

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 Cyprus, the regulation of pharmaceuticals, over-the-counter products and medical devices is carried out through specialised bodies operating under the Ministry of Health (MoH), primarily within the Pharmaceutical Services (PhS). In the case of medicinal products for human use (including pharmaceuticals and biologics), the central regulatory body is the Council of Medicines (CoM), which operates under the Pharmaceutical Services and is responsible for the assessment and granting of marketing authorisations, as well as the ongoing supervision of authorised products on the Cyprus market. This remit also extends to non-prescription medicinal products (over-the-counter medicines). Supplements within the medicines framework only where, having regard to their presentation or function, they meet the legal definition of a medicinal product under Law 70(I)/2001 (reflecting Directive 2001/83/EC).</p> <p>The principal domestic legislation underpinning medicines regulation includes the Medicinal Products for Human Use (Quality Control, Supply and Prices) Law of 2001 (Law 70(I)/2001), as amended, together with the Pharmacy and Poisons Law, Cap. 254, which governs pharmacy practice and the retail sale and supply of medicinal products and Law 29/1977 for Narcotic Drugs and Psychotropic Substances, as amended. Market surveillance and enforcement powers relevant to products placed on the market, including medical devices, are supported by the Market Surveillance Law of 2022 (Law 225(I)/2022) and the relevant regulations (such as 598/2003, as amended, for medical devices, 599/2003, as amended, for Active Implantable Medical Devices, 597/2003 for Medical Devices Used for In vitro Diagnosis etc).</p> <p>Cyprus is a non-federal state, and there is no division of regulatory powers between federal and state authorities.</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 premarket review and approval required by a competent authority?</p>
<p>In Cyprus, therapeutic products are mainly classified by reference to the applicable EU framework, with national law determining the practical consequences for supply channels, licensing and supervision.</p>

Medicinal products for human use (including pharmaceuticals and biologics) are distinguished between products that are supplied only on medical prescription and those that may be supplied without prescription (over-the-counter). That classification directly affects distribution and retail: prescription status determines whether a product may be dispensed only pursuant to a valid prescription and through licensed pharmacy channels, and it also informs advertising and promotional restrictions. Cap. 254 is the principal domestic statute governing pharmacy practice and the retail sale and supply of medicinal products, including rules that underpin the prescription-based supply model.

With regard to premarket review/approval for medicines, Cyprus operates a marketing authorisation system: in practice, a medicinal product must hold a valid marketing authorisation before it may be lawfully placed on the Cyprus market. Law 70(I)/2001 provides the national legal basis for this regime, implemented by the PhS (including through the CoM and the relevant evaluation functions).

Medical devices are classified on a risk basis under the EU medical devices regime. The classes are generally Class I, IIa, IIb and III, and for in vitro diagnostic medical devices the classes are A, B, C and D, with higher-risk classes attracting more stringent conformity assessment and oversight. In Cyprus, the national competent authority is the Cyprus Medical Devices Authority, which oversees the applicable framework, supported by horizontal market surveillance and enforcement powers at national level.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

Wholesale distribution of therapeutic products generally requires a wholesale distribution licence/authorisation issued under Law 70(I)/2001. Key conditions typically include suitable premises and storage/transport arrangements, adequate systems for traceability and product handling (including recalls/complaints), and appropriate organisational controls and responsible personnel.

For medical devices, manufacturers and authorised representatives who have their business headquarters in Cyprus shall be registered with CMDA. Those who operate under the EU medical devices framework as ‘economic operators’, are supervised by CMDA, at national level.

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?

Retail supply of medicinal products to consumers is regulated through the pharmacy regime under Cap. 254, which governs the licensing/operation of community pharmacies and the rules on dispensing/supply to the public. Law 70(I)/2001 underpins regulatory oversight of therapeutic products placed on the Cyprus Market.

Cap 254 contains a specific regime for internet (distance) sales. Online sales are only permitted by persons authorised to supply medicines to the public and, in practice, through registered pharmacies, following prior notification to the Pharmaceutical Council (PhC) (and/or the competent authority in the Member State of establishment) with prescribed business and website details. The website must display specified information including the authority contact details and

the EU common logo linked to the official register. The regime only applies to non-prescription medicines, with the PhC empowered to impose additional public-health conditions.

