

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>The legal framework for therapeutic products in Spain incorporates both European Union and national legislation. At the EU level, Spain applies the medicinal products framework (Regulation (EC) No 726/2004 and Directive 2001/83/EC for human medicinal products and Regulation 2019/6 for veterinary medicinal products) and the medical devices framework (Regulation (EU) 2017/745 (Medical Device Regulation or MDR) and Regulation (EU) 2017/746 (In Vitro Diagnostic Regulation or IVDR)).</p> <p>At the national level, the primary statute is Legislative Royal Decree 1/2015, which governs the authorisation, manufacturing, import, distribution, dispensing, pricing and sanctions for medicinal products, as well as various aspects related to medical devices. This regulation is supplemented by numerous other regulations, as detailed throughout this survey.</p> <p>Biologic therapeutic products, including blood derivatives and advanced therapy medicinal products, are regulated as medicinal products.</p> <p>The Spanish Agency of Medicines and Medical Devices (<i>Agencia Española de Medicamentos y Productos Sanitarios</i> or AEMPS) is the national health authority responsible for key functions, such as granting marketing authorisations and the authorisation of pharmaceutical laboratories, holders of marketing authorizations, manufacturers and importers. The AEMPS is regulated by Royal Decree 1275/2011.</p> <p>Furthermore, Spain is divided into 17 autonomous communities, each with its own competent regional health authority. These authorities hold responsibilities in regard to carrying out inspections and market surveillance within their respective territorial jurisdictions.</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>Medicinal products are classified as either prescription only or over the counter (OTC) and this classification is included in the marketing authorisation (Article 24 of Royal Decree 1345/2007). In regard to prescription medicinal products, AEMPS may apply sub-categories, such as restricted</p>

prescription products (which includes medicinal products reserved for hospital use). The criteria for classifying a product as ‘prescription only’ include the level of risk posed, frequency of use or route of administration, among others.

Regarding their distribution, medicinal products for human use can only be dispensed by: pharmacy offices or hospital pharmacies (Article 3.6 and 19.4 of Legislative Royal Decree 1/2015). In addition, medicinal products designated for hospital use can only be dispensed by hospital pharmacies.

Veterinary medicinal products are only allowed to be dispensed through the following authorised channels: pharmacy offices; authorised retail establishments with an in-house pharmaceutical service; and authorised farmers’ associations with a pharmaceutical service (Article 38 of Legislative Royal Decree 1/2015). These authorised channels are the same for prescription-only medicinal products or OTC products (with some exceptions for certain OTC veterinary medicinal products).

Lastly, concerning medical devices, Spain follows the EU MDR and IVDR frameworks, which classify devices based on risk. Medical devices are classified as Class I, IIa, IIb or III and in vitro diagnostic medical devices are classified as Classes A, B, C or D. Placing these products on the market requires CE marking, obtained through the relevant conformity assessment routes. A notified body is required to be involved in the applicable conformity assessment for medical devices in Classes IIa, IIb and III and for in vitro diagnostic medical devices in Classes B, C and D (as well as for sterile devices in Class I and A).

Certain medical devices may also be subject to prescription requirements.

According to Royal Decree 192/2023, the term ‘medical devices subject to prescription’ comprises the following medical devices: (1) custom-made products; (2) products manufactured in series through industrial manufacturing processes in accordance with the written specifications of any authorised person; (3) products financed by the National Health System; (4) products requiring individualised adaptation; and (5) products intended to be used or applied exclusively by healthcare professionals, and non-medical-purpose products listed in Annex XVI of Regulation (EU) 2017/745, intended to be used or applied exclusively by other professionals.

Furthermore, Royal Decree 942/2025, regulating in vitro medical devices, establishes that the term ‘medical devices subject to prescription’ comprises the following medical devices: (1) products financed by the National Health System; (2) products destined to be used or applied exclusively by healthcare professionals; and (3) human genetic testing.

