

TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)
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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES
<p>1. What are the principal statutes, regulations and competent authorities that govern the import, wholesale distribution, retail sale and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?</p>
<p>In Romania, therapeutic products are mainly regulated by a primary piece of legislation, namely Law No. 95/2006 on healthcare reform, complemented by government decisions or orders issued by the Ministry of Health.</p> <p>The Romanian National Agency for Medicines and Medical Devices (<i>Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România</i> or ANMDMR) is the competent authority for the supervision and approval of activities involving the import, wholesale distribution, retail sale and export of therapeutic products.</p> <p>The import, wholesale and export of medicinal products requires a licence issued by ANMDMR prior to the commencement of such activities, whereas any activities involving narcotics and psychotropic drugs require special authorisations issued by the Ministry of Health. Import, distribution, as well as ancillary services, regarding medical devices require an operating permit issued by ANMDMR. Activities involving veterinary medicines follow a similar framework, with the National Sanitary Veterinary and Food Safety Authority being the responsible regulatory and supervisory authority.</p>
<p>2. How are therapeutic products classified for regulatory purposes (eg, prescription only, over the counter, hospital use, risk classes for devices, etc) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?</p>
<p>In Romania, medicines are classified according to different dispensing categories (ie, primarily prescription-only (Rx) and over-the counter (OTC) medicinal products – Rx medicines may also have potential subcategories based on the dispensing conditions, eg, medicines that are dispensed with a special medical prescription) (Chapter VI of Law 95/2006). Medical devices are classified according to their intended purpose and the level of risk posed. The classification will determine who may supply the product, how it should be supplied and under what means of control and supervision carried out by the public authorities.</p> <p>All medicinal products placed on the Romanian market must have a marketing authorisation valid at the Romanian and/or EU level, whereas the trade and distribution of such products may be conducted only by distributors holding a wholesale distribution licence issued by ANMDMR.</p>

When issuing a wholesale distribution licence, ANMMDR specifies the classification of the medicines involved.

Medical devices are primarily regulated by Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Regulation 2017/745). In Romania, medical devices are classified into Classes I, IIa, IIb and III, considering the intended purpose of the devices and the inherent risks posed (Section I of Regulation 2017/745). All medical devices require a prior licence issued by ANMMDR for their import, distribution and carrying out ancillary services in the field of medical devices. Depending on the class of device involved, certain specific requirements are applicable for the issuance of a licence, with the higher risk classes being subject to the strictest requirements. Distance selling (including through information society services) are permitted subject to a prior licence being issued by ANMMDR (Article 926, paragraph 2 of Law 95/2006).

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

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

The wholesale distribution of medicinal products in Romanian requires a wholesale licence issued by ANMMDR.

Key criteria include compliance with the good distribution practice requirements applicable at the EU level and the issuance of a certificate of good distribution practice for each distribution unit or facility (Article 857, paragraph 13 of Law 95/2006). Other requirements entail the retention of qualified personnel, having a quality control system in place, including a person with extensive experience in the healthcare sector, responsible for ensuring the quality of the medicines is maintained, the traceability of the products and distribution channels, as well as having a proper pharmacovigilance system in place (Article 726 et seq of Law 95/2006).

For the distribution of narcotics and psychotropic drugs, a special authorisation issued by the Ministry of Health is required. Particular standards of production and distribution, as well as traceability requirements are provided in Law No. 339/2005 on the legal regime governing narcotic and psychotropic plants, substances and preparations.

Medical devices put into service and in use are also subject to the following control methods: (1) control through periodic verification; (2) unannounced inspection and testing; and (3) supervision during use (Article 928 of Law 95/2006). Other key requirements include the verification of the conformity of such devices, the designation of a contact person with ANMMDR responsible for record keeping and verifications, appropriate storage and transport conditions, the implementation of a register for medical devices and ensuring the traceability of products (Article 933 of Law 95/2006).

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?

Therapeutic products may only be provided to consumers by authorised pharmacies or drug stores.

Community pharmacies, closed-circuit pharmacies or drug stores require a distinct licence issued by the Ministry of Health and their activity is governed by the good pharmaceutical practice rules

issued by the Ministry of Health in collaboration with the Romanian College of Pharmacists (Article 8 of the Pharmacy Law No. 266/2008). Pharmacies or drug stores are organised as companies whose business activity includes the retail sale of medicines, and they are managed by a chief pharmacist (Articles 6, 7 and 23 of the Pharmacy Law). Their activities entail the dispensing of medicinal products (and other related products, such as cosmetic products and food supplements), the preparation of prescription-based medicines or other health products, as well as the provision of counselling to patients.

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

Internet/distance selling is only permitted for OTC medicines and requires a special authorisation issued by the Ministry of Health (Article 21 of the Pharmacy Law).

