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?

Medicinal products:

The primary legislation for the authorisation, pricing and reimbursement of medicinal products, biologicals and medical devices is: (1) the Pharmaceutical Law (*Farmācijas likums*); (2) the Medical Treatment Law (*Ārstniecības likums*); and (3) Regulations issued based on these laws, eg, Cabinet Regulation No. 344, 'Procedures for Importing and Distributing Active Substances', Cabinet Regulation No. 416, 'Procedures Regarding the Distribution and Quality Control of Medicinal Products', Cabinet Regulation No. 436, 'Procedures for the Importation and Exportation of Medicinal Products', Cabinet Regulation No. 899, 'Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medical Devices Intended for Outpatient Medical Treatment', Cabinet Regulation No. 376, 'Procedures for the Registration of Medicinal Products', Cabinet Regulation No. 57, 'Regulations Regarding Procedures for the Labelling of Medicinal Products and the Requirements to Be Set for the Package Leaflet of Medicinal Products', Cabinet Regulation No 885, 'Procedure for the Classification of Medicinal Products' Cabinet Regulation No. 803, 'Regulations Regarding the Principles for the Determination of the Price of Medicinal Products'.

Medical devices:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices are directly applicable in Latvia. Moreover, Cabinet Regulation No. 46, concerning 'Medical Device Regulations', is applicable to medical devices and, for in vitro medical devices, Cabinet Regulation No. 582, concerning 'Regulations for in vitro Diagnostic Medical Devices' applies.

Several authorities are responsible for applying and enforcing the regulatory framework in relation to medicinal products, biologics and medical devices:

- The Health Inspectorate of the Republic of Latvia exercises state oversight of the health sector, including supervision and regulation of the manufacture and distribution of medicinal products (including biologics) and medical devices.
- The State Agency of Medicines of the Republic of Latvia (SAM) serves several functions, including the registration of medicinal products; issuing permits for the import, export, transit and distribution of medicinal products, as well as preparations intended for clinical trials; it issues permits for the performance of medicinal product clinical trials and

supervises the respective procedures; it evaluates the conformity of medicinal products wholesalers, manufacturers and importers; it determines whether a medicinal product should be categorised as a non-prescription or prescription medicinal product; it performs conformity assessments and the registration of medical devices; it performs conformity assessments and oversight of centres used for the acquisition and storage of living tissue, cells and organs, as well as for the blood collection centres of medical treatment institutions, blood preparation departments and the State Blood Donor Centre; it assesses applications for the receipt of a special permit (licence) for the operation of a pharmacy and for the registration of manufacturers, importers and distributors of active substances; and it also performs a pharmacovigilance role.

- The National Health Service performs the economic evaluation of medicinal products, medical devices, medical technologies and healthcare services to be covered by state budget funds; it determines the prices of medicinal products and medical devices covered by reimbursement schemes; and it draws up a list of medicinal products and medical devices that are reimbursed in regard to outpatient medical treatment.

All of the above are state administration institutions under the supervision of the Ministry of Health.

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?

Medicinal products are classified according to Cabinet Regulation No 885, namely the 'Procedure for the Classification of Medicinal Products', as well as under the Pharmaceutical Law and the relevant European Commission guidelines (eg, Medical Device Coordination Group (MDCG) guidelines, MDCG 2021-24 Guidance on classification of medical devices, MDCG 2022 – 5 Rev. 1, MDCG 2024-13, Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices) to amend the classification of medicinal products for human use. The standard classification covers prescription medicinal products, non-prescription medicinal products (over the counter), medicinal products for in-patient medical treatment (hospital use), narcotic medicinal products, psychotropic medicinal products, narcotic analgesic agents and psychotropic medicinal products. Classifications are determined by the State Agency of Medicines prior to the registration of a medicinal product in the Latvian Register of Medicines.

Medical devices are classified according to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.

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, insurance or financial guarantees) are attached to them?

Licensing requirements are governed by the Pharmaceutical Law and Cabinet Regulation No. 410, concerning 'Regulations on the Licensing of Pharmaceutical Activities'.

Wholesale distribution requires a wholesaler, manufacturer or importer licence to be obtained. If a company is registered in another EU Member State, it may apply for a licence.

Requirements for securing a wholesale licence:

- Applications for conformity assessments and the issuance of a licence to conduct the activities carried out by a medicinal product wholesaler (the template is Annexed to the Cabinet Regulation No. 410, concerning 'Regulations on the Licensing of Pharmaceutical Activities').
- Information and documents input into the template form (including responsible persons, personnel, standard procedures for good distribution practices, special operation activities, distribution, premises, equipment and the working times of the respective warehouse).
- Payment of a fee to the state.
- Once the State Agency of Medicines has reviewed the document, it carries out a conformity assessment check.

