

TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)
Author(s): Gustaf Duhs and Luke Fahy-Spada Firm: Stevens & Bolton, Gustaf.Duhs@stevens-bolton.com ; Luke.Fahy-Spada@stevens-bolton.com
REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES
1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?
<p>In the United Kingdom, the import, manufacture, wholesale distribution, retail supply and export of pharmaceuticals are principally regulated by the Human Medicines Regulations 2012 (HMR 2012). The Medical Devices Regulations 2002 (UK MDR) regulate medical devices.</p> <p>The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK competent authority responsible for the regulation of medicines and medical devices. The MHRA is responsible for issuing the relevant authorisations and ensuring compliance with the relevant standards through licensing, inspection, market surveillance and enforcement across the sector.</p> <p>Healthcare administration is devolved in the UK, so England, Scotland, Wales and Northern Ireland have some differences in regard to the sector. However, the regulation of medicinal products and medical devices is largely centralised at the UK level through the MHRA.</p>
2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?
<p>Medicinal products</p> <p>Medicines in the UK are classified into three dispensing categories:</p> <ul style="list-style-type: none">• Prescription-only medicines (POMs) – supply only on a prescription issued by an authorised prescriber. The POM status imposes significant restrictions on supply, advertising and import.• Pharmacy medicines – sold only under the supervision of a pharmacist in registered pharmacies.• General sales list (GSL) medicines – may be sold without professional supervision in a wide variety of retail outlets. <p>All medicinal products require a marketing authorisation (MA) issued by the MHRA in order to be placed on the market. The UK governing law and basic requirements for obtaining an MA in the UK derive from European Union legislation and have largely remained aligned post-Brexit.</p> <p>Medical devices</p>

Medical devices are classified based on risk, largely mirroring the EU system, into Class I, Class IIa, Class IIb and Class III for general medical devices.

Higher risk devices require assessment by an organisation that has been designated by the MHRA as an ‘approved body’ for the purposes of assessing conformity to the requirements of the UK MDR and must bear a conformity assessment mark when placed on the Great Britain market. Having initially sought to transition from CE marking to UK conformity assessed (UKCA) marking post-Brexit, it now appears likely that both approval and marking regimes will be able to be used in the UK. Manufacturers outside the UK must appoint a UK responsible person (UKRP), and all devices must be registered with the MHRA prior to being placed on the market.

Premarket review is required for higher risk medical devices and all medicines prior to marketing.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

The wholesale distribution of medicinal products requires a wholesale distribution authorisation (human) (WDA(H)) issued by the MHRA. The WDA(H) covers the wholesale distribution of both licensed (authorised) and unlicensed human medicines, as well as investigational medicinal products for use in clinical trials. The WDA(H) licence is mandatory for businesses involved in the storing, supplying, importing and exporting of human medicines, so the holders of these licences can include, but is not limited to, wholesalers, retailers, distributors, importers and exporters (and anyone else handling medicinal products not sold directly to patients). The purpose of the requirement to hold a WDA(H) is to ensure that the regulations and guidelines are being upheld during the procurement, supply, holding and export of such products, as well as ensuring that the quality and integrity of the medicines throughout the supply chain is monitored. The WDA(H) also seeks to prevent the introduction of counterfeit, falsified, substandard or unauthorised products being introduced onto the market.

Holders of the WDA(H) must comply with good distribution practice (GDP), which mandates, to name some examples, that a RP or responsible person (import) when importing is appointed to oversee and ensure compliance with the GDP principles and guidelines; ensure the premises, equipment, quality systems, recordkeeping, audit processes and personnel meet regulatory standards; cooperate with the MHRA to provide necessary documentation and information where required; notify the MHRA of any changes in the WDA(H) details and/or activities; manage the risks associated with the distribution activities; and verify the authenticity and quality of the products before they are procured, stored and supplied.

Applications for a WDA(H) can be made through the MHRA portal, and the facilities, system and procedures must be in place prior to the submission of an application, including GDP training given to staff. A WDA(H) licence also needs to be renewed every five years. Regular MHRA inspections are also carried out to verify compliance.

Further, manufacturers or importers of medicinal products require a manufacturer’s/importer’s authorisation (MIA). A MIA is required for manufacturing, assembly, packaging and the physical importation of human, veterinary or investigational medicines. There must be oversight from a qualified person (QP) and it is the job of the QP to oversee batch release to ensure that the products meet the required standards before they are supplied. There are also specific rules applied for

importing from non-approved countries (outside of the EU/European Economic Area (EEA) or other approved regions), which often require a MIA for the UK.

