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UK: Law & Practice

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UK

Law and Practice

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1. LIFE SCIENCES REGULATORY FRAMEWORK

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

On account of Brexit, the UK is no longer subject to EU single-market rules or the EU legislative framework. However, under the EU-UK Withdrawal Agreement's Protocol on Ireland and Northern Ireland, Northern Ireland continues to follow EU rules. In addition, pre-existing domestic legislation that implemented EU law continues to have effect in the UK.

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

Similarly, UK regulation of medical devices derives from three EU Directives (the Medical Device Directives):

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

These directives are implemented in UK domestic law through the Medical Devices Regulations 2002/618 (UK Medical Devices Regulations).

The more recent EU Regulations on medical devices (Regulation (EU) 2017/745 on medical devices (EU MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU IVDR) do not apply to Great Britain, but do to Northern Ireland.

The Medicines and Healthcare products Regulatory Agency (MHRA) is an executive agency sponsored by the Department of Health and Social Care (DHSC). The MHRA acts on behalf of the UK Licensing Authority, comprising the Secretary of State, and the Ministers for Health, Social Care and Public Health or Safety, with the statutory responsibility to apply and enforce laws governing pharmaceuticals and medical devices in the UK.

1.2 Challenging Decisions of Regulatory Bodies that Enforce Pharmaceuticals and Medical Devices Regulation

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

To this end, an application must be made promptly, and in any event within three months of the decision to be challenged, and 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 a marketing authorisation (MA).

The court's permission is required to proceed with a claim for judicial review.

The grounds for judicial review are evolving, but can be summarised as (i) illegality, (ii) irrationality, (iii) procedural unfairness, and (iv) legitimate expectation.

1.3 Different Categories of Pharmaceuticals and Medical Devices

There are three categories, or legal classifications, of medicinal products. These determine the level of control over supply. In part, classification rests on how much healthcare professional (HCP) input is needed to diagnose and

treat the conditions for which the medicine might be used. The three legal classifications are:

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

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 that include the intended purpose of the device, how long it is intended to be in use and if the device is invasive/surgically invasive, is 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 – low risk;
- Class IIa – medium risk;
- Class IIb – medium risk; and
- Class III – high risk.

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

In vitro diagnostic (IVD) medical devices are currently categorised differently 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 (which is referred to in UK legislation);
- 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.

2. CLINICAL TRIALS

2.1 Regulation of Clinical Trials

Current UK law governing clinical trials of medicinal products is the Medicines for Human Use (Clinical Trials) Regulations 2004/1031, which transposed the EU Clinical Trials Directive 2001/20/EC into UK law, and has been amended to reflect the UK's departure from the EU. Clinical trials must be conducted in accordance with good clinical practice (GCP), the terms of the approved protocol, clinical-trial authorisation and research ethics committee's (REC) approval. EU Clinical Trials Regulation 536/2014, which came into full effect on 31 January 2022, does not apply in Great Britain, but, as a result of the Northern Ireland Protocol, does apply in Northern Ireland.

On 17 January 2022, the MHRA opened a public consultation, outlining proposals to reform UK law and guidance on clinical trials for medicinal products. The aim is to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement.

Clinical investigations for medical devices are regulated by UK Medical Devices Regulations. Requirements relating to clinical investigation under the EU MDR (and EU IVDR once in full force) apply in Northern Ireland.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Before a clinical-trial can commence, an REC must give a favourable opinion, and authorisation must be obtained from the MHRA. A sponsor of a clinical trial must be established in the UK or in a country on an approved country list, which includes EU/EEA countries. Otherwise, the sponsor must have a legal representative.

As of 1 January 2022, applications for all new clinical trials for investigational medicinal products must be prepared, submitted and reviewed via the combined review service–a single application route and co-ordinated review by the MHRA and the REC, leading to a single UK decision on the application. Applications must be submitted via a new part of the Integrated Research Application System (IRAS).

After receipt of a valid application, a combined review assessment will be conducted within 30 days. Following assessment, and ordinarily within 60 days of the submission, the MHRA and the REC will either (i) accept the request, (ii) accept the request subject to conditions, or (iii) not accept the request.

The MHRA will focus on the safety and scientific value of the trial, while the REC will focus on the research proposals and review certain documents relating to the trial, including the trial protocol, the informed consent form, the suitability of the personnel, investigator and facilities, and the investigator's brochure.

The MHRA must be notified by the sponsor at least 60 days in advance of a clinical investigation involving medical devices commencing. Applications should be submitted via the IRAS. The MHRA will consider the documentation and assess the safety and performance of the device, as well as the design of the investigation. A letter will be sent to the sponsor within 60 days with a decision (providing either an "objection" or "no objection"). In addition, an opinion of the REC is required.

