TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

Authors: Nora Vafeiadou, Ioannis Arvanitis and Chrysoula Moldovanidi

Firm: CFGA Law Firm

nora.vafeiadou@lawofmf.gr, chrysoula.moldovanidi@lawofmf.gr, ioannis.arvanitis@lawofmf.gr

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?

As a member state of the EU, Greece is subject to the EU regulatory framework governing the import, export, wholesale distribution and retail sale of therapeutic products. In the field of medicinal products for human use, the principal instruments include the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use as amended and applicable today. This has been transposed into Greek Law by Joint Ministerial Decision No D.YG3a/G.P. 32221/ *Government Gazette* B 1049/2013, Regulation (EC) No 726/2004 establishing the centralised EU authorisation procedure and the European Medicines Agency, Commission Delegated Regulation (EU) 2016/161 on safety features and serialisation, as well as the Guidelines of 5 November 2013 on Good Distribution Practice (GDP) of medicinal products for human use (2013/C 343/01). Medical devices are primarily regulated by Regulation (EU) 2017/745 (MDR), which applies directly in Greece.

At a national level, the core legislative framework is set out in Law 1316/1983, pursuant to which the National Organisation for Medicines (*in Greek, EOF*) was established. EOF is a legal entity under public law, supervised by the Ministry of Health and constitutes the primary competent authority responsible for the authorisation, supervision, and control of medicines and medical devices, including wholesale distribution, market surveillance and the cross-border movement of such products. The national framework is further complemented by Ministerial Decisions implementing EU legislation, such as the above mentioned Joint Ministerial Decision No D.YG3a/G.P. 32221/ *Government Gazette* B 1049/2013, governing, key aspects of the regulatory framework for medicinal products, including marketing authorisation, manufacturing, wholesale distribution and pharmacovigilance and the Ministerial Decision No D3(a)oik.82331/ *Government Gazette* B 4274/2019 governing the pricing of pharmaceutical products, as amended and currently in force.

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?

Therapeutic products in Greece are classified for the regulatory purposes in accordance with EU and national legislation, with distinct legal consequences for their authorisation, distribution and

sale. Medicinal products for human use are classified primarily into prescription-only and non-prescription over-the-counter medicines (OTC medicines), pursuant to Joint Ministerial Decision No D.YG3a/G.P. 32221/ *Government Gazette* B 1049/2013. Prescription-only medicines are further subdivided into those dispensed on a standard prescription (renewable or non-renewable), those requiring a special prescription and those subject to restricted prescription, including medicines intended for use exclusively in hospital settings or under specialised medical supervision.

The National Organisation for Medicines (*in Greek, EOF*) is again the competent authority for the classification of medicinal products, as part of the marketing authorisation process, which directly determines the permitted distribution channels and advertising regime. Prescription-**o**nly medicines may be supplied exclusively through licensed pharmacies and only on a valid prescription, and are subject to strict advertising restrictions prohibiting promotion to the public. Over-the-counter medicines have a more favourable safety profile and broader consumer access but remain subject to controlled advertising rules and require a marketing authorisation. Accordingly, hospital-use only or restricted prescription medicines may be supplied solely to hospitals or authorised healthcare institutions.

In all cases, medicinal products, including biologics, are subject to a mandatory premarket review, and an approval by the authorities such as EOF is required regardless of its classification either as a prescription-only or an over-the-counter medicine. In the absence of a valid marketing authorisation, the import, distribution, or sale of medicinal products in Greece is prohibited.

Accordingly, medical devices and in vitro diagnosis medical devices are regulated under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), respectively, and are classified based on their level of risk. Medical devices fall into four risk classes: Classes I-low risk, IIa-medium risk, IIb-higher risk, III-high risk. In vitro diagnostic devices are classified into Classes: A-low individual risk, low public health risk, B-moderate risk, C-high risk, D-highest risk. This risk-based classification determines the applicable conformity assessment procedure, including the involvement of a Notified Body for higher-risk devices, as well as the scope of technical documentation, clinical evidence, and post-market surveillance requirements.