The ‘medical devices subject to prescription’ as defined in each Royal Decree can only be dispensed through authorised channels. Conversely, medical devices not subject to prescription are available for purchase at various other locations, including supermarkets.

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 is governed by Legislative Royal Decree 1/2015 and Royal Decree 782/2013 (for human use) and Royal Decree 666/2023 (for veterinary use).

Aside from pharmaceutical laboratories, which may distribute their medicinal products under their own authorisations, businesses engaging in wholesale activities, namely wholesale warehouses, contract warehouses and customs-controlled warehouses (only for human use), must hold prior authorisation. Authorisations for wholesale and contract warehouses are granted by the regional health authority where the warehouse is located, whereas warehouses subject to customs control are authorised by the AEMPS. The authorities maintain a public catalogue of all authorised wholesale entities (Article 19 of Royal Decree 782/2013 and Article 21 of Royal Decree 666/2023). All distributors of medicinal products must adhere to the EU's Good Distribution Practices (Article 20 of Royal Decree 782/2013 and Article 12 of Royal Decree 666/2023).

Key conditions for authorisation include maintaining adequate facilities and equipment for proper conservation and distribution, appointing a qualified person (*director técnico*) for each site, and employing necessary personnel to ensure product quality and safety (Article 4 and 5 of Royal Decree 782/2013 and Article 22 of Royal Decree 666/2023).

Royal Decree 782/2013 also regulates brokers (intermediaries with no physical handling of the goods). Because they do not physically handle stock, brokers do not require a licence.

The distribution of medical devices is governed by Royal Decree 192/2023 (for medical devices) and Royal Decree 942/2025 (for in vitro diagnostic medical devices). Unlike distributors of medicinal products, distributors of medical devices are not subject to prior authorisation but must file a prior activity notification with the regional health authority where they are established (and with the competent authority of any autonomous community where an additional warehouse is located).

In addition, distributors must be registered in the AEMPS marketing register. However, as this register is not yet operational, operators must notify the placement of their products on the market in accordance with Royal Decree 1591/2009 (the prior regulation governing medical devices).

Lastly, distribution activities must also be carried out under the supervision of a responsible technician and in a way that guarantees the proper storage and preservation of the products.

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?

As established in Question 2, retail sales of medicinal products are only allowed to occur through specific channels. All such establishments require administrative authorisation issued and supervised by the competent autonomous community.

The key conditions vary for each channel. For example, pharmacy offices must be owned by pharmacists and operate with the pharmacist's continuous professional presence (Law 16/1997). Regarding the online sale of medicinal products, this activity can only be carried out through the websites of authorised pharmacy offices. For more information, see Question 5.

For medical devices, businesses must file a prior start-of-activity notification with the regional health authority where they are established (and, if applicable, with the authority for any warehouse located in another autonomous community). Pharmacies are exempt from this notification requirement unless they perform individualised adaptation activities for medical devices. In all cases, the establishments must ensure the proper storage and preservation of the medical devices.

The sale of medical devices through vending machines is permitted, provided that product integrity and safety are not compromised, subject to certain restrictions. Furthermore, street vending or

itinerant sales of medical devices and in vitro diagnostic devices are prohibited (Article 24 of Royal Decree 192/2023 and Article 19 of Royal Decree 942/2025).

Moreover, the public sale of in vitro diagnostic medical devices designed for self-testing must be conducted exclusively through pharmacy offices or directly through a pharmacy's own website, without the involvement of intermediaries. However, software designed for self-testing is exempt from this channel restriction.

Retail establishments engaged in the individualised adaptation of medical devices are subject to specific regulations governing their operations.

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

Legislative Royal Decree 1/2015 prohibits the online sale of all medicinal products and medical devices that require a prescription (Article 3.5 of Legislative Royal Decree 1/2015).

