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?

Finland regulates therapeutic products, principally, under the Medicines Act (395/1987). This is complemented by the Medicines Decree (693/1987), and the Medical Devices Act (719/2021) which supplements the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). In addition, the key provisions relating to the pricing of medicines can be found in the Health Insurance Act (1224/2004).

The Finnish Medicines Agency (Fimea) is the national supervisory authority which grants marketing authorisations, pharmaceutical wholesale and manufacturing licences, conducts quality oversight and market surveillance. Fimea also supervises the conformity and marketing of medical devices and the operators in the sector in Finland in collaboration with other EU authorities. The Pharmaceuticals Pricing Board (PPB) decides on which medicinal products are included in the reimbursement system, as well as their wholesale prices and reimbursement categories.

Key regulations are the Medicines Act and Administrative Regulation 1/2019 on Good Distribution Practice of Medicinal Products issued by Fimea as well as the EU Good Distribution Practice Guidelines. Industrial manufacture of medicines requires a pharmaceutical manufacturing authorisation; and wholesale distribution of medicines requires a wholesale distribution authorisation, both issued by Fimea. The import of medicinal products and investigational medicinal products from outside of the EEA also requires the aforementioned authorisations. Export (generally outside the EU/EEA) of medicinal products which have been granted marketing authorisation in Finland require a Certificate of a Pharmaceutical Product (CPP) issued by Fimea for export purposes.

The industrial manufacture of medicines must comply with the principles of good manufacturing practice (GMP), for which the key regulation is the Administrative Regulation 6/2022 issued by Fimea on Good Manufacturing Practices of Medicines and the Manufacture of Medicines used in Clinical Trials, which supplements the relevant EU legislation including the EU Guidelines for Good Manufacturing Practice.

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?

Medical devices are classified into classes I, IIa, IIb and III, taking into account their intended purpose and their inherent risks. Classification is carried out in accordance with Annex VIII of the MDR. Medical devices intended for in vitro diagnostics are classified into categories A, B, C, and D according to their intended use, in accordance with the rules set out in Annex VIII of the IVDR. Higher risks demand stricter controls, extensive documentation, and deeper market scrutiny for sale and distribution.

The primary distinction in medicinal products is inpatient (ie, hospital) and outpatient medicines. With respect to trade and distribution outpatient medicines may generally be reimbursed through Finland's National Health Insurance system (Chapter 5, section 1, Health Insurance Act). In addition, medicines are classified by medicine groups according to the chemical form of their active ingredient and their intended use. In the Anatomical Therapeutic Chemical (ATC) classification, aimed at healthcare professionals, medicines are divided into groups according to the organ or organ system they affect and their chemical, pharmacological, and therapeutic properties.

Another important distinction between medicinal products is prescription and over-the-counter (OTC) medicines. Prescription medicines may only be supplied from pharmacies with a prescription, whereas OTC medicines may be supplied from pharmacies without a prescription. A medicinal product can have package sizes which are authorised for marketing both as prescription and OTC products. The marketing of prescription medicines, narcotics, and medicinal products containing psychotropic substances to consumers is banned (s 91a, Medicines Act). The key provisions governing the marketing of medicinal products are contained in the Medicines Act and the Consumer Protection Act (38/1978). In addition, the Code of Ethics published by Pharma Industry Finland (PIF) is a key set of rules regarding the marketing of medicinal products.

Additionally, medicines are generally classified into biological and non-biological products. Pharmacies must substitute a prescription medicine with a commonly available cheapest interchangeable medicinal product. When supplying a prescription-based biological medicine or biosimilar, the pharmacy must carry out the substitution if it is the first supply based on a prescription or if the user of the medicine has been using the same biological medicine or biosimilar for six months, or if six months have passed since the previous supply (s 57b, Medicines Act).

Additional classifications are mainly: medicines which affect the central nervous system (CNS); medicinal products containing substances classified as narcotics; medicinal products containing alcohol; as well as advanced therapy (ATMP) medicines, which are subject to specific requirements supplementing the general requirements for the sale and distribution of medicines, with the aim of ensuring the safe use of particularly high-risk medicinal products and preventing misuse.

Medical products must have been issued with a valid marketing authorisation in order to enter the Finnish market. The premarket review is completed as part of the marketing authorisation process. Medical devices must be registered prior to placing them in the Finnish market.

