COUNTRY COMPARATIVE GUIDES 2024

The Legal 500 Country Comparative Guides

United Kingdom
LIFE SCIENCES

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in United Kingdom.

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UNITED KINGDOM
LIFE SCIENCES

1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

Medicinal Products

In the UK, the key legislative framework for regulating the development, manufacture, commercialisation and use of human medicinal products is primarily derived from EU legislation, in particular:

- Directive 2001/83/EC on the Community code relating to medicinal products for human use (the "**Code for Human Medicines Directive**"); and
- Regulation (EC) 726/2004 on the authorisation and supervision of medicines and establishing a European Medicines Agency (the "**EMA Regulation**").

The Human Medicines Regulations 2012 (the "**HMR**") (as amended) implemented the above-mentioned EU legislation in the UK law.

Medical Devices

In the UK, the key legislative framework for regulating the development, manufacture, commercialisation and use of medical devices in the UK also derives primarily from EU legislation. However, following the UK's departure from the European Union ("**Brexit**"), the medical devices legislation in the UK is currently in a state of transition. The historical key legislation (which is still relevant at the time of writing) includes:

- Directive 90/385/EEC on active implantable medical devices (the "**Implantable Medical Device Directive**");
- Directive 93/42/EEC on medical devices (the "**Medical Device Directive**"); and
- Directive 98/79/EC on in vitro diagnostic medical devices (the "**In Vitro Diagnostic Medical Device Directive**").

The Medical Devices Regulations 2002 (as amended) ("**MDR**") implemented the above-mentioned EU legislation in the UK.

Two new EU Regulations entered into force on 26 May 2017, which supersede the abovementioned Directives, namely:

- Regulation (EU) 2017/745 on medical devices (the "**Medical Devices Regulation**"); and
- Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the "**In Vitro Diagnostic Medical Devices Regulation**").

EU Members States were required to implement (i) the Medical Devices Regulation into national law by 26 May 2021, and (ii) the In Vitro Diagnostic Medical Devices Regulation by 26 May 2022 (although, see Question 1 of the EU Chapter for timing amendments). Neither of the EU Regulations were implemented as national law in the UK during the Brexit transition period and consequently were not automatically retained as law in the UK. Accordingly, the above-mentioned original EU Directives (as implemented by the MDR) continue to apply in Great Britain (following Brexit, with alternative arrangements for Northern Ireland to align more closely with the EU). However, the UK did introduce The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 which amended the MDR to introduce certain provisions which mirror the Medical Devices Regulation. Such amendments included the broadening of the regulatory regime to capture certain devices for aesthetic and other non-medical purposes.

Medicines and Medical Devices Act 2021

The Medicines and Medical Devices Act 2021 (the "**MMD Act**") was enacted into UK law on 11 February 2021. The MMD Act provides a framework for the Medicines and Healthcare products Regulatory Agency (the "**MHRA**") (the UK Government agency responsible for the regulation of medicines and medical devices in the UK) to amend the existing regulatory framework regarding medicines and medical devices in the UK. The MMD Act also introduced greater enforcement powers with

respect to breaches of regulatory requirements concerning medical devices in the UK. However, the civil enforcement provision (Section 31) will not apply in the UK until it is implemented pursuant to a statutory instrument.

As at the date of preparing this Chapter, the UK Government intends to introduce new regulations for medical devices that prioritise patient safety and patient access to medical devices, with the aim of securing the UK's position as an attractive market for medical technology innovators[1].

The approach to this reform was outlined in the UK Government's response to the 2021 consultation on the future regulation of medical devices in the UK[2]. The UK Government aims to ensure there is a proportionate and phased approach to the implementation of the future medicinal products and medical devices regulatory framework, which supports system readiness and minimises the risk of supply disruption for UK patients. At present, the UK Government intends for the regulations to be delivered via four statutory instruments, with priority measures to enhance post-market surveillance set to be put in place first during 2024, with core elements of the new framework expected to be in place in 2025.

Food and Food Supplements

Food safety and standards are devolved matters in the UK, with separate bodies in each of England, Wales, Scotland and Northern Ireland taking responsibility for developing and enforcing policies concerning, among other things, food safety, hygiene and labelling standards. The Food Standards Agency ("**FSA**") is a non-ministerial government department that is responsible for food safety and food hygiene in England, Northern Ireland, and Wales, working with local authorities to enforce food safety regulations. It also has responsibility for labelling policy in Wales and Northern Ireland, and nutrition policy in Northern Ireland. The Food Standards Scotland ("**FSS**") is the non-ministerial government department of the Scottish Government responsible for food safety, food standards, nutrition and food labelling in Scotland.

Despite the complexities that arise from a devolved policy system in the UK, there is key UK legislation that applies across the four UK nations. In particular:

- the Food Standards Act 1999 – established the FSA and granted the authority with certain functions and powers in relation to food safety standards.
- the Food Safety Act 1990 (as amended) – provides the framework for all domestic food legislation and ability for secondary legislation to implement EU food laws.
- The Food Information Regulations 2014 – enables local authorities to enforce assimilated Regulation (EU) 1169/2011 on food information to consumers (e.g. allergen information).

In addition, there is specific national legislation in each of the devolved nations governing aspects of food requirements, including food additives, food imports, food contact materials, food labelling etc.

Following Brexit, relevant EU legislation concerning food and foodstuffs have been implemented into national law, including:

- Regulation (EC) No 178/2002 on General Food Law.
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

The FSA defines a food supplement as "*any food the purpose of which is to supplement the normal diet and which is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination and is sold in dose form*".

Food supplements are regulated in the UK under the Food Supplements (England) Regulations 2003 (as amended), and the equivalent regulations in Scotland, Wales and Northern Ireland as well as all other applicable food law.

When the UK was an EU Member State, details of vitamins and minerals, and vitamin and mineral substances that may be used in the manufacture of food supplements, were contained in lists in annexes to Directive 2002/46/EC, which is implemented in England by the Food Supplements (England) Regulations 2003 (as amended), and equivalent regulations in Scotland, Wales and Northern Ireland. These lists have now been inserted as Schedules to the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 to ensure that they continue to have effect in Great Britain following the UK's withdrawal from the EU.

The above-mentioned regulations do not control the use of substances other than vitamins and minerals, and vitamin and mineral substances which may be used in the manufacture of food supplements, but any other ingredients used must be safe for human consumption and not be injurious to health.

The UK Government's guidance[3], states that, in respect of the interaction between GB and Northern Ireland:

"*Information is shared with Northern Ireland as all nutrition issues continue to be considered on a 4-nation basis: and importantly, officials and ministers in Northern Ireland continue to play a vital role in policy development under the arrangements agreed in the UK-wide common framework for nutrition-related labelling, composition and standards (NLCS). Northern Ireland's full participation in risk assessment and risk management processes ensure that any decisions taken in GB (England, Scotland and Wales) account for the potential impacts across the UK.*"

The guidance also provides that pursuant to the Northern Ireland Protocol, EU legislation in respect of food supplements continue to be directly applicable in Northern Ireland (see Question 1 of the EU Chapter).

Footnote(s):

1
https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices/implementation-of-the-future-regulations

2
https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom

3
https://www.gov.uk/government/publications/food-supplements-guidance-and-faqs/guidance-notes-on-legislation-implementing-directive-200246ec-on-food-supplements

2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

Medicinal Products

Pre-marketing considerations

See Question 7 in respect of clinical trials requirements, prior to a marketing authorisation ("**MA**") application.