The wholesale distribution of medical devices does not require a specific licence, but economic operators (manufacturers, importers, distributors, UKRPs) must comply with the UK MDR, including verification of a conformity assessment and CE/UKCA marketing, correct labelling and documentation retention, appropriate storage conditions and cooperation with the MHRA for post-market surveillance.

4. Are there any distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies or other retailers), and what key conditions are attached to them?

The retail supply of medicinal products in the UK is primarily regulated by the Medicines Act 1968 and HMR 2012. Businesses that are not registered pharmacies may only sell medicines classified as GSL products, which are considered low risk and suitable for sale without pharmacist supervision. These products can be sold in supermarkets, convenience stores and other general retail outlets. Medicines classified as pharmacy medicines require the supervision of a pharmacist and can only be sold from registered pharmacy premises. POMs cannot be sold directly to consumers without a valid prescription and must be dispensed by a registered pharmacy under the oversight of a pharmacist.

Community pharmacies must be registered with the General Pharmaceutical Council (GPhC) and operate under strict regulatory frameworks. Each pharmacy must be supervised by a responsible pharmacist, who is in charge of ensuring compliance with the legal and professional standards during the sale and supply of medicines. Pharmacies are permitted to sell GSL medicines freely, supply pharmacy medicines under pharmacist supervision and dispense POMs when presented with valid prescriptions. Pharmacies must also comply with professional standards relating to patient safety, recordkeeping and counselling, ensuring that medicines are supplied appropriately and safely.

Online pharmacies are subject to additional requirements to ensure the safe remote supply of medicines. They must be registered with the GPhC and meet its standards for distance selling. While the MHRA-approved distance selling logo is no longer mandatory in Great Britain, it remains a requirement in Northern Ireland. Internet pharmacies must implement robust identity verification processes, maintain secure systems for prescription validation and provide appropriate patient counselling remotely. They must also comply with advertising restrictions, including the prohibition on promoting POMs directly to the public. These measures aim to protect consumers and prevent the misuse or diversion of medicines.

Retailers and distributors of medical devices do not require a specific wholesale licence. However, they must comply with the UK MDR. This includes ensuring that devices carry the correct UKCA or CE marking, meet conformity assessment requirements and are labelled appropriately. Businesses must maintain documentation for traceability, implement proper storage conditions and cooperate with the MHRA on post-market surveillance and vigilance reporting. These obligations apply to all economic operators in the supply chain, including manufacturers, importers, distributors and UKRPs.

5. What rules govern the sale of therapeutic products to consumers over the internet (including social media and marketplace platforms)?

The UK applies the principle that offline rules apply equally online. Authorised medicines may only be sold in accordance with their classification: GSL medicines can be sold freely without

supervision; pharmacy medicines require pharmacist oversight; and POMs can only be dispensed by MHRA-registered pharmacies when presented with valid prescriptions. Only pharmacies registered with the GPhC are permitted to dispense POMs online; they must meet the GPhC's standards for distance selling, including identity verification, secure prescription handling and remote counselling. Recent GPhC guidance places additional safeguards on the remote prescribing of higher-risk medicines, mandating two-way communication (eg, teleconsultation or general practitioner (GP) verification) rather than relying solely on online questionnaires.

Internet sellers of medicinal products must follow the same advertising rules that apply offline. Under HMR 2012 and enforced by the MHRA and the Advertising Standards Authority (ASA), it is prohibited to advertise POMs directly to consumers, while advertisements for GSL and pharmacy medicines must be accurate, balanced and not misleading (Committee of Advertising Practice (CAP) Code Rule 12.12). Online pharmacies must also display their registered status and, where applicable, the MHRA distance-selling logo. They are required to carry out proper identity and age verification, maintain secure records and ensure patient counselling is provided even when supply is remote.

For medical devices, the rules applying to offline supply also apply online. Economic operators, including online retailers and marketplaces, must ensure that devices carry UKCA or CE marking (depending on the product and market), conform to the UK MDR and have proper labelling and documentation. Once available for sale, devices are subject to post-market surveillance, and any serious incidents must be reported and managed in compliance with the MHRA's vigilance requirements, even when products are sold via online platforms.

Platforms facilitating unlawful supply may be required to remove listings. The MHRA actively performs surveillance and may seize non-compliant products dispatched to UK consumers. Additionally, public authorities encourage users to report suspicious listings through the MHRA's 'Report a suspicious online seller' service.