Unlike medicinal products, medical devices are not subject to a marketing authorisation granted by a national authority. However, compliance with the MDR/IVDR and lawful CE marking are mandatory prerequisites for their placement on the Greek market, alongside registration and market surveillance by the competent authority (EOF).

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?

In Greece, businesses engaging in the wholesale distribution of therapeutic products must obtain a wholesale distribution licence issued by EOF, in accordance with Joint Ministerial Decision No D.YG3a/G.P. 32221/ *Government Gazette* B 1049/2013. As part of the licensing process, applicants must demonstrate their lawful establishment and operation, legal rights to the storage premises, and the appointment of a suitably qualified responsible person, as required under Greek pharmaceutical law. Applicants are also required to submit detailed information on personnel, organisational structure and quality systems.

A key condition for both the granting and maintenance of the wholesale distribution licence is full compliance with the EU Guidelines on Good Distribution Practice (GDP). Wholesalers must

operate appropriate storage facilities, meeting defined technical standards, including temperature control, security and traceability measures, and must maintain documented procedures ensuring the integrity of medicinal products throughout the supply chain. Adequate insurance coverage for professional liability is also required, while any material changes to the licensed activity must be promptly notified to EOF. Licensed wholesalers are recorded in the relevant national registers maintained by EOF and are subject to ongoing inspections and supervision.

With respect to medical devices and in vitro diagnostic medical devices, distributors are not required to obtain a marketing authorisation, but must comply with the obligations applicable to distributors under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR). Prior to placing devices on the market, distributors must verify, inter alia, that the devices bear the CE marking, that an EU declaration of conformity has been drawn up and that the manufacturer and the device are duly registered in the applicable nation and EU databases, including those maintained by EOF and, where applicable, EUDAMED. Distributors of medical devices are likewise subject to registration, record-keeping and market surveillance obligations, and must cooperate with the competent authorities in the exercise of their supervisory powers.

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?

Distinct licensing and notification requirements apply in Greece to businesses that provide therapeutic products directly to consumers, depending on the type of product and the distribution channel. Different rules apply to businesses that provide therapeutic products directly to consumers such as community pharmacies or internet pharmacies. The retail sale of medicinal products is, as a general rule, restricted to licensed community pharmacies. The establishment and operation of pharmacies requires a licence issued by the competent regional authorities.

While ownership of a pharmacy is no longer limited to pharmacists, the operation of the pharmacy and the scientific responsibility for dispensing medicines must be entrusted to a licensed pharmacist, who must meet the applicable professional requirements. The operating licence requires that the premises meet suitability standards, verified through inspection, and the submission of planning, fire safety, and other technical documentation. Pharmacies are required to comply with Good Pharmacy Practice (GPP) as defined by the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP), and the pharmacist is fully responsible for dispensing medicines, maintaining appropriate storage standards, executing prescriptions, and ensuring compliance with the applicable regulatory framework.

Online sale of therapeutic products is allowed only for licensed pharmacists and only with respect to non-prescription (over-the-counter) medicines in accordance with Article 85c of Directive 2001/83/EC, as transposed into Greek law. Pharmacies engaging in distance sales are subject to specific notification and registration requirements, according to Ministerial Decision G5(b)/G.P. oik 20293 *Government Gazette* B 787/2016.

These requirements include prior notification to and certification granted by the Panhellenic Pharmaceutical Association, as well as compliance with EU rules on distance selling, including the use of the common EU logo identifying legally operating online pharmacies. The online sale of prescription-only medicines to consumers is strictly prohibited.

This section focuses on medicinal products. Other categories of therapeutic products, such as medical devices, are subject to a distinct regulatory framework and are addressed separately in the response to Question 5, below.