Retailers supplying non-medicinal categories to consumers are generally not subject to the same pharmacy licensing regime, although they remain subject to product-specific rules and market surveillance/enforcement.

Medical devices supplied to consumers are subject to the EU medical devices regime (as applied in Cyprus), overseen by CMDA. No further registration is required in Cyprus for any medical devices already registered by another EU Member-State, as they already bear the CE marking and are accompanied by all appropriate certificates of conformity. However, they must notify CMDA of the products they intend to place on the Cyprus market, by completing the relevant Notification form. It is noted that CMDA accepts Greek as the official language for products intended for use by non-health professionals, while English may be accepted for products intended solely for health professionals.

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

Cap. 254 (including Art 19Z, adopted to align with EU law) sets out a framework for the distance selling of medicinal products to the public via information society services, including the EU common logo identifying authorised online suppliers. In Cyprus, however, according to the position communicated by the Pharmaceutical Services, there are currently no registered online pharmacies and the sale of medicines via the internet is not permitted, reflecting the principle that medicines are only to be supplied through a pharmacist. An exception applies only for medicines falling under the Second Schedule to Cap. 254, pursuant to which any person may sell to the public medicines specifically listed in the Second Schedule, provided that they are sold in their original packaging, or packaging in which they were placed/replaced and sealed by a pharmacist.

There is no specific clause for online sales of medical devices, however Law 225(I)/2022 provides a horizontal market surveillance statute, ensuring that only compliant products are made available on the market.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

Importation of therapeutic products into Cyprus is governed by applicable EU regulatory framework for each product category, with national oversight by MoH (PhS and CoM) as mentioned in Law 70(I)/2001. The main rule is that importation is prohibited unless licensed by the CoM.

The national framework imposes specific batch-testing/quality assurance obligations for medicinal products imported into Cyprus from third countries. In particular, the qualified person (as set out in clause 42 of Law 70(I)/2001) must ensure that, for each batch imported into the Republic, a Member State has carried out a full qualitative analysis, a quantitative analysis at least of all active substances, and all other necessary tests/controls to ensure compliance with the marketing authorisation requirements. Where a batch has already been tested in a Member State in accordance with this requirement, it is not subject to re-testing on import into Cyprus provided it is accompanied by control reports signed by a qualified person. The Council of Medicines may grant exemptions from these testing obligations where relevant EU-third country agreements are

in place ensuring equivalent GMP standards and that the requisite controls have been performed in the exporting country. (as reflected in the relevant implementing provisions of Law 70(I)/2001, including Art 4, as applicable).

Tariffs can be imposed. They are calculated through the tool provided by Customs department, available through their website.

It is noted that for medical devices, Customs authorities tend to apply heightened scrutiny to CE-marking and conformity documentation, consistent with the EU framework governing the placing on the market and market-surveillance controls.

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

As a starting point, Cyprus customs rules recognise that certain pharmaceuticals are subject to prohibition/restriction at the border: Customs explicitly lists ‘narcotic drugs, psychotropic substances and other controlled pharmaceuticals’ as banned for importation. For medicines generally, the domestic retail/pharmacy framework (Cap. 254) underpins the prescription-based supply model and regulated dispensing/supply through pharmacies.

For travellers, a month’s quantity of prescribed medicine is permitted, provided that travellers hold or can demonstrate their prescription.

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?

For medicines, Cyprus has an specific distance-selling framework for supply to the public via information society services under Cap. 254 (online pharmacy regime). It is reiterated that online sales are only permitted by persons authorised to supply medicines to the public (through registered pharmacies), following prior notification to the PhC.

Customs controls may still apply at the border, and ‘controlled pharmaceuticals’ are listed by Customs as prohibited for importation. For medical devices, online selling is generally captured by the EU ‘economic operator’ obligations and supervised nationally through the competent authority and market surveillance powers.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

In Cyprus, parallel importation of medicinal products is permitted but is regulated through a specific parallel import licence process with strict safeguards. As a rule, a business must obtain a parallel import licence from the CoM before importing a product from another EU Member State, and the product must be authorised in the Member State of origin and sufficiently similar to a product already authorised in Cyprus. An exception applies for certain centrally authorised products, where a separate Cyprus parallel import licence is not required but the parallel importer must notify the European Medicines Agency and the CoM.

