TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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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?

The Danish regulatory framework for therapeutic products is based on national legislation implementing and supplementing EU law.

Medicinal products

The principal national statutes are the Danish Medicines Act, related executive orders, and directly applicable and transposed EU legislation. Key EU legal acts include: the Community code on medicinal products for human use (Directive 2001/83/EC); the Falsified Medicines Directive (2011/62/EU) and its Delegated Regulation (EU) 2016/161 on safety features and serialisation; the pharmacovigilance framework, Regulation (EC) 726/2004; Regulation (EC) 1234/2008; and related acts. Good manufacturing and distribution practice requirements follow national executive orders and the EU GDP Guidelines (5 November 2013).

Veterinary medicines

The main legal basis is Regulation (EU) 2019/6 on veterinary medicinal products, with wholesale distribution governed by Commission Implementing Regulation (EU) 2021/1248. Good manufacturing practice requirements are set out in Commission Implementing Regulation (EU) 2025/2091.

Medical devices

The sector is governed directly by the Medical Device Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Regulation (EU) 2017/746 (IVDR). It is supplemented by the Danish Act on Medical Devices, implementing executive orders (including on advertising and language requirements), and national guidance. The MDR and IVDR set requirements for conformity assessments, CE marking, UDI/traceability, and obligations for economic operators.

The Danish Medicines Agency (DKMA) is the competent authority for the authorisation and supervision of import, manufacture, wholesale distribution, retail supply, and export of medicinal products and medical devices. The DKMA also conducts pharmacy oversight. The Danish Patient Safety Authority supervises healthcare providers. The Danish Customs Agency oversees customs

controls, and procurement and competition matters may involve the Danish Competition and Consumer Authority.

Denmark is a unitary state, where EU regulations apply directly, and EU directives are implemented by national legislation. The DKMA maintains updated legislation and guidance on its website and publishes authorisations to the EudraGMDP database.

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 premarket review and approval required by a competent authority?

Medicinal products

Under Danish law, medicinal products are classified as either prescription-only medicines (POM) or over-the-counter medicines (OTC). POM includes different dispensing groups, depending on whether the products are intended for hospital use or are otherwise subject to restricted distribution. Classification is determined in the marketing authorisation and relevant DKMA decisions and regulated by the Executive Order on Prescriptions and Dispensing of Medicinal Products.

- POM medicines may only be dispensed by authorised pharmacies on presentation of a valid prescription. Advertising and distance selling are restricted, and wholesale and retail activities must comply with GDP and pharmacy rules.
- OTC medicines may be sold by authorised pharmacies and, for defined categories, by registered non-pharmacy retailers subject to conditions on assortment, storage, staff training, and age-related restrictions.
- Controlled substances (eg, narcotics) are subject to additional regulatory controls.

Placing a human medicinal product on the Danish market requires approval (marketing authorisation) from the DKMA or through an EU procedure, except for limited exemptions such as magistral preparations, compassionate use, and named-patient supply.

Medical devices

Devices are classified by risk under the MDR (Classes I, IIa, IIb, III) and, for IVDs, under the IVDR. Classification determines the conformity assessment route and whether notified body involvement is required. Before being placed on the Danish market, devices must comply with MDR/IVDR requirements, including CE marking, conformity assessment, UDI/traceability, Danish-language labelling and instructions for end-users (with limited professional-use exceptions), and identification of the responsible EU economic operator (manufacturer, authorised representative, importer). Importers and distributors must verify compliance, maintain traceability, and cooperate with market surveillance authorities.

Higher-risk devices may be restricted to professional use or require healthcare supervision. Denmark imposes no additional pre-market authorisation requirements for devices beyond those set out in the MDR/IVDR.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

Wholesale distribution of therapeutic products in Denmark requires prior authorisation under section 39 of the Danish Medicines Act, as well as ongoing compliance with applicable regulatory requirements.

Medicinal products and intermediates

Companies distributing medicinal products must hold a Wholesale Distribution Authorisation (WDA) issued by the DKMA. Core conditions include:

- compliance with Good Distribution Practice (GDP);
- appointment of a Responsible Person;
- suitable premises, equipment, personnel and security systems; and
- an effective quality-management system with procedures for documentation, recalls, and complaints.

Entities handling controlled substances are subject to additional security and reporting obligations. Carriers that provide only transport services do not require a WDA, provided they do not unpack, repackage, or relabel products, and contractual responsibilities are clearly defined. The DKMA conducts periodic inspections to verify compliance.

Veterinary medicines

Wholesale distribution is governed by Commission Implementing Regulation (EU) 2021/1248 on Good Distribution Practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6, applied alongside national executive orders.

