

**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?

In Estonia, the primary national legislation for the handling import, wholesale, retail, export, marketing authorisation, clinical trials, advertising and the supervision of medicines and biologicals is the Medicinal Products Act (MPA) and its regulations.

Medical devices are primarily regulated at EU level by the directly applicable regulations, namely: the Regulation on Medical Devices (Regulation (EU) 2017/745 – MDR); and the Regulation on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746 – IVDR). At the national level, Medical Devices Act (MDA) and its regulations are applicable if not controlled by EU regulations.

The State Agency of Medicines (SAM), under the Ministry of Social Affairs, is the central competent authority for granting marketing authorisations; licences for manufacture, import, export and wholesale; quality oversight; pricing; and market surveillance and supervision. The Estonian Health Insurance Fund (EHIF) is responsible for reimbursement of healthcare services and therapeutic products (pharmaceuticals/biologics and medical devices). The Health Board (HB) exercises supervisory functions in respect of use of medical devices within the healthcare sector. The Tax and Customs Board (TCB) enforces border controls.

Import and export and wholesale of medicines require special activity licences and permits issued by the SAM and compliance with marketing authorisations and other applicable requirements. Retail supply is provided through licensed pharmacies staffed by registered pharmacists.

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?

Marketing authorisation valid in Estonia is required for every specific medicinal product. Such authorisation is not required only for restricted range of products, such as magistral and officinal formulae products, whole blood and blood components, herbal substances etc.

Marketing authorisation can be obtained in one of the following ways: (1) the national procedure – an application submitted to the SAM; (2) the centralised procedure – an application submitted to the European Medicines Agency; (3) the decentralised procedure and the procedure of mutual recognition – an application is submitted to a medicines agency of another EU Member State. Under the national procedure, the SAM issues and renews marketing authorisations. The standard decision period can take up to 210 days.

Medicines are classified at the time of granting marketing authorisation, as: prescription-only ('R'), OTC ('K'), or restricted-use prescription medicines. Restricted-use subcategories include narcotic-prescription ('N'), specialist-prescription for narrow specialties ('E'), and hospital-use only ('H'). OTC medicines may be supplied by pharmacies without a prescription; whereas prescription medicines require dispensing from pharmacies on a valid prescription, with special rules applying for narcotics prescriptions. A general pharmacy can apply for the right of distance sale of medicinal products including prescription medicines. Public advertising of prescription medicines is prohibited, except in cases of pre-approved vaccination campaigns. All promotional must be accurate and not misleading.

Medical devices are governed by EU MDR/IVDR, which are directly applicable, and the Medical Devices Act (MDA). Under IVDR, medical devices are classified as classes I, IIa, IIb and III; and in vitro diagnostic devices as A, B, C and D. The SAM acts as the competent authority for MDR/IVDR, determines product status, and performs market surveillance. No traditional marketing authorisation or premarket approval is required. Instead, depending on the class of the device, manufacturers, authorised representatives, importers and distributors must comply with EU MDR/IVDR requirements in respect of products (quality, safety, etc.), economic operators (required personnel, internal procedures, etc.) and economic operations (documentation obligations, notification obligations, etc.). Some devices are for professional use only.

No licence is required for import, wholesale, distribution, distance sale and export of medical devices. However, economic operators have obligations under the MDR/IVDR. Public advertising of medical devices is permitted but all promotion must be accurate, not misleading and comply with all general requirements for advertising under the Advertising Act.

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?

A wholesale distribution authorisation or a manufacturing authorisation is required for medicines. Wholesale distribution and brokering of human medicines and active substances must comply with Good Distribution Practice (GDP).

Key requirements include implementing a quality system with defined management responsibilities, processes, and risk management principles, including periodic management review of the quality system, assessment of risks affecting storage and quality with mitigation measures and contingency plans where necessary (see Conditions and Procedures for Wholesale Distribution of Medicinal Products (CPWD s 1¹). Facility standards require separate marked areas for receipt and dispatch enabling receipt control, protection from weather, security

measures restricting unauthorised access to storage and document areas, and alarm systems for storage condition deviations with regular testing and documentation. Personnel requirements include appointing a qualified person and deputies for each operation, sufficient competent staff, training programmes with documented effectiveness evaluation, and compliance with GDP and position-specific training. The qualified person for wholesale must hold a university degree in pharmacy (or veterinary medicine for veterinary medicines) and have at least one year's experience in the last five years in wholesale, manufacturing or pharmacy.

There are no wholesale licence or authorisation requirements for medical devices. Importers and distributors must comply with economic operator obligations under the Medical Devices Act and MDR/IVDR.

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?