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?

The wholesale distribution of medicinal products is based on a single-channel principle, whereas medicinal products of a pharmaceutical company are typically supplied through one of the few wholesalers in Finland which specialise in pharmaceutical distribution.

Engaging in wholesale distribution requires a pharmaceutical wholesale licence issued by Fimea. A pharmaceutical wholesaler is required to have appropriate premises, equipment and personnel in accordance with the Medicines Act. Compliance with good distribution practices according to the Administrative Regulation 1/2019 issued by Fimea as well as EU Good Distribution Practice Guidelines is a prerequisite for operations. In particular, the wholesaler must have an accountable director in a direct employment who is responsible for the compliance of the operations and the appropriateness of the distribution of medicines. The accountable director must be a licensed pharmacist (s33 Medicines Act).

Traditional herbal medicinal products and homoeopathic medicinal products intended for human use and released for consumption must also be registered at Fimea.

Medical devices must be registered as applicable – either in the national CERE register maintained by Fimea or in the EUDAMED register maintained by the European Commission. A notification obligation also applies, according to which Fimea must be notified about such operations and the medical device before placing it on the market or making it available (s 49, Medical Devices Act). In addition, device manufacturers must, for example, have at least one Responsible Person for regulatory compliance who has the required expertise in the field of medical devices.

Compliance is required when placing medical devices on the market or putting them into service, especially the requirements set out by the MDR and Medical Devices Act. Before placing a medical device on the market, distributors must check, among other things, that the device bears the CE marking, that the EU declaration of conformity has been drawn up, and that the device is accompanied by the information provided by the manufacturer.

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?

In Finland, medicines may only be sold to the public from a pharmacy, a subsidiary pharmacy, a pharmacy service point, or a pharmacy online service (s38 a, Medicines Act). The operation of a pharmacy business requires a licence granted by Fimea (pharmacy licence). A pharmacy licence is granted for the operation of a specific pharmacy business in a municipality or part thereof and may only be granted to a licensed pharmacist. Traditional herbal medicinal products and homeopathic preparations may, however, be sold elsewhere, unless Fimea has decided otherwise during registration (see response to Question, 3 above).

Distributors who make medical devices available to retailers, healthcare and social welfare operators, and other professional users in Finland are subject to a registration obligation (s49,

Medical Devices Act). The notification is made to Fimea either in the CERE or EUDAMED register.

It is worth noting that, according to a pending government proposal (HE 111/2025), a limited range of self-care medicines would be subject to modified price regulation and not be taken into account in pharmacy taxation. Consequently, marketing authorisation holders could apply for sales channel expansion outside pharmacies for this range of products. Retail sales of such self-care medicines would be based on a self-care medicine retail licence.

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

In Finland, only licensed pharmacists are permitted to offer online pharmacy services (see the response to Question 4, above). Operating an online pharmacy service requires advance notification to Fimea. Fimea must also be notified of the commencement and termination of operations and essential amendments to the service. Provisions of the Consumer Protection Act on distance selling also apply to online pharmacy services. Fimea supervises online pharmacy operations as part of pharmacy supervision but does not approve individual applications in advance.

Key regulations regarding online pharmacy services are found in the Medicines Act, the Medicines Decree, the Administrative Regulations 2/2011 on Online Pharmacy Services and 2/2016 on Delivery of Medicines issued by Fimea. In addition, distance selling of medicines must comply, inter alia, with general consumer and retail sale regulations and the protection of customer privacy. With regard to prescription medicines, online pharmacies may only supply when an electronic prescription has been issued.

The above applies when medicines, as defined under the Medicines Act, are sold to consumers over the internet. The sale of other therapeutic products to consumers are not subject to similar pharmacy service-related requirements but must also comply with, inter alia, general consumer and retail sale regulations.

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)?

In Finland, import of medicinal products requires that the importer is either authorised to manufacture medicinal products industrially in a pharmaceutical factory, or holds a wholesale distribution authorisation issued by Fimea, or is a pharmacy conducting authorised pharmacy activities. Other business operators may import medicinal substances for production activities, in which case, business operators must notify Fimea of such imports. (s17, Medicines Act). Importers must retain a list of imported medicines, indicating the medicine's quantity, country of import, supplier, and date of import.

