pharmaceuticals can also be detained by the UK customs authority – the UK Border Agency ("UKBA") – on entry into the UK from outside the EEA. Under Regulation 608/2013 (the "Customs Regulation"), the holder of an intellectual property right ("IPR"), including a patent or a trade mark, can register its right with the UKBA and ask the UKBA to detain goods that are suspected of infringing that right.

10.2 Restrictions on Trade Marks

For pharmaceuticals, under the Centralised Procedure, the EMA will authorise a product name. A single name must be used throughout the EU, except in exceptional cases (eg, where the proposed trade mark has been cancelled, opposed or objected to under trade mark law in a Member State).

The EMA has issued guidelines on the acceptability of names or human medicinal products. The requirements include that:

- the invented name of a medicinal product should not be liable to cause confusion in print, handwriting or speech with the invented name of another medicinal product;
- the invented name of a medicinal product should not convey misleading therapeutic and/or pharmaceutical connotations;
- the invented name of a medicinal product should not be misleading with respect to the composition of the product;
- the invented name should not convey a promotional message with respect to the therapeutic and/or pharmaceutical characteristics and/or the composition of the medicinal product;
- the invented name should not be offensive or have an inappropriate connotation;
- the invented name should not consist wholly of initial letters (acronyms) or code numbers, nor include punctuation marks; and
- the invented name should not be liable to confusion with the INN.

The usual rules in relation to registration of any trade marks also apply, although the EMA will not take into consideration aspects of intellectual property rights/trade mark registration within its review.

In relation to National Procedure, the MHRA's guidelines on appropriate trade marks for medicinal products are much the same as the EMA's guidance.

The UK Medical Devices Regulations 2002 does not contain any restrictions on the product names or trade marks of medical devices. However, as with any trade mark for a medical device in any EU country, the following should be avoided:

- names/signs that overstate the efficacy of the device;
- names/signs that claim superiority over similar products, which cannot be substantiated; and
- names/signs that imply that the device is unique in its effectiveness.

The new EU Medical Devices Regulations (Regulation (EU) 2017/745, the "MDR" and Regulation (EU) 2017/746, the "IVDR") entered into force on 25 May 2017 but will not apply fully until after the transition period has ended, on 25 May 2020 and 2022 respectively. During the transition period, devices can be placed on the UK market under the current EU Medical Devices Directives, or the new EU Medical Devices Regulations (if they fully comply with the new EU Medical Devices Regulations). Article 7 of the MDR and the IVDR include a new requirement concerning claims. In particular, trademarks used in connection with the labelling, instructions for use, making available, putting into service or advertising of a medical device are prohibited if they may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

- ascribing functions and properties to the device that it does not have;
- creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
- failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose; or
- suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

When placing devices on the market in the UK under the new EU Medical Device Regulations (which are directly effective in the UK), Article 7 must be complied with.

10.3 Importation and Distribution Restrictions

Once goods bearing a trade mark have been placed on the market within the EEA by or with the consent of the trade

mark holder, the trade mark holder's right to object to the resale of those goods within the EEA is exhausted. Therefore, the trade mark holder cannot object to the resale of unaltered genuine products from within the EEA but can object where products are imported from countries outside the EEA, unless the importer can demonstrate unequivocal consent from the trade mark holder to their importation.

It may be necessary for the distributor to alter the original packaging of a genuine product to comply with UK regulatory requirements: although medicinal products sold in the UK may retain labelling in the language of the source country, they must also have an English patient information leaflet and English language labelling. If alterations are necessary (rather than merely commercially desirable), then the trade mark holder will be unable to object, as long as certain specified conditions are met, including prior notification to the trade mark holder.

With regard to medical devices, the information on the packaging and label of a medical device placed on the market in the UK must be in English (irrespective of whether or not the information is also in another language, and whether or not the device is for professional use).

The instructions for use accompanying a medical device may be either in English or in another officially recognised EU language, provided that (if the instructions are not in English) any packaging, label or promotional literature must carry a clear statement in English stating the language in which the instructions are given. This general rule is subject to an exception in relation to in vitro devices, for which the information must be in English if the device may reach a final user in the UK, unless the MHRA has authorised the use of another Community language(s). If the in vitro device is a device for self-testing, the instructions for use and label must include a translation into the official language of any member state of the community in which the device reaches a final user.

Where products are authorised nationally, a licence is required in order to distribute pharmaceutical products imported from elsewhere in the EU, although the procedure for obtaining such a licence is simpler than the procedure for obtaining an MA for the original product. Where products are authorised centrally, the EMA must be notified of proposed parallel importation relating to medicinal products. There are no parallel import licences for medical devices. See **8 Import and Export** for details of the requirements for imports and exports of medicines and medical devices.

10.4 IP Protection

Intellectual property protection is available for the trade dress and design of pharmaceuticals, medical devices or their packaging, subject to the normal restrictions on the relevant IPR and the labelling requirements of the pharmaceutical regulatory laws. The packaging of a product, the precise design of a tablet or the design of a medical device is capable of being protected as a registered or unregistered design, subject to the usual requirements for such protection. In addition, the trade dress and packaging of a pharmaceutical product or medical device may be protected by a right in the tort of passing off. In order to establish a claim in passing off, it is necessary to show (i) goodwill attaching to the claimant's goods or services; (ii) a misrepresentation by the defendant that his goods are those of the claimant; and (iii) that this misrepresentation has caused harm to the claimant.

10.5 Data Exclusivity

Innovator pharmaceutical companies benefit from a period of regulatory data protection and marketing protection to protect the investment made in developing a medicinal product. The regulatory data protection period is eight years, during which a generic applicant cannot cross-refer to the innovator's pre-clinical and clinical data to obtain a marketing authorisation for a copy product. In addition, the marketing protection period is a further period of two years (making a total of ten),during which a copy product that is authorised based on the innovator's pre-clinical and clinical data cannot be placed on the market. This combined period of "eight plus two" years is often known as the data/marketing exclusivity period. There is also the possibility of extending this period by an additional year in certain circumstances, such as on the approval of a new indication bringing significant clinical benefit when compared with existing therapies.

There are no protection or exclusivities for medical devices.

11. Competition Law

11.1 Activities Constituting Infringement

UK competition law is similar in all material respects to EU competition law, except – in addition to prohibitions against anti-competitive agreements and abuse of dominance – there is an additional criminal offence attaching to individuals who cause undertakings to enter into certain cartel agreements. In relation to the pharmaceutical sector, pharmaceutical undertakings in the UK have been found to infringe competition law in the following circumstances.

In January 2002, the then Competition Commission Appeal Tribunal upheld a decision of the Director General of Fair Trading that Napp Pharmaceuticals had abused its dominant position in the market for sustained release morphine tablets and capsules in the UK. While charging high prices to customers in the community segment of the market, Napp supplied the products to hospitals at discounts which were found to have the object and effect of hindering competition. The pricing behaviour comprised selectively supplying

the products to hospitals at lower prices than to customers in the community segment, and supplying to hospitals at excessively low prices. In addition, Napp was found to have charged excessive prices to customers in the community segment (Case No 1001/1/1/01 Napp Pharmaceutical Holdings Limited v Director General of Fair Trading).

In March 2004, the Competition Appeal Tribunal upheld a decision of the then Office of Fair Trading ("OFT") that Genzyme had engaged in a margin squeeze in the downstream market for the supply of home care services for patients suffering from Gaucher's disease (Case No 1016/1/1/03 Genzyme Limited v The Office of Fair Trading [2004] CAT 4).

The OFT has also undertaken two sector studies in the pharmaceutical sector – one concerning the Pharmaceutical Price Regulation Scheme (report, February 2007) and the other on the distribution of medicines in the UK (report, December 2007).