The retail supply of medicines is provided as 'pharmacy services' by licensed general (community), hospital or veterinary pharmacies (MPA ss 29 and 30). The activity licence holder may be a state authority, local government body, other public legal person, natural person acting as an entrepreneur, or private legal person, excluding non-profit associations (MPA s 41). Pharmacy services may only be provided in pharmacies holding a corresponding activity licence and in their structural units. To ensure the quality and safety of pharmacy services, only Health Board registered pharmacists and assistant pharmacists may provide pharmacy services in a pharmacy, including the sale of medicines and counselling of patients.

The ministerial regulation establishes requirements for premises, equipment, technical facilities, personnel, work organisation, medicines accounting and reporting, distance selling of medicines, and provision of pharmacy services via video call (Conditions and Procedure for the Provision of Pharmacy Services (CPPPS) s 1). Pharmacies must have appropriate furnishings, work tools and equipment, security measures (including alarm systems), and communication devices.

General pharmacy licence holders may engage in the distance selling of medicinal products for human use and over-the-counter veterinary medicinal products, provided they hold the requisite authorisation (MPA s 31). The SAM grants such authorisation on application, subject to compliance with the applicable requirements and conditions and payment of the applicable state fee (MPA s 31). The requirements for distance selling of medicinal products are set out in the MPA and its regulations, including specifications for website functionality and the provision of free individual counselling to customers.

There is no distinct licence required for a business that provides medical devices directly to consumers.

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

Only general pharmacies that have been granted authorisation for distance selling may sell medicinal products over the internet. In principle, offline rules also apply to online sales, with specific provisions for distance sales and online interfaces.

Distance selling may only be conducted through an authorised website displaying the common logo that complies with the technical, electronic and cryptographic requirements established in the guidelines referred to in Article 85c(3) of Directive 2001/83/EC (MPA s 31). The delivery of medicines ordered through distance selling is only permitted from a pharmacy holding the relevant authorisation in Estonia or from a pharmacy with corresponding authorisation established in an EEA Member State or Switzerland (MPA s 33).

The distance selling website must clearly display the general pharmacy name and location address, the activity licence holder's business name and licence number and validity, contact details of the SAM and a hyperlink to its website listing pharmacies offering distance selling, ordering and delivery conditions, pharmaceutical counselling options, links to package leaflets published on the SAM's website, and information that dispensed medicines are not subject to repurchase and may only be returned to the pharmacy for destruction. The pharmacy must ensure the availability of free individual counselling by a pharmacist or pharmaceutical technician regarding the correct and safe use and storage of medicines, which must be provided prior to order confirmation. Customers must be advised to read the package leaflet carefully before use and to consult a physician or pharmacist if their medical complaints persist or side effects occur. If the pharmacy service provider allows counselling to be refused, the customer must confirm awareness of counselling options and correct and safe use and storage of the medicine.

The sale of medical devices over the internet is not subject to similar specific rules.

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 of medicinal products is regulated under the MPA and its regulations. For such purposes, 'import' means applying the free circulation customs procedure or bringing goods from an EEA Member State into Estonia (MPA s 17).

Products requiring a special permit from the SAM include medicines (including clinical trial medicines and expired medicines), active pharmaceutical ingredients, human or animal cells, tissues and organs for medical or scientific use, blood preparations, narcotics and psychotropics (schedules I–IV and VI), hormones, antibiotics (except up to 100 mg for laboratory use), alkaloids, and organotherapy products (Conditions for Import and Export of Goods Requiring a Special Permit from the SAM).

The import of medicines may be conducted by holders of wholesale distribution authorisations, manufacturing authorisations (for their own production), healthcare service providers (only in restricted cases), cell/tissue/organ handling authorisation holders, educational or research institutions, and other legal persons with the SAM's prior consent (MPA s 18).

Medical device importation does not generally require any specific licences or authorisations, but importers must ensure conformity, correct labelling and comply to economic operator obligations established under the MDR or IVDR.

Customs classification and tariff treatment are governed by Estonian and EU customs legislation. Border inspections are conducted on a risk-based approach, and the SAM retains the authority to suspend the sale and dispensing of medicines (MPA s 101¹) and medical devices, including at temporary storage locations, customs warehouses and free zones within the meaning of the Customs Act. Supervisory authorities can order return or ban the import of noncompliant products.

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?

Consumers may import medicines for personal use, or for accompanying animals, in limited quantities without a licence, subject to the applicable therapeutic products and customs regulations (MPA s 25; regulations thereof). Travellers may carry up to ten different over-the-counter medicines (up to five retail packages of each) for personal use; and for accompanying animals, up to five different medicines (up to three retail packages of each), as well as prescription medicines in the prescribed quantity. When travelling with prescription medicines, the traveller must carry a physician's notice confirming the need for the medicines, a copy of the paper prescription, or an extract of the electronic prescription. Additional requirements apply to narcotics and psychotropics.