Medical devices

Distributors and importers must comply with MDR Articles 13–14, including verification of CE marking and the EU Declaration of Conformity, appropriate storage and transport, traceability, cooperation with market surveillance, and complaint/vigilance handling. Manufacturers, authorised representatives, importers, distributors, and certain specialised retailers established in Denmark must register as actors with the DKMA before making a device available in Denmark.

4. Are there 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 attach to them?

Medicinal products

Community pharmacies require a concession (authorisation) from the DKMA under the Danish Pharmacy Act. Key conditions include qualified personnel, suitable facilities and IT systems, patient counselling, dispensing practices, and compliance with pricing and reimbursement rules. Branch pharmacies and pharmacy outlets are subject to specific requirements.

Internet pharmacies must be approved by the DKMA and comply with distance-selling rules, including prescription verification, counselling, secure dispensing and delivery, and display of the EU common logo (green for human medicines; blue for veterinary medicines).

Certain OTC medicines may also be sold outside pharmacies by DKMA-authorised non-pharmacy retailers, subject to conditions on product assortment, storage, staff training, and age-related restrictions.

Medical devices

Retailers and distributors may sell CE-marked devices if they comply with MDR distributor obligations and Danish-language information requirements. Higher-risk devices may be limited to professional supervision or healthcare settings. Manufacturers, authorised representatives, importers, distributors, and certain specialised retailers established in Denmark must register as actors with the DKMA before making a device available in Denmark.

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

Online sale of therapeutic products is subject to both sector-specific and general e-commerce legislation.

Medicinal products

Prescription-only medicines may be sold online only by authorised pharmacies, which must verify prescriptions, provide appropriate counselling, and ensure secure dispensing and delivery. OTC medicines may be sold online by authorised pharmacies and, for certain categories, by registered non-pharmacy retailers in accordance with DKMA rules.

Online platforms and marketplace operators must ensure that only authorised sellers list medicinal products. Unlawful listings may trigger enforcement under Danish e-commerce, consumer protection, and marketing legislation.

Medical devices

Online sale of CE-marked devices is permitted, provided sellers supply clear product information and instructions in Danish, and comply with UDI and traceability obligations. Marketplace operators are expected to remove non-compliant listings and cooperate with the DKMA during enforcement and market-surveillance actions.

IMPORT

6. What is 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 import and release of therapeutic products are governed by EU law as implemented in Denmark and overseen by the DKMA in cooperation with the Danish Customs Agency. Medicinal products and medical devices are subject to distinct regimes.

Medicinal products

Import of medicinal products into Denmark requires authorisation from the DKMA.

For EU-released finished medicinal products sourced within the EU/EEA, the importer must hold a Wholesale Distribution Authorisation (WDA) and comply with Good Distribution Practice (GDP) requirements, including by having appropriate quality agreements with suppliers.

Import from countries outside the EU/EEA requires a Manufacturing and Import Authorisation (MIA). Each imported batch must undergo EU Qualified Person (QP) certification prior to release for EU/EEA distribution, and where applicable, re-analysis to confirm compliance with the approved marketing authorisation.

Medicinal products placed on the Danish market must hold a valid marketing authorisation issued either nationally by the DKMA or centrally by the European Commission, subject to limited exemptions such as magistral preparations, compassionate use, or named-patient schemes. Customs classification follows the EU Combined Nomenclature, with duties under the EU Common Customs Tariff and Danish VAT on import.

Border inspections are risk-based and may include documentary, identity, and targeted physical checks by the DKMA and Danish Customs.

Medical devices

Importers of medical devices, as defined under the EU Medical Device Regulation (MDR) (Regulation (EU) 2017/745), must verify that the device bears a valid CE marking, is accompanied by an EU Declaration of Conformity, and properly identifies the manufacturer and, where applicable, the authorised representative.

Importers must ensure that labelling and Instructions for Use (IFU) are provided in Danish for consumer products, subject to limited professional-use exceptions. They must also ensure compliance with UDI and traceability obligations and state their own name and address on the device or its packaging.

Devices are subject to EU customs procedures, and the DKMA conducts risk-based market surveillance both at the border and within the national supply chain to monitor ongoing 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 mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

Private individuals may import limited quantities of therapeutic products for personal use, subject to origin, product type, and quantity limits.

Medicinal products

Travellers from the EU/EEA may bring medicines for their own treatment if lawfully sold to private individuals in the country of purchase. The authorities may request packaging or a prescription as documentation.

To those from outside the EU/EEA, quantities are limited to up to three months' personal use, and supporting documentation may be required.

Postal import of prescription medicines by private individuals is generally prohibited, and medicines containing euphoriants (narcotic or psychotropic substances) are strictly banned regardless of origin.