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

Pursuant to the Joint Ministerial Decision D.YG. 32221/ *Government Gazette* B' 1049/2013, the online sale of Prescription-Only Medicines is strictly prohibited. Only non-prescription (over-the-counter) medicinal products may be sold online by duly licensed pharmacies, under the conditions set out in national law and EU legislation.

In addition to medicinal products, certain medical devices may also be made available through online channels, including social media and marketplace platforms, provided that they comply with the applicable EU regulatory framework, in particular Regulation (EU) 2017/745, and relevant national provisions. The reference to medical devices in this section reflects their distinct legal treatment and complements, rather than contradicts, the medicinal product-focused analysis in the response to Question 4.

Law 4316/2014 and Ministerial Decision G5(b)/G.P. oik. 20293 *Government Gazette* B' 787/2016 designate the Panhellenic Pharmaceutical Association as the competent Greek authority for the certification and supervision of the lawful operation of online pharmacies. Pharmacies interested in obtaining such certification should file an application with the Panhellenic Pharmaceutical Association.

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)?

Import of therapeutical products from a third country outside the EU, requires a product/ distribution licence again granted by the EOF according to Article 57 paragraph 3 of the Joint Ministerial Decision D.YG3a/G.P. 32221/ *Government Gazette* B' 1049/2013. The licence applicant is required to determine the medicines that will be imported, as well as their place of production and inspection, to have appropriate premises or equipment for the products' control and storage and to have at least one Responsible Person whose qualification for this position is assessed by EOF. The Responsible Person ensures that the medicines coming from Non-EU countries are subject to appropriate controls and testing and comply with applicable quality and safety standards.

Pharmaceutical products are classified in one of the tariff classes of Chapter 30 of the EU Common Customs Tariff and specifically, in tariff classes 3001, 3002, 3003, 3004, 3005 and 3006. The vast majority of these products are free of conventional rate of duty. Whereas the standard VAT rate in Greece is 24 per cent, a super-reduced rate of six per cent is applicable to medicines of CN3003 and 3004 as well as to vaccines of CN3002 intended for human medicine, in accordance with Greek VAT legislation.

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?

Consumers in Greece may only import therapeutic products for personal use either by carrying them across the border when travelling or by receiving them by mail. The quantity should be reasonable and proportionate to the duration of the consumer's stay. The authorities may request additional documentation in case of large non-corresponding quantity. In such cases, it is

particularly important for consumers to be able to present a valid doctor's prescription when importing prescription-only medicines.

Import of medicines is only permitted when intended for personal use, in which case the provision of appropriate supporting documentation (ie, prescriptions) is required. As a general rule, medicines destined exclusively for personal use are exempt from customs duties and taxes, subject to verification by the customs authorities. However, in case of failure to prove so, customs may detain or refuse the shipment.

When a medicine has not been authorised for sale in Greece or the EU, it is mandatory that EOF approves the import through a pharmacy or a doctor requesting the import for a specific case.

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?

Joint Ministerial Decision D.YG. 32221/ *Government Gazette* B' 1049/2013 explicitly forbids distance selling of prescription-only medicines directly to consumers. Distance selling (eg, online sales) of over-the-counter medicines is only permitted through lawfully operating pharmacies. According to Joint Ministerial Decisions YA G5(a)51194 *Government Gazette* B 2219/2016 and YA G5 (b)/G.P. 20293 *Government Gazette* 787/2016 exclusively the pharmacies which lawfully function in Greece will enjoy the right to maintain an electronic pharmacy platform which will sell OTC medicines (excluding, as mentioned, prescription-only medicines). As a result, foreign suppliers may not ship medicinal products (whether prescription-only or over-the-counter) directly to consumers in Greece via e-commerce or mail order, unless they operate through a licensed pharmacy established in Greece.

The above restrictions do not apply to therapeutic products which do not fall within the legal definition of medicinal products. This category includes, indicatively, medical devices, food supplements, and cosmetics, each of which is governed by a distinct regulatory framework under EU and national law.