In October 2010, Reckitt Benckiser agreed to pay a fine of GBP10.2 million for abuse of dominance relating to the withdrawal and delisting of a presentation of its heartburn product Gaviscon in circumstances that would make it difficult for physicians to prescribe the generic equivalent of the withdrawn product.

In June 2014, the new Competition and Markets Authority ("CMA") (the successor organisation to the OFT and the Competition Commission) opened an investigation into an unnamed party in relation to a suspected loyalty-inducing discount scheme in the pharmaceutical sector. The case was closed in June 2015 on administrative priority grounds and the party concerned was issued with a warning letter. The CMA did not reach a view on whether the discount scheme infringed competition law. Rather, it concluded that committing resources in order to determine whether an infringement had been committed was not warranted in the particular circumstances, as further investigation of the conduct would have had limited, if any, impact on consumer welfare.

However, the CMA took the opportunity to issue general guidance on the application of competition law to discounts or rebates implemented by dominant companies. The guidance largely restated the approach from existing EU case law, including Intel (T-286/09). It explains that discounts and rebates that are not conditional on the customer obtaining all or most of its requirements from the dominant company may nevertheless be considered loyalty-inducing if:

- the discount or rebate is retroactive (ie, it applies on the total number of units purchased once a certain volume is reached, not just on the units above that threshold); and
- in order to obtain the benefit of the discount or rebate, the customer is required to purchase contestable sales from the dominant company (ie, units that the customer is able and willing to purchase from either the dominant supplier or its competitors).

Contestable sales can be contrasted with non-contestable sales, or the dominant company's "assured base", for which there is no competition as the customer is either unable to satisfy this proportion of its demand other than through the dominant company or has a strong preference not to do so. If the discount or rebate applies to contestable as well as non-contestable sales, then in order to compete for the contestable sales a competitor must compensate the customer for the loss of the discount not just over those contestable units, but also over the non-contestable units. This makes it more difficult for that competitor to compete with the dominant company. The loyalty-inducing effect is likely to be even stronger where the discount or rebate is structured such that the customer is able to reduce its units.

The guidance also endorses the relevance of the as-efficient-competitor test by reaffirming that a discount or rebate may raise concerns if it forces a supplier competing for the contestable portion of demand to price below the dominant company's long-run average incremental cost of production.

11.2 Pay-for-Delay Agreements

The CMA's infringement decision against GlaxoSmithKline and several generics companies mentioned above is based on reverse payment patent settlement theory in relation to the generic entry of paroxetine. The theories of harm cover both abuse of dominance and restrictive agreements.

11.3 Life Cycles Strategies Versus Generic Drug Companies

The then OFT's decision against Reckitt Benckiser, mentioned above, was based on the theory that Reckitt Benckiser withdrew its NHS presentation of Gaviscon Original Liquid from the NHS prescription channel. The timing of the withdrawal – after the product's patent had expired, but before the publication of the generic name for it – meant that pharmacists could not readily dispense a generic version. Any search for the equivalent products would instead have pointed to a replacement, protected product, Gaviscon Advance Liquid. The OFT held that such a means of migrating patients to the protected product amounted to an abuse of dominance because of its impact on generic entry. In the same case, the OFT initially investigated an alleged campaign to delay generic entry through interventions with the regulatory bodies but closed that line of the investigation on the basis of administrative priorities.

11.4 Proceedings for Breach of Competition Law

Alleged infringements of competition law may be the subject of complaints to the CMA. Certain designated consumer bodies are entitled to bring "super-complaints" to the CMA.

Such a complaint will be that any feature, or combination of features, of a UK market is, or appears to be, significantly harming the interests of consumers. Super-complaints will be fast-tracked and responded to within a certain period. The CMA may also investigate a matter of its own volition. Actions for civil remedies may be brought in the High Court (Chancery Division) by anyone with sufficient interest, such as a competitor, supplier or customer who has suffered loss or damage as a result of an alleged infringement of UK or EU competition law. The remedies available include damages and/or injunction. These actions may be stand-alone (ie, those that seek to establish the infringement and seek a remedy) or follow-on (ie, those that rely on a prior finding of an infringement by a competent competition authority, and seek only to establish that damage has occurred). The applicant must prove its case by reference to the civil standard of proof. In addition, any person who has suffered loss or damage as a result of an infringement of UK or EU competition law may bring a damages action before the Competition Appeal Tribunal; these are follow-on actions only. Claims on behalf of individuals may also be made to the Tribunal by certain recognised representative bodies acting on behalf of identified consumers.

11.5 Most Relevant Proceedings

In April 2016, the CMA imposed fines of almost GBP45 million on GlaxoSmithKline and various generics companies for concluding reverse payment settlement agreements in respect of the supply of paroxetine in the UK. The CMA also decided that GSK's conduct amounted to an abuse of a dominant position. The decision is currently under appeal to the CAT.

Also in 2016, the CMA imposed a fine of almost GBP90 million on Pfizer and Flynn Pharma in relation to excessive pricing of phenytoin sodium capsules. The case concerned the delisting of a branded product, taking it out of UK price control and relaunching it as a generic whilst multiplying the price at both wholesale and retail level. This decision is also currently under appeal to the CAT.

There are also a number of additional ongoing CMA investigations in relation to pharmaceutical products, and the CMA has stated in its current annual plan that the pharma sector continues to be a focus area.

12. Transactions/Collaborations

12.1 Important Legal Provisions

Transactions/Collaborations

Key Contractual Terms

The following two sections focus on important or customary provisions that are particularly significant in transactions in the pharmaceutical and medical device sectors. The degree of relevance or importance of each will vary depending upon the assets being bought, and in particular the stage of development of those assets (research, development or marketed product stage).

Share Purchase Deals

Besides other usual preconditions for completion of the transaction, an important matter to specify as a condition for share purchase deals can be a waiver of "change of control" termination rights in key contracts. Although such termination rights may be less common than, for example, prohibitions on assignment of a contract, long-term contracts (eg, clinical trial contracts, IP in- and out-licences, development and/or commercialisation agreements, and supply and manufacturing agreements) are a key part of many pharmaceutical and medical device businesses, and the treatment of such contracts should be considered an important deal term for both buyer and seller.

Some warranty areas will be of particular importance in this sector, notably those regarding the value of key assets and revenue generation, or reputational and regulatory risk. "Value" warranties are those relating to IPRs (where key warranties will concern title to – and validity and enforceability of – IPRs, together with comfort regarding challenges, and potentially freedom-to-operate), key long-term contracts such as those referred to above (where key warranties will concern termination rights and disputes), and inventory (which might be clinical trial materials, work-in-progress or finished product, and where key warranties will address shelf life, location and usability/saleability, as applicable to the product). Key "reputational" and "regulatory" warranties include: record-keeping and compliance with regulatory requirements specific to the assets; the existence and duration of any regulatory exclusivity periods in respect of pharmaceutical products; product liability claims and insurance cover; and anti-corruption policies and procedures (particularly for mature businesses that sell to government agencies).

In relation to inventory, the regulatory requirements,that apply to the product as regards manufacturing, packaging and product labelling for patients/prescribers must also be considered, in addition to the usual transitional arrangements that may be required to permit buyer or seller to use the name and trademarks of the other on packaging. Regulatory authorities, for example, impose a maximum period during which stock with packaging/labelling that refers to the seller or its manufacturer may be sold.