2.3 Public Availability of the Conduct of a Clinical Trial

Any favourable opinion by an REC is conditional upon the clinical trial being registered on a publicly accessible database.

From 1 January 2022, the Health Research Authority (HRA) will automatically register those clinical trials submitted through IRAS with the International Standard Randomised Controlled Trial Number (ISRCTN) registry.

For any submissions made up to 31 December 2021, clinical trials were still required to be registered using an established international register such as the ISRCTN Registry or ClinicalTrials.gov. Information about trials being conducted in the UK is made publicly available on the HRA research summaries website and the UK "Be Part of Research" website.

In addition, 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 international pharmaceutical association requirements.

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

2.4 Restriction for Using Online Tools to Support Clinical Trials

There are no restrictions on using online tools to support clinical trials or clinical investigations. However, all advertising, and all materials provided or directed to subjects, will be reviewed by the REC.

2.5 Use of Resulting Data from the Clinical Trials

Resulting data from clinical trials is likely to be considered as special-category (sensitive) personal health data for the purposes of the data protection legislation, even if it is in coded/pseudonymised form, and will be afforded greater protection than non-special category personal data. The Data Protection Act 2018 and the UK GDPR provides that pseudonymisation is a security measure that can be used to protect personal data, but it does not take the data outside the scope of the UK GDPR.

The resulting data can be transferred to a third party or affiliate, providing that any UK GDPR provisions governing such a transfer are complied with.

2.6 Databases Containing Personal or Sensitive Data

If the database contains personal or special-category (sensitive) personal health data, the UK GDPR would need to be complied with. The key requirements would be that the data is processed lawfully, that the data stored is relevant, up to date and limited to what is required, that sufficient security measures are put in place, that the data is not stored for longer than is necessary, and that the relevant individuals have been informed of the use and storage of their data. The party managing the database would also need to comply with the UK GDPR more widely.

3. MARKETING AUTHORISATIONS FOR PHARMACEUTICAL OR MEDICAL DEVICES

3.1 Product Classification: Pharmaceutical or Medical Devices

The HMRs define a medicinal product as:

- 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.

UK Medical Devices Regulations define 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 the product is presented; and
- the method by which the principal intended action is achieved.

Where the assessment is not straightforward, or disagreement arises, the MHRA's Medicines Borderline Section is able to issue determinations. Where there is doubt, a product will be classified as a medicinal product.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

The general rule is that a medicinal product may only be placed on the UK market if it has been

granted a marketing authorisation. Applications must be made to the MHRA.

Biological medicinal products must meet the same quality, safety and efficacy criteria to obtain an MA as those for non-biological medicinal products. However, since biological medicinal products are especially sensitive to change in starting materials or manufacturing conditions, specific requirements apply to biological medicinal products, as set out in Annex I to EU Directive 2001/83, as amended by Schedule 8B of HMRs.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

MAs for medicinal products in UK are valid for five years. However, an MA 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 grounds relating to pharmacovigilance to proceed with one additional five-year renewal.

The MHRA may revoke, vary or suspend a UK MA in certain situations, including if the MHRA believes 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 the public, or that the product's composition is not as described in the application for the MA, or the material supplied with it.

With regard to medical devices, a UKCA 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 various notices to manufacturers, for example, prohibition notices, to ban the supply of any goods that are considered unsafe or do not comply with UK Medical Devices Regulations.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

Medicinal Products

An application for a UK national MA must be made to the MHRA and must include the particulars and research data or justifications for exceptions that are described in the HMRs. Following Brexit, UK MAs are split into various types, depending on the parts of the UK to which they apply.

A number of new routes have been introduced post-Brexit to allow for quick recognition of products that are approved in the EU, and to allow greater flexibility in the UK procedures (such as a "rolling review" that permits the submission of an application in module(s)).

Applications intended to cover the marketing of a product in Northern Ireland must continue to comply with the requirements of EU Directive 2001/83 and EU Regulation 726/2004.

Medical Devices

As of 1 January 2021, there is a new route to market, with an accompanying mark, to place a device on the Great Britain market–UK Conformity Assessed mark (UKCA)–which is based on the requirements derived from current EU legislation. EU CE marking (the acronym for the French "*Conformité Européenne*" or "European conformity") will continue to be recognised in Great Britain, and certificates issued by EU-recognised Notified Bodies (NBs) will continue

to be valid for the Great Britain market, until 30 June 2023.

EU rules will continue to apply in Northern Ireland and EU CE marking is required. In addition, if the manufacturer chooses to use a UK NB for mandatory third-party conformity assessment for purposes of the Northern Ireland market, the UKNI mark must be applied in addition to the CE mark.