Medical devices may be supplied directly to consumers, including via cross-border e-commerce or mail order, provided that they comply with the applicable EU regulatory framework, notably Regulation (EU) 2017/745, including requirements relating to conformity assessment, CE marking, labelling, and post-market surveillance.

Food supplements and cosmetics are also subject to specific EU regimes, including Directive 2002/46/EC and Regulation (EC) No 1223/2009, which impose obligations on safety, labelling, and consumer information. In the context of e-commerce, such products must also comply with general EU rules on consumer protection and product safety.

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 general, parallel importation of therapeutic products is acceptable within the EU pursuant to the principle of free movement of goods. The parallel importer may repackage a proprietary medicinal product and relabel it or replace the original label with the label used in the market of destination, provided that the repackaging does not adversely affect the original condition of the product or damage the reputation of the brand and its owner.

In Greece, parallel importation of medicines is subject to prior approval and regulatory monitoring by the EOF. Parallel importers must demonstrate that the medicine is essentially

similar to a product authorised in Greece and that all applicable requirements relating to quality, safety, pharmacovigilance and traceability are met. Parallel importation does not result in the granting of a new marketing authorisation, but is only permitted in respect of medicines which are already authorised on the Greek market. In this context, it is sufficient that a reference medicinal product holding a valid marketing authorisation in Greece exists, with which the imported product is essentially similar.

Re-labelling and re-packaging must comply with national requirements, including Greek-language labelling, identification of the parallel importer and applicable safety features, while preserving product quality and GDP (Good Distribution Practice) compliance.

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?

In Greece measures to address shortages of medicinal products and ensure the adequate supply of the domestic market are primarily adopted and enforced by the National Organisation for Medicines (EOF), which, in this context, imposes and supervises compliance with the obligation of wholesale distribution licence holders to ensure the appropriate and constant supply of therapeutic products and medicines to the Greek market, including through the monitoring of stock levels and the imposition of temporary export restrictions on specific products.

Covering the needs of Greek patients and the domestic market is the ultimate priority, and only where this criterion is met may the wholesale distributors proceed with the export of medicines in case of procuring them directly from pharmaceutical businesses, according to legislative decree 96/1973, as amended by L. 3580/2007 with the addition of Article 12A.

The National Organisation for Medicines (*in Greek, EOF*) is the competent authority keeping record of these exports and monitoring the adequacy of the product in the market. EOF continuously assesses availability and may adopt restrictive measures where shortages or risks of shortage are identified. In particular, EOF has the authority to impose temporary export restrictions on specific medicinal products, which are published in the form of binding catalogues and are frequently used in practice, including in recent years (eg, 2024 and 2025).

Within the EU, wholesale distribution licence owners may export to any person holding a legitimate distribution licence according to the applicable law. Medicines exported to non-EU countries must be formerly approved by EOF and may be exported exclusively from their producers.

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?

According to Article 57 of the Joint Ministerial Decision D.YG. 32221/ *Government Gazette* B' 1049/2013, a production licence granted by EOF is required for manufacturing medicines who are exclusively destined for export, which effectively constitutes a form of export-only authorisation. Such products are not approved for domestic marketing in Greece and may be manufactured solely for export to third countries or other jurisdictions.

The acquisition of such licence/authorisation requires that the applicant: (1) determines the medicines and pharmaceuticals forms to be manufactured, as well as their place of manufacturing; and (2) meets the applicable requirements relating to facilities, equipment and production processes. The manufacturer must appoint a suitably qualified and responsible person and comply with Good Manufacturing Practice (GMP) standards as set by the World Health Organization, which are subject to inspection and supervision by EOF and the European Medicines Agency (EMA).

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?

