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Greece

Law and Practice
Angela Livgieri and Danai Panopoulou

Trends and Developments
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ALG Manousakis Law Firm

GREECE

Law and Practice

Contributed by:
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ALG Manousakis Law Firm

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ALG Manousakis Law Firm is a law firm established in 2011 by Ioannis and Alexandros Manousakis. Based in Athens, ALG is an international law firm with lawyers qualified in 6 EU jurisdictions and Switzerland. ALG's team consists of 50 lawyers and 25 paralegals. With deep expertise in corporate and commercial law, the firm offers tailored solutions across various industries. Their client base includes 30 pharmaceutical/biotech and five medical device companies, supported by the firm's lawyers in contracting negotiation, ensuring compliance, and developing robust data privacy frameworks. The firm has a proven commercial and administrative litigation track record, with a high rate of success, especially in commercial claims and tax and administrative litigation.

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation

Pharmaceuticals

European legislation

- Directive 2001/83/EC ("Directive") on the Community code relating to pharmaceutical products for human use, as amended and in force.

National legislation

- Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973) on the trading of pharmaceutical and cosmetic products, as amended and in force.
- Law 1316/1983 (Government Gazette A' 3/11/11.1.83) on the establishment, organisation and competence of the National Organisation for Medicines (EOF, as per its Greek acronym), as amended and in force.
- Joint Ministerial Decision DYG 3a/32221/2013 ("JM Decision") (Government Gazette B' 1049/29.04.2013) on the implementation of Directive 2001/83/EC of the European Parliament and the European Council on the Community Code relating to pharmaceutical products for human use, as amended and in force.
- Joint Ministerial Decision D3 (α) 52922/2025 (Government Gazette 230/B/22-1-2026) on the simplification and rationalization of procedures for contract execution and financial management of clinical trials with medicinal products, non-interventional studies with medicinal products, clinical research with medical devices, clinical performance studies with in vitro diagnostic products, and research projects without medicinal products, medical devices, or in vitro diagnostic products.

Medical Devices

European legislation

- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices ("MDR").
- Regulation (EU) 2017/746 of the European Parliament and Council of 5 April 2017 on in vitro diagnostic medical devices ("IVDR").

National legislation

- Joint Ministerial Decision DY8d/130648/2009 on "Medical Devices" (Government Gazette B' 2198/02.10.2009), for the harmonisation of national legislation with the provisions of Directive 93/42/EEC "on Medical Devices", as amended by Directives 98/79/EC, 2000/70/EC, 2001/104/EC, 2007/47/EC and Regulation (EC) 1882/2003.
- Joint Ministerial Decision DY8d/130644/2009 on "Active Implantable Medical Devices" (Government Gazette B' 2197/2.10.2009), for the harmonisation of national legislation with the provisions of Directive 90/385/EEC "on the approximation of the laws of the Member States relating to Active Implantable Medical Devices", as amended by Directives 93/42/EEC, 93/68/EC, 2007/47/EC and Regulation (EC) 1882/2003.
- Joint Ministerial Decision DY8d/3607/892/2001 on "In Vitro Diagnostic Medical Devices" (Government Gazette B' 1060/10.8.2001), for the harmonisation of national legislation with the provisions of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 "on In Vitro Diagnostic Medical Devices".
- Joint Ministerial Decision D3 (α) 52922/2025 (Government Gazette 230/B/22-1-2026) on the simplification and rationalization of procedures for contract execution and financial management of clinical trials with medicinal products, non-interventional studies with medicinal products, clinical research with medical devices, clinical performance studies with in vitro diagnostic products, and research projects without medicinal products, medical devices, or in vitro diagnostic products.

Regulatory Bodies

The competent national authority with regulatory oversight over pharmaceutical products and medical devices is EOF, established by Law 1316/1983 (Government Gazette A' 3/11/11.1.83) as an entity of public law.

Within the framework of its mission, EOF is responsible for:

- receiving and approving applications for marketing authorisations;
- receiving and approving applications for clinical trials and monitoring clinical trials;

- approving and monitoring manufacturing facilities in order to ensure compliance with Good Manufacturing Practices (GMP);
- monitoring the quality, safety and efficacy of products within its competency;
- receiving applications for the pricing of pharmaceutical products and proposing pricing to the Ministry of Health; and
- approving and monitoring wholesale facilities.

EOF, in the scope of its mission, is autonomous, and the Ministry of Health can only revoke its decisions based on a legally justifiable basis.