If a seller is prepared to give a non-compete covenant, it should frame the restriction with reference to the specific characteristics of the sold products in order to give clarity as to the scope of the restriction, and to avoid conflict with retained businesses. For pharmaceutical products, this will commonly be by reference to the active pharmaceuti-

cal ingredient, the method of action, and/or the therapeutic indication; for medical devices, this will commonly be by reference to the intended purpose of the device. A buyer should also review any non-compete restrictions to ensure that none of the target company's contracts contain elements that will restrict that business's current operations, post-acquisition,.

If signing and closing the transaction are not simultaneous, then the seller should consider whether specific obligations are required regarding the maintenance of key assets, such as maintaining and enforcing key IPRs and MAs.

Transactions involving early stage companies backed by venture capital, founders and management will need to deal with any share options, warrants to acquire shares and/or convertible debt that may be in issue. Besides tax considerations, the basic structuring question that will determine whether the rights are acquired or released is whether or not the purchase price is such that holders of options/warrants/convertibles will be in or out of the money at closing.

Asset Purchase Deals
Clear identification and listing of the assets being sold and those that are being excluded should be a priority at the start of the transaction. Although asset purchase deals in the pharmaceutical and medical device sectors are no different in principle from an asset sale in other sectors, IPRs and regulatory authorisations should be carefully identified so as to, for example, agree the treatment of any rights to which the seller may need access post-closing. Ownership of inventory, and the permits and authorisations required to manufacture, hold and sell it, should also be clearly identified, for example by warehouse location and/or stock-take provisions. The distribution channel(s) for both pharmaceutical products and medical devices need to be clearly understood to ensure that manufacture, inventory handling and delivery are maintained despite the change of ownership and in accordance with all applicable regulatory requirements. Identifying, locating and transferring records associated with the relevant products can also be key – besides marketing and customer records, there will also be strict requirements as to handling and maintenance of, for example, MA dossiers and pharmacovigilance records for medicines. More detailed provisions for post-closing access to records and product samples may be required than would be the case in less regulated sectors.

As with any asset sale, the transaction agreement will need to deal with the method of transfer for each category of asset to be transferred. For most categories (IPRs, contracts, employees, etc), the method for a pharmaceutical or medical device sector transaction will be no different to that in other sectors. However, arrangements for the transfer of product permits and authorisations (for example, manufacturing authorisations and MAs) should be considered in detail. Even if no other transitional services are required by the buyer from the seller, it is usual for the seller to provide a level of continued co-operation and support in order to ensure that permits/authorisations are transferred smoothly.

With regard to key contracts, the points made above for a share sale in respect of termination rights and conditionality apply equally in respect of an asset sale, but in relation to restrictions on assignment rather than change of control.

Legal provisions as to the buyer's and the seller's responsibility for product liability will often be important. If the parties so choose, a buyer could assume responsibility for all such liability regardless of when the relevant material/product was supplied or sold, in effect as if the deal were a share sale. Perhaps more likely, the parties will allocate responsibility by reference to the date upon which the material/product was manufactured or supplied/sold. In any event, the parties should indemnify each other according to the responsibility assumed, and ensure that they have insurance cover to match that allocation. If the buyer takes pre-closing responsibility, it may need rights to access the seller's insurance cover in respect of that period.

The points made above as to key warranty areas on a share acquisition apply equally to acquired categories of assets on an assets acquisition, as do the points made regarding non-compete covenants.

Joint Ventures
The legal provisions set out above in relation to sales of assets or shares apply equally to transfers of assets or shares into joint venture vehicles.

Joint ventures in the pharmaceutical and medical device sectors present specific issues in respect of termination, which should be provided for. The parties may want to consider whether they should have exit or termination rights upon the occurrence, or non-occurrence, of the key milestones considered below under **12.2 Customary Agreements to Bridge the Valuation Gap**. The joint venture parties should also consider how IPRs owned by the joint venture should be allocated between them.

Licence Agreements
There are a number of provisions/issues that are particular to licence agreements in the pharmaceutical and medical devices sectors.

Diligence : Negotiation of licence agreements in these sectors will often focus on the level of efforts ('commercially reasonable efforts' or similar) that the licensee should use when developing and commercialising the products in question. Given the enforcement risk of dispute over the inter-

pretation of these terms if it came to litigation, the parties should spend time on defining this, and will frequently seek to define these terms by reference to an objective standard based on the efforts that a company with similar products at a similar stage of development or commercialisation would reasonably be expected to employ. Practice is also developing to include very specific diligence requirements, either in place of or to clarify general endeavours requirements.

Regulatory matters : As a general rule, the licensee of a pharmaceutical product will want the right to apply for and/or hold the relevant MAs for that product in the licensed territory. Whether the licensee of a medical device will be viewed as the manufacturer (or, under the Medical Devices Regulation, an importer or distributor) of the device – and its resultant regulatory responsibilities – will turn on the circumstances of each case. In any event, given the valuable data/information that is required to support regulatory filings, licensors will want to be kept informed of the licensee's interactions with the relevant regulatory bodies and to ensure messaging is aligned with the approach taken for products marketed elsewhere. Licensors of pharmaceutical products may seek the ability to refer to the licensee's MAs in regulatory filings in other fields/territories, and will also want to ensure that MAs are transferred to the licensor (or its nominee) promptly upon any termination or expiry of the licence. Licensors will also seek to control the ability of the licensee to apply for additional authorisations that would potentially expand the scope of the licensed activities, for example sales of the licensed product in combination with other products.

Sharing of data : Where licences involve ongoing development work (eg, clinical trials and other studies), cost allocation and access to the results will be of key importance. Licensors may wish to use data generated by a licensee in regulatory filings outside of the field/territory. Equally, licensees may want access to data from trials/studies carried out by the licensor (or its other licensees). Regulating access to/use of such data can be complex, particularly where third parties (eg, a licensor's other licensees) are involved.

Warranties and covenants : Licensing transactions tend to have fewer warranties and covenants compared to M&A transactions, but there is a strong emphasis on regulatory and intellectual property warranties (eg, that the licensor has all relevant rights to be able to grant the licence to the licensee, that the licensee's exercise of the rights under the licence does not infringe any third party IP rights, and that the licensor has not granted any other rights with respect to the licensed products to third parties). Restrictions on the commercialisation of competing products by the licensee and/or licensor are a common feature of licences in this sector. It important to consider not only the scope of such restrictions on either party's current activities, but also what effect they may have on future licences and other deals. For example, the restriction may oblige a party to divest any competing product acquired in the future. Any such forced sale (particularly where the required timescales for divestment are short) could significantly undermine the value of the assets being sold.

Intellectual property : Given the importance of IP in licensing transactions, the IP provisions will be heavily discussed. Issues commonly arise around ownership (and in particular joint ownership) of inventions and improvements, as the position around how they may be exploited by both parties varies between different jurisdictions and may also give rise to competition law concerns where licensees are required to assign or exclusively license their rights back to licensors. The licensee will often require the first right to prosecute, maintain, enforce and defend licensed IP rights within its territory, but the licensor will equally seek to ensure that it has sufficient controls to protect its interest if the licensee fails to do so. Trade mark matters may also be a concern if the licensor and licensee will share a brand.

Governance : Given the potential long duration of licences in these sectors, and the complexities of bringing products to market and obtaining pricing and reimbursement approvals, the parties will often look to put detailed governance structures in place, to ensure that key decisions can be made quickly and with the involvement of the relevant stakeholders. It is common to see a steering committee structure to allow the parties to consult with one another on key decisions around commercialisation of the products, often with specialist sub-committees to deal with issues that arise during development, manufacture, etc. The circumstances in which these committees may– and may not – make decisions that are binding on the parties are often subject to detailed discussion, and a robust dispute resolution procedure should be put in place to ensure that any differences of opinion are escalated and addressed appropriately.