For controlled substances, travellers must present appropriate documentation (eg, a prescription or Schengen certificate) and typically are limited to 30 days' supply.

Over-the-counter (OTC) medicines are subject to more flexible rules provided quantities are reasonable and products are lawfully marketed in the country of purchase.

Distance purchases of OTC medicines from authorised EU pharmacies are permitted if the seller complies with EU and DKMA distance-selling requirements, including listing in the DKMA's register.

Medical devices

Private import of CE-marked medical devices for personal use is generally permitted if the device is intended solely for the importer's personal use and not for professional use or resale.

8. May foreign suppliers 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?

The direct shipment of therapeutic products to consumers via e-commerce is strictly regulated to ensure safety, traceability, and compliance with EU and Danish requirements.

Medicinal products

Foreign suppliers may only ship prescription medicines directly to Danish consumers if they operate as authorised pharmacies under Danish and EU distance-selling rules. They must:

- display the EU common logo linked to the DKMA's register of authorised pharmacies;
- verify prescriptions and patient identity; and
- comply with GDP and Danish pharmacy legislation.

In practice, local establishment is often required for pharmacy operations to enable DKMA oversight. Certain OTC medicines may be sold via distance sales by authorised EU-based entities, provided the supplier complies with harmonised EU rules and is listed with the DKMA for online retail.

Medical devices

If a supplier is established outside the EU, the EU-based entity placing the device on the market is the importer under the MDR and must fulfil importer obligations, including registration, labelling, verification, and traceability.

EU-based online sellers act as distributors and must ensure Danish-language information for consumer products, with limited professional-use exceptions.

Online platforms facilitating sales may themselves be considered economic operators under Article 16 MDR if they modify product presentation or information. The DKMA monitors online sales channels and may take enforcement action against unauthorised distance sales or misleading advertising.

Direct-to-consumer shipment of prescription medicines into Denmark is uncommon due to stringent authorisation, verification, and patient-safety requirements.

9. How is 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 original quality, safety, and traceability?

The DKMA authorises parallel import of directly distributed medicinal products, ie, medicinal products traded in Denmark through a distribution channel agreed with the patent holder.

Parallel importers must hold a WDA under section 39 of the Danish Medicines Act. Parallel importers that relabel, repackage, or conduct batch release must also hold a manufacturing authorisation.

Parallel import of medicines is permitted subject to an MA for parallel import by the DKMA for each product.

To obtain an MA, the parallel importer must:

1. demonstrate equivalence between the active substance and form of administration of the parallel imported medicinal product with the directly distributed medicinal product;
2. import the medicinal product from an EU/EEA country (export country);
3. ensure the medicinal product holds a valid marketing authorisation in the export country;
4. ensure appropriate re-packaging and re-labelling, (eg, text of re-packaging and re-labelling must be written in Danish, retaining export country), outer packaging is permitted if the original bar code is covered and any remaining foreign language text visible on outer packaging following relabelling with Danish text does not state anything contrary to Danish rules;
5. maintain product quality and FMD serialisation/traceability; and
6. comply with pharmacovigilance requirements.

Parallel importers must apply for a separate MA for each export country.

Intellectual-property rights are limited by the EU exhaustion doctrine. Under the Bristol-Myers Squibb line of cases (C-427/93, C-429/93, C-436/93), trade mark owners may require that

repackaging not harm the product's reputation and that they be notified of packaging changes before marketing the parallel-imported product.

Parallel import of biologics is subject to specific assessments conducted on a case-by-case basis, during which the DKMA may require additional documentation. By way of example, applicants seeking to parallel import blood products must, inter alia:

1. demonstrate complete traceability from donors to the finished product, and vice versa;
2. demonstrate complete traceability from the export country to the individual batch of product; and
3. demonstrate that procedures are in place to notify the applicant and the DKMA of any potential risk of seroconversion for HIV, hepatitis A, B, and C, and vCJD in the specific batch; and declare that data necessary for complete traceability will be stored for at least 30 years.

MAs for parallel import are valid for five years from the date of issue and may be renewed for additional five-year periods.

For medical devices, parallel trade in CE-marked devices is permissible if MDR/IVDR compliance and original quality and safety are maintained, UDI/traceability is preserved, required compliance information is not obscured, and Danish-language labelling/IFU are provided for Danish end-users (subject to limited professional-use exceptions).

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public-health emergencies), and how are such measures administered and enforced?

In the event of an anticipated or emergency supply situation, the DKMA may adopt temporary quantitative restrictions, permit requirements, or notification duties on exports of therapeutic products to address shortages or public health emergencies, often coordinated at EU level.