On intellectual property, the law applies the EU ‘exhaustion of rights’ principle: where the rights-holder (or someone acting with their consent) has first placed the product on the market in

another EU Member State, the rights-holder generally cannot use trademark or patent rights to block parallel imports into Cyprus, subject to limited exceptions.

Where re-labelling or re-packaging is necessary to comply with Cyprus labelling/leaflet rules and the reference product's authorisation, it may be allowed, but it must not damage the product or the trademark's reputation. The new packaging must identify the manufacturer and the repackager, and the trademark owner must be notified in advance (and may object in defined circumstances).

Finally, parallel importers must preserve quality, safety and traceability by keeping records (including origin, quantities and batch numbers) and ensuring key particulars (including the parallel import licence number and importer details) appear on the outer packaging.

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public-health emergencies), and how are such measures administered and enforced?

Cypriot medicines law does not set out a general system of export quotas for medicinal products. However, it does impose export-relevant controls on manufacture and quality compliance. In particular, it is required that the manufacture of medicinal products in Cyprus is subject to licensing, including where the products are intended only for export (ie, export does not remove the need for a manufacturing authorisation).

As at the date of this report, there is no specific, ongoing UK-related derogation applicable to exports under Law 70(I)/2001.

Finally, the manufacture, import and distribution in Cyprus of active substances, including those intended for export, must comply with GMP and GDP principles for active substances, by reference to the principles and guidelines under Directive 2001/83/EC, as reflected in the national law.

Regarding medical devices, CMDA may issue, on request, a free sales certificate confirming that the manufacturer/authorised representative is established in Cyprus and that the CE-marked device may be placed on the EU market under the applicable EU medical devices framework.

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?

Cypriot medicines legislation does not provide for a specific 'export-only' or 'dual-labelling' marketing authorisation regime permitting the manufacture of medicinal products solely for export without domestic approval. As a general rule, the regulatory framework presupposes that medicinal products manufactured, imported or distributed by authorised operators comply with the applicable quality, safety and regulatory standards set under Law 70(I)/2001 and related provisions.

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 circulation in Cyprus, medicines must comply with the labelling and package leaflet rules set out in Law 70(I)/2001, which include mandatory particulars on the outer/immediate packaging and the content requirements for the leaflet (Chapter VI of Law 70(I)/2001: Articles 35–38).

Under Law 70(I)/2001, Article 35, the outer (or, where none, immediate) packaging must include specified particulars (including name, strength/form, INN, batch number, expiry date, MA number, MAH details, and other warnings), and must also include the product name in Braille, as specified in Article 35A. Article 35(7) requires the mandatory labelling particulars to be in Greek and/or English, subject to limited derogations, including for certain orphan medicines and in specific low-volume import scenarios. Patient information leaflets are generally mandatory and must contain the prescribed content set out below and must be drafted in clear terms in Greek and/or English:

1. identification of the medicine (name, strength, pharmaceutical form, and – in certain cases – the common name, plus a plain-language description of its therapeutic class/type of activity);
2. therapeutic indications;
3. key information needed before use (contraindications, precautions, interactions, and special warnings);
4. instructions for correct use (dose, method/route, frequency/timing, duration where limited, what to do in overdose or missed doses, and when to seek advice);
5. possible side effects and what to do; and
6. practical information such as expiry-date warning, storage precautions, signs of deterioration where relevant, full qualitative composition and quantitative active substances, contents/pack size, and the name/address of the marketing authorisation holder and manufacturer, together with the date of last revision.

Anti-counterfeiting/traceability is addressed through the ‘safety features’ requirement. For relevant products the law requires features enabling verification of authenticity and identification of individual packs, and sets out when such safety features apply (generally for prescription medicines, with risk-based exceptions/extension powers). It is also noted that CoM reviews/approves labelling and leaflet mock-ups as part of the marketing authorisation process.