IMPORT

6. What requirements are set as part of the import control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions and routine or risk-based border inspections)?

The MHRA is responsible for overseeing all of the medicines entering the UK market.

The relevant UK import framework is dependent on the status of the therapeutic product that is proposed to be imported. Broadly, therapeutic products can either be classified as licensed medicine or an investigational medicinal product. Each determination will be submitted to differing import requirements.

Licensed medicine

In order to import licensed medicine into the UK, importers must obtain one or more of the following licences:

- a wholesale distribution licence;
- a manufacturer's licence; or
- marketing authorisation.

However, if the therapeutic product contains a controlled substance, the Home Office will need to be engaged.

A wholesale distribution licence is required if the therapeutic product is to be imported from: (1) a country on an approved country list for supply in the UK or another country; or (2) the EEA if the product is being imported into Northern Ireland for supply in the UK or another country; or (3) a country that is not on an approved list to then be exported to another country also not on an approved list; or (4) the EEA if the product is being imported into Northern Ireland to then export the product to a non-EEA country.

A manufacturing authorisation will be required for the importation of licensed therapeutic products from a country not on an approved list for use in the UK or to supply it to a country on an approved list. Northern Ireland differs again, a manufacturer's licence is required for the importation of licensed therapeutic products from outside the EEA for use in the EEA or for supply to an EEA country.

A marketing authorisation will be required in order to sell a human medicine. There are different types of marketing authorisation licences available, which differ in terms of the process. A qualified person must certify that the product has been manufactured and tested accordingly to the licence and good manufacturing practice. The MHRA may also inspect the manufacturing site in which the product is being produced before the granting of any licence.

Unlicensed medicine

In order to import unlicensed therapeutic products into the UK, there are two licences available: a manufacturer's specials licence or a wholesaler dealer's licence. The former is for the importation of therapeutic products from a country not an approved list or for Northern Ireland, from outside the EEA, and the latter is for importation from a country on an approved list. Notification to the MHRA of such an importation is required.

Investigation medicinal products

Importing investigational medicinal products (IMPs) into Great Britain from MHRA-approved countries requires engagement with a UK manufacturing and import authorisation (MIA (IMP)) holder. Each batch must be certified by a qualified person in the exporting country before release, with a UK qualified person maintaining oversight. IMPs may be imported via a GB hub or direct to trial sites, and written agreements must define the responsibilities shared among all of the involved parties. The UK qualified person must have access to key documentation, including certification evidence and shipment records. Acceptable certification includes official batch certificates or equivalent documentation. Retention samples need not be stored in Great Britain but must remain accessible. Importing non-investigational products may require a WDA(H) licence and a responsible person for import (RPi). Robust documentation and qualified person oversight are essential to ensure compliance.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Consumers may import medicines for personal use into the UK, and this does not generally require particular formalities provided the context as a whole makes it clear that the products are for personal use. For medicines containing controlled substances, travellers may bring up to a three-month supply of Schedule 2–4 (Part I) controlled-substances medicines, provided they were lawfully prescribed and are carried on the traveller's person.

Importing or possessing controlled drugs outside these conditions or importing Schedule 1 controlled drugs without a licence from the Home Office is prohibited.

Importation of prescription medicines by post raises legal risks because arranging supply from outside the UK may be interpreted as unlawful distribution, although possession for personal use is generally not criminalised. A business would either need to use a licensed importer to import the medicines or apply for the licences set out above. However, individual consumers can bring up to three months' worth of a medicine into the UK if it has already been prescribed elsewhere.

Medical devices may be imported by consumers provided that the medical devices comply with general product safety requirements.

There are no duties or declarations required for personal importation for personal use, but importation by post may be treated as commercial supply and lead to customs requirements and duties.

8. Are foreign suppliers allowed to ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification or labelling obligations – if any – must they satisfy?

Foreign suppliers may not supply medicinal products directly to UK consumers unless they operate through an MHRA-registered UK pharmacy. All medicines must be authorised for the UK market and dispensed by a UK pharmacist.

Foreign manufacturers of medical devices must appoint a UKRP, register devices with the MHRA and comply with the UK MDR 2002. Importers must retain documentation and ensure conformity.

Importing medicines into Great Britain from MHRA-approved countries (including Northern Ireland) may be conducted by holders of a GB WDA(H). If supplied from Northern Ireland to Great Britain, no RPi oversight or additional licensing is required.