With limited exceptions, before a medicinal product can be placed on the market in the UK, it must have been granted a MA by the MHRA. An MA application is made via the MHRA's Submissions Portal and must include an electronic Common Technical Document (eCTD). Depending on the intended market (i.e., UK, GB or NI), only certain pathways to obtaining a MA will be available.

Following the UK's exit from the EU, the MHRA introduced temporary "reliance routes" for the EU, allowing for applicants with an EU MA to go through an accelerated review procedure to obtain a MA within the UK. Such routes expired at the end of 2023, and from 1 January 2024, the UK Government introduced a new International Recognition Procedure (IRP). The IRP allows for fast-tracked MHRA reviews of medicinal products that have been approved in certain non-UK jurisdictions to obtain/update a MA in the UK or GB. Such non-UK jurisdictions consist of Australia, Canada, EEA/EU, Japan, Switzerland, Singapore and the United States.

See Question 4 for post-marketing considerations.

Medical Devices

Pre-marketing considerations

Firstly, it must be determined whether a product is a medical device, pursuant to the MDR. Once determined if a product is a medical device, it must comply with the applicable Part of the MDR for the type and classification of product, which sets out the essential requirements that must be met for patient safety.

Necessary conformance assessments and relevant technical requirements documentation/dossier must be completed and prepared, respectively, for the medical device in order to demonstrate that it meets the necessary standards, operates in the correct manner and is suitable for UK Conformity Assessed ("**UKCA**") marking. UKCA marking requirements are currently based on the requirements of the relevant Annexes to the Directives listed below, which have been modified by Schedule 2A of the MDR:

- Directive 90/385/EEC on active implantable medical devices;
- Directive 93/42/EEC on medical devices;
- Directive 98/79/EC on in vitro diagnostic medical devices.

The details of what is required are very specific to the features, uses and functions claimed of the medical device and its applicable classification. It is likely that the work involved to compile such technical documentation could be undertaken to serve both securing an CE certification for the EU market and UKCA certification for the UK market.

Once it is established a product is a medical device, the classification of the device must be determined. Such classification is given to medical devices depending on the level of risk associated with it (i.e., the highest risk has the strictest control).

There are four different classifications a medical device could fall under (although in vitro diagnostic medical devices have different and separate categories):

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

As a general rule, higher class medical devices will need to comply with more stringent regulatory requirements and approvals/certifications will be subject to more onerous controls due to the increased risk to patient safety. Factors taken into account when determining a medical device's classification will include the intended purpose, intended length of use and whether it is invasive/surgically invasive. Classification will initially be determined by the manufacturer of the medical device before being confirmed by a UK Approved Body designated by the MHRA (e.g., the BSI) when performing conformance assessment. The UK Market Conformity Assessment Bodies (UKMCAB) database serves as the UK's database of conformity assessment bodies.

Once classification has been determined, the medical device will need undergo conformity assessment to demonstrate it has met the relevant requirements under the MDR. As a general rule, class II devices and above, or a Class I device that is sterile / has a measuring function, will usually require an independent conformance assessment by a UK Approved Body (e.g., the BSI).

An Approved Body ensures manufacturers and their medical devices comply with the relevant requirements of the MDR. Depending on the nature of the device, their assessment will include a review of clinical and scientific data (to support the safety and claims for which the device is used), manufacturing processes, and the quality management system relating to the device (e.g., evidence of quality processes relating to development, change processes/updates, data storage, complaints etc.). If the medical device is deemed to comply with the applicable standards, a UKCA certificate can be issued (i.e., the UK equivalent to the 'CE certificate' used in the EU to indicate that a product has passed certain conformity/safety self-assessments and certification). A UKCA mark is then placed on the device to show that it has passed the conformity assessment in the UK. Until a UKCA certificate has been issued, the device cannot be labelled with the UKCA mark nor placed on the GB market. UKCA marks are not recognised in the EU, EEA or Northern Ireland markets, as such, relevant products require a CE marking for sale in these markets.

Lastly, before a medical device can be made available on the GB market, it and the manufacturer must both be registered with the MHRA via its Device Online Registration System. Registration requirements differ for Northern Ireland.

See Question 4 for post-marketing considerations.

3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

Food Supplements

Under current UK law, there are no requirements to register food supplements with the relevant authorities in the UK. However, foods used within food supplements, that are novel, will be considered "novel foods" and therefore required a novel food application. Similarly, if the 'food supplement' is being marketed for, or its intended use is for, medical or health purposes, then it may be subject to the medicinal products regulations (see Question 1).

The Food Supplements (England) Regulations 2003 ("**FSR**") (and equivalent regulations in Scotland, Wales and Northern Ireland), set out certain requirements that must be satisfied before the food supplements can be delivered to the end customer, including that the product must:

- be sold under the name "food supplement";
- name the category of vitamin / mineral / other substance with nutritional / physiological effect;
- include a recommendation for daily consumption;
- have a warning not to exceed the recommended daily dose;
- not include any mention, express or implied, that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

According to FSA guidance, EU Food Law (see Question 1 and 3 of the EU Chapter) continues to apply in Northern Ireland, pursuant to the Northern Ireland Protocol, and before any novel foods are placed on the Northern Ireland market, they must go through the EU authorisation process.

Novel Foods

Before a 'novel food' can be placed on the GB market, it must first obtain authorisation from the relevant food

regulatory authority.

The retained Regulation (EU) 2015/2283 defines 'novel food' as any food that was not used for human consumption to a significant degree within the EU or the UK before 15 May 1997. Such novel foods require authorisation before they can be placed on the market in Great Britain.

Authorisation is either applied for through the "traditional food notification" route (i.e., foods with 25+ years of human consumption in a country outside the UK), or the "full application" route. Both application routes are made through the FSA.

In a full application, the applicant must submit an application containing all administrative data, information specific to the novel food (e.g., compositional data), data and reports. The validation and risk assessment, and final decision, can take up 17 months.

Pursuant to the retained Regulation (EU) 2015/2283, the relevant authority may impose post-market monitoring requirements, which may include, on a case-by-case basis identification of the relevant food business operators.

4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

Medicinal Products

Once an MA is obtained from the MHRA, the MA holder will be subject to a number of obligations, including:

- placing the product on the market within three years of the MA being granted (regulation 67 of the HMR);
- notifying the MHRA of the date on which the product that the MA relates to is placed on the market (regulation 73 of the HMR);
- keeping under review the methods of manufacture and control of the product to which the MA relates and taking account of scientific and technical progress (regulation 74 of the HMR);
- provide the MHRA with any new information the MA holder obtains that might vary the MA (e.g., positive / negative results of clinical trials, data of use of the medicinal product where use is outside the terms of the MA, etc.) (regulation 75 of the MHR);
- keeping the product information up to date with current scientific knowledge (regulation 76 of the HMR);
- complying with the "Blue Guide", a guide prepared by the MHRA which sets out rules on the advertising and promotion of medicinal products in the UK.

Further to the above, stakeholders involved in the supply and development chain of medicinal products may, depending on their commercial activity in the UK, require additional licences from relevant competent authorities including:

- Wholesale Distribution Licence / Authorisation (this must be held by any individual or company that sells or supplies medicines to anyone other than patients – see Question 12);
- Controlled Drugs Licence (controlled drugs are drugs named in misuse of drugs legislation (Misuse of Drugs Act 1971 and schedules 1 to 5 of the Misuse of Drugs Regulations (MDR) 2001), and therefore, if a company possesses, manufactures, produces or supplies such drugs in England, Wales or Scotland, a licence is needed);
- Manufacturer's and Importer's Licence (a licence required where manufacturing happens partially or totally in, or import is from, a country not on the approved country for import list (a third country)).