A permit must be obtained from the SAM where the quantity of over-the-counter medicines to be carried exceeds permitted limits.

Medicines may be sent abroad or to Estonia from one natural person to another. A single shipment may contain up to ten unopened retail packages without a permit from the SAM. The sending of anabolic steroids, narcotics and psychotropics, whole blood and blood components, cells and tissues intended for medical use, and advanced therapy medicinal products is not permitted (MPA s 25).

There is no specific consumer import/export regulation for medical devices, but supervisory authorities may restrict or ban the import of devices which violate applicable restrictions. Customs declaration, tariff classification, and duties are governed by Estonian and EU customs legislation.

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?

Medicines can only be shipped directly to Estonian consumers via e-commerce or mail order by Estonian pharmacies holding a distance selling authorisation or by a pharmacy established in an EEA Member State or Switzerland which holds the corresponding authorisation (MPA s 33 (2¹)). Other (foreign) suppliers cannot ship medicines directly to Estonian consumers.

The online sale of medical devices directly to consumers via e-commerce or mail order is explicitly not restricted and does not require any specific licence or authorisation. However,

foreign suppliers and importers must ensure compliance with MDR or IVDR when placing medical devices on the Estonian (EU) market.

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?

Parallel importation of medicines is permitted in Estonia through a secondary marketing authorisation (in Estonian: *teisene müügiluba*) (MPA s 66). Such authorisation is granted to holders of wholesale or manufacturing authorisations where the following conditions are satisfied: (1) the medicine for which the secondary authorisation is sought is clinically identical to a medicine holding a valid marketing authorisation in Estonia; (2) the medicine is imported from another EEA Member State; (3) the medicine holds a valid marketing authorisation in that EEA Member State; and (4) the marketing authorisation holder in Estonia and in the exporting EEA Member State is the same entity or belongs to the same group of pharmaceutical manufacturers.

A secondary marketing authorisation remains valid for the same period as either the marketing authorisation of the directly imported medicine in Estonia or the marketing authorisation of the parallel imported medicine in the country of origin. Where sale of the medicine under the primary marketing authorisation in Estonia has been suspended or terminated for economic reasons, the SAM may, by decision, permit the secondary marketing authorisation to remain valid for a specified period.

The holder of a secondary marketing authorisation has all the rights and obligations of a marketing authorisation holder. Medical devices may also be traded in parallel under the MDR and IVDR. These regulations impose specific obligations on the economic operator (the parallel importer/distributor), particularly regarding repackaging, relabelling, and intellectual property rights.

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?

The export of medicinal products is regulated under the MPA and its regulations. For such purposes, ‘export’ means applying the export customs procedure or dispatching goods from Estonia to an EEA Member State (MPA s 17).

The export of products requiring either special permit or notification of the SAM include medicines (such as clinical trial medicines and expired medicines), active pharmaceutical ingredients, human or animal cells, tissues and organs for medical or scientific use, blood preparations, narcotics and psychotropics (schedules I–IV and VI), hormones, antibiotics (except up to 100 mg for laboratory use), alkaloids, and organotherapy products.

The export of medicines may be conducted by holders of wholesale distribution authorisations, manufacturing authorisations (for their own production), healthcare service providers (only in

restricted cases), cell/tissue/organ handling authorisation holders, educational or research institutions, and other legal persons with the SAM's prior consent (MPAs 18).

The export of medical devices does not generally require any specific licences or authorisations, but importers must comply with economic operator obligations.

The SAM may, as an emergency measure, prohibit the export of medicines where ensuring uninterrupted supply is important from the perspective of human or animal health and where other medicines with the same active substance and strength are not marketed in Estonia or are marketed in insufficient quantities (MPA s 20).

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?

Estonian law does not provide for a specific 'export-only' or 'dual-labelling' authorisation regime for medicinal products. There is no export-only authorisation for medical devices. Devices manufactured in Estonia that are not produced for Estonian/EU market and are not placed on the market in Estonia/EU and are only exported must not meet EU medical device regulations.

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?

Packaging for medicinal products must be in Estonian, and the product must be accompanied by Estonian-language information on composition, active ingredient content, use and storage, etc, except in cases provided by law (MPA s 13).

Security features requirements apply for human medicinal products, as set out in Commission Delegated Regulation (EU) 2016/161, including unique identifiers enabling verification of authenticity and tamper-evident devices (MPA s 10²). Marketing authorisation holders and wholesalers must verify the authenticity and integrity of security features and deactivate unique identifiers when dispensing to the public (MPA s 44).