Requirements for securing a manufacturing or importer licence:

- Application to the State Agency of Medicines for a conformity assessment and the issuance of a licence.
- Information and documents input into a specific form, as outlined in the Annex to Cabinet Regulation No. 410, concerning 'Regulations on the Licensing of Pharmaceutical Activities' (this includes information on the manufacturer, the quality management system, personnel, premises, quality control system, distribution, procedures to ensure superior manufacturing practices and complaint management procedures); it also includes a description of the respective manufacturing facility.
- If the medicinal product is manufactured only for export, then a List of Manufactured Medicinal Products Intended for Export document must be submitted, a template is also available in the Annex to Cabinet Regulation No. 410, 'Regulations on the Licensing of Pharmaceutical Activities'.
- Payment of a fee to the state.
- After the State Agency of Medicines has reviewed the document, it carries out a conformity assessment check.

Authorisations are also required for:

- the import and export of narcotic and psychotropic substances or medicinal products;
- unregistered medicinal products;
- parallel imports; and
- orphan drugs.

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 are attached to them?

Yes, according to the Pharmaceutical Law and Cabinet Regulation No. 410, concerning 'Regulations on the Licensing of Pharmaceutical Activities', the retail distribution of medicinal products requires a licence for the operation of a general-type pharmacy.

A general-type pharmacy may be established by the following persons:

- A natural person – a pharmacist as part of a practice or joint practice in accordance with the Civil Law (for those performing an economic activity) or as an individual merchant.

- A legal person (a company with share capital) – the shareholder (at least 50 per cent of the shares) is a pharmacist or at least half of the board members are certified pharmacists.

A general-type pharmacy may be opened only at a pharmaceutical activity site that has been deemed to be in compliance with the following criteria:

- A populated area (a town or village) – if the maximum permitted number of pharmacies has not been exceeded (up to 4,000 inhabitants, two pharmacies may operate in the relevant populated area), and be situated at least 500 meters from another functioning general-type pharmacy where medicinal products are prepared or which operates 24-hours a day.
- Outside of populated areas (rural municipalities) – at least five km from any other functioning general-type pharmacy.
- In exceptional cases, a pharmacy may be opened by a pharmacist's assistant (as an individual merchant or as the only shareholder of a company holding the respective share capital), if the number of inhabitants in the municipality, town or rural area does not exceed 4,000 and no general-type pharmacies or pharmacy branches are operating within a range of five km (in such a case the State Agency of Medicines issues a limited licence for a general-type pharmacy for five years).

In order to receive a licence, a free-form application must be submitted to the State Agency of Medicines, requesting approval for the chosen pharmaceutical activity location. The application must indicate the precise address of the planned pharmaceutical activity site; the cadastral designation of the group of premises in which the pharmacy will be located; and whether special operation activities in the pharmacy are planned (see below). After receiving a positive decision from the State Agency of Medicines on the approval of the pharmaceutical activity site, the applicant must, within 60 days, submit all the required information under Annex 6 of Cabinet Regulation No. 410, concerning 'Regulations on the Licensing of Pharmaceutical Activities' (including information on the premises, distribution, storage, special operation activities and personnel).

Applications for 'special operation' activity licences can also be obtained to supplement the operation of general-type pharmacies, and cover the following:

- For the distribution of psychotropic medicinal products, a responsible person must be appointed (and a replacement person in their absence) for this specific type of activity. The pharmacy must also provide a special lockable drawer or cabinet for the storage of any sensitive products.
- For the distribution of psychotropic substances, the same requirements apply as for psychotropic medicinal products.
- For the distribution of narcotic medicinal products and the respective psychotropic medicinal products, it is additionally required to appoint a responsible person (and a replacement person in their absence) for this specific type of activity. The pharmacy must also provide a special lockable safe or a lockable metal cabinet attached to a floor/wall for secure storage. The safe must be equipped with a sound or light alarm when its door is opened. The safe may be installed in a separate room, in the medicine storage room, in an administrative room or in the medicine manufacturing room. In exceptional cases, the safe may be placed in a reception room.
- For the distribution of narcotic and the respective psychotropic substances, the same requirements apply as for narcotic and the respective psychotropic medicinal products.
- For the preparation of medicinal products inside a pharmacy, it is also required to appoint a responsible person, who oversees a process in which at least two employees are available, one to prepare medicinal products and one to perform the quality control in terms of the respective preparations. The preparation of medicinal products must be carried out in a

separate specially equipped room, which has separate workplaces for the preparation of liquid, soft and solid dosage forms; which can be used to carry out an analysis of medicinal products and purified water; and which can be used to undertake the proper packaging of medicinal products. If both non-sterile and sterile dosage forms are produced, then a separate specially equipped room for the preparation of sterile dosage forms is required, ensuring aseptic conditions, as well as the auxiliary rooms for ensuring the preparation of medicinal products.