As previously noted, medical devices are given a classification depending on the level of risk associated with their use. Each risk classification also has a separate conformity assessment procedure. If the relevant requirements are met, the Approved Body will issue a UKCA certificate. Only UK-Approved Bodies may conduct conformity assessments in relation to a UKCA mark. They are not able to issue CE certificates other than for the purposes of the "CE UKNI" marking, which is valid in Northern Ireland.

Low-risk Class I medical devices do not need to go through a conformity assessment procedure. For all devices, once the relevant assessment has been completed successfully, the manufacturer may place a UKCA mark on their medical device and put their device on the market in Great Britain.

To place a device on the Great Britain or Northern Ireland market, all devices must now be registered with the MHRA. The MHRA will only accept registration of devices from manufacturers where the manufacturer is based in the UK. Therefore, manufacturers based outside the UK are required to appoint a UK Responsible Person that is established in the UK.

3.5 Access to Pharmaceutical and Medical Devices without Marketing Authorisations

The HMRs 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, the UK allows exceptions whereby a product can be placed on the market without an MA – the main one of which is often called "named-patient supply" and applies 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 authorised to prescribe;
- 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

Certain conditions set out in the HMRs must also be met.

When named-patient supply of medicinal products is offered to a co-ordinated patient group, this is referred to as a "compassionate-use scheme". However, the legislative provisions of named-patient supply continue to apply.

The Early Access to Medicines Scheme (EAMS) is a voluntary, non-statutory scheme which 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 satisfactory treatments.

Where devices are custom-made for individual patients, or intended for clinical investigation, they do not need a UKCA mark. Custom-made

medical devices are defined as devices manufactured specifically in accordance with a duly qualified medical practitioner's written prescription that gives, under his or her 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 UK Medical Devices Regulations that relate to custom-made devices.

The MHRA may also approve exceptional use of a non-compliant device on humanitarian grounds. These devices do not need a UKCA mark. A manufacturer can apply to the MHRA to supply a medical device that does not comply with the law 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 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

MA-holders must operate a pharmacovigilance system to monitor the safety of their product's life cycle, and to detect any change to their risk-benefit balance. They must have an appropriately qualified person (QP) responsible for pharmacovigilance located in the EEA (however, where this person does not reside and operate in the UK, there will be a need for a national contact person for pharmacovigilance who resides and operates in the UK), 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.

The MHRA may grant an MA subject to one or more conditions, including post-marketing obligations such as the requirement to conduct post-authorisation safety and efficacy studies. The MA-holder must incorporate any such condition into the risk management system for the product.

The MHRA requires that, once a medical device has been placed on the UK market, the manufacturer monitor and report to it any serious adverse incidents associated with the product. The manufacturer must also take appropriate safety action when required.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

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

The MHRA releases very little information in relation to pending applications.

Following the grant or the refusal of an MA, the MHRA generally releases detailed information about the application and authorisation, both proactively via disclosures on their websites and also in response to third-party information requests. The 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.

For medical devices, Approved Bodies are private entities. Therefore, access to information provisions that apply to public bodies do not apply. As such, both before and after UKCA marking, the information pertaining to the device remains the property of the manufacturer. Once regis-

tered with the MHRA, a manufacturer's details will be added to the Public Access Database for Medical Device Registration. Other information held by the MHRA could be requested under the FOIA, but will only be provided where no exceptions under the FOIA apply.

3.8 Rules against Illegal Medicines and/or Medical Devices

The EU Falsified Medicines Directive (FMD) ceased to apply in Great Britain at the end of the transition period. As such, pharmacies in Great Britain are no longer using the UK Medicines Verification System and medicines with a marketing authorisation valid only in Great Britain are not required to have a Unique Identifier. However, the MHRA encourages companies to retain the tamper-evident device.

Under the Northern Ireland Protocol, Northern Ireland will continue to comply with the FMD, for at least four years from the end of the transition period.

The Medicines and Medical Devices Act 2021 includes a power to put in place a bespoke falsified-medicines system and a public consultation on the system is expected.

Falsified medicines should be reported to the MHRA via the Yellow Card reporting site.

The Medicines and Medical Devices Act 2021 consolidated and streamlined the MHRA's enforcement powers regarding medical devices, which includes falsification and illegal distribution of medical devices. The MHRA may issue compliance, suspension, safety and requests for information notices. It is a criminal offence for a manufacturer to breach a notice as well as civil sanctions.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

See **10. IP Other than Patents**.

4. MANUFACTURING OF PHARMACEUTICAL AND MEDICAL DEVICES

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

A manufacturer licence issued by the MHRA is required in order to manufacture, assemble or import licensed, unlicensed or investigational medicinal products. The process involves submission of an application and inspection of the designated manufacturing site by the MHRA to verify compliance with good manufacturing practice (GMP). A manufacturer licence remains in force until it is revoked or surrendered. Manufacturers of medical devices are not required to obtain a specific authorisation for the manufacture of their products, but are required to register with the MHRA in order to place the medical devices on the market in the UK. A statutory fee of GBP100 applies to registration and updating information. As previously noted, the MHRA will only register devices where the manufacturer or their UK Responsible Person has a registered place of business in UK.