Accompanying information for medical devices distributed in Estonia must be provided in Estonian and in an appropriate format when the device is intended for lay users. For devices intended solely for professional users, information may be provided in Estonian or English (MDA s 16). The declaration of conformity for medical devices distributed in Estonia must be prepared in Estonian or English or translated into Estonian or English (MDA s 16).

Traceability requirements are established by the MDR and IVDR so that all lifecycle stages (design, production, distribution, post-market) are linked via Unique Device Identifiers (UDI) and EUDAMED registration.

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?

The pricing of medicines is regulated by the MPA and its regulations, under which the Government of the Republic has enacted threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation. The mark-up for different price groups must create equal interest for handling all medicinal products in wholesale and retail trade. The weighted average mark-up in wholesale trade is between seven-to-ten per cent and in retail trade between 21 and 25 per cent.

In wholesale trade of medicinal products, proportionate mark-ups are applied. The threshold values of mark-ups depend on the purchase price of one original: for example, if the price of one original is up to €1.60, the threshold value for the mark-up is 20 per cent; if the price for one original is over €12.78, the threshold value for the mark-up is three per cent. The mark-up in wholesale trade of medicinal products must not exceed €6.39 per sales packaging.

Proportionate and fixed mark-ups are applied in the retail trade of medicinal products. The threshold values of mark-ups depend on the purchase price of one original. The mark-up in retail trade of medicinal products must not exceed €6.39 per sales packaging.

Generally, only medicines which are included in the list of medicinal products of the EHIF, are reimbursed. Reimbursement of a medicine is based on the reference price or price agreement between the Health Insurance Fund and the medicine's manufacturer or representative.

The SAM may revoke a marketing authorisation where a medicinal product has not been available from the authorisation holder for three consecutive years, unless it is necessary to keep the authorisation in force for the public health purposes.

Pricing of medical devices is not regulated. Generally, only medical devices which are included in the respective list of the EHIF, are reimbursed. Reimbursement of a medical device is based on the price agreement between the EHIF and the device's manufacturer or representative.

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 SAM is mainly responsible for market surveillance and enforcement of regulations regarding medicines and medical devices. The SAM is empowered to: enter premises and facilities; examine premises and facilities; take movables into storage; take samples of products and substances; question and summon persons; require presentation of documents, etc.; and monitor and evaluate compliance with applicable legislation.

In exercising supervision, the SAM has, by its administrative order, the right to suspend the sale and dispensing of products, terminate the sale or dispensing, ban advertising, suspend and terminate the clinical study of a medicinal product, demand that the marketing authorisation

holder or the wholesaler inform the public or healthcare professionals about risks relating to a product, etc. If an administrative order is not complied with, a penalty payment of up to €9,600 may be imposed in cases of medicinal products, and up to €32,000 in cases of medical devices. Depending on the violation, non-compliance can result in a fine of up to €32,000, suspension or revocation of the marketing authorisation of the medicinal product, a ban on economic activities, and revocation of the activity licence.

Criminal sanctions apply under the Penal Code for the unlawful handling of medicines, including unauthorised cross-border transport, manufacturing, marketing or possession of counterfeit medicines are punishable by a fine or imprisonment of up to three years for natural persons, and by a fine for legal persons. The maximum fine for a legal person can be up to €40m.

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?

Recent legislative and regulatory developments in Estonia affecting therapeutic products have included several notable changes.

A new Guideline for health technology assessment in Estonia replaces the Baltic States Pharmacoeconomic Evaluation Guidelines. The Guideline covers all health interventions including medicines, medical devices, diagnostic tests, therapeutic procedures, and preventive measures and affects the reimbursement of pharmaceuticals. The new wording of the Health Insurance Fund's list of medicines came into force on 1 January 2026, affecting the availability and reimbursement of medicines.

Hospital exemption requirements and restrictions were loosened in 2025 by permitting the manufacture of advanced therapy medicinal products for a broader range of patients and eliminating restrictions on the number of manufacturers and patients. The amendments also reduced administrative burden and shortened authorisation timeframes. Nevertheless, requirements for medicine quality, efficacy, and safety remain.

There is an initiative for amendment of the reimbursement and mark-up regulations regarding products compounded in a pharmacy. The MDA has been amended to align with MDR and IVDR. Supervisory authority over medical devices was changed: previously the Health Board had responsibility, from January 2025 the SAM takes on the role. The Product Conformity Act was amended to strengthen the SAM's supervisory powers over medical device safety requirements under these EU regulations. The EUDAMED database will become mandatory from 28 May 2026, and a new Medical Devices and Assistive Devices Registry will be launched in Estonia.

The Estonian regulatory framework for therapeutic products continues to evolve in alignment with EU pharmaceutical and medical device legislation, with ongoing harmonisation of requirements for conformity assessment, market surveillance and traceability systems.