Certain conditions and restrictions apply when medicinal products are imported from outside the EEA. If a medicinal product with a marketing authorisation or registration is imported from a state outside the EEA, the importer must hold a manufacturing authorisation for the industrial

manufacture of medicinal products. The importer must ensure that these medicinal products have undergone a quality control inspection in accordance with the marketing authorisation requirements in Finland or another EEA country.

Importers of medical devices must register in EUDAMED and comply with the obligations imposed on importers by the MDR and Medical Devices Act. Importers must, inter alia, ensure that the device bears a CE marking and that the EU declaration of conformity has been drawn up, the manufacturer's details are included, the device has the markings required by law and is accompanied by the required instructions for use, and that the devices have been assigned a UDI identifier, as applicable.

In Finland, the Customs supervises compliance with import regulations under the Medicines Act (s81a, Medicines Act). The Customs has (investigative) powers under the Customs Act (304/2016), which include, inter alia, right to inspection, detention, seizure, and confiscation of imported goods. The Customs may stop goods being exported from, imported into, or transported through Finland if there are reasonable grounds for doing so in order to prevent or investigate an offence other than a customs offence.

All goods imported into EU countries from outside the EU are classified according to the EU's Common Customs Tariff. The tariff has a specific Combined Nomenclature (CN) commodity code for each category of goods, which is used to determine the customs duty.

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?

In Finland, the rules regarding import of medicinal products for personal use are included in the Medicines Act and the Government Decree 1088/2002 on Importing Medicinal Products to Finland for Personal Use, which sets out the conditions and the quantitative limits for such imports. These import restrictions are based on the classification of the product in Finland.

Consumers may import medicinal products to Finland for their own personal use, provided that such products are lawfully marketed in the country of purchase and purchased from an authorised supplier. The importation of medicinal substances is not permitted. The purchase of prescription medicines must be based on a valid prescription issued by an authorised person. The consumer must be able to demonstrate, when required, that the imported product is intended for their own personal use.

A private individual may bring medicinal products, as well as homeopathic and anthroposophic products, from an EEA country for their personal use for a maximum of one year and receive by mail a quantity sufficient for a maximum of three months' use. From non-EEA countries a private individual may bring medicinal products with them for personal use in quantities corresponding to a maximum of three months' use. The purchase and receipt of medicinal products by mail order from countries outside the EEA is prohibited.

A private individual may import a medicinal product classified as a narcotic drug for personal use from a Schengen country for a maximum of 30 days and from another country for a maximum of 14 days. Quantitative limits on certain medicinal substances apply. In addition, medicinal products containing narcotic substances which, according to the product information, cause

clinically significant and dangerous interactions when used together, may not be imported at the same time. Medicinal products containing narcotics may not be purchased or received by mail from outside Finland.

Additionally, private individuals may only bring with them legally acquired veterinary medicinal products, which may not contain narcotics, in quantities corresponding to a maximum of one month's use from abroad. The importation of vaccines and other immunological veterinary medicinal products is banned. Moreover, veterinary medicinal products may not be purchased or received by mail from outside Finland and must be imported at the same time as the animal to be treated.

An import declaration must be submitted for goods when they are imported from outside the customs and fiscal territory of the EU.

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?

In Finland, any medicinal product may only be sold to the public or otherwise released for consumption if it has a valid marketing authorisation in Finland granted either by Fimea or the relevant EU institution.

With regard to medicinal products, only pharmacies are allowed to sell medicines to the public (see response to Question 4, above). Consumers may order and receive medicinal products for their own personal use by mail, but certain conditions, restrictions, and quantitative limits apply (see response to Question 7, above). In principle, local presence is not required in cases of foreign providers supplying therapeutic products to consumers through an online or other distance selling service.

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?

In Finland, parallel importation requires Fimea authorisation in cases where the medicinal product is imported by an operator other than the marketing authorisation holder or its representative. Such authorisation may only be granted if the product is to be imported from an EEA country and if there is no therapeutic difference between the parallel import and the product that has previously been granted a marketing authorisation (s21d, Medicines Act). The products must contain the same active substance, and the formulations must be sufficiently similar in terms of safety and efficacy.