The MA holder is to operate a pharmacovigilance system, which includes maintaining and making available on the request of the MHRA a pharmacovigilance system master file, operate and monitor a risk management system, and update the risk management system where there are new risks / changes in risks (regulation 182 of the MHR). The MA holder must also submit pharmacovigilance data to the MHRA, according to UK requirements, including:

- UK and non-UK Individual Case Safety Reports;
- Periodic Safety Update Reports;
- Risk Management Plans;
- Post-Authorisation Safety Studies (PASS) protocols and final study reports.

As a matter of best practice, a manufacturer of medicinal products may also want to consider policies and processes needed to be put in place to lawfully operate businesses in the UK. Such policies and processes include setting up a management quality system and a site master file, as well as employing the appropriate

qualified and experienced individuals to act as a "qualified person". A "qualified person" is responsible for ensuring that each individual batch of medicinal product has been manufactured and checked in compliance with applicable laws and regulations.

In addition, businesses may want to consider appointing a person responsible for regulatory compliance (i.e., responsible for ensuring that a business' products and commercial activities comply with applicable laws and regulations) and an EU authorised representative (i.e., acts as the business' regulatory representative in the European Single Market and is the point of contact between the business and the European national regulatory authorities), (as applicable).

In addition, key stakeholders operating in the pharmaceutical industry within the UK may also need to comply with specific industry codes if they have joined any industry bodies or organisations (e.g., the Association of the British Pharmaceutical Industry ("**ABPI**")).

The MHRA runs the "Yellow Card" scheme, whereby the public (including patients, parents and carer givers) and healthcare professionals report problems experienced with healthcare products, to the MHRA. The MRHA collects and monitors such information on suspected safety concerns involving healthcare products. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products. For products authorised for sale or supply in Northern Ireland, EU pharmacovigilance requirements will continue to apply in addition to UK requirements.

Medical Devices

Once a medical device has been placed on the UK market, the manufacturer is responsible for monitoring the product and reporting serious adverse incidents to the MHRA.

The manufacturer will have a responsibility to implement an effective post-market surveillance system to ensure that any problems or risks associated with the use of the device are identified early, reported to competent authorities, and acted upon.

The manufacturer will also be obligated to perform certain "proactive" acts of vigilance, which include: (i) continually ensuring the safety of the medical device, calculating a risk and benefit balance; (ii) informing development of future iterations of the device; and (iii) conducting field safety corrective actions to prevent or reduce the risk of the occurrence of a serious incident in relation to the medical device. In addition, improvements and updates to the medical device may require different levels of reassessment, including potentially by an Approved Body. The extent and effect of any improvement/update, and its impact on the operation and functionality of the device will determine what reassessment, if any, is necessary.

If an incident arises through use of the medical device, the manufacturer will have an obligation to react appropriately by (i) reporting "serious" incidents; (ii) engaging in both voluntary and mandatory reporting, and (iii) reporting trends, in each case, to the MHRA. The MHRA defines a "serious incident" as any incident that directly or indirectly led, might have led, or might lead to the death of the user, the temporary deterioration of the user's state of health or a serious public health threat.

As mentioned above, manufacturers must also comply with relevant product marking and conformity assessment requirements for medical devices. On 1 January 2021, UKCA markings entered into force in Great Britain, and from 1 July 2023, a UKCA mark has been mandatory to place a device on the GB market.

UKCA mark requirements are based on the requirements of the (i) Implantable Medical Device Directive, (ii) Medical Device Directive, and (iii) In Vitro Diagnostic Medical Device Directive, which were implemented into UK law by the MDR.

Medicinal Products and Medical Devices that are reported to be defective will need to be immediately recalled in accordance with the relevant regulations. In the UK, there are both voluntary and mandatory recall procedures for medicinal products and medical devices.

5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?

Medical Products and Medical Devices

See Question 1. The MHRA is the UK regulatory body responsible for approving and controlling the distribution of medicines and medical devices (including software/apps that have a medical function/purpose).

The MHRA has a number of enforcement powers via different UK legislation, including:

- prohibition notices to ban the supply of any goods which are considered unsafe or do not comply with regulations;
- notices to warn which requires a

manufacturer to issue a warning at their own expense about any relevant goods, which 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;
- forfeiture orders for goods where there has been a contravention of a safety provision;
- notice to obtain information where 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;
- compliance notice to formally outline perceived offences and request correction of a non-compliance;
- restriction notice, in order to restrict the availability of a particular medical device, or of devices of a particular class or description.

In serious cases, if the MHRA considers that a company has committed a serious offence by failing to comply with the relevant medical and consumer regulations or the conditions of a notice issued to it, then the company may be subject to criminal prosecution. Prosecution could carry a penalty of an unlimited fine and/or 6 months' imprisonment.

In respect of controlled drug licences (see Question 2), the Home Office is responsible for issuing/amending/varying such licences. Applications for a controlled drug licence can be made on the Home Office's website and will require an applicant to register to the Home Office's online licensing system and for certain security checks (e.g. Disclosure and Barring Service (DBS) checks) to be performed.

Food

See Question 1 – the FSA (for England, Wales and Northern Ireland), and the FSS (for Scotland) are the regulatory bodies in respect of certain food safety and standards.

Food Supplements

The following authorities are responsible in each of the UK nations for legislation in respect of food supplements:

- the Department of Health and Social Care for national and EU retained law in England;
- the Welsh Assembly for the policy area of food supplements legislation;
- the Food Standards Agency Devolved Administrations of Scotland and Northern Ireland, respectively, where separate but similar Regulations apply.

The legislation is enforced through local Trading Standards Offices and Port Health Authorities.

6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.

Medicinal Products / Medical Device

Subject to certain exceptions, if the MHRA proposes to refuse the grant of an MA application, then it must first consult an "appropriate committee" of experts that has been appointed by the MHRA. If the committee agrees with the MHRA's proposal, it will issue an opinion stating it cannot advise the MHRA to grant the MA.

If the applicant disagrees with an MHRA decision to refuse granting the MA, they have the right to request a review of the decision, the applicant can request to make oral / written representations to the relevant committee, usually within 28 days. Any supporting evidence usually has to be supplied within six months of the request being made.

With regards to decisions made by UK Approved Bodies in respect of conformity assessments of medical devices, the rules governing any appeal procedure will vary between UK Approved Bodies. However, by way of example, the BSI provide for applicants with the opportunity to appeal any decision made by the BSI within 21 days of receipt of any relevant decision. Appeals will be investigated according to the BSI Regulatory Services appeals procedure, in compliance with the accreditation/regulatory rules governing BSI. The decision made by BSI, which is the subject of the appeal, will remain in force pending the outcome of the appeal, which the Client and BSI each agree shall be final.[4]

In addition to the above, applicants may also seek to appeal decisions made by the MHRA via the courts by way of judicial review. A judicial review is a challenge against the way a decision has been made by a public body, as opposed to the conclusions reached. The main grounds for judicial review are based on allegations of illegality, irrationality and procedural impropriety in decision making. In bringing a judicial review, the MA applicant should follow the Pre-Action Protocol for Judicial Review[5], which sets out the steps for the parties before making a claim. If the claimant proceeds in

bringing the claim, it will need to file a claim form under strict time limits. The court will require specific documents, in certain forms, under detailed and prescriptive instructions. A claim will only then proceed if the court grants permission.

Appeals against other medical device regulatory decisions taken by MHRA will be specified in the relevant legislation. Appeals will not be processed through the Chartered Institute of Arbitrators.