5. DISTRIBUTION OF PHARMACEUTICAL AND MEDICAL DEVICES

5.1 Wholesale of Pharmaceutical and Medical Devices

A wholesale distribution authorisation (WDA) issued by the MHRA is required in order to: (i) sell, supply, offer for sale, procure, hold or export POMs, pharmacy (P), traditional herbal and GSL

medicines on a wholesale basis in the UK, (ii) import Qualified Person (QP)-certified medicinal products into Great Britain from EEA countries, and (iii) export medicinal products to EEA countries. WDA holders located in Northern Ireland (NI) can still bring medicinal products into NI from Great Britain, provided certain additional conditions are met.

The facility involved in wholesale distribution is subject to inspection by the MHRA before a licence is granted. A WDA remains in force until it is revoked or surrendered.

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

5.2 Different Classifications Applicable to Pharmaceuticals

See **1.3 Different Categories of Pharmaceuticals and Medical Devices**.

6. IMPORTATION AND EXPORTATION OF PHARMACEUTICALS AND MEDICAL DEVICES

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

Importing and exporting medicinal products is governed by the HMRs (or EU Directive 2001/83 in relation to Northern Ireland). Importing medical devices is governed by the UK Medical Devices Regulations (or the relevant EU Directive in relation to Northern Ireland). There are no specific rules regarding exporting medical devices.

HM Revenue and Customs is responsible for border control. The MHRA Enforcement Group is responsible for applying and enforcing the HMRs and the UK Medical Devices Regulations.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Importers of pharmaceuticals and medical devices require an Economic Operator Registration Identification (EORI) number, which is entered onto all UK customs declarations. Importers must be a UK-resident business for certain UK customs issues, including the declarations.

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.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

Importing medicinal products into Great Britain from outside the EEA requires a manufacturer's import authorisation (MIA) granted by the MHRA. Importing QP-certified medicines into Great Britain from the EEA may be performed under a WDA which authorises import. Importing medicinal products into NI from Great Britain may be conducted under a WDA, provided certain additional conditions are met.

Import for personal use by the importer or a member of their immediate family (up to a three-month supply) does not require an authorisation.

No authorisation is required to import medical devices, but importers should notify the UK Responsible Person or the Northern Ireland-based Authorised Representative (as described in **3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices**) as they are required to provide the MHRA with a list of device-importers.

6.4 Non-tariff Regulations and Restrictions Imposed upon Importation

Details of specific tariff duties and measures that apply to particular goods in the UK are contained in the Integrated Tariff of the UK. An importer or exporter is responsible for the correct tariff classification of goods. Her Majesty's Revenue and Customs (HMRC) has developed an online trade tariff tool to assist in product classification.

6.5 Trade Blocs and Free Trade Agreements

Under the EU-UK Trade and Co-operation Agreement, there are no tariffs or quotas on trade in medicinal products and medical devices between the EU and the UK, and mutual recognition of GMP inspections and certificates. The UK has also entered into a free-trade agreement with Japan which provides for mutual recognition of drug-safety testing and inspections before export. The UK remains a member of the World Trade Organization (WTO).

7. PHARMACEUTICAL AND MEDICAL DEVICE PRICING AND REIMBURSEMENT

7.1 Price Control for Pharmaceuticals and Medical Devices

Statutory controls on pharmaceutical pricing are set out in the National Health Service Act 2006 and subordinate legislation.

The 2019 voluntary scheme for branded medicines pricing and access (VPAS) – a voluntary agreement negotiated between the DHSC and the ABPI – which controls prices of branded medicinal products indirectly by controlling profits made by scheme members from their National Health Service (NHS) business, and by establishing a budget cap on the total expenditure by the NHS on branded health service medicines, with member companies making scheme payments to the DHSC (calculated as a percentage of eligible net sales) as quarterly rebates to cover excess expenditure. The VPAS is an agreement which is not binding under the law of contract; however, the Secretary of State may enforce sums payable under the Scheme.

New branded health services medicines which contain a new active substance and are supplied by VPAS member companies are subject to free pricing at launch, as are line extensions of such medicinal products launched within 36 months of licensing of the initial indication in the UK. The prices of such products must be notified to the DHSC prior to launch. The price for all other branded health service medicines supplied by VPAS member companies must be agreed with the DHSC.