Compensation : Licence agreements in the pharmaceutical and medical devices sectors typically involve a combination of up-front payments (generally payable at signing), milestone payments that are payable upon achievement of specified development and commercialisation targets or events, and royalty payments based on net sales. Defining the events that trigger milestone payments and the basis on which net sales should be calculated requires careful drafting.

Commercial Agreements

With regard to other commercial agreements in the pharmaceutical products and medical devices sector (such as contract manufacturing agreements or services agreements), the following provisions are likely to be of importance.

GMP and GDP compliance : The principles and guidelines of "good manufacturing practice" (or GMP) and "good dis-

tribution practice" (or GDP) are commonly used in commercial agreements for pharmaceutical products and medical devices to cover all aspects of the manufacturing and distribution process, ensuring that the products in question are consistently produced and controlled to the quality standards appropriate to their intended use, obtained from the licensed supply chain and consistently stored, transported and handled under suitable conditions. GMP and GDP requirements for pharmaceutical products and medical devices derive from a variety of legislation, guidance and international standards, and whilst these standards are broadly harmonised throughout the EU, engagement with the parties' quality management function at an early stage is recommended.

Supply chain oversight : The legislation underpinning the sale and supply of pharmaceutical products in the EU (Directive 2001/83) imposes obligations on manufacturers, importers, wholesale distributors and brokers to ensure that they only obtain their supplies from, and sell to, other persons or entities with the appropriate authorisations to do so, and has recently been updated to require the addition of anti-tamper features and unique identification codes to prescription-only medicines. Traditionally, the supply chain for medical devices has been subject to less regulatory scrutiny but, following the implementation of new EU regulations for medical devices and in vitro medical devices, economic operators throughout the supply chain are now subject to their own regulatory responsibilities.

Duty to ensure continued supply : All UK MA holders and distributors of authorised pharmaceutical products are under a legal obligation to ensure appropriate and continued supplies of that product so that the needs of patients in the UK are met. In practice, this means that issues such as materials shortages, capacity constraints, business continuity and disaster recovery planning are likely to be of greater importance in any manufacturing and supply/distribution-related arrangements.

Compliance with Industry Codes of Practice : The Association of the British Pharmaceutical Industry's Code of Practice (the ABPI Code) sets standards for the promotion of medicines and the provision of information to patients and the public in the UK, and the Association of British Healthcare Industries' Code of Business Practice sets similar standards in respect of medical devices. Pharmaceutical/device companies generally look to reflect the applicable obligations imposed on them by these codes of practice in their commercial agreements. For example, if a pharmaceutical company engages an agency to run a meeting involving healthcare professionals, the agency will generally be contractually obliged to comply with the ABPI Code in relation to the selection of the meeting venue and the provision of hospitality/payment of expenses to the attendees.

Pharmacovigilance : MA holders are obliged to operate appropriate pharmacovigilance and risk management systems in respect of their marketed medicines (see **3.6 Ongoing Obligations** for an explanation of pharmacovigilance). Similarly, medical device manufacturers are required to have quality management systems in place. This means that commercial agreements with pharmaceutical and medical device companies often include pharmacovigilance and safety-related provisions that put obligations on service providers and other contracting parties to take action if they become aware of any information relating to the safety of products marketed by the pharmaceutical company (eg, adverse reactions suffered by patients). These obligations can take many forms, and it is important for service providers to understand their scope, including, in particular, any time limits for notifying the other party (which are generally short).

12.2 Customary Agreements to Bridge the Valuation Gap

Customary Deal Terms to Bridge the Valuation Gap

Transactions in the pharmaceutical and biotech sectors involve more earn-out/milestone value than transactions in the medical devices sector, and considerably more than most other sectors. Unless the assets in question comprise entirely mature products, it is common to find contingent payment provisions to deal with value variables. For early stage businesses, the triggers for payment of milestones will commonly be study results, regulatory filings or approvals, grant of MAs, and achieving first sales. For other businesses, earn-out payment provisions tend to be triggered by the business attaining minimum levels of licence/royalty receipts and/or product sales. Detailed terms may be added to clarify when milestones are deemed to have been achieved, and the agreement may contain specific dispute (expert) resolution procedures for disputes relating to milestone payments.

The level of obligation imposed on a buyer to achieve a milestone (eg, "commercially reasonable/best efforts") should be a key consideration for both buyer and seller. For transactions involving larger buyers, the buyer may be required to apply the same level of effort it applies to its own products. Transactions commonly include detailed and specific requirements as to the steps to be taken, in addition to a general reasonable or best efforts obligation. There may be difficult decision points during a product's path-to-market if the buyer and seller will have conflicting interests, which should be covered with more specific obligations (or even rights to take back the underlying product assets).

The agreement may also include terms to deal with earn-out rights if there is a change in control of the buyer or if the relevant assets are sold.

In public (listed) transactions, it is not unusual for entitlements to contingent payments to be structured as tradeable

instruments (contingent value rights), which are themselves listed.

In more complex transactions, a party may also retain or extract value, other than purely from the sale and purchase price, by entering into revenue-generating commercial agreements as part of the overall transaction, such as co-development or co-promotion agreements.

12.3 Purchase Price Adjustments

Purchase Price Adjustments

A range of price adjustment methods are often used in share sale transactions, although they are not specific to transactions in the pharmaceutical or medical device industries. In common with private transactions in many sectors, it is quite usual to provide for completion accounts to be drawn up post-closing, following which the sale price will be subject to a "true up" adjustment based upon actual net assets, or more commonly actual working capital/net debt, measured against the estimate upon which the completion payment was calculated.

"Locked box" provisions are not uncommon, although more frequently used with venture capital or private equity-led seller transactions, rather than with industry sellers. Such provisions are a substitute, in effect, for completion accounts-based adjustments, but these provisions only trigger a payment back to the buyer if the seller has breached a pre-closing obligation not to extract cash out of the target company (the "locked box").

Retentions (holdback) from the purchase price at closing, or payment into an escrow account, are also common features of sale transactions in this sector, and are usually used to create security for the buyer in respect of warranty or indemnity claims, and to that extent can operate in practice as price adjustment provisions. Retention/escrow feature particularly in private transactions involving early stage businesses and/or where there are multiple sellers.

12.4 Deal Protection Terms

Deal Protection Terms

Transactions that are being negotiated on a bilateral basis – whether they have been bilateral from the start or have reached that point after an initially competitive process – are commonly protected for the buyer by an appropriate period of exclusivity given by the seller. Strict non-disclosure agreements are also customary in the pharmaceutical and medical device sectors, reflecting the particular need to protect valuable confidential technical data and know-how.

In common with transactions in other sectors, larger-value and public transactions may well be covered for the buyer and/or the seller by other forms of protection against "execution risk". If there are significant preconditions to closing, which are more often the responsibility of one party or the other (such as obtaining shareholder or regulatory approval), then that party may agree to pay a break (termination) fee if the condition is not satisfied. English public companies are subject to certain regulatory restrictions upon the size of the break fee they can agree to pay.

A seller may look for some form of "cash confirmation" protection in a significant-value private sale ("cash confirmation" protection is required for public transactions covered by the Takeover Code in any event), especially if there is expected to be a considerable gap between signing and completion. In a private transaction, the scope of the comfort given is a matter for negotiation but can include seller diligence, and buyer confirmation, of the terms and conditions of the buyer's binding debt finance facilities.

12.5 Local Antitrust Approval

Local Antitrust Approval

Share sale and joint venture transactions should be assessed against applicable merger control regimes (either at EU or member state level, depending generally on the size of the parties); a filing, approval and therefore conditions precedent to closing may be required or advisable, as with M&A transactions in other industries. Certain asset sales may also fall within the merger regime, where these assets essentially constitute part of a business to which turnover can be ascribed.