Food Supplements

As mentioned above, food supplements do not need to be registered with any specific food regulatory authority in the UK. However, novel foods used in supplements will need to be authorised as a novel food (see Question 3). Whilst these decisions cannot be expressly challenged, the Food Safety Act 1990 will permit applicants to appeal against certain decisions the relevant regulatory authority has made (e.g., against food hygiene rating or inspection).

Footnote(s):

4
https://www.bsigroup.com/en-US/medical-devices/policy/

5
https://www.justice.gov.uk/courts/procedure-rules/civil/protocol/prot_jrv

7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.

Medicinal Products

Overview of Key UK Legislation

The key legislation and regulatory framework for UK clinical trials is the UK Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) (the "**UK Clinical Trials Regulations**") which implements the provisions of the EU Clinical Trials Directive (2001/20/EC) (the "**Clinical Trials Directive**") into national law in the UK.

Following the UK's withdrawal from the European Union, the UK is no longer able to take part in the European regulatory network for clinical trials, and regulatory responsibilities transferred to the MHRA. The MHRA is responsible for clinical trial approvals, oversight, and inspections in the UK and alongside the UK Research Ethics Service, the MHRA grants permission for clinical trials to be conducted in the UK in accordance with the UK Clinical Trials Regulations. For completeness, as a result of the Northern Ireland Protocol, different rules apply in Northern Ireland than in Great Britain. Broadly, Northern Ireland continues to follow the EU regulatory regime but its national competent authority remains the MHRA.

As of January 2022, all new Clinical Trials of Investigational Medicinal Products ("**CTIMPs**") in the UK have been subject to a combined review from the MHRA and the UK Research Ethics Services, in collaboration with the Health Research Authority ("**HRA**"). Applicants only need to submit a single application to obtain (a) Clinical Trial Authorisation; and (b) a favorable opinion from the Research Ethics Committee ("**REC**"), both of which will be delivered to the applicant at the same time.

In March 2023, the UK Government announced new proposed legislation to reform the UK clinical trials regulatory framework, aiming to, amongst other things, ensure patients and their safety are the focus of all clinical trials, create a proportionate and flexible regulatory environment, and to streamline approvals and reduce approval times.

The Process

An applicant must first determine if their clinical study requires an MHRA authorisation by determining whether the substance being tested is a "medical product", and whether the trial constitutes a "clinical trial" pursuant to the UK Clinical Trial Regulations.

Once determined a clinical trial is being carried out, a sponsor needs to be identified who takes responsibility for the initiation, management and financing (or arranging the financing) of a clinical trial. Two or more organisations may agree to act as co-sponsors or joint sponsors. In the UK, it is a legal requirement for any clinical trial of an investigational medicinal product (CTIMP) to be sponsored. A sponsor must be incorporated in the UK. The sponsor is responsible for ensuring that a clinical trial complies with the legislation and Good Clinical Practice ("**GCP**").

An application for MHRA authorisation of a clinical trial is made through the Integrated Research Application System ("**IRAS**"), and as detailed below, the clinical trial will be automatically registered with the ISRCTN Register. The application will require a list of documentation to be submitted alongside it, such as a covering letter, investigational medical product dossier, a manufacturer's authorisation and content of the

labelling of the investigational medicinal product.

The initial combined review assessment will usually be completed within 30 days of being submitted. The applicant will be told the outcome of the submission and REC's review, which will either be:

- acceptance of the request for a clinical trial authorisation;
- acceptance of the request for a clinical trial authorisation subject to conditions; or
- grounds for non-acceptance of the request for a clinical trial authorisation.

If grounds for non-acceptance is received, the applicant will have the opportunity to respond, usually within 14 days, which can be extended on request.

Medical Devices

Overview of Key UK Legislation

The key legislation and regulatory framework for clinical investigations across England, Wales and Scotland for medical devices is the MDR. The Northern Ireland Protocol requires Northern Ireland to continue to align with EU rules for devices after 1 January 2021. Therefore, the Medical Device Regulation (EU) 2017/745 and the in vitro Diagnostic Medical Device Regulation (EU) 2017/746 (IVDR) apply in Northern Ireland.

A clinical investigation may be required as part of the process to obtain a UKCA/CE marking for a medical device.

The Process

Approval from the MHRA and HRA is required before any clinical investigation can start, which includes a requirement for a positive independent ethical opinion from a REC. The MHRA must be informed at least 60 days prior to starting a clinical investigation via email with specific details. All clinical investigations involving a site in Northern Ireland must be submitted to the MHRA in line with the requirements of EU MDR 2017/745.

An application for the clinical investigation is made through the IRAS system. For Great Britain, the MHRA assessment will usually take up to 60 days, starting the day after the application has been accepted. Experts will assess the safety and performance of the device, as well as the design of the clinical investigation proposed. By the end of the 60-day period, the MHRA will provide a result of objection or no objection. The HRA assessment will take approximately 40 days. Where there are grounds for an objection, the MHRA will arrange a teleconference, where possible, to attempt to find a resolution within the 60-day assessment period.

The assessment process is different in Northern Ireland; the assessment begins on the date the MHRA confirms it has received a valid application. Dependent of whether experts are consulted, a decision is provided within 45 – 65 calendar dates, providing an objection or no objection result. In the event of there are grounds for refusal, the MHRA will, where possible, arrange a teleconference to attempt resolution within the assessment period.

8. Is there a public database for clinical trials in your country, and what are the rules for publication?

From 1 January 2022 the HRA automatically registers clinical trials with ISRCTN Registry.

The WHO International Clinical Trials Registry Platform (ICTRP) website provides access to clinical trials in countries all around the world.

For trials involving both UK and EU sites, a record in the EU Clinical Trials Register will exist (other than adult Phase 1 studies).

Publishing clinical trial results

A summary of the results of a clinical trial must be published (i) within 6 months of the end of trial for paediatric clinical trials, (ii) or within one year of the end of trial for non-paediatric clinical trials. Such results should be published on the register that the clinical trial is registered. The report does not need to be submitted to the MHRA, however, a short confirmatory email should be sent to the MHRA once the result-related information has been uploaded to the public register and a link provided.

That being said, as a matter of best practice, if a clinical trial is not published on a public register, then summary results should be submitted to the MHRA.

A final report should also be submitted to the Research Ethics Committee within the same timeframe for reporting the summary of results.

9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?

In the UK, the UK General Data Protection Regulation (which, to a large extent, mirrors the EU GDPR) and the Data Protection Act 2018 ("**DPA**", together the "**UK GDPR**") regulate the processing of personal data.

The term "**personal data**" is defined very broadly, covering essentially any information that directly or indirectly identifies a living individual (a "**data subject**"). Data generated in the course of or in connection with clinical trials that directly or indirectly identifies an individual (including genetic data or other data concerning health, including the provision of health care services or health status, together "**health data**") will fall under this definition. Under the UK GDPR, health data is subject to a higher level and standard of protection, given its sensitive nature.

The term "processing" is also defined very broadly, covering any activity in relation to personal data, including initial collection or generation, analysis, as well as transfers to third parties.

The UK GDPR regulates the processing activities of "**controllers**" (persons who determine the purposes and means of processing of personal data) and "**processors**" (persons, such as third party IT service providers, who process personal data on behalf of and on specific instructions from controllers).