If a company is not a member of the VPAS, it is regulated by the parallel Statutory Scheme, currently set out in the Branded Health Service Medicines (Costs) Regulations 2018 (as amended). The Statutory Scheme is applicable only to branded health service POMs. From 1 April 2018, it has involved a payment scheme, calculated as a percentage of net sales, similar to the VPAS. The maximum price which may be charged for a branded health service medicine within the Statutory Scheme is that directed by the Secretary of State.

In primary care, the price of some medicinal products may be 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 goods and 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 medicinal product, or where a product is prescribed by brand name, it will be reimbursed at the manufacturer's NHS list price.

Medical devices will only be routinely dispensed in primary care through the NHS if they are included in the Drug Tariff. The DHSC/NHS Business Services Authority (NHSBSA) agrees the reimbursement price of the medical device with the manufacturer at launch, and this is principally 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.

7.2 Price Levels of Pharmaceutical or Medical Devices

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 Department of Health should have regard when agreeing or directing a price under the VPAS or the Statutory Scheme.

7.3 Pharmaceuticals and Medical Devices: Reimbursement from Public Funds

All authorised medicines validly prescribed on an NHS prescription may in principle be reimbursed from public funds, unless expressly excluded under the National Health Service (General Medical Services Contracts) (Prescription of Drugs, etc) Regulations 2004.

In primary care, patients receive medicines prescribed by their GPs from community pharmacies. Patients in England must pay a fixed price for NHS prescriptions, unless they fall within one of a number of exempt categories. Prescription charges have been abolished in Northern Ireland, Scotland and Wales.

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

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). NHS bodies in England are required by regulations to make funding available so that patients can access treatments recommended by the NICE. The NICE assesses some medical devices and diagnostic tests through parallel procedures.

The All Wales Medicines Strategy Group (AWMSG) issues guidance in Wales on new technologies immediately following launch. 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 (DHSSPS) considers NICE guidance and reviews it for legal, policy and financial consequences only, before deciding on implementation.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

While, theoretically, NHS prescribers may prescribe any product considered clinically appropriate for their patients, in practice, NHS commissioners control which medicines may be prescribed through local or national formularies,

largely determined by the cost-effectiveness of individual products. Treatments recommended by the NICE should be included automatically in NHS formularies in England. In contrast, products not recommended by the NICE are generally not funded on a routine basis. An equivalent approach is taken to products recommended by the AWMSG, the SMC and the DHSSPS.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

Community pharmacists purchase products from manufacturers or wholesalers and are reimbursed by the NHSBSA at the rate specified in the Drug Tariff, or, where no reimbursement price is set in the Drug Tariff, at the manufacturer's list price. When the price paid by the pharmacist is less than that reimbursed by the NHSBSA, the pharmacist makes a margin of profit. The extent of this margin is monitored by the NHSBSA and claw-backs are imposed to ensure that pharmacy profits do not exceed defined limits.

There is no generic substitution by community pharmacists in 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). Where a product is prescribed by its INN, the pharmacist may dispense any product that meets the specifications/INN described and is likely to select the lowest-cost product. Generic substitution is standard practice in the hospital context.

8. DIGITAL HEALTHCARE

8.1 Rules for Medical Apps

There are no specific rules governing medical apps in UK. Standalone software and medical apps that meet the definition of a medical device will be regulated as medical devices and are required to be UKCA-marked.

8.2 Rules for Telemedicine

Physicians can, and do, provide medical attention remotely in UK, including through mobile devices. However, there are currently no specific and separate rules for telemedicine. Under English law, the provision of telemedicine services constitutes the provision of healthcare, which is a regulated activity under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, subject to the supervision of the Care Quality Commission (CQC), the independent regulator of health and social care services in England.

The practice of medicine is regulated by the General Medical Council (GMC). The same standards apply to doctors, regardless of whether they practise in physical or virtual clinics.

8.3 Promoting and/or Advertising on an Online Platform

There are no special legal provisions applicable to the online advertising and promotion of medicines and medical devices. Pharmaceutical and medical technology companies may use online portals, web pages and social networking sites to promote their products, provided they follow the applicable UK medicines advertising legislation and the medical devices legislation (which implement the existing EU rules), guidance and codes of practice. Breaches of these requirements through online activities are enforced in the same way as activities involving traditional methods of communication.

In practice, pharmaceutical companies rely on the guidance provided by the MHRA and, under the self-regulatory system, the Prescription Medicines Code of Practice Authority (PMCPA) and the Proprietary Association of Great Britain (PAGB).

The MHRA Blue Guide confirms that material posted on UK websites (including social networking sites, blogs and discussion forums) and/or aimed at a UK audience is subject to UK medicines advertising legislation.

The ABPI Code, which is administered by the PMCPA, covers online advertising and promotion of POMs, and states that promotional material directed to a UK audience provided digitally must comply with all relevant requirements of the Code.

