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?

The principal regulations governing the sale of non-prescription medicines outside community pharmacies include Decree Law No. 176/2006 of 30 August 2006 (the 'Medicinal Products Act'), Decree Law No. 97/2015 of 1 July 2015 (and associated ordinances), Decree Law No. 307/2007 of 31 August 2007 and Decree Law No. 134/2005 of 16 August 2005. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (otherwise known as the Medical Device Regulation (MDR)), Decree Law No. 145/2009 of 17 June 2009 and Decree Law No. 29/2024 of 5 April 2024 and Ordinance No. 256/2016 of 28 September 2026 govern medical devices. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 (otherwise known as the In Vitro Diagnostic Regulation (IVDR)) and Decree Law No. 189/2000 of 12 August 2000 apply to in vitro medical devices.

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?

Therapeutic products are classified for regulatory purposes according to their nature, intended use and the level of risk posed. This classification determines the applicable legal regime governing any premarket assessment, market placement, commercialisation and distribution.

Medicines are classified as either prescription-only medicines or non-prescription medicines. Non-prescription medicines are further subdivided into over-the-counter medicines and non-prescription medicines exclusively dispensed through pharmacies, where such restriction is justified by the product's safety profile or therapeutic indications.

In addition, prescription-only medicines may be subject to specific prescribing regimes, specifically renewable medical prescriptions, special medical prescriptions or restricted medical

prescriptions, the latter being reserved for use in certain specialised healthcare contexts, typically hospitals.

All medicines are subject to prior marketing authorisation as a condition for their placement on the market, regardless of their classification.

Under the MDR, medical devices are classified into four risk classes (I, IIA, IIB and III), according to Article 51 and Annex VIII. In vitro medical devices are also classified into four risk classes (A, B, C and D), according to Article 47 and Annex VIII of IVDR.

Medical devices are not subject to individual administrative authorisation prior to market placement. Instead, market access is conditional upon compliance with stringent conformity assessment procedures and the affixing of CE marking. For Class I devices, the conformity assessment is generally carried out by the manufacturer (subject to limited exceptions), whereas for Class IIa, IIb and III devices, the involvement of a notified body is mandatory.

In vitro diagnostic medical devices are likewise not subject to individual administrative authorisations. Instead, they must comply with the applicable conformity assessment procedures and bear CE marking prior to market placement, according to a risk-based regime comparable to that applicable to medical devices.

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 practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

The wholesaling of medicines in Portugal requires prior authorisation from the Portuguese Medicines and Health Products Agency (*Autoridade Nacional do Medicamento e Produtos de Saúde* or Infarmed). Approval depends on a properly submitted request, technical management and suitable facilities. Once authorised, distributors must meet all of the applicable legal duties, including good distribution practices.

For medical devices, including in vitro medical devices, wholesale distributors are not subject to prior authorisation but must register their activity and the relevant establishments with Infarmed prior to commencing distribution activities in Portugal. Distributors must have a technical manager and suitable facilities and equipment for the proper storage, conservation and distribution of medical devices.

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?

In Portugal, only pharmacies are authorised to provide prescription medicines to consumers. Non-prescription medicines outlets that are not pharmacies are allowed to provide non-prescription medicines to the public.

The establishment of pharmacies must be authorised by Infarmed and such authorisation depends on the number of pharmacies, number of inhabitants and distance to other pharmacies and to health facilities, such as hospitals and health centres, in the intended place of installation. The authorisation to install a pharmacy is granted through a competitive licencing process. Non-prescription medicines outlets are only subject to registration with Infarmed.

Sales of medicines by mail or online require prior notification to Infarmed, and the website carrying out such activities must display specific information, including the common European verification logo and Infarmed's contact details. For medical devices, including in vitro devices, the MDR and IVDR require that any distance selling activity fully complies with the respective regulations.

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

Please review the answer to Question 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 legal regime governing the importation of therapeutic products in Portugal is essentially set out in the Medicinal Products Act, which stipulates that the importation of therapeutic products is subject to prior authorisation by Infarmed.