Data Protection considerations when designing and deploying clinical trials that are subject to the UK GDPR include:

- **Allocation of responsibilities**: Clinical trials engage a range of different entities who may have an interest in, or otherwise access and share patient data produced during trials, such as sponsors, investigators, database providers for potential participants, trial sites, medical professionals administering the trial, and clinical research organisations. It is critical that entities properly consider, and accurately establish the data protection roles of these participants, including within clinical trial agreements and any ancillary agreements and ensure that all data protection obligations are appropriately assigned to the correct party.
- **Legal basis for processing**: The UK GDPR prohibits processing of any personal data unless it fits within at least one of six conditions, generally known as the "legal bases" for processing. The legal bases are: (i) consent; (ii) necessary for the performance of a contract; (iii) necessary for compliance with a legal obligation; (iv) necessary to protect the vital interests of a data subject or another person; (v) necessary for performance of a task carried out in the public interest or in exercise of official authority vested in the controller; and (vi) necessary for purposes of legitimate interests. In addition, to process health data, controllers must also be able to satisfy more stringent conditions, including reliance on data subjects' explicit consent for processing for specified purposes (e.g., as collected as part of onboarding for the clinical trial). There is a very high threshold for obtaining valid consent under the UK GDPR, so any processing based on consent will require close review and analysis.
- **Transparency and provision of information**: Data subjects have a right to be informed about what of their personal data is processed, how it is processed, and other certain information. This information is typically provided to data subjects at the time their personal data is collected via a "privacy notice", for example during onboarding for a clinical trial.
- **Security and breach notification**: The UK GDPR requires both controllers and processors implement appropriate technical and organisational security measures to protect personal data. This is particularly important for clinical trials where information processed about individuals may be sensitive and immutable.

10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?

In addition to the UK Government's announcement of introducing a new regulatory framework for clinical trials, which will, amongst others, reduce approval times for clinical trials (see Question 7), in March 2021, the UK Government published its 10-year initiative: *Saving and Improving Lives: The Future of UK Clinical Research Delivery*. In June 2021, the "The Future of UK Clinical Research Delivery: 2021 to 2022 implementation plan" was published which set out steps to progress the initiative during 2021 to 2022.

In June 2022, the UK Government published "The Future of Clinical Research Delivery: 2022 to 2025 implementation plan". One of the five overarching themes of the initiative is "*research enabled by data and digital tools to ensure the best use of resources, leveraging the strength of UK health data assets to allow for more high-quality research to be delivered*".

The plan sets out the step that sees further development and utilisation of innovative data-driven methods and

digital tools to reshape the way clinical research studies are designed, managed and delivered across the whole of the UK.

It sets out a number of ways that the UK Government will improve study planning, recruitment and follow-up, including:

- "NHS DigiTrials" and Clinical Practice Research Datalink (via MHRA) will allow for a significant increase in the scale of identification of people who match the eligibility criteria for specific studies;
- investment in health data infrastructure for research and development in England; and
- the National Institute for Health and Care Research will invest in data and digital platforms (e.g., Be Part of Research and NIHR BioResource) to provide tools and support in order to deliver virtual and decentralised studies.

11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.

Medicinal products

Under the HMR, a manufacturer of medicinal products in the UK must first obtain a 'manufacturer licence' from the MHRA. There are different manufacturer licences depending on the specific type of medicinal product intended to be manufactured (e.g., a "Manufacturer licence for investigational medicinal products" is a licence for the manufacture of investigational medicinal products for use in clinical trials).

The application for the manufacturing licence should contain specific and factual information about the production and/or control of the pharmaceutical operations to be carried out.

Only once the MHRA has inspected a manufacturing site and it is satisfied that the information within the application is accurate and compliant with the legislation, will it issue a manufacturing licence.

The holder of a manufacturing licence has to comply with obligations under the HMR, including compliance with the principles and guidelines of good manufacturing practice.

A manufacturer licence is required before a company can apply for a marketing authorisation.

A certificate of Good Manufacturing Practice ("**GMP**") is issued to a manufacturer if the outcome of the inspection confirms that the manufacturer complies with the principles of GMP.

GMP is a minimum standard medicine manufacturers have to meet in their processes. Products must:

- be consistent high quality;
- be appropriate for their intended use;
- meet requirements of the making authorization or product specification.

The MHRA will carry out inspections of manufacturing sites to check for GMP compliance, when an applicant initially applies, but also then periodically. A GMP compliance report must be completed before inspection.

Any deficiencies found during inspections are graded at three levels:

- critical deficiency – such deficiency produces or significantly risks producing a harmful product;
- major deficiency – a non-critical deficiency which for example has or may produce a product that does not comply with its marketing authorisation; or
- other – a deficiency that indicates departure from GMP (but not enough to be critical/major).

An applicant must respond to any deficiencies found to propose corrective actions and dates for completion of such actions. If the inspector accepts this, it will provide the GMP certificate. If not acceptable, the applicant may go through the "compliance escalation process", aiming to achieve compliance before regulatory action is required.

Should compliance not be agreed, or critical deficiencies found, the inspector will contact the Inspection Action Group, who can refuse or suspend the licence, increase site inspections or request a meeting with the licence holder.

In addition to GMP, the manufacturer may be required to comply with additional GxP requirements, such as Good Distribution Practice ("**GDP**") and Good Pharmacovigilance Practice ("**GPvP**"). For example, if the manufacturer is the MA holder, they will be required to comply with GPvP, being the minimum standard for monitoring the safety of medicines placed on the UK market. As with GMP, the MHRA will conduct regular inspections of MA holders to determine whether they comply with GPvP obligations established in the UK. If pharmacovigilance activities are performed outside the

UK, the MHRA may ask company personnel from other country sites to participate in an inspection at a UK site and/or may liaise with inspectorates in other regulatory agencies to perform an inspection at site(s) in their country or to share results from recent inspections, where confidentiality agreements are in place.

Further, any site that is involved in storing, manufacturing or serving as a distribution facility for controlled drugs will need to be subject to a controlled drugs licence granted by the Home Office (see Questions 4 and 5). Controlled drugs licensees may be subject to certain legislation in respect of their premises (e.g., the Misuse of Drugs (Safe Custody) Regulations 1973 (S.I. 1973/798) (MD SCR 1973) in respect of storage of specific controlled drugs). Each licensee and their premises will carry different and specific risks that should be mitigated with security measures.

Manufacturers will also require other licences and permits in relation to operating facilities generally, including in relation to certain chemicals which will require certain licences/permits depending on the chemical.

Medical devices

Manufacturers wishing to place a device on the GB market need to register with the MHRA (see Question 2). Where a manufacturer is not established in the UK, they must appoint a UK Responsible Person to register and act on their behalf. The UK Responsible Person must provide written evidence to the MHRA that they have the manufacturer's authority to act as their UK Responsible Person. Importers and distributors are not required to appoint a UK Responsible Person.

The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations. As noted above, this includes registering the manufacturer's devices with the MHRA before the devices can be placed on the GB market.

The responsibilities of the UK Responsible Person are set out in the MDR. However, key responsibilities include:

- ensuring that the declaration of conformity and technical documentation have been prepared and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer (see Question 2);
- responding to requests from the MHRA and providing the MHRA with all the information and documentation necessary to demonstrate the conformity of a device.
- cooperating with the MHRA on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by medical devices;
- informing the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a medical device for which they have been appointed.

Food / Food Supplements

Food manufacturers must register their manufacturing sites with the relevant local authority. Depending on the type of food and drink products manufactured at the site, manufacturers may also require additional certifications and approvals. For example, if the manufacturer produces organic ranges, it will need to obtain certification of organic status from an approved certification body (e.g., the Soil Association). Similarly, if the manufacturer intends to mark its food or drink products with the Fairtrade mark, it will need to be approved as a registered licensee by the Fairtrade Foundation.