Co-operation agreements or commercial transactions (or asset sales not subject to the merger regime) do not require – and parties cannot obtain – antitrust pre-approval. In such cases, the parties must self-assess to determine whether the transactional documents are valid and enforceable under competition law. They are assisted in this by several relevant EU block exemptions, which apply automatically in the UK – namely the block exemptions, and accompanying European Commission guidelines on technology transfer agreements, research and development, and vertical restraints.

12.6 Tax Treatment of Asset Deals Versus Share Deals

A key question in any acquisition, whether cross-border or purely domestic, is whether to buy or sell shares in the company that carries on the business or whether to acquire the business assets. Many more considerations other than tax will be relevant to this issue, but the tax consequences of either option will be important from both the buyer's and seller's perspectives.

In broad terms, with a share sale the buyer inherits all the tax history of the target company (together with 'hidden' tax liabilities that may only come to light after closing) but tax continuity is maintained, whereas with an asset sale there are relatively few legacy issues in tax terms but the continuity of

ownership is broken. For example, the seller may find that it suffers a claw-back of reliefs if the price a buyer wants to pay for (and attribute to) a particular asset exceeds its value for tax depreciation purposes.

Which option is better and for whom will be a matter of careful examination, and the ultimate choice – as well as depending on factors other than tax – may come down to the relative bargaining strengths of each party and their desire to do the commercial deal. However, currently the requirements of the seller's disposal planning will usually dictate that a share sale is the preferred route, particularly in the pharmaceutical and medical device sectors.

In a UK context, it is usual on a share sale for the buyer to require and have the benefit of a seller indemnity for historic tax issues that may come to light after closing (as well as to conduct detailed tax due diligence, partly through detailed warranties designed to flush out tax concerns). Such an indemnity is not given (and is usually not necessary) on an asset sale, and will also be resisted, or reduced in scope, where the seller is a private equity entity. In certain European jurisdictions outside the UK, warranties given on 'an indemnity basis' may take the place of the typical form of UK tax indemnity. Both the typical form of UK indemnity and the European variant are intended, in effect, to operate as a post-closing adjustment of the price paid. If the buyer is happy with the strength of the seller's credit standing and the scope of the indemnity, it may be happy to assume a certain level of tax risk, but the availability of tax risk insurance can help to limit further the buyer's exposure and the seller's liability. Rates vary but, broadly speaking, premiums can be 4% to 6% of the purchase price.

Seller's Preferences

A UK resident will usually (if commercially possible) wish to sell shares, regardless of the identity of the buyer and regardless of whether or not the buyer is establishing a UK resident acquisition vehicle. This is because a seller (whether a corporate body or an individual) will often be able to claim exemption from tax or reliefs that reduce the effective rate of tax on the sale proceeds. A corporate seller can claim the benefit of an exemption for the sale of a target company's shares, provided certain conditions are met (largely relating to the requirement for the target company to be carrying on an active trade as opposed to a passive investment business), if it owns 10% or more of the target company's shares and has owned them for a year before the disposal. Individual sellers can claim 'entrepreneurs' relief' in the UK for disposals of shares in trading companies, again provided that certain conditions are met, including that they are employees or officers of the company, and have a minimum holding of 5% and an entitlement to voting power of 5%. Many other European jurisdictions have similar 'participation exemption' regimes which apply to share sales. Finally, in some circumstances, both corporate and individual sellers can roll over gains on the disposal of shares into shares or debt instruments issued by the buyer, but note that the shares or debt instruments must be issued by the entity that acquires the shares, and further detailed conditions must be satisfied. Questions can arise concerning rollover where non-UK buyers issue instruments to be exchanged for shares, and it is key to ensure that whatever form of instrument is issued can enable the seller to claim rollover.

Very broadly speaking, sellers in the UK will prefer not to sell assets because exemptions and reliefs will not be available to shelter or reduce taxable gains to the same extent as for a sale of shares. Asset sales are rarer in the UK.

Buyer's Preferences

Often a buyer will prefer to acquire assets because it is simpler and because fewer tax 'legacy' issues arise with asset purchases (VAT (sales tax) can be a notable exception). Real estate in the UK is subject to a transfer tax at 5% for commercial land and buildings, and if there is a significant real estate component then the transaction tax costs may be significantly increased with an asset purchase (by contrast, the acquisition of shares is subject to a transfer tax at only 0.5% of the price). However, as noted above, share sales are far more common and are driven by the seller's disposal planning.

In addition, if the availability of the UK patent box tax regime is key to the economics of the deal, it may be easier to acquire a target company that has an existing entitlement to claim the patent box than to acquire a patent from it and try to establish entitlement to treatment of income under the favourable terms of that regime. On the other hand, where a patentable asset is not yet capable of commercial exploitation so that relevant income is yet to be generated from it, then the buyer may acquire that asset and develop it so as to come within the new regime. Note, however, that, amongst other things, the patentable asset will almost certainly need to be owned by a UK vehicle company or held by and for the benefit of a UK branch of a non-UK buyer so that patent income comes within the UK tax net. Furthermore, the amount of profit to be taxed at the patent box rate is restricted by the 'nexus fraction', which is based on the amount of qualifying R&D expenditure incurred by the patent box company on a particular patent relative to the overall R&D expenditure and any relevant intellectual property acquisition costs in relation to that patent. The availability of R&D tax reliefs and allowances throughout the EU is always going to be a major consideration when deciding on both the form of an acquisition and the location of an acquisition structure.

In the pharmaceutical and medical devices sectors, given the relatively generous nature of some of the exemptions and reliefs available to both corporate and individual sellers

of shares in trading companies, buyers in the UK may find considerable pressure to accommodate a seller's tax preferences; a buyer that is not prepared to do so could find itself at a distinct competitive disadvantage in a bid situation. Few bidders are prepared to pay a substantial premium over the price that other bidders are offering to acquire shares in order to gross up the price for tax.

Tax Risk Assessment

Proper tax due diligence (through a forensic examination of a target company's financial information, interviews with key managers and answers to tax enquiries) should highlight areas of tax risk that may help in determining which option the buyer may prefer (assuming the seller will or is likely to comply). In the pharmaceutical and medical device sectors, particular exposures can relate to the following:

- *Payroll taxes* : This is an area where compliance can fall short, particularly with staff travelling to and from various jurisdictions in pursuance of their duties. However, more significantly, in the UK and elsewhere in Europe, it is common practice in the pharmaceutical and medical devices sectors for self-employed consultants to be hired either directly or through personal service companies (referred to as PSCs), for significant periods of time (up to several years in many cases). Tax authorities look closely at these arrangements to determine whether in their view they are, in effect, 'disguised' employments. If they are, then amounts paid under contracts should have been subject to payroll taxes, including employers' social security contributions of 13.8%. Where there is a PSC, the risk of having to account for payroll taxes falls on the PSC and not the 'employer' company.
- *Transfer pricing, Diverted Profits Tax and Hybrid Mismatches* : Complex intra-group arrangements can exist even in the smallest of businesses, and the prices at which intra-group supplies of services and assets (particularly intangible assets) are made between members of groups across borders is an area in which tax authorities are dedicating significant resources and introducing complex anti-avoidance rules in order to protect national tax bases. The so-called 'export' of 'profit potential' by the transfer of intangibles offshore is something that can have an impact on the tax risk profile of pharmaceutical and medical device groups in particular. In recent years, in addition to strengthening its transfer pricing resources, HMRC has championed the introduction of rules that seek to tackle situations involving the artificial diversion of profits from the UK and tax arbitrage achieved through use of hybrid instruments and entities. Both these sets of rules may need to be considered in detail where cross-border IP transfers and royalty flows take place.
- *Value-added tax* : This is an area that can often fall short of high compliance standards, and complex issues can arise in the context of cross-border supplies of goods and services, particularly where sales are made directly to non-business customers.