OTC medicines may be sold over the internet and exclusively by pharmacies authorised by the Ministry of Health. The website or portal through which such products are presented and sold must meet specific requirements (eg, must verify the identity of the patients, ensure that there is a direct link between the patient and the pharmacist, send a questionnaire to the patient and provide a hyperlink to the Ministry of Health's website, etc). Medicines may only be sold and dispensed online to patients who over the age of 18. The pharmacies authorised to sell medicinal products online must also have a brick-and-mortar unit, duly organised as per the legal standards, from which it fulfils the online orders (Article 32 et seq of the Regulation, as of 2019, on the establishment, organisation and operation of pharmaceutical units).

For medical devices, distance selling of medical devices through information society services requires prior authorisation from ANMDMR, subject to certain exceptions when such authorisation is not required.

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)?

Romania regulates the import of therapeutic products under Law 95/2006 and customs law. The import of medicines from third countries (ie, non-EU countries) requires a manufacturing licence issued by ANMDMR (Article 755, paragraph (3) of Law 95/2006). Also, the authorisation documentation must include the following technical documents, among others: (1) a standard file, prepared in accordance with the Good Manufacturing Practice Guide for Medicinal Products for Human Use, which importers are required to prepare for each import site, considering the specific nature of the import activity and (2) the provision of details related to the commitment to report the exact situation of each import (Article 4 of Order 1295/2015). Additionally, ANMDMR undertakes inspections to ensure that the manufacturing standards of the imported medicines are at least equivalent to the good manufacturing practice standards set at EU level and that such activities are being carried out by manufacturers legally authorised to do so (Article 7612 of Law 96/2006).

For the import of medicines containing narcotics and psychotropic drugs, after obtaining the necessary manufacturing authorisation, relevant undertakings must also obtain special authorisations for the import of this type of medicine issued by the Ministry of Health (Article 13 of Order 1295/2015).

The import of medical devices requires prior authorisation by ANMDDMR (Article 926, paragraph 2 of Law no. 95/2006).

As an EU Member State, common external customs duties and rules apply in terms of qualifications and custom controls. Romania also requires that the importing entity is registered to interact with customs and, thus, has an EORI (Economic Operator Registration and Identification) number. Border checks are conducted under the EU's risk-based import control system, with Romania's customs authorities ensuring compliance and coordinating with the health regulators to intercept any illegal or non-compliant shipments.

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

Consumers may import small quantities of therapeutic products for personal use, subject to therapeutic products and customs regulations at the EU and local level.

Medicinal products that are not (yet) authorised in Romania may nevertheless be made available with the approval of the ANMDDMR for patients with special needs that cannot be met by products covered by existing national marketing authorisations. Such access is granted on the basis of a medical prescription issued by a healthcare professional on the patient's special needs, accompanied by the relevant supporting documentation. A special authorisation is granted for the quantity specified in the prescription, provided that it does not exceed the amount needed for 12 months of use. Still, that medicine needed to meet such special needs must be authorised in at least one country within the European Economic Area (EEA) or in a third country (Article 2 et seq. of the Regulation on implementing the provisions of Article 703(1) and (2) of Law 95/2006).

No specific rules are provided for medical devices in this regard. However, the import of medical devices for marketing purposes must be notified to ANMDDMR and an import licence must be obtained in order to conduct such activities.

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

The shipment and disposal of therapeutic products directly to consumers via e-commerce or mail order may only be undertaken by authorised pharmacies. Online sales are permitted only by pharmacies authorised by the ANMDDMR to sell medicines online and any such pharmacy must also operate a physical (brick-and-mortar) unit from which the orders are fulfilled.

Foreign pharmacies, whether established within or outside the EU, cannot obtain authorisation from ANMDDMR for online sales or a mail order licence in Romania, as Romanian law does not contain a procedure for foreign pharmacies to apply for such licences.

However, in line with EU principles on the free movement of goods, OTC medicinal products may be supplied to Romania by pharmacies established in EU Member States and duly authorised under the respective national legislation.

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?

For medicines, a parallel importation licence issued by ANMDMR is required, with the exception of medicines authorised at EU level through a centralised procedure overseen by the European Medicines Agency. ANMDMR manages parallel importation activities as per the statutory EU regulations, as well as Court of Justice of the European Union (CJEU) case law. Under common EU rules, to be granted a parallel importation licence, a medicine must be authorised in a foreign jurisdiction and must be sufficiently similar to the original medicine authorised and distributed directly in Romania (although there might be some differences in the excipients). The efficacy and safety standards of the original medicine are also applicable to the parallel imported medicine (Article 5 et seq. of the procedure for issuing parallel import licences for human medicines as of 2008). If the parallel importer intends to make changes to the labelling and outer packaging, etc, in addition to the distribution licence, it must also hold a manufacturing authorisation (Article 11 of the aforementioned procedure).