As with other factories, a food or drinks manufacturer will also need to give consideration to and comply with any general legislation or requirements concerning the operation of a factory. For instance, obtaining appropriate insurance and complying with health and safety regulations. Moreover, businesses that handle 50 tonnes or more of qualifying packaging materials must register with the following agencies (as applicable):

- the Environment Agency in England;
- Natural Resources Wales;
- the Northern Ireland Environment Agency; or
- the Scottish Environment Protection Agency (SEPA) in Scotland.

12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.

Medicinal Products

Under the HMR "distributing a production by way of wholesale dealing" is defined as: "*selling or supplying it, or procuring or holding it or exporting it for the purposes of sale or supply to a person who receives it for a purpose… Those purposes are selling or supplying the product or administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person*."

A wholesale dealer licence must be held by any individual or company that sells or supplies medicines to anyone other than patients. Such a licence allows a distributor to:

- sell, supply, offer for sale or supply pharmacy, prescription only, traditional herbal and GSL medicines wholesale;
- import unlicensed medicinal products from countries inside the EEA; and
- export medicinal products to countries of EEA;

The Rules and Guidance for Pharmaceutical Distributors (The Green Guide) provides distributors with guidance, information and UK legislation on distribution of medicinal products, including guidance on pharmacovigilance for wholesalers, the naming of sites on a licence, self-inspection, and the responsible person for import.

A distributor must comply with conditions set out in regulations 43 – 45AB of the HMR 2012, which includes compliance with Good Distribution Practice ("**GDP**") which requires them to obtain medicines from the licensed supply chain and to ensure that they are consistently stored, transported and handled under suitable conditions, as required by the MA or product specification.

Medical Devices

Following the UK's departure from the European Union, there is no requirement for suppliers or distributors to register with the MHRA.[6] That being said, in cases where the Great Britain importer is not the UK Responsible Person, the importer is required to inform the relevant manufacturer or UK Responsible Person of their intention to import a medical device. In such cases, the manufacturer or the manufacturer's UK Responsible Person is required to provide the MHRA with details of such medical device importers.

Obligations around storage, transportation and checking device labels for the CE marking or UKCA marking continue to apply. However, the importer or distributor's name and address do not need to be present on the label unless the importer or distributor are acting as the UK Responsible Person for the purposes of the UKCA marking.

Food / Food Supplements

As is the case for food manufacturers, food distributors must also register their business and premises with the relevant local authorities (see Question 11).

Footnote(s):

6 https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market

13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

Medicinal Products

Within the UK and for state-funded healthcare (i.e., via the NHS), two pricing arrangements for branded medicines exist:

- The Voluntary Scheme for Branded Medicines Pricing and Access.
- The Statutory Scheme.

The Voluntary Scheme for Branded Medicines Pricing and Access

The 2024 Voluntary scheme for branded medicines pricing, access and growth ("**2024 Voluntary Scheme**") came into force on 1 January 2024 (following expiry of the 2019 Voluntary Scheme for Branded Medicines Pricing and Access). The 2024 Voluntary Scheme is made between The Department of Health and Social Care representing the devolved nations of the UK, NHS England, the Association of the British Pharmaceutical Industry and manufacturers or suppliers of branded health service medicines that have joined the 2024 Voluntary Scheme. The scheme is in place for 5 years, until 31 December 2028.

The 2024 Voluntary Scheme is also supported by the National Institute for Health and Care Excellence (NICE) who has a central role in its operation and approval of medicines being available via the NHS.

In respect of sales of branded health service medicines, payments are made by scheme members under two different payment mechanisms covering sales of (i) newer medicines, with payment percentage being amended at the start of each year, and (ii) older medicines, with payment percentage set a basic level of 10%. A series of adjustments will be made by the UK Government to the allowed sales baseline in each year of the 2024 Voluntary Scheme. Most branded medicines are subject to the 2024 Voluntary Scheme as that generally provides a higher reimbursement than the Statutory Scheme.

The Statutory Scheme

Manufacturers or suppliers of branded health service

medicines who do not participate in the 2024 Voluntary Scheme are, by default, subject to the Statutory Scheme. The Department of Health and Social Care is responsible for the Statutory Scheme across the UK, and the payments that companies make under the scheme in respect of the UK are allocated to each part of the UK on an agreed basis each year. The UK Government have stated they will consult in early 2024 on further amendments to the Statutory Scheme in order to maintain equivalence with the 2024 Voluntary Scheme, which was not possible to be completed for 1 January 2024.

Private Prescriptions

Medicines can also be prescribed/purchased through privately-funded arrangements (including private healthcare). The pricing for such medicines is not prescribed by the above schemes and generally there is freedom of pricing subject to other controls including antitrust laws.

Medical Devices / Food Supplements

As at the date of preparing this Chapter, we are not aware of any formal schemes in the UK that govern the pricing and reimbursement of medical devices or food supplements.

14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?

UK Advertising Regulatory Framework

Advertising in the UK is regulated through the BCAP Code (the "**Broadcast Code**" which covers ads on TV and radio) and the CAP Code (the "**Non-broadcast Code**" which covers other ads, including online ads) (together, the "**Advertising Codes**").

The Advertising Codes are enforced by the Advertising Standards Agency ("**ASA**"), the UK advertising regulator, and set out a number of general and specific rules for businesses to comply with when advertising their goods or services in the UK. For example, restrictions on materially misleading consumers (Rule 3.1), restrictions on materially misleading by omitting material information or presenting information in an unclear, unintelligible, ambiguous or untimely manner (Rule 3.3), and the requirement to state significant limitations and qualifications (Rule 3.9). There are also specific rules that target specific goods and services. For instance, Rule 12 of the CAP Code provides restrictions on the advertisement of medicinal products and medical devices, whereas Rule 15 provides restrictions on the advertisement of food and food supplements.

In addition to the Advertising Codes, there are also certain restrictions on the advertisement of certain products imposed by product-specific regulations, as set out below.

Medicinal products/Medical Products

The advertisement, marketing, promotion and/or endorsement of any medicinal products in the UK are subject to very strict controls and restrictions. For instance, companies are permitted to advertise over-the-counter medicines, general sales list medicines and pharmacy medicines to consumers in the UK (subject to not being misleading or inaccurate). However, there is a general prohibition on the marketing or advertisement to non-medical professionals of prescription-only-medicines ("**POMs**") or any medicine that is not licensed by the MHRA (or for products in Northern Ireland, the European Commission).

Regulatory bodies have provided guidelines for promotion and marketing to healthcare professionals that members of the pharmaceutical industry are to follow. For example, the MHRA publishes the Blue Guide which contains details of its opinions on the interpretation of pharmaceutical advertising legislation. The purpose of the Blue Guide is to ensure that the advertising of medicines is in line with legislation and agreed standards of good practice in order to protect and not mislead. Similarly, the ABPI publishes its code of practice, which is administered and regulated by a separate body, the Pharmaceutical Medicines Code of Practice Authority. The ABPI Code sets standards for the promotion of medicines to health professionals and other relevant decision makers in the UK. It includes requirements for the provision of information to patients and the public, and managing relationships with patient groups. The ABPI Code also applies to a number of areas that are non-promotional.

The Blue Guide and ABPI Code do not contain any express prohibitions on the use of clinical trial or meta-analyses data (whether or not the same involved the company's employees) in connection with the advertisement of a medicinal product. However, such advertisement will be subject to certain general advertising requirements as set by applicable law in the UK, including a requirement not to be misleading or inaccurate.