Depending on whether the imported medicinal product is licensed in Great Britain or in the exporting country, or is intended for export, special categorisation under the WDA(H) licence is necessary. An RPi may be required unless importing an unlicensed medicine for use as a special medicinal product or for re-export.

9. How is the parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging and requirements to maintain the product's original quality, safety and traceability?

Parallel import licence applications are categorised as simple, standard or complex based on the formulation and origin. Since the implementation of the Windsor Framework on 1 January 2025, the MHRA will licence all medicines across the whole of the UK and parallel distribution notices (PDNs) will no longer be valid in Northern Ireland.

A parallel import licence allows the marketing of a medicine authorised in an EEA Member State in Great Britain, provided the imported product is therapeutically equivalent to its GB counterpart and manufactured under good manufacturing practice standards. Applicants must hold a WDA(H) for import, storage and sale, and a manufacturer's licence for re-packaging or assembly is required.

Packaging, labelling and patient information leaflets must comply with GB requirements, including excipient disclosures and user-tested leaflets. All excipients in parenteral, ophthalmic and topical medicinal products must appear on the labelling. For all other medicines, only the excipients of known effect should be declared on the labelling. Obligations concerning the monitoring of the medicines apply, including adverse reaction reporting, recall procedures and MHRA notifications of withdrawals.

EXPORT
<p>10. Are there any quantitative quotas, permits or other measures that restrict or condition the export of therapeutic products (for example, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?</p>
<p>To export medicines, you will need the relevant authorisations for the role that is being undertaken, for example, a drug manufacturer or marketing licence. For pure export only, a wholesale dealer's licence will typically be required.</p> <p>Regulation 43(2) of HMR 2012 imposes a requirement on licence holders to ensure, within the limits of their responsibility, the continued supply of medicinal products to the UK to ensure domestic supply. The UK government has published a list of medicines that cannot be exported. Exporting any of the listed medicines will be a breach of Regulation 43(2) of HMR 2012 and may lead to regulatory action by the MHRA, which may include suspending the wholesale dealer's licence.</p> <p>For any controlled drugs, an exporter will need to obtain a Home Office controlled drug licence before it is legally allowed to export. Registration for such a licence will be through the National Drugs Control System and will be valid for two months or until the importer's permit expires. The export licence is separate to any licence required for the drug itself.</p> <p>Medical devices to be exported will require MHRA registration. Medical devices in Great Britain must be registered with the MHRA using the Device Online Registration System and devices must comply with the UK MDR. When such requirements are met, the device may bear the UKCA mark. For Northern Ireland and the EU, parties will need to use an EU recognised body to undertake a mandatory third-party conformity assessment in order to obtain a CE mark.</p> <p>For a non-UK manufacturer, the appointment of a UK responsible person to hold the technical files is necessary. UK firms exporting to the EU will also be required to have in place an EU authorised representative.</p> <p>In addition to the UKCA and CE marking, exporters may also be required to hold a certificate of free sale prior to exporting.</p>
<p>11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing and, if so, what standards, labelling or record-keeping obligations apply?</p>
<p>In the UK, there are mechanisms that allow for the manufacture and export of therapeutic products that are not otherwise authorised for domestic marketing. Such authorisation will be made under Regulation 156 of HMR 2012, which grants the MHRA the power to make an Article 126a authorisation provided the following conditions are met:</p> <ul style="list-style-type: none">• there are no existing UK authorisations;• there are no pending UK authorisations; and• the authorisation is justified on public health grounds. <p>For such products, the MHRA may grant export-only marketing authorisations, allowing the manufacture of products exclusively for export purposes. These products must comply with good manufacturing practice standards, batch release requirements and export labelling rules. Such products, however, will not be reviewed for UK market authorisation purposes, as they are not permitted to be marketed domestically.</p>

Medical devices manufactured solely for export need not bear UKCA or CE marking unless placed on the UK market.

LABELLING, TRACEABILITY AND PRODUCT INFORMATION

12. What local-language labelling, patient information, unique device identification, serialisation, anti-counterfeiting or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

Therapeutic products imported into the UK must comply with HMR 2012 and the product labelling rules as set out in part 13, and must be written in English. Under Schedule 24, the label must also include the product name, strength, form, batch number, expiry date, storage conditions, warnings, MA holder and MA number and other information.

Regulation 260 of HMR 2012 mandates that such products must also include patient information leaflets (PILs) (unless all information is already contained on the label). This PIL must meet MHRA readability standards, and contain certain information, see Schedule 27 of HMR 2012.