In addition, the parallel import regime imposes explicit traceability and identification obligations: parallel importers must keep records of origin, quantities and batch numbers and ensure that key particulars (including the importer details and the parallel import licence number) appear at least on the outer packaging.

Law 225(I)/2022 is a horizontal market surveillance/enforcement statute and does not itself create medical device-specific CE-labelling rules. Such requirements arise under the EU medical devices framework and are enforced nationally through market surveillance powers.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

Cyprus operates a formal medicines price-control regime administered through the MoH and Pharmaceutical Price Control Committee, with the statutory pricing framework sitting under Law 70(I)/2001. In practice, this regime can materially affect market entry and distribution strategy, as pricing applications are expected to be supported by defined documentation (including, for

imported products, evidence of the product's prices in the country of export/origin and the CIF price for Cyprus). The Committee publishes the medicinal product price list, pricing tools (including a checklist for non-prescription medicines), related schemes/lists (including co-payment related lists).

In addition, reimbursement under the General Healthcare System (GESY) significantly influences availability and distribution channels, given the role of the Health Insurance Organisation (HIO) as the single payer and the use of product lists and reimbursement processes which, in turn, affect which products are commonly supplied through contracted providers and pharmacies.

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?

Cyprus regulators have broad inspection, enforcement and sanctioning tools for non-compliance affecting the distribution of therapeutic products. Under Law 70(I)/2001, the Minister may appoint Authorised Inspectors, who may, at reasonable times, enter non-residential premises where medicines are manufactured, stored, offered for sale or sold, inspect facilities and/or records (including wholesale-distribution compliance), take samples and seize products reasonably suspected to be connected with breaches or offences and needed as evidence, with laboratory testing and a right to object/re-test; obstruction is a criminal offence. The regulators may investigate complaints or act ex officio and, on finding breaches of specified statutory and EU-derived obligations (including, inter alia, safety-features and clinical trials frameworks). They may order/recommend cessation and non-recurrence, formally record infringements, impose administrative fines up to €25,000 and daily penalties up to €200 for continuing breaches, with reasoned decisions and a representations procedure, and recover unpaid sums as a civil debt. Criminal liability also applies to placing unauthorised medicinal products on the market, unlawful wholesale supply, and the manufacture, distribution, agency, import or export of falsified medicinal products; this specifically includes the distance selling of falsified medicinal products to the public. Such offences are punishable by up to five years' imprisonment and/or up to €50,000 in fines, and the court may also order seizure. Where the offence is committed by a legal person, directors and other relevant officers may also incur liability.

In parallel, Cap. 254 supports retail/pharmacy supply-chain enforcement through authorised inspection, licence or book inspection and sampling, criminalises obstruction and provides general penalties (including possible seizure) for breaches of the law, regulations, licence conditions. Where relevant (eg, products within its market-surveillance scope), Law 225(I)/2022 provides an administrative enforcement track for non-compliant products and non-cooperation/obstruction, with administrative fines up to €30,000 (and €60,000 for subsequent offences) plus daily penalties up to €500, hearing rights, hierarchical appeal to the Minister and recourse to the Administrative Court, and recovery as a civil debt, alongside criminal offences for serious-risk products, breach of enforcement notices and provision of false/misleading information.

Finally, for controlled drugs/precursors, Law 29/1977 equips police or authorised persons with inspection of producers/suppliers, compulsory production of records and stock inspection, search and seizure powers (including warrants and seizure of evidential items), plus confiscation and/or destruction orders and offences for non-compliance or false information, thereby enabling robust disruption of unlawful distribution channels.

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

A recent and potentially relevant legislative development is the draft bill The National Centre for Clinical Evidence and Quality of Health Services Law 2025 proposed by MoH, which is pending before the Parliament’s Health Committee,. The bill would institutionalise a National Centre tasked with developing/adapting international clinical and pharmaceutical protocols and guidelines for Cyprus, training health professionals, patients, stakeholders, and monitoring, supervising and evaluating implementation of such protocols across all levels of care. While not a trade measure as such, it could materially influence therapeutic product availability and distribution in practice by shaping prescribing, dispensing protocols, formulary-type guidance, and system-wide compliance monitoring, with downstream effects on demand patterns and market access for imported and locally supplied products.