Medical Devices

Currently, the Medicines and Medical Devices Act 2021 and the MDR do not contain express provisions for the

regulation of advertising medical devices other than to prohibit marketing of devices that do not conform to the legislation.

Food / Food Supplements

In July 2007, a Regulation of the European Parliament and of the Council of the European Union on nutrition and health claims made on foods (the NHCR) came into force (Regulation 1924/2006). This regulation was retained in national UK law following Brexit, and was subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (the "**Nutrition Regulations**"), which transferred the responsibilities from the EU organisations to relevant GB bodies involved in the risk assessment and risk management processes covered by nutrition legislation.

The protocol on Ireland/Northern Ireland means that EU legislation relating to nutrition continues to be directly applicable in Northern Ireland.

Under the Nutrition Regulations, only health claims that are on the list of authorised health claims can be used on food/food supplements. The only exceptions to this are general, non-specific claims and trade marks or brand names that are also health claims.

Under the Food Supplements (England) Regulations 2003, food supplements cannot be sold if the advertising of the food supplement includes any mention, express or implied, that a balanced and varied diet cannot provide appropriate quantities of nutrients in general.

15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?

Patents

In order for a medicinal product, medical device, or food supplement to be the subject of a patent, in general it must meet the basic patent requirements of being new, inventive, capable of industrial application and not be considered excluded subject matter, pursuant to the Patents Act 1977 (as amended). A method of medical treatment or diagnosis, a discovery, or a scientific theory cannot be patented.

The Patents Act 2004 amended the Patents Act 1977 in respect of medical inventions, to implement the European Patent Convention as revised in 2000 (EPC 2000). The Patents Act 2004 introduced a new provision providing that the invention of a method of treatment of the human or animal body by surgery or therapy, or a method of diagnosis practised on the human or animal body, is not patentable. Although, biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

Claims to medical devices are allowed, as long as the invention is not a claim to the device "when used" in methods of surgery/therapy/diagnosis (e.g., a claim to heart monitor that was characterised partly by its method of use would not be allowed).

Trade marks

Trade marks are subject to the Trade Marks Act 1994 ("**TMA**"), along with relevant case law. Under the TMA, in order for a trade mark to qualify for registration it must:

1. satisfy the definition of a trade mark;
2. satisfy the absolute ground requirements; and
3. not fail any of the relative grounds.

The definition of a trade mark is any sign, capable of being represented in the register and capable of distinguishing goods and services from others.

To satisfy the absolute ground requirements, a trade mark must (i) not fail the definition of a trade mark, (ii) be distinctive, (iii) not be descriptive, and (iv) not be generic/commonly used.

Under the relative grounds, a trade mark will be refused where it is it, and its goods or services applied for, are identical/similar to an earlier trade mark and its protected goods or services, where there exists a likelihood of confusion.

Trade marks can be used for branding and commercialising medicinal products, medical devices, food and food supplements. However, separate from trade mark legislation, the MHRA also provides guidance and restrictions in connection with the naming of medicinal products (see Question 17).

16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.

Under the Patents Act 1977 (as amended), a patent is infringed where the patent is in force and a person does,

without proprietor consent, any of the following in the UK:

- where the invention is a product, they make, dispose of, offer to dispose of, use or import the product or keep it whether for disposal or otherwise;
- where the invention is a process, they use the process or offer it for use in the UK when they know, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent; or
- where the invention is a process, they dispose of, offer to dispose of, use or import any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

Further, a patent is also infringed where the patent is in force and a person knowingly (or would be obvious to a reasonable person), without proprietor consent, supplies or offers to supply in the UK to an unauthorised person with any means, relating to an essential element of the invention, for putting an invention into effect.

However, an act will not constitute infringement, if:

- it is done for experimental purposes relating to the subject-matter of the invention;
- it consists of the impromptu preparation in a pharmacy of a medicine for an individual in accordance with a prescription or consists of dealing with a medicine so prepared;
- it consists of an act done in conducting a study/test/trial necessary for toxicological and pharmacological tests.

If the proprietor or exclusive licensee of a patent commences patent infringement proceedings, it is typical that the defendant will counterclaim to invalidate the patent. Of course, the prospects of any counterclaim being issued will need to be assessed on a case-by-case, however, it can be a useful tool in the context of any settlement negotiations happening between the parties in parallel to the court proceedings.

SPCs

A Supplementary Protection Certificate ("**SPC**") provides for extended monopoly protection to compensate for the time under the patent's term where the product could not be used due to delays in obtaining regulatory approval to market the patented invention. The SPC provides the patent holder with additional protection over the active ingredient identified in the claims of the original patent. It enters into force when the patent expires and lasts up to five years.

Remedies

A claimant bringing patent infringement proceedings may seek a number of remedies, including:

- an injunction;
- damages or an account of profits.

17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?

Where the proposed name for a medicinal product has been registered as a UK trade mark, an assessment by the MHRA, including safety considerations, will determine whether the proposed name is suitable for use. Such assessment will look at ensuring minimalisation of the potential risk of confusion with the name of another medicinal product.

The international non-proprietary name (INN) identifies the active ingredient of a pharmaceutical product. Each INN is globally recognised and public property. A trade mark cannot be too close to or derived from an INN.

18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

In the UK, product safety is governed by a wide legal and regulatory framework, with certain high-risk products, such as medicines, medical devices and food supplements (which are classified as a food), being subject to additional regulation.

Key Legislation

The main legislation which may result in product liability in respect of medicinal products, medical devices and/or food supplements in the UK is:

- the Consumer Protection Act 1987 (the "**CPA**"), as amended, which implemented the EU Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (the "**Product Liability Directive**") into UK law;
- the common law tort of negligence; and
- contract law.

In practice, it is common for claimants to bring actions under a combination of the above three legal principles. These parallel actions are often used by claimants to seek to avoid statutory time limitations.

Product liability generally gives rise to civil liability. However, criminal offence provisions exist for breaches of certain product safety laws (see Question 19).

19. Please provide a short overview of risks of liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

As discussed in Question 18, there are three main bases for liability in respect of medicinal products, medical devices, foods, and food supplements in the UK: (i) the CPA, (ii) negligence, and (iii) breach of contract.

Liability Under the CPA

The CPA imposes strict liability (regardless of intent/negligence) for defective products.

Producers, suppliers and importers of medicinal products, medical devices, foods and food supplements, including individuals and body corporates, may also be subject to criminal sanction under criminal offence provisions under the CPA. It is an offence for a person to fail to comply with the requirements of the safety regulations made under the CPA. Those safety regulations include the MDR (as amended), but not the HMR in respect of medicinal products and medical devices. A person guilty of this offence is liable to imprisonment for up to six months or an unlimited fine.

Liability in Negligence

A claimant who has suffered personal injury or damage to their property as a result of a defective product may also be able to bring a common law action for negligence against the manufacturer.

To succeed in a claim in negligence, the claimant must prove on the balance of probabilities that (i) the manufacturer owed them a duty of care, (ii) the manufacturer breached that duty, (iii) the breach caused the damage in question, and (iv) the damage could reasonably have been foreseen.

In contrast to a strict liability claim under the CPA, a product liability claim in negligence with respect to a defective medicinal product or medical device will also require the claimant to demonstrate an element of 'fault' on the manufacturer's part (e.g., a breach in their duty of care).

Liability Pursuant to Contract Law

Pursuant to the law of contract, a purchaser of a product may be able to claim against the seller for breach of any relevant express terms in the purchase contract, and/or any relevant term that is implied into the contract. Common law and statue provide for certain terms to be implied into a contract in various circumstances.