Digital promotional materials relating to OTC medicines, over which companies have full editorial control, must comply with the PAGB Consumer Code and, like other forms of advertising of OTC medicines to members of the public, must be submitted to the PAGB for approval (in an offline format).

The Association of British Healthcare Industries (ABHI) provides a self-regulatory regime for the medical technology or devices sector as set out in its Code of Business Practice. The ABHI Code confirms that online advertising of medical devices is subject to the same requirements as other forms of advertising. The web-based promotion of self-care medical devices is subject to the PAGB Medical Devices Consumer Code.

The advertising of OTC medicines and medical devices is also subject to supervision by the Advertising Standards Agency (ASA).

8.4 Electronic Prescriptions

Electronic prescriptions are used commonly within the NHS in the UK and may also be used for private prescriptions. These must comply with data protection laws and confidentiality requirements.

8.5 Online Sales of Medicines and Medical Devices

Online sales are regulated in the same way as traditional sales channels. Therefore, POMs may only be supplied online after being dispensed from a registered pharmacy by a pharmacist in accordance with a prescription from an appropriately qualified HCP.

Distance-selling pharmacies may remain on the NHS pharmaceutical list, entitling them to dispense medicines from an NHS prescription if they comply with the requirements of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013.

8.6 Electronic Health Records

Electronic health records (EHR) are not subject to specific regulation in UK. However, these records must comply with data protection laws and confidentiality requirements.

Where special-category (or other) personal data are transferred to a cloud platform, both the transferring entity and the cloud platform must comply with the UK data protection legislation, including the associated requirements for transferring personal data out of the UK.

9. PATENTS RELATING TO PHARMACEUTICALS AND MEDICAL DEVICES

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

UK patent law is governed by the Patents Act 1977.

From 1 January 2021, the Patents (Amendment) (EU Exit) Regulations 2019 (the Patents Regulations 2019), the Intellectual Property (Amendment etc) (EU Exit) Regulations 2020 (the IP (Amendment) Regulation 2020) and the Supplementary

Protection Certificates (Amendment) (EU Exit) Regulation 2020 (the SPC Regulation 2020) came into effect to bring EU legislation into UK law as far as possible to maintain the systems and processes that were in place before Brexit. UK patent law, including the patent-enforcement system in UK, remains substantively unchanged.

Patent-infringement and validity claims form the bulk of the cases issued before UK courts. The increasing amount of data required to be disclosed in patent specifications is a challenge for the grant of pharmaceutical and biotech patent inventions, particularly in relation to second or further medical uses.

A number of exclusions to patentability relate exclusively to pharmaceutical or biotech inventions (eg, methods of treatment by surgery or therapy, methods of diagnosis, and uses of human embryos for industrial or commercial purposes).

9.2 Second and Subsequent Medical Uses

Claims to second and subsequent medical uses (and, indeed, first medical uses), including in relation to dosage regimes and new or selected patient populations, are patentable as long as:

- they fulfil the usual requirements of patentability, with the claimed therapeutic effect needing to be plausible; and
- the claims are drafted in a particular approved form, which, since 2010, is in the form "substance X for use in the treatment of indication Y".

Such claims can include, in certain circumstances, second or further medical uses to medical devices (eg, a dye used for surgery where the dye is a medical device).

9.3 Patent Term Extension for Pharmaceuticals

Patent-term extensions in UK are in the form of supplementary protection certificates (SPCs). The Patents Regulation 2019, the IP (Amendment) Regulation 2020 and the SPC Regulation 2020 have largely retained the pre-Brexit processes and systems under EU Regulation 469/2009 (the SPC Regulation, as amended) and Regulation 1901/2006 (the Paediatric Regulation, as amended).

An SPC provides for a period of extended exclusivity for a patented medicinal product for a maximum period of five years. An additional six-month extension is possible if the patent-holder completes an agreed Paediatric Investigation Plan to determine whether the product is safe for use in children. From 1 January 2021, the process of applying for a UK SPC remains largely the same, although greater care is needed, including monitoring the MAs granted in the UK and the EEA, as the SPC filing deadlines and SPC expiry dates may differ between the UK and the EEA. In addition, the territorial scope of SPCs granted in the UK only extend to the part of the UK for which a valid MA has been granted on filing the SPC application, unless the applicant subsequently applies for the UK SPC to be extended to cover the whole of the UK. Moreover, holders of SPCs granted prior to 1 January 2021, which were based on authorisations from the EMA, may need to provide information on the converted UK authorisation for recordal purposes.

9.4 Pharmaceutical or Medical Device Patent 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 merely to 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.

It is also an (indirect) infringement to supply, or offer to supply, in the UK the means relating to an essential element of the invention, for putting the invention into effect, knowing (or it being obvious to a reasonable person in the circumstances) that those means are suitable for putting, and are intended to put, the invention into effect in the UK.