The DKMA oversees compliance with the Danish Customs Agency. Enforcement tools include orders, administrative penalties, and, where applicable, referrals for criminal prosecution. EU emergency measures, where applicable, are implemented and enforced in Denmark.

The Danish government may also choose to enact urgent measures through the legislative process, while the EU may implement urgent measures as well, such as Commission Implementing Regulation (EU) 2020/402 on export authorisations for personal protective equipment.

As of November 2025, the DKMA has not imposed such restrictions.

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?

Medicines

Manufacture for export without a Danish marketing authorisation is permitted under a valid GMP manufacturing authorisation, provided that products are not placed on the Danish market. Manufacturing must comply with GMP, batch documentation must meet recipient-country requirements, the exporter must register the medicinal product in the DKMA's export registry, and export certificates must be obtained from the DKMA.

Medical devices

Within the EU, devices require MDR compliance and CE marking to be placed on the market; products intended exclusively for export outside the EU are not placed on the EU market, but operators remain subject to applicable traceability/vigilance obligations where the MDR applies.

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?

Medicines

Before domestic circulation, outer and inner packaging and the patient information leaflet must be in Danish (subject to limited exceptions). Prescription medicines must bear safety features under the FMD (a unique identifier in a 2D data matrix and an anti-tampering device). Labelling must include batch number, expiry date, storage conditions, and MAH details, and serialisation data must be uploaded to the national medicines verification system. For export, labelling must meet the destination country's requirements and traceability documentation must be maintained.

On 1 January 2025, the Nordic medicines authorities, including the DKMA, launched a five-year pilot on English-only common Nordic packages for selected human medicines to assess the feasibility of using English on packaging and in package leaflets.

Medical devices

The MDR/IVDR require UDI (Device Identifier and, where applicable, Production Identifier), identification of the device and economic operators, and Danish-language labelling and instructions for end-users when supplied in Denmark, with limited professional-use exceptions where English is required by public health interests. Importers and distributors must ensure traceability and cooperate with market surveillance. For export outside the EU, labelling may follow the recipient country's rules, but EU-based economic operators may still have traceability and vigilance duties.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

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

Medicines

Pricing and reimbursement for pharmacy medicines are administered by the DKMA and the Reimbursement Committee. Hospital-only medicines are financed by the regional authorities. The Danish Medicines Council assesses clinical use and cost-effectiveness of hospital medicines and recommends standard treatments; the five regions decide hospital formularies accordingly.

Frameworks for generics and biosimilars, mandatory substitution to the cheapest alternative, 14-day competitive pricing within therapeutic substitution groups, and the stepped pricing model materially affect market access and distribution. OTC distribution outside pharmacies requires DKMA authorisation and fees, shaping retail availability and online presence.

Hospital purchasing is conducted by Amgros, the regional procurement partnership, through public tenders and direct agreements, influencing availability and supply obligations.

Mandatory supply, stockholding, and reporting obligations apply to critical pharmacy medicines under Executive Order No. 869/2024.

Medical devices

Hospital purchasing of medical devices follows public-procurement rules, typically via regional framework agreements and tenders assessing price and quality. Market access is also shaped by Danish advertising rules (Executive Order No. 715/2022 and Guideline No. 9469/2024), including restricting professional-only information online to eligible professionals.

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 DKMA has investigative powers including scheduled and unannounced inspections, information and document requests, sampling and testing, and orders to remedy non-compliance. Remedial measures include administrative orders and prohibitions, suspension or revocation of authorisations, recalls and withdrawals, seizure, publication of warnings, administrative fines, and referral for criminal prosecution. Enforcement is risk-based, prioritising serious breaches (eg, falsified medicines, GDP/GMP non-compliance, unsafe or non-compliant devices). Reactive enforcement may follow patient reports, political attention, or competitor complaints. Companies may appeal DKMA decisions to the Ministry of the Interior and Health. Judicial review is available before or after exhausting administrative recourse.

15. Is there 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?

Ongoing MDR/IVDR implementation includes progressive activation of EUDAMED modules, expansion of UDI, and strengthened market surveillance. The Commission's 2025 update to the MDR/IVDR language-requirements table confirms Denmark's Danish-language rules for end-users with limited professional-use exceptions.

The ongoing pilot project for English-only common Nordic packages for human medicines may also significantly affect the cross-border movement of medicines in the future.

Medicines supply-resilience measures continue, with stockholding and reporting duties for critical medicines under Executive Order No. 869/2024. Authorities are intensifying online enforcement against unlawful sales via social media and marketplaces, leveraging the EU common logo framework and national market-surveillance powers. The DKMA actively administers parallel-import applications and renewals, including clarifications on batch pooling. Danish medical-device advertising guidance (Guideline No. 9469/2024) provides updated interpretative criteria affecting market access and compliance.