In respect of medicinal products / medical devices, breach of contract claims may be more difficult for a patient to bring against the device or product manufacturer if, in fact, the product used for a procedure was purchased by a physician/clinic, rather than the patient themselves. Instead, the patient may have a contractual claim against the physician/clinic, who in turn may claim against the manufacturer.

When considering what statute is relevant to a contract for the sale of a product, it is first necessary to determine whether the purchaser is a business or a consumer. For business-to-business contracts, the Sale of Goods Act 1979 (the "**SGA**") implies various terms into contracts for the sale of goods where the purchaser is not a consumer (e.g., that the goods must be of satisfactory quality). For business-to-consumer contracts, the Consumer Rights Act 2015 (the "**CRA**"), implies various terms into contracts for the sale of goods where the purchaser is a consumer, which includes the implied term that goods must be of satisfactory quality.

Where a claimant only seeks to obtain compensation for damage to the product itself, which is expressly excluded as a head of damage under the CPA, a contractual claim may be the most appropriate avenue of redress. In such case, reliance may be placed on the term implied into the contract by the SGA or CRA that goods must be of satisfactory quality.

20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

The legal framework for medical devices is set out in Question 1. On 8 July 2021, the MHRA published updated guidance on "Medical Devices and standalone software including apps". In its guidance, the MHRA specified that "*software that gives information about the presence or*

amount of a pharmaceutical or other therapeutic measure from results generated by an IVD", such as *"Apps and software that are intended to monitor blood glucose"* may be considered to be a medical device.

21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.

Under the HMR, the holder of a wholesale dealer licence must ensure, within the limits of its responsibility, the continued supply of medicinal products to pharmacies, and other persons who may lawfully sell medicinal products by retail or supply them in circumstances corresponding to retail sale, so that the needs of patients in the UK are met.

22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.

Medicinal Products

In additional to relevant legislation, codes of practices in respect of medicinal products include:

- **The Association of the British Pharmaceutical Industry (ABPI) Code of Practice.** This is applicable to the advertising to healthcare professions and other relevant entities in respect of proprietary medicines;
- **The Proprietary Association of Great Britain (PAGB) Professional and Consumer Codes**. These codes determine the rules which related to advertising of over the counter medicines.

Medical devices

In additional to relevant legislation, codes of practices in respect of medicinal devices include:

- **The Association of British Healthcare Industries (ABHI) Code of Practice**, including the **ABHI Guidelines on Advertisements & Promotions** which are addressed solely or primarily to healthcare professionals, and the ABHI Guidelines on Interactions with Healthcare Professionals, a voluntary code, enforced by the ABHI, which binds its members; and
- **The PAGB Medical Devices Consumer Code**, applicable to advertising by PAGB members of certain self-care medical devices.

Other codes of practice are in force in respect of sector-specific medical devices.

23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.

The UK Supreme Court provided the following recent judgment:

- **Secretary of State for Health & Anor v Servier Laboratories Ltd & Ors ("Servier")**: the case concerned an application by Servier to strike out an allegation that Sevier's actions in relation to an attempt to enforce European Patent EP 1 296 947 (the Patent) amounted to the tort of causing loss by unlawful means. In its decision, the Court defined the tort of unlawful means as consisting of acts intended to cause loss to a claimant by interfering with the freedom of a third party in a way which is unlawful as against that third party and which is intended to cause loss to the claimant. The Court held that the case law identified that the acts in question had to be acts which interfered with a third party's freedom to deal with a claimant. On the facts no such interference was established since none of the alleged acts could be said to have interfered with the freedom of the claimant to deal with Courts or the EPO. Servier had simply defended and enforced a patent that was later held to be invalid. The Court therefore granted Servier's application and the allegation was struck out.

The Competition Market Authorities (the "**CMA**") recently investigated three health care mergers in the UK:

- **Cochlear Limited ("Cochlear") / Oticon Medical ("Octicon"):** Cochlear, a company involved in the manufacture and supply of hearing devices namely bone conduction solutions ("**BCS**"), was acquiring Octicon. The

seller of Octicon was also involved in the manufacturer and supply, as well as development, of hearing implants, including BCS, through Octicon. The CMA found that the merger would lead to a reduction in choice, quality and innovation, as well as increased prices. The CMA narrowly interpretated the market, excluding other hearing solutions from the frame of reference, and also relied on a potential competition theory of harm, finding that the parties would become closer competitors in the Active BCS segment. Overall, the CMA blocked the acquisition of the BSC element of the transaction.

- **Bestway Panacea Holdings Limited ("Bestway") / Lexon UK Holdings Limited ("Lexon") and Asurex Limited ("Asurex"):** Bestway, a pharmacy retail chain, and pharmaceutical distributor, acquired Lexon and Asurex, two pharmaceutical wholesalers, in April 2023. The CMA limited the market to retail pharmacies, and a catchment of the local area, finding the companies had a combined 30/35% share of supply, with an increase of 5% from the merger. The CMA provisionally found issues within 12 local areas. Bestway remedied this by undertaking to sell seven of its own pharmacies to pre-approved purchasers.
- **UnitedHealth Group Incorporated ("UnitedHealth")/ EMIS Group Plc ("EMIS"):** UnitedHealth, a company offering software systems for GPs, acquired EMIS, a company involved in IT healthcare solutions, including primary care electronic patient record ("**EPR**") systems via its EMIS Web brand. There was a third party whose software system was the only other system, other than UnitedHealth's system, that integrated with the primary care EPR systems. The CMA found that the merger would not lead to the parties limiting competitors' access to EMIS Web's systems, since any foreclosure strategy would not be profitable and would also be in part prevented by the NHS's rules and standards.

24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.

Although a range of legislation and regulation can apply to the use and implementation of AI (such as Data Protection laws – see Question 9), the UK does not currently have any legislation that is specific to AI governance, or its use in healthcare.

The UK Government recently released its response to a consultation into AI governance, within which it confirmed that it was looking to implement voluntary regulatory guidance, rather than mandatory legislation.

The UK Government also confirmed that the UK Intellectual Property Office working group was not producing a voluntary code of practice for copyright and AI at this moment in time.

25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.

- In 2023, the UK Government announced a life sciences growth package, 'Life Sci for Growth', investing £650 million into the life sciences sector. The package included various policies/investment proposals, including looking to improve the regulatory landscape for UK commercial clinical trials, by proposing to cut the regulatory burden of clinical trial approval and to invest £121 million to speed up commercial clinical trials and improve access to real-time data. It also proposed £154 million to increase the capacity of the UK's biological data bank, and up to £250 million to incentivise pension schemes to invest in the most promising science and tech firms. There have been no further updates on this package as of yet and it is currently unclear the extent of implementation of the package.
- The International Recognition Procedure ("**IRP**") was implemented by the MHRA from 1 January 2024, allowing developers of new medicines from around the world to now submit applications via this IRP. The IRP allows MHRA to take into account the expertise of trusted regulatory partners in other countries when authorising medicines. Such partners being regulators in Australia, Canada, Japan, Singapore, Switzerland and the USA, as well as the European Medicines Agency, individual EU member states and those in the EEA (European Economic Area).
- On the 4 December 2023 the UK and EU

signed a bespoke new agreement finalising the UK's association to Horizon Europe. Subject to a number of exceptions, the UK's "Associated Country" status allows UK applicants to participate in the full Horizon Europe programme onwards with the same rights as EU participants. Such exceptions are to the (i) European Innovation Council ("**EIC**") Fund, which provides equity finance support to EIC Accelerator projects; and (ii) limited exceptional cases where the eligibility for individual funding calls is limited to member states or certain other countries under current Work Programmes.

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