Medical devices may also be subject to parallel trade, but the limitations arising from the need to protect health and safety and the need to protect intellectual property rights must be observed. Specific rules, particularly related to re-labelling and re-packaging must be assessed as well, as per the relevant EU regulations and CJEU case law (Recital 37 of Regulation 745/2017).

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?

Export activities are integrated as a form of wholesale distribution. Therefore, a wholesale distribution licence issued by ANMDMR is required even if the medicines are intended solely for export (Article 699, pt. 17 of Law 95/2006).

The government, based on a proposal by the Ministry of Health, may, for reasons related to public health, restrict or prohibit the export of certain medicines for human use for specific periods of time (Article 889 of Law 95/2006).

No specific provisions are stipulated for the export of medical devices. However, as export would be considered a form of distribution, securing prior authorisation in order to carry out such activities is mandatory. Moreover, for export purposes and upon request, the Member State in which a manufacturer (or the authorised representative) has its registered place of business shall issue a certificate of free sale, declaring that the manufacturer has its registered place of business on its territory and that the device in question bearing CE marking may be marketed within the EU (Article 60 of Regulation 2017/745).

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?

As a general rule, all medicinal products, even those intended for export only, require a manufacturing licence in Romania and must comply with good manufacturing practices and good distribution practices for active substances (Article 763 of Law 95/2006).

The same applies for medical devices.

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?

The standard information contained on the labelling must be in Romanian and, optionally, in other languages, provided that the same information appears in all of the languages used. In the case of certain orphan medicines, the information listed on the main/secondary package may, based upon a justified request, appear only in one of the official languages of the EU (Article 785 of Law 95/2006). Mandatory information includes the product name, therapeutic indications, expiry date, composition, dosage, storage instructions, warnings and side effects (Article 781 of Law 95/2006). Traceability is ensured via the product code, serial number, batch number and expiration date (Article 6 of Detailed Rule for safety features appearing on the packaging of medicines for human use as of 2018). Counterfeiting risks are mainly addressed through the standard EU safety features displayed on the main/secondary packaging, as provided by EU Regulation 2016/161.

Medical devices must be labelled as per standard EU rules and each device shall be accompanied by information to identify the device and its manufacturer, as well as relevant safety and performance standards (Annex I, Article 23 of EU Regulation 2017/745). The declaration of conformity and the CE marking certificate and, where applicable, the manual or instructions for use and the purchase invoice must be archived in order to ensure and document traceability (Article 933 para. (1) pt. f) of Law 95/2006).

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 Ministry of Health approves the maximum prices of medicines authorised for marketing in Romania, except for medicines authorised by the European Medicines Agency through its centralised procedure and purchased at the EU level, medicines whose pharmaceutical form is ‘medicinal gas’ and OTC medicinal products that are not included in the list containing the international non-proprietary names of medicinal products available to insured persons with or without a personal contribution on the basis of a prescription in the social health insurance system, as well as the international non-proprietary names corresponding to the medicinal products granted under national health programmes (Article 890 of Law 95/2006).

Moreover, marketing authorisation holders and wholesalers must comply with public service obligations, by maintaining and reporting minimum monthly stocks of each medicine for which they hold a marketing/distribution licence in Romania. Minimum mandatory stocks are equal to the average monthly turnover for the last three months for each medicine (Order No. 269/2017 on the obligation to ensure adequate and continuous stocks of medicines).

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?

ANM DMR is the authority responsible for supervising the market and imposing sanctions for violations of the law, in collaboration with European Medicines Agency. Generally, non-

compliance with trade and distribution rules are administrative offences, provided they are not committed in circumstances that would constitute criminal offences under criminal law.

ANDMDR may conduct announced and unannounced dawn raids of premises used by manufacturers, importers or wholesalers. It also investigates quality, safety and traceability issues via complaints, alerts or Ministry referrals (Article 4 para. (3) pt. 3 of Law No. 134/2019 on the reorganisation of the National Agency for Medicines and Medical Devices, as well as the amendment of certain legislative acts).

ANMDMR may impose fines of up to RON 100,000 (approx. €20,000) and other administrative measures (eg, product seizures, facility closure, the suspension or revocation of licences and authorisations) (Article 857 et seq. of Law 95/2006).

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

Certain national developments are expected to follow measures being brought in at the EU level aimed at improving the availability of essential medicines and the security of the supply chain.

Also, several amendments are expected in the near future with respect to the online selling of OTC medicines via online platforms, in order to align Romanian law with recent EU case law (eg, CJEU Case C-606/21).