The only exception to this authorisation requirement applies to therapeutic products imported from third countries with which the European Union has concluded an agreement that exempts them from national import authorisation.

For the purpose of this response, it is important to distinguish between importation, ie, bringing medicinal products from countries outside the EU, and parallel importation, ie, bringing a medicinal product that is similar to another product commercialised in a Member State from countries within the EU. Both are regulated and impacted by local rules in the following ways:

- The importation of medicinal products is subject to a specific authorisation issued by Infarmed, which allows the company to conduct importation activities.
- The parallel importation of medicinal products is subject to a specific marketing authorisation issued by Infarmed that only allows the company to import a specific medicinal product (that is not authorised in Portugal) to Portugal.

Finally, with respect to taxation, the Portuguese legal framework imposes fees that are specifically applicable to the marketing of medicinal products (currently the fee corresponds to 0.4 per cent of the reference price of the medicinal product).

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?

The question of whether companies may sell therapeutic products or medical devices remotely and deliver them to a patient's home (in particular, in another country) is a question of local law and varies from country to country.

While we recognise that there is a general EU framework safeguarding the possibility of selling therapeutic products online that includes a European common logo identifying the entities authorised to do so (with a view to mitigating falsification), it is also true that home delivery is subject to different limitations in each country of the EU.

In the case of Portugal, while pharmacies (for medicinal products subject to medical prescriptions and medicinal products not subject to medical prescriptions) and entities authorised to sell over-the-counter medicines (medicinal products that are not prescription only) may sell therapeutic products online, they can only deliver these products either in the municipality where they are based or to adjacent municipalities.

From the consumer's perspective, there is no legal rule prohibiting individual consumers in Portugal from ordering a medicine online (including from another country) and having it delivered to their home. That said, Infarmed has previously issued guidance suggesting that it does not authorise the importation of medicinal products for personal use. As a result, if customs clearance is required for such products, there is a risk that Infarmed may not approve their release.

As to the possibility of carrying medicinal products personally across the border, this is permitted, and travellers may carry the quantity necessary for their stay. For prescription medicines, it is recommended that the person also has a prescription or medical statement attesting to the therapeutic need for the product.

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?

Portuguese law does not regulate this type of activity carried out by foreign suppliers.

The law only foresees that pharmacies and entities authorised to sell over-the-counter medicinal products duly authorised in Portugal may sell non-prescription medicinal products at a distance to consumers residing in another Member State, in accordance with Directive 2011/62/EU. These entities must display the common EU logo, which allows consumers to confirm the legality of the establishment by connecting to the database of the competent authority in Portugal.

Suppliers established outside the EU may not, as a rule, sell therapeutic products directly to Portuguese consumers, as this practice is considered illegal and subject to customs seizure and potential sanctions. Infarmed has even previously issued guidance suggesting that it does not authorise the importation of medicinal products for personal use and if customs clearance is required for such products, there is a risk that Infarmed may not approve their release.

As for medical devices, foreign suppliers wishing to market devices on the Portuguese market must ensure that they bear valid CE marking, designate an authorised representative established in the EU (where applicable) and ensure compliance with Portuguese language labelling requirements, including instructions for use.

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 the product's original quality, safety and traceability?

The Medicinal Products Act authorises the parallel importation of therapeutic products provided that (1) the therapeutic product holds a valid marketing authorisation in the Member State of origin; (2) it is marketed in accordance with the conditions laid down in the Medicinal Products Act and other legislation; (3) the therapeutic product in question has the same quantitative and qualitative composition in terms of active therapeutic products, the same pharmaceutical form and the same therapeutic indications, although different excipients or different quantities of excipients may be used, provided that this has no therapeutic impact; and (4) the authorisation does not pose a risk to public health.

In addition, the therapeutic product subject to parallel importation must comply with a set of specific elements, in addition to the requirements for the re-labelling or re-packaging of products set out in the Medicinal Products Act, namely: (1) the name of the therapeutic product; (2) the intellectual property indication; (3) the name or company name and domicile or headquarters of the parallel importer; and (4) the registration number assigned by Infarmed.