The Falsified Medicines Directive's (FMD) safety features regime does not now apply in the UK.

For medical devices requiring UKCA marking (or CE marking until 30 June 2030), the manufacturer's details, UKRP details (if relevant), safety information, and, for many device classes, unique device identification (UDI) must be provided. Devices must be registered in the MHRA's database.

PRICING, REIMBURSEMENT AND MARKET ACCESS

13. Are there any price control, reimbursement, public procurement or stock/supply-related obligations that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

The UK operates several domestic regulatory regimes that, while not trade measures, significantly affect the availability and distribution of therapeutic products. Price control mechanisms, such as the voluntary and statutory schemes for branded medicines, influence commercial decisions on supply, while National Institute for Health and Care Excellence (NICE) reimbursement assessments determine which therapies are routinely commissioned and, therefore, widely distributed within the National Health Service (NHS).

Public procurement frameworks, particularly national NHS supply chain tenders, also shape distribution channels by centralising purchasing and often restricting supply to approved suppliers. Legally binding stock obligation rules, most notably Regulation 43(2) of the HMR 2012, require manufacturers and wholesalers to maintain UK supply, and the government enforces this through a regularly updated list of medicines that cannot be exported or hoarded. Breaching these domestic supply obligations can lead to MHRA regulatory action, including the suspension of a wholesale dealer's licence.

Additional requirements also influence distribution, including the need for Home Office controlled-drug export licences for scheduled substances and the requirement for medical devices to be registered with the MHRA before placement on the UK market or before a certificate of free sale can be issued for export. These frameworks collectively shape supply chain behaviour and materially affect the availability of therapeutic products in the UK.

ENFORCEMENT, COMPLIANCE AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions and remedial measures (administrative, civil or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

The Medicines and Medical Devices Act 2021 (MMD 2021) introduced a set of enforcement provisions including compliance notices, suspension notices, information notices and a specific recall power. While not yet in force, Schedule 3 of MMD 2021 will make provision for a criminal offence for breaching a provision of the UK MDR. Until then, the Consumer Protection Act 1987 will continue to apply to breaches of the UK MDR. The General Product Safety Regulations 2005 may also apply to consumer products that are also medical devices, where these products are not covered by the UK MDR.

The Secretary of State has a duty to enforce the UK MDR, and the MHRA is enabled to exercise investigatory powers (including powers of entry) (Schedule 5 of the Consumer Rights Act 2015). These powers include entry, inspections, the seizure and detention of products and documents and civil sanctions, including monetary penalties and enforcement undertakings, among others.

Of course, there are other more general rules that apply to the trade in and distribution of therapeutic products, such as competition and consumer law, as enforced by the Competition and Markets Authority, and these remain highly relevant to the regulation of the life sciences sector in the UK.

15. Is there any recent case law, legislative or policy developments, noteworthy enforcement trends or anticipated reforms that may significantly alter the regulation of trade, distribution or cross-border movement of therapeutic products in the future?

The UK's withdrawal from the EU has had and continues to have significant consequences for the regulation of UK cross-border trade and the distribution of medicines. Significant further changes are likely with a current UK government that is seeking closer relations with the EU, while the political party that is currently most popular is in favour of greater divergence.

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 is due to enter into force in April 2026 and will directly affect cross-border research and develop (R&D) supply chains and investigational product distribution. Key changes relate to documentation and investigational medicinal product (IMP) management across borders and new offences relating to IMP record-keeping, distribution irregularities and falsified information submitted to regulators.

The MHRA has announced proposals to improve patient access to world leading medical devices and strengthen the med-tech sector in Great Britain. The proposals include indefinite recognition of CE-marked devices following further consultation, the introduction of international reliance pathways to accelerate market access for devices approved in trusted jurisdictions, such as Australia, Canada, and the United States, and removal of physical domestic approvals route (UKCA) marking once the UDI system is fully implemented.

Additional measures include streamlining the UKCA process to help prioritise new technologies, such as artificial intelligence (AI)-driven devices and enhancing post-market surveillance to improve patient safety and reduce regulatory duplication for manufacturers.

The MHRA is in the process of significantly revising the UK medical devices regime to minimise the regulatory burden on business by aligning more generally with the EU Medical Devices Regulation and In Vitro Diagnostics Regulation. The secondary legislation to amend the UK MDR is expected to be staggered throughout 2026.

The MHRA recently launched an open call for evidence (December 2025) on AI in healthcare to inform future legislation, covering both standalone medical devices and AI-assisted decision-making in medicines regulation.