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 that the infringement be "imminent" in order for an injunction to be granted; the patent-holder only needs to prove that there is a sufficiently strong probability that, in the absence of an injunction, the other party will infringe the patent.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

There are a number of general exemptions from patent infringement which might apply to pharmaceutical products and medical devices:

- acts carried out privately and for purposes which are not commercial;
- acts carried out for experimental purposes relating to the subject-matter of the invention are also not infringing; this includes anything done in or for the purposes of a medicinal product assessment, which in turn includes work done in the UK for the purposes of obtaining an MA for a medicinal product anywhere in the world and health-technology assessments (there is no equivalent express provision relating to medical devices);
- the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or dealing with a medicine so prepared.

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.

9.6 Proceedings for Patent Infringement

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

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

In recent years, there have been an increasing number of cases where the patentee does not seek an injunction, provided an appropriate royalty is agreed or awarded by the court for future infringement.

An action for infringement can be brought in the Patents Court or in the IP 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 with a more streamlined procedure.

Higher-value claims must be brought in the Patents Court.

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, 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.

A two-year mandatory disclosure pilot scheme was introduced after 1 January 2019, which has been extended to 31 December 2022. It is anticipated that there will be further consultation with court users and the judiciary before the scheme finishes. Notwithstanding the pilot, disclosure is already limited to some degree for patent cases. The alleged infringer may still submit a product or process description to avoid giving disclosure in relation to infringement.

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. The parties may, if necessary, also provide evidence of experiments relating to infringement or validity, subject to a tightly controlled procedure.

Disclosure, as well as witness and expert evidence, is significantly more limited in IPEC cases.

Invalidity is available as an effective defence to an infringement claim on the basis that there cannot be infringement of an invalid patent. If validity is challenged, the alleged infringer is required to serve "grounds of invalidity".

9.7 Procedures Available to a Generic Entrant

There is no requirement for pre-launch declaratory actions by a generic entrant. 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 risks facing infringement claims or injunction applications by patent-holders and this may prevent the launch of the product.

A generic entrant who wishes to clear the way may start an action to revoke a patent or SPC. Alternatively, or in addition, the generic entrant may seek declaratory relief from UK courts:

- that its proposed product does not infringe an issued patent or SPC;
- that, in the case of a pending patent or SPC application, its product was known or obvious at the priority date of the relevant patent application; and/or
- that any application for an SPC would be invalid because it would not comply with the conditions in the SPC Regulation.

10. IP OTHER THAN PATENTS

10.1 Counterfeit Pharmaceuticals and Medical Devices

A rights-holder has a number of options for tackling counterfeit pharmaceuticals and medi-

cal devices, such as trade-mark infringement, patent infringement, copyright infringement or passing off.

A trade-mark infringement action is typically more straightforward than a patent-infringement action and generally the action of choice. Trade-mark infringement carries both civil and criminal liabilities under the UK Trade Marks Act 1994. It is possible to bring a private criminal prosecution against an infringer, although criminal proceedings are more usually brought by the UK's Trading Standards Authorities or by the MHRA. In addition, the MHRA has the power to bring criminal proceedings against counterfeiters under the HMRs. 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).

Counterfeit goods may be subject to border seizure actions. HMRC, together with the Border Force, is responsible for preventing counterfeit goods from entering the UK.

From 1 January 2021:

- existing EU applications for actions (AFAs) filed via an EU Customs office remain valid and enforceable in the EU, but have ceased to have effect in the UK;
- existing EU AFAs filed via HMRC remain valid and enforceable in the UK but have ceased to have effect in the EU;
- any new EU AFA filed via an EU Customs office will apply across the EU only and will not be enforceable in the UK; and
- new UK AFAs must be filed online via the HMRC portal. Applicants must specify whether the AFA is to cover Great Britain and Northern Ireland, Great Britain only, or Northern Ireland only. Only UK IP rights can be relied upon in the new UK AFAs.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

The MHRA assesses the invented name of medicinal products individually and in conjunction with a specific medicinal product. Where the proposed invented name has been registered as a trade mark in the UK for use with a medicinal product, an assessment by the MHRA, including safety considerations, determines whether the proposed invented name is suitable for use for the medicinal product. When reviewing the proposed invented names, the MHRA applies criteria based on public-health concerns, such as the potential for confusion with other products.

The UK Medical Devices Regulations provide that trade marks 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.

Trade-mark owners can, in principle, prevent imports of genuine medicines and medical devices into the UK if they were not first placed on the UK market by the owner or with its consent. The doctrine of exhaustion of IP rights also applies to genuine medicines and medical devices that have first been placed on the market in the EEA by the trade-mark owner or with its consent.