- For 24-hour pharmacies, it is additionally required to appoint a responsible person to ensure proper operations, whereby the pharmacy must employ more than two employees. For the night-time service, a special box must be installed at the entrance to the pharmacy for dispensing products and receiving payments.
- For the online distribution of non-prescription medicines, it is additionally required to appoint a responsible person to ensure the respective functionality. Moreover, a special pharmacy website must be created that complies with the applicable requirements and that also meets the requirements of the Law on Advertising. Rules detailing the distribution of non-prescription medicines to customers must be published, as must the pharmacy's internal procedures for organising the distribution of non-prescription medicines. The Health Inspectorate performs compliance checks on such websites.

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

Please see the response to Question No. 4.

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 import of medicinal products is regulated by the Pharmaceutical Law, Cabinet Regulation No. 410, concerning 'Regulations on the Licensing of Pharmaceutical Activities' and Cabinet Regulation No. 436, concerning 'Procedures for the Importation and Exportation of Medicinal Products'. For unregistered medicinal products, parallel imports and other areas, importation will require a special licence and authorisation. (See Question No. 3.)

Oversight of the import of medicinal products is carried out through coordinated activities involving the Customs Office, Food and Veterinary Service, Health Inspectorate and the State Agency of Medicines.

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?

A natural person is permitted to import medicinal products for personal use from abroad (for example, in their luggage) or receive these by post, if they are in their original packaging, their manufacturer and the country of manufacture are identifiable on the packaging and a purchase receipt or equivalent document confirming the purchase of the medicinal product is enclosed.

When entering Latvia from a Schengen country, the import of medicinal products for personal use containing substances included in Lists II and III (both lists are annexed to the Law on the

Procedures for the Coming into Force and Application of the Criminal Law) is permissible if a certificate issued by the competent authority of the relevant country on the use of narcotic or psychotropic substances for medicinal purposes has been issued and is available for inspection.

When entering Latvia from a country outside of the Schengen area, the import of medicinal products for personal use containing substances included in Lists II and III is permissible if the medicinal products containing the substances included in List II are intended for a course of treatment that does not exceed 14 days and medicinal products containing the substances included in List III must be intended for a course of treatment that does not exceed 30 days. The respective person in possession of the above must be able to prove, upon request, their need to use the respective medicinal products by presenting a prescription, a copy of the prescription or other documents attesting thereto.

However, a natural person is not permitted to:

- import narcotic analgesics, new psychoactive substances and active substances from foreign countries for personal use;
- import anabolic steroids, testosterone, growth hormones or their analogues from third countries for personal use;
- receive narcotic analgesics, new psychoactive substances and active substances, as well as anabolic steroids, testosterone, growth hormones or their analogues in a postal consignment; or
- send and receive those medicines included in Lists II and III using domestic and international postal consignments.

The quantity of medicines received from foreign countries for personal use at one time may cover:

- 12 months of use, if the given medicinal product is imported or received in a postal consignment from a country within the European Economic Area;
- 14 days of use, if the given anabolic steroid, testosterone, growth hormone or its analogue is imported from a country within the European Economic Area; or
- six months of use, if the given medicinal product is imported from a third country.

In cases where a medicinal product is purchased through distance selling (ie, online), the address of the pharmacy, its licence number, the online pharmacy's website, the institution issuing the pharmacy's licence and the registered address must be indicated on the postal item's packaging.

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?

See the response to Question No. 7. (No local presence is required.)

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?

The parallel importation of medicinal products is regulated by the Pharmaceutical Law, Cabinet Regulation No. 416, concerning 'Procedures for the Distribution and Quality Control of Medicinal Products' and Cabinet Regulation No. 57, concerning 'Regulations on the Procedures for Labelling Medicinal Products and Requirements for Instructions for the Use of Medicinal Products'.

Parallel imports of medicinal products are permitted only if the parallel importer has received authorisation from the State Agency of Medicines.

The parallel importer must also inform the State Agency of Medicines on the sale price of the relevant medicinal product in Latvia (per each medicinal form, depending on the amount of active substances in the respective medicinal product unit and the number of medicinal product units in a given package), excluding value-added tax, and must notify the Agency of the actual date of the commencement of distribution of the medicinal product in Latvia.