For OTC human medicinal products, online sales to the public (including through social media platforms) are governed by Royal Decree 870/2013. This Decree authorises sales only through the websites of pharmacy offices, excludes non-authorised medicinal products and officinal preparations, and bans sales through any information society services other than the regulated pharmacy website channel. The Decree also bans the use of intermediaries and requires that sales be made directly by the dispensing pharmacy (Article 1 of Royal Decree 870/2013). A pharmacy office must notify the competent authority of the autonomous community where it is located of the start of its distance-selling activity at least 15 days in advance (Article 4 of Royal Decree 870/2013).

Regarding medical devices and in vitro diagnostic medical devices, the applicable regulations do not impose specific conditions for the online sale of products that are not subject to a prescription.

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)?

For medicinal products, Spain's import framework is set by Legislative Royal Decree 1/2015, Royal Decree 824/2010 and AEMPS' Circulars 1/2025 and 2/2012.

Importers of medicinal products must hold an AEMPS authorisation as a pharmaceutical importer. They must also have suitable premises and technical and control equipment that is adequate for the intended activity, meeting legal requirements for the manufacture, control and proper conservation of medicinal products. They are required to appoint a qualified person, a head of manufacturing and a head of quality control.

Only medicinal products that are authorised and entered in the Register of Medicinal Products are allowed to be imported (Article 72 of Legislative Royal Decree 1/2015).

Imports of medicinal products, including investigational medicinal products, are subject to prior authorisation by the AEMPS. The holder of the AEMPS import authorisation is the entity that is required to lodge a customs import declaration.

For medical devices, importation requires a prior operating licence granted by the AEMPS.

Those who are engaged in importing medicinal products or medical devices must, on the same terms as manufacturers, maintain insurance, a bond or an equivalent financial guarantee to cover health damages arising from safety issues (Article 72 of Legislative Royal Decree 1/2015).

Customs classification and tariff treatment follow EU customs law, with cooperation between the Health Ministry and customs authorities during clearance. Border controls are risk based.

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?

For medicinal products, Legislative Royal Decree 1/2015 prohibits the sale of prescription medicinal products by correspondence and by telematic procedures. OTC medicinal products can be sold only through pharmacy offices' websites (see Question 5). In practice, this means that private individuals cannot lawfully receive prescription medicinal products by post from abroad, and even OTC products ordered from a foreign seller will be non-compliant unless the seller is an authorised Spanish pharmacy.

Travelers are allowed to carry their personal medication, although the corresponding prescription or medical report may be required upon entry into or exit from Spain. The amount of medication a traveller can carry should be appropriate for the prescribed treatment, not exceeding the quantity necessary for a three-month period, to avoid suspicion of illicit trafficking. Larger quantities may be accepted if duly justified. Special regimes apply to narcotics, psychotropic substances and athletes.

Additionally, the entry of small quantities of unauthorised veterinary medicinal products (except for immunological ones) into Spain is permitted for animals in transit for exhibitions, competitions or tourism.

For medical devices, the sale of prescription devices by correspondence and by telematic procedures is forbidden.

Regarding medical devices that require a prescription, importation is permitted. However, importers in Spain who introduce products from third countries into the EU market must obtain an import licence under Royal Decree 192/2023. Similarly, any individual or legal entity physically importing such medical devices into Spain must also obtain an import licence (Article 7 of Royal Decree 192/2023). In addition, the medical device must comply with the MDR/IVDR regulatory framework.

Furthermore, when placed on the market in Spain, the products must include the data and information outlined in Section 23 of Annex I of the MDR/IVDR, presented, at least, in Spanish (Article 5 of Royal Decree 192/2023 and Article 5 of Royal Decree 942/2025).

Customs declaration and tariff classification follow EU customs law, while the application of duties and value-added tax (VAT) follow Spanish tax law.

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 Questions 5 and 7.

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?

Parallel importation of medicinal products authorised in Spain is governed by Royal Decree 1785/2000. Centrally authorised products fall outside of that Decree and are governed at the EU level under Regulation (EC) 726/2004.