12.7 Protection of Licensees

The insolvency of a licensor can have a significant impact on licensees of IPRs. In terms of the protection granted to licensees under English law, much will depend on the circumstances, including, for example, the terms of the relevant licence agreement and the general commercial viability of the arrangements.

Under English law, licence agreements will not automatically terminate upon the occurrence of an "insolvency event" affecting one of the parties (eg, administration or insolvency). However, licence agreements in the pharmaceutical and medical devices sectors commonly include a contractual right for the unaffected party to terminate in such situations. If this is the case, the first issue for a licensee to consider is whether or not they want the licence agreement to continue. If they do not, the licensee can terminate the agreement (taking care to comply with the relevant notice provisions).

In many cases, however, a licensee will want the agreement to continue but, unfortunately, this may not always be within the licensee's control. For example, if a licence is unprofitable or gives rise to a liability for the licensor to pay money or perform any other onerous act, a liquidator may be entitled to "disclaim" the licence under section 178 of the Insolvency Act 1986. This could be the case if the licence concerns patent registrations in many countries and the licensor is obliged to pay substantial renewal fees (although it seems more likely that a liquidator would want to preserve the value of the patents).

The effect of a "disclaimer" is to terminate the rights, interests and liabilities of the licensor in the property concerned, with effect from the date of the disclaimer. This does not necessarily mean that the licence will come to an end, as the rights or liabilities of the licensee are only affected to the extent necessary for releasing the licensor from its obligations.

If the licence is not terminated or disclaimed, a liquidator may seek to realise value for the licensor's creditors by assigning or otherwise transferring the licensor's interest. In such cases, issues such as whether the licence agreement included an option for the licensee to purchase the IPR in the event of the licensor's insolvency and/or whether the licence agreement can be assigned without the licensee's consent will all be important in determining the next steps pursued by the liquidator.

Contributed by Arnold & Porter LLP ***Authors:*** Lincoln Tsang, Adela Williams, Jackie Mulryne, Ewan Townsend

13. Investigations/White Collar

13.1 Focus of Investigations

In the UK context, regulators are likely to focus corporate investigations on offences contrary to the Bribery Act 2010. In particular, companies should be aware that they may be liable to prosecution for offences contrary to section 7 of the Bribery Act 2010 if they do not have adequate procedures in place to prevent bribery by their direct employees, employees of subsidiary companies and agents acting on their behalf. Where healthcare professionals and organisational managers are public officials, there may be scope for investigating offences of conspiracy to commit misconduct in public office if the public official has acted in a manner that breaches the public's trust in their role – for example, if a public official received money from a pharmaceutical company for authorising the use of a particular product over a competitor's product. Investigators in the UK are likely to concern themselves with attributing blame for this sort of behaviour at a corporate level.

Current investigations concern the manner in which companies interact with healthcare professionals and others with responsibility for authorising the use of one particular product over competitors' products, in particular price fixing and the offer and securing of supply contracts by the provision of improper incentives.

13.2 Important 'Do's' and 'Don'ts'

An investigation into a pharmaceutical company is most likely to be conducted by the SFO and focus on issues such as fraud, bribery and corruption. Under the leadership of David Green QC, the SFO has adopted a more aggressive and proactive stance in relation to enforcement than under previous Directors.

Whether a company is notified of an investigation or reports issues of concern, it is vitally important for any subject of an SFO investigation to gauge the dialogue with the SFO appropriately. The prosecutors will be looking for a great deal of co-operation and full and frank disclosure from companies under investigation, much as the prosecuting bodies in the USA do. The key from a defence perspective is to ensure that every decision made, and every response given, is reasoned and reasonable. These types of investigations are incredibly complex and will almost certainly last for multiple years. In addition, there will more than likely be a long list of complex legal issues that will need to be considered at every step of the way, such as the prosecutors requesting sight of confidential or legally privileged information. The issue of privilege has become significantly more complex in the last 12 months, as described below.

Accordingly, it is of paramount importance to ensure that the prosecutors know from the outset where the line of co-operation is drawn. If this relationship is poorly managed, or if communications break down, this will more than likely prevent a suspect company from achieving a favourable disposal. However, a well-managed dialogue and relationship will set the foundations for proper consideration of representations on disposal. It will always be at the prosecuting body's discretion to prosecute or not, but with the introduction of Deferred Prosecution Agreements ("DPAs") it is now possible for a company that complies with an SFO investigation appropriately to perhaps avoid prosecution and instead fix the wrongdoing, and ensure it does not happen again. To date, DPAs have been agreed in SFO investigations into Standard Bank, "XYZ" (an as-yet unnamed SME based in England), Rolls-Royce and Tesco.

Moreover, organisations providing goods or services to the NHS should consider implementing and maintaining appropriate anti-fraud and security management arrangements in order to avoid falling foul of not only the SFO, but also the Crown Prosecution Service and the NHS's own anti-fraud, bribery and corruption agency, NHS Protect.

13.3 Recent Landmark Cases

The issue of claiming privilege in investigations conducted by an enforcement agency has become significantly more complicated in the last 12 months following the decision of the English High Court in a declaratory relief claim brought by the SFO against natural resources company ENRC. This decision appeared to narrow significantly the ambit of litigation privilege. Subsequently, the judgment has received both positive and negative judicial treatment (in different forums) and has been widely criticised by practitioners. It is currently subject to a pending appeal, due to be heard later this year.

13.4 Distinct Characteristics of Investigations

There does not appear to be any reason to differentiate the sort of investigation that would focus on pharmaceutical companies from other corporate criminal investigations. Whilst investigations into pharmaceutical companies will likely be protracted and involve investigations across different jurisdictions (which in itself can cause difficulties for the investigator and suspect alike), this is similar to any corporate investigation. If companies or individuals are charged, they are tried in the same criminal courts, and the same burden and standard of proof apply during their trials. However, it is important to note that a conviction for bribery offences may have the significant added punitive effect of barring convicted corporations from participating in public procurement contracts.

Contributed by Arnold & Porter LLP ***Authors:*** Lincoln Tsang, Adela Williams, Jackie Mulryne, Ewan Townsend

14. Product Liability

14.1 Specific Legal Regime

Claims in respect of defective products, including medicinal products and medical devices, may be brought in the UK in negligence, in contract and under the Consumer Protection Act 1987 (the "CPA"), which implements the Product Liability Directive, 85/374/EEC, in the UK.

Most prescription-only medicines and prescribed medical devices are supplied under NHS provisions; such prescription and dispensing has been found not to be contractual but rather pursuant to a statutory obligation. Therefore, contractual remedies will only arise for the supply of medicines and medical devices under private prescriptions or purchased over the counter ("OTC").

Special compensation arrangements apply to persons suffering severe disablement as a result of certain vaccinations, with the Vaccines Damage Payments Act 1979 providing for the payment of fixed compensation to qualifying claimants. Compensation schemes are also sometimes set up to resolve specific claims, eg, the schemes relating to HIV and Hepatitis C contamination of blood products. No-fault compensation schemes may be available to persons who suffer injury as a consequence of participation in a clinical trial.