In accordance with the Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by setting out detailed rules for the safety features appearing on the packaging of medicinal products for human use and the Joint Ministerial Decision No D.YG3a/G.P. 32221/ *Government Gazette* B 1049/2013, packaging, labelling and product information criteria should be met so that therapeutic products circulate domestically. Required details include the product name, active substances and their quantities, pharmaceutical form, contents, method and route of administration, key warnings (including keeping out of reach of children), expiry date, storage conditions, disposal instructions where relevant, batch number, marketing authorisation holder and authorisation number, and instructions for use for self-medication products. The above information should be in the Greek language. Moreover, the packaging of every medicinal product should bear a unique identifier consisting of the following:

1. a code allowing the identification of at least the name, the common name, the pharmaceutical form, the strength, the pack size and the pack type of the medicinal product bearing the unique identifier ('product code');
2. a numeric or alphanumeric sequence of maximum 20 characters, generated by a deterministic or a non-deterministic randomisation algorithm ('serial number');
3. a national reimbursement number or other national number identifying the medicinal product, if required by the Member State where the product is intended to be placed on the market;
4. the batch number; and
5. the expiry date.

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?

The Ministry of Health issues pharmaceutical price lists to determine the prices of medicines, based on external reference pricing, taking into account the lowest prices in selected EU Member States. Pricing of pharmaceutical products requires an application to the National Organisation for Medicines (*in Greek, EOF*) pursuant to Ministerial Decision No D3(a)oik.82331/ *Government Gazette* B 4274/2019 regarding the pricing of pharmaceutical products, as amended and currently in force.

The National Organisation for the Provision of Health Services (EOPYY) is responsible for negotiating, contracting, and remunerating public/state and private-contracted healthcare providers, covering the healthcare costs for over 95 per cent of the domestic population. An official Positive Reimbursement List is issued, which includes the therapeutical products that are reimbursed, and the insured person pays a patient contribution. Furthermore, high-cost medicines are fully covered by EOPYY and they are distributed directly through EOPYY-operated pharmacies or designated hospitals.

EOF regularly requires pharmaceutical warehouses to declare their stock levels of medicine in order to regulate shortage issues.

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?

The National Organisation for Medicines (in Greek, *EOF*) in cooperation with the EMA are obligated to ensure that legal requirements governing medicinal products are met. For example, they may inspect the manufacturing or commercial establishments or laboratories, take samples, examine documents, archives etc. relating to the object of the inspection.

Except for civil and criminal liability, any violation of the laws governing the import, wholesale distribution, retail sale, and export of therapeutic products may result in the imposition of administrative sanctions, including administrative fines of up to €100,000, depending on the nature and severity of the infringement.

EOF may also adopt remedial measures, such as the suspension or revocation of licences, the prohibition of placing products on the market and the withdrawal or recall of medicinal products, where this is necessary to protect public health.

In practice, these powers are actively exercised, particularly in the context of inspections relating to Good Distribution Practice, market surveillance, shortages of medicinal products and unlawful export activity, with EOF combining preventive, corrective and punitive measures to ensure compliance and safeguard patient safety.

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?

At EU level, the pharma package is the first major revision of EU pharmaceutical laws since 2004. Its aim is to better meet patient needs by boosting innovation and competitiveness through incentives for new antimicrobials, rare disease medicines and treatments for children, addressing security of supply and shortages to ensure the timely availability of safe and affordable medicines across the EU. On 11 December 2025 the Council and the European Parliament reached an agreement on the final shape of the new rules. The package sets out reforms to encourage innovation, improve patient access to treatments, prevent shortages and reduce environmental impact, while keeping the EU pharma industry competitive.

On a national level, Joint Ministerial Decision D3(a) 6030/ *Government Gazette* B 407/2025 constitutes the most recent attempt at Greek legislation to align with EU legislation and more specifically with Directive 2001/83/ EC. Such measures form part of a broader trend towards strengthening regulatory monitoring and harmonisation.

From an enforcement perspective, recent trends in Greece include increased regulatory focus on supply obligations, stock monitoring, Good Distribution Practice compliance and the prevention of shortages, as well as the active use of export restrictions where necessary. These developments indicate a continued emphasis on safeguarding public health and ensuring the uninterrupted availability of therapeutic products on the domestic market.