If the parallel importer undertakes any reconditioning, re-packaging or re-labelling in Spain, it must hold a manufacturer's authorisation covering those secondary packaging activities. If it does not perform those operations in Spain, it must, at least, hold a wholesale distribution authorisation for any distribution activity it is involved in. In all cases, the operations must not affect the original state of the medicinal product, and the importer must be able to guarantee proper conservation and distribution. In addition, the parallel importer must retain data related to each batch subject to parallel trade for up to two years after the product's expiration date (Article 2 and 4 of Royal Decree 1785/2000).

Before commercialisation, the parallel importer must notify the Spanish marketing authorisation holder of its intention and, if requested, it must provide a sample of the reconditioned product so the authorisation holder can verify that the presentation does not damage the trademark's reputation (Article 4 of Royal Decree 1785/2000).

The presentation of the product (labelling and leaflet) must comply with Chapter III of Royal Decree 1345/2007. The packaging must show the batch number and the name and address of the parallel importer, with a clear indication that the product is placed on the market via parallel importation (Article 2 of Royal Decree 1785/2000).

With respect to intellectual property rights, within the EU, trademark and patent rights are exhausted after the first instance of marketing in the European Economic Area (EEA) for which consent was granted, so the marketing authorisation holder cannot oppose subsequent resale solely on intellectual property grounds.

The parallel import of medical devices is governed by the EU MDR and IVDR frameworks.

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?

Legislative Royal Decree 1/2015 establishes an obligation for laboratories to ensure the supply and continuity of service, while empowering the government to adopt 'special measures' regarding manufacturing, importing, distributing and dispensing in order to safeguard the supply of medicinal products (Article 3 of Legislative Royal Decree 1/2015).

Distributing medicinal products outside the national territory for which there are supply shortage problems with healthcare implications constitutes a very serious infraction (Article 111.2.c)²² of Legislative Royal Decree 1/2015).

Furthermore, Royal Decree 824/2010 imposes the obligation to submit a prior notification to the AEMPS regarding the exportation of medicinal products, as well as shipments to other EU Member States. This regulatory mechanism allows the AEMPS to oversee export activities and, where deemed necessary, to restrict or suspend such actions in situations involving supply shortages or health emergencies.

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?

Pharmaceutical laboratories intending to manufacture unauthorised medicinal products in Spain for export must request express authorisation from the AEMPS. To obtain this authorisation, they must provide information on the pharmaceutical form and the complete qualitative and quantitative composition, as well as possess the corresponding manufacturing authorisation for the relevant pharmaceutical form and type of medicinal product (Article 55 of Royal Decree 824/2010).

The issuance of the manufacturing authorisation inherently includes the issuance of an export certificate for the destination country.

These batches must comply with EU Good Manufacturing Practices (Article 26 of Royal Decree 824/2010). The medicinal product intended for export is not required to meet the legal conditions regarding the format, presentation, texts, labelling or packaging, provided that the principles of Legislative Royal Decree 1/2015 are respected.

Before any batch is released, the qualified person must certify that the batch complies with the applicable regulation, and the batch-release register must be kept available to the authority for at least five years. In addition, batch documentation must be retained until at least one year after the product’s expiry or five years from the qualified person’s certification, whichever is longer. Likewise, finished product samples must be retained for at least one year after the expiry date (Article 18, 31 and 33 of Royal Decree 824/2010).

Regarding medical devices, those manufactured exclusively for export to third countries that do not comply with the requirements of the MDR or the applicable Royal Decree must be labelled to unequivocally identify them as export-only products (Article 29 of Royal Decree 192/2023 and Article 23 of Royal Decree 942/2025).

In terms of record keeping, manufacturers of medical devices must comply with the relevant product traceability obligations.

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?