Most claims for compensation for personal injuries caused by defective medicinal products and medical devices are brought under the CPA, which imposes strict (no fault) liability on the producer of a defective product. The "producer" is defined as the manufacturer, the importer of the product into the EU or the person who holds himself out as producer by affixing his mark to the product (an "own brander"). A person who supplies the product may also be liable if he or she fails to identify the producer or at least the person who supplied the product to them when asked to do so. A product is defective for the purposes of the CPA if it is not as "safe as persons generally are entitled to expect", taking account of all the circumstances, including any instructions or warnings provided with the product and the manner in which it has been marketed. The claimant is required to prove that the product was defective and establish a causal relationship between the defect and the injury.

In negligence, liability will be established if it is shown that the defendant owed a duty of care to the claimant, that he breached that duty by failing to take reasonable care, and that the breach caused the damage complained of. Such claims are commonly brought against the manufacturer of a defective product and/or – where a medicinal product is involved – against the holder of the MA, although claims may be brought against other parties in the supply chain if fault can be established.

Claims for breach of contract relating to products in the life sciences field are most commonly brought in respect of medicines and medical devices (such as breast implants) supplied by private clinics. Supply of a defective product will almost certainly involve breach of express or implied terms of the contract. Standard terms are implied into all contracts for the sale of goods, unless the parties agree to exclude them. Products must be of satisfactory quality and comply with the description applied to them. Additional obligations apply to contracts between a business and a consumer ("consumer contracts"): there is a presumption that goods that malfunction during the first six months after delivery were in breach of contract at the time of supply.

Claims for breach of statutory duty can be brought where legislation is intended to create a private law right, actionable by an individual harmed by the breach. However, no such rights have been found to arise from breach of consumer statutes and to date there has been no UK litigation similar to the consumer fraud litigation pursued in some US states.

14.2 Standard of Proof for Causation

The claimant has the burden of proving, on the balance of probabilities, that the defendant's product caused or materially contributed to the claimant's injuries. The traditional test of causation is the 'but-for test': the claimant must prove that, but for the defendant's negligence or the supply of a defective product, the claimant would not have sustained the injury.

There is no general presumption of causation. However, the CJEU's decision in Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt, Case C-503/13, which is binding on the UK courts, indicates that, where a product such as an implanted medical device is part of a batch of potentially defective products, liability may be established under the Product Liability Directive without proof that the product has actually malfunctioned and caused injury.

14.3 Specific Defences

There are no specific defences applicable to claims relating to medicinal products or medical devices.

However, several defences are provided by the CPA, which the defendant has the burden of proving. Therefore, it is a defence to a claim that a product is defective if:

- the defect is due to compliance with legal obligations imposed by UK or EU law;
- the defective product was not supplied by the defendant;
- the product was not supplied for profit and in the course of business;
- the defect did not exist at the time the product was supplied by the defendant to another;
- the so-called "development risks defence" applies – ie, the state of scientific and technical knowledge at the relevant

time was not such that a producer of products of the same description as the allegedly defective product might be expected to have discovered the defect if it had existed in his products while they were under his control; and
- the producer of a component product can show that the defect was due to the design of the final product, or to defective specifications provided to him by the producer of the final product.

Liability under the CPA and in negligence may also be limited by the principles of contributory negligence. In negligence, a defence of volenti is available if the claimant freely and voluntarily agreed to run the risk of injury in full knowledge of the nature and extent of the risk. Otherwise, the defendant will defeat the claim if the claimant cannot establish each of the elements of negligence. No specific defences arise in contract, but the claim will fail if the claimant cannot establish the breach of contract and damage due to that breach.

14.4 "Regulatory Compliance Defence"

Under the CPA, a regulatory compliance defence is available if the manufacturer can show that the defect is due to compliance with UK or EU laws. The defence has limited scope and only applies, for example, in the case of alleged failure to warn where the 'defective' warnings were mandated by UK or EU regulators, not where those warnings were negotiated or otherwise agreed with regulators.

Otherwise, there is no general defence under the CPA, in negligence, or in contract, in circumstances where the manufacturer is able to demonstrate compliance with regulatory and statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product, although such compliance is of evidential value and may help in the defence of claims.

14.5 Market Share Liability

As set out above, the test of causation is whether the defendant's product caused or materially contributed to the claimant's injury. What amounts to a 'material contribution' depends on whether the alleged injury is divisible, and whether there are possible alternative causes. If the injury is non-divisible and there are several possible causes but it cannot be established which caused the injury, causation may not be established. However, causation may be established in the case of a divisible injury where the injury is caused by multiple factors that have an additive or multiplicative effect. In these circumstances, liability is likely to be apportioned to reflect the extent of the defendant's liability for the injury. These principles have not been applied to pharmaceutical product liability claims.

The English courts have not adopted so-called "market share" liability. Where it is not possible to establish which of several possible producers manufactured the defective product, the claimant's evidential burden cannot be met and the claim will be dismissed.

14.6 General Statute of Limitation Period

The primary limitation period for actions in tort (including negligence claims) and for breach of contract is six years from the date on which the cause of action accrued. Special time limits apply to personal injury claims, including those brought in negligence or under the CPA. In such cases, the claim must be brought within three years of the date on which the cause of action accrued (ie, the date of injury or death) or the date of knowledge by the claimant of the facts required to bring a claim. The court has a discretionary power to disapply this time limit where it would be equitable to do so.

Special rules apply to persons under a disability (children and persons with mental incapacity), and time generally only begins to run for limitation purposes when the claimant dies or ceases to be under a disability. Where an action is based on the defendant's fraud or concealment, the relevant limitation period does not begin to run until the claimant has discovered, or could with reasonable diligence have discovered, the fraud or concealment.

In addition to limitation provisions, a right of action under the CPA is extinguished ten years after the defective product was put into circulation ("the ten year longstop"). The ten-year period runs even in circumstances where the claimant is under a disability.

14.7 Information Against Manufacturers

There is no specific 'claim for information'. However, under the Civil Procedure Rules, the parties are expected to comply with applicable Pre-Action Protocols, providing that the key documents that would be relied upon by one party or would adversely affect the case of one of the other parties should be disclosed before proceedings are commenced. If a party wishes to obtain additional specified documents, he or she may seek an order under rule 31.16 of the CPR for pre-action disclosure against a party likely to be involved in proceedings. This application will be granted if the Court is satisfied that such disclosure is necessary in order to assist the dispute to be resolved without proceedings, or to save costs. The Court may also make an order under CPR 31.17 for disclosure against a third party who is not involved in the proceedings, where the documents sought are necessary in order to dispose fairly of the claim or to save costs.

It is possible to seek disclosure of information from a public body via a request under the Freedom of Information Act 2000. The public body is required to respond to a request within 20 working days, disclosing the information sought by the applicant unless it falls within one or more of the exemptions listed under the Act. The exemptions are catego-

rised as absolute or qualified; information that falls within an absolute exemption should not be disclosed, but information within a qualified exemption is subject to a public interest test and must be disclosed unless the public interest in withholding the information outweighs the public interest in disclosure. An applicant who is dissatisfied with the response of a public body to a request for access to documents may appeal the decision to the Information Commissioner.

14.8 Available Damages

The types of damages that may be recovered vary depending on the legal basis of the claim. Under the CPA, damages are available in respect of death or personal injury (both physical and psychiatric injuries) or damage to property for private use and consumption (if the property damage exceeds the minimum threshold of GBP275). Damages are not recoverable in respect of damage to the defective product itself.

In negligence, damages can be recovered for death or personal injury (including mental injuries) and damage to property. Pure economic losses that are not consequent on physical damage are not generally recoverable.

In contract, damages are usually awarded for monetary loss (for example, in respect of damage to property and to the defective product itself), but they can include non-pecuniary losses, such as damages for death or personal injury (including mental injury). Economic losses, such as loss of profits, are recoverable if they are a foreseeable consequence of the breach.