Labelling requirements – if parallel imported medicinal products contain therapeutic indications, which are approved by another EU Member State, but are not approved in respect of the medicinal products included in the Register of Medicinal Products of the Republic of Latvia, such information must be provided within an adhesive label appended to the given products. The content of the labelling and the packaged leaflets contained inside parallel imported medicinal products must conform to the labelling and packaging standards applicable for medicinal products included in the Register of Medicinal Products of the Republic of Latvia, only allowing for the following differences: the name of the medicinal product, excipients or colouring matters with a colour code and the name and address of the manufacturer.

EXPORT

10. Are there 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?

As of 1 July 2020, the State Agency of Medicines maintains a list of reimbursable medicinal products, and those medicinal products specified by the State Agency of Medicines, which are necessary to prevent public health risks, and whose export is restricted via an assessment of their availability during the previous three months, information on remaining stocks at Latvian wholesalers, the availability of analogue medicinal products and reports received by the Agency on availability risk factors. The State Agency of Medicines, when assessing the availability of medicinal products, may in individual cases allow the export of medicinal products included in this list.

The criteria for including a medicinal product in the export restriction list are as follows:

- the marketing authorisation holder (MAH) or the wholesaler of the given medicinal product has notified the Agency of an interruption in the supply of the given medicinal product (applies until the supply of the medicinal product is restored); and
- in the past three months, the lack of availability of the respective medicinal product has been established and verified by Latvian medicinal product wholesalers (with such an interruption lasting at least 24 hours).

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?

No 'export-only' or 'dual-labelling' authorisations apply in Latvia. However, a notification obligation is applicable in the opposite scenario, ie, when medicinal products in Latvia are planned to be distributed to EU or European Economic Area markets.

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?

The MAH must notify the State Agency of Medicines regarding the start of the distribution of the respective medicinal product in Latvia, as well as inform the Agency about their sale prices twice a year at precise six-month intervals, as well as in situations where the manufacturer's price changes.

Medicinal products distributed in Latvia must have labelling and package leaflets in the country's official language. In a situation where the MAH cannot ensure that the information is in the official language (including when the medicinal product manufacturer repackages a given medicinal product), the MAH may request authorisation enabling the distribution of such medicinal products from the State Agency of Medicines.

Traceability and identification requirements stem from Directive 2011/62/EU and Delegated Regulation (EU) 2016/161.

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 inclusion of a medicinal product or medical device in the List of Reimbursable Medicinal products is carried out in accordance with Cabinet Regulation No. 899, on 'Procedures for the Compensation of Expenses for the Purchase of Medicines and Medical Devices Intended for Outpatient Treatment'.

Reimbursed medicinal products are divided into different categories or lists, as follows:

- List A – medications of equivalent efficacy (mutually interchangeable, where one active ingredient is produced by several manufacturers);
- List B – medications protected by a patent (no medications exist of equivalent efficacy);
- List C – medications where the cost of treating one patient exceeds €4,268.62 and the manufacturer agrees to cover the reimbursement costs of the medication for a certain number of patients from its own funds; and
- List M – medications registered throughout Latvia for mothers, pregnant women and children under 18 years of age, which are reimbursed at a rate of 50 per cent.

Cabinet Regulation No. 376, on 'Procedures for the Registration of Medicinal Products', also provides for a sunset clause, meaning the State Agency of Medicines may decide to revoke the registration of a medicinal product if:

- The medicinal product has not been placed on the market in Latvia within three years of the decision to register the relevant medicinal product. This does not apply where at least one pharmaceutical sales package is distributed in Latvia.
- The registered medicinal product, which has previously been placed on the market in Latvia, has not actually been marketed for three consecutive years.
- The registration holder has notified the State Agency of Medicines of the cessation of distribution of the medicinal product in Latvia.
- A decision to refuse re-registration has entered into force.

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?

Liability regarding damage to persons or property following on from the supply of defective or faulty products can be claimed on the basis of a tort (non-contractual) or contract (contractual), ie, civil liability.

Administrative liability can be imposed by competent authorities in the form of fines, orders to take particular actions, a prohibition to engage in particular actions for a breach of certain statutory requirements under the Pharmaceutical Law and other applicable laws.

Criminal liability may arise only for serious offences, eg, manufacturing medicinal products/medical devices in the form of a business or in large volumes without holding a licence or the sale of medicinal products manufactured without authorisation where such medicinal products could have caused a threat to human health or life or have resulted in death or serious injury.

For the applicable oversight powers of the authorities, please refer to the response to Question No. 1.

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 the cross-border movement of therapeutic products in the future?

From 1 July 2026, pharmacy owners whose total turnover in the last five years has exceeded five per cent of the total pharmacy turnover in Latvia in at least one year will be obliged to publish on their websites, easily accessible information, about the medicinal products available in each pharmacy and their respective prices.