Before a human medicinal product can be imported into Spain, its labelling and package leaflet must be available in Spanish and must comply with Royal Decree 1345/2007. The outer packaging must include authentication and traceability elements (in particular, the generation of a unique identifier (UDI)), the national code and, where applicable, the National Health System coupon (Article 32 and Annex III of Royal Decree 1345/2007).

For veterinary medicinal products, EU Regulation 2019/6 governs the relevant labelling and leaflet requirements.

For medical devices, the EU MDR and IVDR govern CE marking, UDI assignment and placement and EUDAMED obligations. Additionally, Royal Decrees 192/2023 and 942/2025 require economic operators to register products with the AEMPS before commercialisation by providing their commercial name, UDI-device identifier (DI), and Spanish-language labelling and instructions. Operators must also maintain records with UDIs, lot/serial numbers, shipment dates

and supplier/customer identifiers to ensure traceability (Article 18 and 19 of Royal Decree 192/2023; Article 15 and 16 of Royal Decree 942/2025). As previously noted, this register is not yet operational.

For exports, see Question 11.

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?

Once a medicinal product obtains marketing authorisation, but before it is placed on the market, the Ministry of Health initiates a financing procedure to determine if the product will be covered by the National Health System (Article 92 of Legislative Royal Decree 1/2015). This procedure also applies to some types of medical devices. Reimbursement is limited to therapeutic products prescribed under the National Health System using the required official prescription. Prescriptions issued during private medical practice are not reimbursed.

If a medicinal product is not marketed within three years of its authorisation or is withdrawn from the market for three consecutive years, its authorisation may be deemed lapsed (Article 21.4 of Legislative Royal Decree 1/2015). This does not apply to veterinary medicinal products (Regulation (EU) 2019/6).

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?

Legislative Royal Decree 1/2015 authorises health administrations to perform ‘the inspections necessary to ensure compliance’. Inspectors, upon proving the relevant identity of the premises, may enter any covered facility in Spain without prior notice at any time, conduct tests and examinations, take samples and carry out any acts needed to discharge their inspection duties.

Legislative Royal Decree 1/2015 grades infringements as minor, serious or very serious and sets detailed typologies for medicinal products and for devices. Sanctions are calibrated according to their seriousness and any aggravating factors. Minor infringements draw financial penalties of up to €30,000; serious infringements range from €30,001 to €90,000; and very serious infringements range from €90,001 to €1m, with the authority to exceed that ceiling up to five times the value of the infringing products or services.

Spain’s Criminal Code includes a cluster of offences targeting dangerous or fraudulent therapeutic products. It penalises dispensing deteriorated or expired medicinal products that endanger life or health; altering a medicine’s genuine composition or imitating medicinal products that pose the same endangerment; and a suite of falsification-related crimes covering import, export, advertising, offering, selling, facilitating or distributing falsified or altered medicinal products, active substances, excipients or medical devices when these acts pose a risk to life or health. The Code also criminalises fabricating false documents tied to medicinal products or medical devices to commit or facilitate these crimes, and it provides for aggravated penalties where the offender is a healthcare professional or public authority, where the products are offered on mass media or to vulnerable persons, where the offender belongs to a criminal group or where the acts occur within public-facing establishments.

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?

Several significant legislative and regulatory developments are underway in Spain and at the EU level.

At the national level, on 8 April 2025, Spain's Council of Ministers approved a draft bill for a new Law on Medicines and Medical Devices. Once enacted, this bill will repeal and replace Legislative Royal Decree 1/2015, updating Spain's core legislation in this area. The draft, which received substantial public feedback, is now proceeding through the legislative process.

Moreover, Spain has initiated procedures to amend the regulations on the financing and pricing of medicinal products.

Furthermore, a royal decree regarding the evaluation of health technologies is also being developed. This royal decree will complement Regulation (EU) 2021/2282.

At the EU level, the MDR and IVDR frameworks are being revised. On 16 December 2025, the European Commission proposed a simplification of the current rules for medical devices.

Lastly, the EU Pharma Package is also being revised, with its approval anticipated during 2026.