Although it is possible to claim punitive damages under English law, they are limited to situations where the defendant's conduct was calculated to make a profit that exceeds the compensation recoverable by the claimant, or where there has been oppressive, arbitrary and unconstitutional conduct by government servants. It is doubtful whether they are available in product liability actions.

English law does not generally permit recovery of the cost of 'medical monitoring' tests or investigations, unless the product has actually been shown to be defective. Such medical monitoring costs are recoverable only as medical expenses consequential upon the main injury.

14.9 Maximum Limit on Damages

There is no limit on the damages that may be claimed by a single claimant and/or available from one manufacturer.

14.10 Recent Decisions

Few cases concerning liability for defective pharmaceutical products or medical devices in the UK have been reported. The evidential burden on claimants of proving liability and causation of their injuries is significant.

Wilkes v Depuy International Ltd [2016] EWHC 3096 addressed the assessment of defect, in a case involving a metal "C-stem" hip prosthesis. The claimant had been implanted with the prosthesis, which subsequently fractured; he brought a claim against the manufacturer under the CPA alleging that the C-stem was defective at the time it was put into circulation. The Court confirmed that the meaning of "all the circumstances" at s3(2) of the Act was wide and must mean "all relevant circumstances". Whether a product conformed to the producer's specification or relevant standards could be a relevant circumstance, as could regulatory approval, the risk-benefit balance, any instructions for use provided to a clinician, whether the defect could have been avoided, and cost.

The test as to the level of safety that persons "generally are entitled to expect" is objective: it is not what persons actually expect but what, as a matter of law, they are entitled to expect. The court noted that safety is a relative concept; no medicine can be risk free if it is effective, and a product is not defective simply because a safer design could be envisaged.

Significantly, the court in Wilkes rejected and diverted from the approach followed in A v National Blood Authority and Ors [2001] 3 All ER 298 ("the Hepatitis C Litigation"), which adopted a rigid classification of products as "standard" or "non-standard" and required the identification of "the harmful characteristic which caused the injury" as a first step, before defect could be identified.

14.11 Trial

Trial is by a judge alone.

14.12 Disclosure Obligation

Under English law, the parties are required to provide disclosure of documentary evidence (construed widely to include videotapes, telephonic recordings and documents stored electronically) in accordance with the Civil Procedure Rules following a reasonable and proportionate search for disclosable material. The scope and extent of the search must be described in a formal disclosure statement. Disclosure usually takes place after pleadings setting out the parties' cases have been served. However, in appropriate cases, the court may order pre-action disclosure of documents.

In claims involving personal injuries, the standard rule is that a party to an action is required to disclose the documents within his control on which he relies and which adversely affect his own case or support another party's case, although the court may dispense with or limit such disclosure in appropriate cases. However, the court has wide powers to make any alternative order that it considers to be appropriate. In determining the scope of disclosure, the court will take account of the associated costs. and will ensure that these are proportionate to the overall sums in issue in the proceedings.

The factual and expert evidence that the parties intend to rely upon at trial must be provided in the form of witness statements and expert reports that are exchanged by the parties prior to the trial. The court will generally control the number of factual and expert witnesses whose evidence may be relied upon.

14.13 Potential Changes to Legal Regime

There have been no recent discussions regarding potential changes in the legal regime for liability for pharmaceutical products.

15. Privacy & Data Protection

15.1 Legislation and Regulation

The current legislation governing privacy and data protection across the EU Member States is derived from the EU Data Protection Directive 95/46/EC (the "Directive"), which has been implemented by national legislation across the member states. In the UK, the Directive has been implemented by the Data Protection Act 1998 (the "DPA").

The Directive will soon be replaced by the European General Data Protection Regulation (2016/679) (the "GDPR"), which will be directly applicable across all EU Member States from 25 May 2018. Although directly applicable across all EU Member States as a regulation (rather than a directive) without the need for national implementing legislation, the GDPR does allow for member state supplementation in certain areas (such as in relation to processing personal data relating to criminal convictions and offences).

The UK is implementing the GDPR into a new UK Data Protection Bill (the "Bill"), which will replace the DPA and will apply post-Brexit. The Bill is currently working its way through Parliament, having completed its House of Lords stages, and is currently awaiting its second reading in the House of Commons.

Other legislation and regulations also apply to privacy and data protection, notably: the Privacy and Electronic Communications (EC Directive) Regulations 2003 (as amended) in the UK, which apply to electronic communications and are particularly relevant for marketing communications; the Regulation of Investigatory Powers Act 2000, which relates to law enforcement investigatory powers and covers the interception of communications and surveillance; and other sector-specific regulations and codes.

15.2 Regulatory Bodies

The UK Information Commissioner's Office (the "ICO") is the regulatory body responsible for applying and enforcing the privacy and data protection legislation and regulations in the UK.

15.3 Health Related Information

Health-related information is treated as "sensitive personal data" under the current legislation, and will be treated as a corresponding "special category" of personal data under the GDPR. There are stricter conditions for processing health-related information under both the current legislation and the GDPR.

Under the GDPR, two legal conditions need to be satisfied in order for health-related information to be processed (eg, collected / recorded / structured / stored / used or disclosed). One of the conditions relating to the general processing of personal data needs to be satisfied – for instance, that the processing is necessary for the performance of a contract with the relevant individual, or for legitimate purposes pursued by an organisation (which must be balanced against the rights of the individual). Another condition relating to the processing of special categories of personal data also needs to be satisfied – for instance, the relevant individual has given explicit consent to the processing of their health information for one or more specified purposes.

Health-related information can also be subject to regulation under some legislation relevant to the life sciences sector, such as that relating to clinical trials or the processing of human cells and tissue samples.

15.4 Sanctions

Under the current legislation, the ICO can impose a fine of up to GBP500,000 for breach of the DPA. This maximum fine is being greatly increased; for the most serious breaches of the GDPR, the maximum fine that can be issued by national regulators under the GDPR is EUR20 million or 4% of an undertaking's total worldwide annual turnover of the preceding financial year (whichever is higher).

Under the GDPR, Member States will also be able to set rules on further sanctions that national regulators may enforce, such as those that are currently open to the ICO (for instance, enforcement notices, requiring organisations to comply with the legislation, or powers to enter and inspect premises).

Under the GDPR, individuals who have suffered damage as a result of an infringement of the GDPR also have the right to compensation from the company responsible for the infringement.

15.5 Special Requirements for Cloud Platforms

Transferring personal data to cloud platforms and storing personal data on those platforms will need to comply with the data protection legislation, including the aspects of the legislation relating to the "special category" of health information. Therefore, careful attention needs to be paid to the

legal bases upon which such information is being processed by the cloud customer and cloud provider.

It is likely that the cloud customer would be classed as a "data controller" under the legislation, as it is likely to be determining the purposes and means of the personal data transfer and storage. The cloud provider would likely be classed as the "data processor" under the legislation, as it would be responsible for storing the personal data on behalf of the cloud customer. However, the determination of the respective positions would depend on the particular activities undertaken by each party. The distinction is important for the purposes of the GDPR (which places obligations on data processors as well as data controllers). Under the GDPR, data controllers must also enter into contracts with data processors that must contain certain provisions (for instance, relating to security measures and data subjects' rights).

If there is a transfer of personal data out of the EEA to a cloud platform based in a country that has not been deemed to have an "adequate" data protection regime by the European Commission, protective measures would also need to be put in place, such as standard contractual clauses that have been approved by the European Commission or the EU-US Privacy Shield.

Arnold & Porter
25 Old Broad Street
Tower 42
London
EC2N 1HQ
United Kingdom

Tel: +44 (0)20 7786 6100
Fax: +44 (0)20 7786 6299
Web: www.arnoldporter.com