The authorisation applicant must already hold a wholesale distribution authorisation in Finland at the application stage. Applications for parallel distribution of centrally authorised medicinal products are processed by the European Medicines Agency (EMA). The Administrative Regulation on Parallel Import of Medicinal Products 4/2014 issued by Fimea must be followed.

Re-packaging must be carried out in an EEA pharmaceutical manufacturing facility holding a manufacturing authorisation for the industrial manufacture of medicinal products, and GMP must

be followed during re-packaging. If the trade name of the parallel import product differs, it shall comply with Fimeas Administrative Regulation 4/2019 on Applications for and Maintenance of Marketing Authorisations and Registration of Medicinal Products. Two different trade names may appear on the inner packaging which shall be separately mentioned on the outer packaging. Differences in pack sizes and types (including packaging method) should not pose a threat to public health. The shelf-life must correspond to the one approved in the country of procurement but may not exceed that approved for a medicinal product already in commercial circulation in Finland. The expiry date of a parallel import product must be clearly visible on both the inner and outer packaging.

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 (generally outside the EU/EEA) of medicinal products that have been granted a marketing authorisation in Finland requires a Certificate of a Pharmaceutical Product (CPP) issued by Fimea for export purposes. Exports from Finland are only permitted to operators with legal authorisation to purchase medicines in their respective country.

If a threat of availability disruption affects a medicinal product or active substance intended for the prevention or treatment of a life-threatening conditions, a condition which progresses without medication or significantly impairs health, or which is of great importance to public health, the Ministry of Social Affairs and Health may temporarily restrict or target the distribution, sale, or release for consumption of the medicinal product or active substance for a fixed period to protect public health. In cases where the Ministry's order is not complied with, Fimea may ban the continuation of such an operation or order an operator to fulfil its obligations under the law (s19a, Medicines Act).

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?

Fimea issues CPP certificates to marketing authorisation holders for the export of medicinal products abroad (usually outside the EU/EEA). The CPP certificate and its guidelines are based on the WHO certification model and implementation recommendations. Fimea only issues export certificates for medicinal products which have been issued a marketing authorisation in Finland.

LABELLING, TRACEBILITY, 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?

Detailed instructions on sales labelling are provided in Fimea's Administrative Regulation 3/2019 and Normative Guideline 1/2019 on Labelling and Package Leaflets for Medicinal Products. The

Commission Delegated Regulation (EU) 2016/161 for the safety features appearing on the packaging of medicinal products for human use must also be complied with, as applicable.

Package labelling of a medicinal product must at least be written in Finnish and Swedish. However, the composition of the medicinal product may be indicated only in Latin and labelling of certain low-demand products may be provided only in one of the EU's official languages. Labelling must be easily comprehensible and based on approved product characteristics.

The outer or immediate packaging must include product name, strength, pharmaceutical form, composition and active substance(s), package size, administration method, warnings, expiry date (month/year), special storage conditions (if necessary), special precautions for disposal of unused medicines or packaging (if necessary), marketing authorisation holder and possible authorised representative details, marketing authorisation number, batch number, Nordic product number, safety features, dosage instructions for non-prescription medicines and additional information for proper use of the product is required. The information requirements for small immediate packages the are more limited. Additional requirements concerning veterinary, traditional herbal and authorised homeopathic and anthroposophic products apply.

For medical devices, the device identification, serialisation, anti-counterfeiting, or traceability requirements are primarily regulated under the MDR. Medical devices must, as a rule, bear the CE marking of conformity in accordance with Annex V of the MDR. Instructions for the use of medical devices must be in Finnish, Swedish, or English, unless provided in the form of internationally recognised symbols. However, the information required for the safe use of the device must be in Finnish and Swedish. (Chapter 2, s5 Medical Devices Act).

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?

In Finland, medicinal products for treatment of disease sold through pharmacies to outpatient care on a prescription basis may be reimbursed under the National Health Insurance (NHI) system (Chapter 5, s1 Health Insurance Act). The PBB set the reimbursement status and confirms a wholesale price for medicinal products to be reimbursed under the NHI system.

The pricing of inpatient care medicinal products is connected to the public procurement process of such medicinal products. In Finland, the procurement of medicinal products by a public body must be put out to tender when a certain threshold is exceeded. The Council for Choices in Health Care in Finland (COHERE Finland) recommends whether the medicinal product in question should be included in the range of public health services and, therefore publicly funded.