In terms of the requirements to retain the product's original quality, safety and traceability, therapeutic products subject to parallel importation must comply with the same requirements as other therapeutic products.

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?

The manufacture of therapeutic products intended for export is subject to manufacturing authorisation issued by Infarmed.

With regard to measures to mitigate shortages or resolve public health emergencies, Portugal has legal mechanisms in place that allow the competent authorities to intervene in the supply chain. Infarmed has the power to monitor the availability of therapeutic products on the domestic market and may adopt restrictive measures on exports when stock shortages occur or when there is a risk of shortages of therapeutic products that are considered essential.

In addition, marketing authorisation holders and wholesale distributors are subject to prior notification requirements for the export of certain therapeutic products, as well as obligations to maintain stocks adequate to meet the needs of the domestic market. The failure to comply with these obligations may give rise to administrative proceedings and the imposition of administrative penalties.

In the European context, Portugal also applies the mechanisms provided for in Regulation (EU) 2015/479 on the common regime applicable to exports, which allows for the adoption of safeguard measures in exceptional circumstances.

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?

Therapeutic products for export are always subject to manufacturing authorisation. Without prejudice, if the manufacturer does not hold a marketing authorisation, they must provide Infarmed with a statement explaining why they do not have such a marketing authorisation.

Furthermore, therapeutic products intended exclusively for export are not subject to the rules set out in the Medicinal Products Act relating to packaging, labelling and presentation.

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?

With regard to therapeutic products, the labelling and package insert must be written in Portuguese.

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?

Non-reimbursed medicines are usually subject to the free price regime, while reimbursed medicines are subject to maximum prices, which are administratively established. In the latter case, medicinal products may not be placed on the market until the applicable maximum retail price has been approved by Infarmed. The price is made up of: (1) the ex-factory price (maximum price at the stage of production), (2) the wholesaler and retailer selling margins, (3) a specific tax on the sale of medicines and (4) value-added tax (VAT). The price of medicines is periodically reviewed based on the international referencing system. The reference countries are annually established through an ordinance issued by the Minister of Health.

In addition to price regulation, entities in the medicines supply chain are subject to a general obligation to ensure the continuity of supply and patient access.

Reimbursed medical devices are also subjected to maximum prices, while non-reimbursed medical devices benefit from the free price regime.

There are ordinances that set the maximum prices applicable to certain medical devices or to certain groups of medical devices.

Finally, the acquisition of medicines or medical devices by public entities (namely hospitals) is subject to Portuguese public procurement rules and procedures.

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?

Without prejudice to civil, disciplinary or criminal liability, Infarmed holds supervisory, investigative and sanctioning powers under the legal regimes governing the manufacture and distribution of medical devices and medicines for human use. In practice, administrative proceedings may be preceded by requests for information and inspections.

For medicines, infringements may give rise to an administrative offence punishable by a fine ranging between €2,000 and 15 per cent of the offender's turnover or €180,000, whichever is lower.

Failure to comply with the distribution rules applicable to medical devices constitutes a serious economic offence, punishable by a fine of up to €24,000, depending on the size of the infringing entity.

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?

The European Commission's draft proposal to simplify the MDR and IVDR frameworks may have implications on the Portuguese market. Notably, it envisages stricter information requirements for the online distribution of medical devices. In parallel, the EU Commission proposes to simplify the reporting obligations, such as requirements regarding the re-packaging/re-labelling of devices already placed and further distributed in the internal market. More broadly, the 'Pharma Package'

currently under discussion may also affect the regulation of the trade and distribution of therapeutic products by reshaping supply chain obligations.

The proposed EU regulations on critical medicines and biotechnology sectors will also certainly impact the regulations applicable to therapeutic products. Both proposals are currently going through the EU legislative process and are expected to be adopted by the end of 2026 or early 2027.