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection is available for the trade dress and design of pharmaceuticals, medical devices and their packaging. The packaging of a product, the precise design of a tablet or the design of

a medical device may potentially be protected by copyright, registered or unregistered design rights, and sometimes by trade marks. The applicability and extent of such protection will depend on whether the trade dress or design in question meets the criteria for such protection. In addition, medicinal products or medical devices may be protected by a right in the tort of passing off, which protects the goodwill associated with those products.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

Innovator pharmaceutical companies developing a chemical or biological medicinal product may benefit from a period of regulatory data protection and marketing protection to protect the investment made. 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 an MA for a copy product. The marketing protection period is a further two years (making a total of ten years) 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 referred to as the data/marketing exclusivity period. The marketing protection period can be extended by an additional year on the approval, within eight years of first grant of the medicinal product, of a new indication bringing significant clinical benefit when compared with existing therapies. Non-cumulative periods of one year of regulatory data protection can be awarded in respect of research data to support new indications added to established products or that were required to accomplish a switch from POM to pharmacy supply. Orphan medicinal products may benefit from an exclusivity of up to ten years, or 12 years with an extension for conducting paediatric studies.

There are no exclusivities for medical devices.

11. COVID-19 AND LIFE SCIENCES

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

The MHRA and the DHSC have implemented temporary flexibilities in the regulation of medicines and medical devices to support the supply chain and wider response to COVID-19. These flexibilities typically do not displace or diminish the applicable regulatory obligations, but provide flexibilities from certain requirements, such as deferral of periodic supplier and customer requalification and the ability for responsible persons to act for another company within the same group of companies without variation, and other related initiatives.

11.2 Special Measures Relating to Clinical Trials

The MHRA has put in place measures to prioritise and provide assistance for clinical trials applications submitted for COVID-19, such as dedicated contact points and procedures for rapid scientific advice, reviews and approvals.

The National Institute for Health Research set out a framework in May 2020 for restarting research activities paused as a result of COVID-19, providing a flexible structure for local decision-making.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The HMRs permit temporary authorisation of a medicinal product in response to the confirmed or suspected spread of pathogenic agents, etc. The HMRs were amended on 16 October 2020 in response to the COVID-19 pandemic. Among other things, the amendment strengthened existing provisions that allow for the temporary licensing of medicines and vaccines, following

which several COVID-19 vaccines were granted temporary authorisations.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

The MHRA introduced exceptional GMP flexibilities for medicines' manufacturers during the COVID-19 outbreak, enabling manufacturers to release additional quality-system capacity to focus on ensuring continuity of supply using quality risk-management principles, and to address specific challenges created by international travel restrictions.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

The MHRA adopted a flexible approach for medicines imported from third countries, and has published guidance allowing, for example, certain unexpected minor deviations in the finished product specifications where, in the QP's professional judgement, safety and efficacy is not compromised.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Government and regulators have supported the use of existing regulatory flexibilities in a number of areas, such as the switch to remote consultation in primary care delivery and the use of digital data collection tools.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

The government has not announced any intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

The HMRs protect MA-holders or the person responsible for placing the product on the market, manufacturers (and their respective employees), and HCPs, from civil liability for loss and damage resulting from the use of an unauthorised or off-label medicinal product, if that use was required or recommended by the UK licensing authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation which may cause harm to human beings–including COVID-19. The HMRs were amended on 16 October 2020 in response to the COVID-19 pandemic. A number of the changes were temporary and due to lapse on 1 April 2022, but, following a consultation conducted in 2021, certain of these temporary provisions will be extended.

11.9 Requisition or Conversion of Manufacturing Sites

No existing provisions were used, nor were any new ones introduced, to allow the requisition or conversion of manufacturing sites due to COVID-19.

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

In March 2020, the Cabinet Office issued a Procurement Policy Note (PPN), on options available to public bodies (including NHS bodies and local authorities) in relation to procurements under the Public Contract Regulations 2015 (PCR) in the context of COVID-19. The PPN focused on procurements conducted in situations of extreme urgency, including the use of accelerated timelines, extending or modifying a contract during its term and contracts awarded without competition or advertisement.

Arnold & Porter is an international law firm at the intersection of business, law and regulatory policy, serving clients whose business needs require expert US and/or European cross-border regulatory, litigation, and transactional services. The firm has a particularly high reputation for advising on UK and EU law relating to pharmaceuticals, biotechnology and healthcare products, medical devices and assisting clients in interpreting, and complying with, the regulatory framework that surrounds these products. The authors would like to acknowledge the contributions of Libby Amos-Stone, Shishu Chen, Nadia Gracias, Katya Farkas, Fenella Fletcher-Flood, Eleri Williams and Sofia Wilson.

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