Pharmaceutical wholesalers must ensure that they have sufficient medicines available for sale. Pharmacies and subsidiary pharmacies must stock the most affordable medicines. Recent amendments have introduced an obligation for pharmacies, subsidiary pharmacies and pharmacy online services to offer the purchaser the most affordable prescription medicinal product.

Finland operates an obligatory storing regime for medicines vital to healthcare, general surgery and intensive care. The Act on Obligatory Storing of Medicines (979/2008) is supplemented by the Government Decree 1114/2008 on the Mandatory Stockpiling of Medicines determines

mandatory stock obligations. Pharmaceutical manufacturers, importers of medicinal products, and healthcare units operating in Finland are subject to stock obligations. Fimea supervises compliance and maintains the list of products subject to obligatory storing, while the National Emergency Supply Agency compensates manufacturers and importers for storage costs.

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?

Fimea monitors compliance with trade and distribution rules through licensing procedures, regular inspections, and quality testing. Inspectors have the power to access all facilities, review and copy documents, take samples of substances and products, and photograph premises. Licence holders must provide Fimea with information and documentation on the import, manufacture, inspection, distribution, and sale of medicinal products as necessary for Fimea to carry out its duties, subject to confidentiality provisions.

When non-compliance is detected, Fimea can issue orders to correct defects, which require immediate action. If defects endanger proper manufacture or if a manufacturer fails to comply with correction orders, Fimea can order manufacturing to cease until further notice. Where marketing violates the Medicines Act, Fimea can ban continuation or renewal of marketing activities and order correction of marketing materials for safety reasons. These prohibitions and orders can be enforced through conditional fines.

Fimea has the authority to partially or fully revoke manufacturing licences if requirements are no longer met or if essential safety or quality obligations have been breached. Similarly, marketing authorisations can be revoked if new research or other evidence shows that the conditions for granting authorisation no longer exist.

Criminal penalties are also regulated under the Medicines Act and Criminal Code. Intentional or grossly negligent violations constitute a medicine offence punishable by fines up to a year's imprisonment. Such violations include unlawful manufacture, import, storage, sale, or supply of medicinal products, or failure to notify, provide information, or keep proper records.

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?

Amendments to the Health Insurance Act and Medicines Act have introduced new pricing regulations to promote competition and reduce medicine prices, directly benefiting patients through lower costs. Pharmacies, branch pharmacies, and online services must now offer the most affordable prescription medicines and stock the cheapest options.

Conditional reimbursement regulations have been made permanent, improving access to new medicines by sharing introductory costs between society and pharmaceutical companies. Supplementary amendments address the Regulation (EU) 2021/2282 on Health Technology Assessment. These changes came into force on 1 January 2025.

The comprehensive pharmacy sector reform entered into force on 1 January 2026. Pharmacies may, inter alia, deviate from prescriptions and correct obvious errors in predefined situations, such as national supply disruptions. A limited range of self-care medicines may be sold outside pharmacies under modified price regulation. Prescription medicine pharmacy fees will be reduced across all classes. Pharmacy tax will shift from turnover to profit margin based on sales margins. The Health Insurance Act will account for prescription deviations in reimbursements and allocate conditional reimbursement repayments fully to the state.

Fimea is preparing revised medicine supply regulations, with consultation by the spring of 2026 and publication scheduled for September 2026 to coincide with the Kanta medication list launch.

The European Union Council and European Parliament have agreed on a proposal for new EU pharmaceutical legislation (the Pharma package), which represents the most extensive change to pharmaceutical regulation in two decades. It is expected to enhance competitiveness, enable new innovations, and promote the availability of medicines across the EU.

Proposed amendments:

- Extensive Medicines Act amendments are proposed for pharmacy operations, including separate online pharmacy licences, service quality requirements, deregulation of quantity and location restrictions, and enabling limited liability companies and chain formation.
- A working group established in spring 2024 proposes reforming medicine assessment processes to ensure consistency between outpatient and hospital settings, recommending long-term consolidation of assessment and decision-making into a single unit.
- Fimeas report on mechanical dose dispensing proposes a separate national operating licence independent of pharmacy licences and regulation ensuring dose dispensing products meet therapeutic needs and are interchangeable and reimbursable.