1.2 Challenging Decisions of Regulatory Bodies

Pharmaceuticals

When a marketing authorisation for a pharmaceutical product is rejected, the applicant can appeal to the Committee for Medicinal Products for Human Use (under Article 49 of the JM Decision). The Committee will issue a decision on the appeal within 60 days of the submission. If the applicant's appeal is denied, they can further contest this decision by appealing to the Administrative Court of First Instance.

Additionally, objections to the price bulletin issued by the Ministry of Health can be raised through a petition for annulment submitted to the Conseil d'État (Council of State (ΣτΕ)).

Objections against the decision of the Ministry of Health for non-inclusion in the Reimbursement List may be raised by a petition of annulment before the Three-Member Administrative Court of Appeal.

Medical Devices

In Greece, the EOF oversees the marketing of medical devices. This includes ensuring that these devices comply with the legal requirements outlined in the Joint Ministerial Decision DY8d/130648/2009, as amended by Ministerial Decision YA A4g/88159/2017. This framework appoints the EOF as the authority overseeing medical devices in Greece and outlines the applicability of the MDR and IVDR within the country. The relevant legal provisions also include Article 2, Paragraph 2; Article 3, Paragraph 1; and Article 6, Paragraph 2 of Law 1316/1983 (Government Gazette A' 3/11/11.1.83), along with the applicable provisions of the MDR and IVDR.

If the EOF decides to withdraw a medical device from the market, the manufacturer has the right to appeal this decision at the Administrative Court of First Instance for annulment.

1.3 Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals

Prescription-only medicines require a doctor's prescription for purchase, are dispensed by pharmacies, and are subject to stricter regulations regarding their distribution and marketing. Following their approval, over-the-counter (OTC) products can be sold without a prescription but remain subject to specific pricing and distribution requirements.

Medical Devices

The MDR and the Joint Ministerial Decision DY8d/130648/2009 (Article 9 and Annex IX) classify medical devices as follows:

- Class I requires only self-certification by the manufacturer;
- Class IIa involves a notified body for conformity assessment;
- Class IIb requires the involvement of a notified body and a more rigorous assessment (eg, clinical evaluation and performance data are required); and
- Class III requires a full assessment by the notified body (including a design dossier review, robust clinical data requirements and clinical trials).

2. Clinical Trials

2.1 Regulation of Clinical Trials

Pharmaceuticals

The legal framework applicable to clinical trials in Greece is laid down in the Regulation (EU) No 536/2014 ("CTR") on clinical trials on pharmaceuticals for human use.

The provisions of the CTR were transposed into Greek law by the Joint Ministerial Decision G5a/59676/2016.

In order to conduct a clinical trial in Greece, prior approval from EOF is required following an application submitted via the Clinical Trials Information System ("CTIS"), referred to in Article 80 of CTR (art. 3.1 of Ministerial Decision No G5α/59676/2016).

The application, the clinical trial protocol, the information material addressed to patients, the informed consent form, the labelling, the patient cards, and the insurance contract must be submitted in Greek. The rest of the file documentation may be submitted in English.

For clarity, non-interventional studies fall outside the scope of CTR and are governed in Greece by Joint Ministerial Decision D3 (α) 52922/2025, which sets out the procedural requirements for approval, contract execution and conduct of such studies.

Medical Devices

The legal framework applicable to clinical investigations (or performance studies, in the case of in vitro diagnostic medical devices) is set out in Section VI of the MDR and, as the case may be, in Section VI of the IVDR. In Greece, the MDR and the IVDR are directly applicable in conjunction with the Joint Ministerial Decision DY8d/130648/2009 (Article 15 of the said Decision specified the clinical-related rules).

Joint Ministerial Decision D3 (α) 52922/2025 sets out the rules for the clinical trial procedure for medical devices in line with articles 62-82 of MDR and 58-77 of IVDR, while it provides for a mandatory agreement template to be used as part of the clinical trial application (see more details on the procedure in 7. Import and Export of Pharmaceuticals and Medical Devices).

2.2 Securing Authorisation to Undertake a Clinical Trial

Pharmaceuticals

Clinical trials are subject to scientific and ethical evaluation and are approved in accordance with Article 8 of the CTR. The EOF conducts a scientific evaluation of the clinical trial. If the EOF has been granted the status of "reporting" member state, it notifies the sponsor and the other concerned member states via the CTIS within six days of submitting the application file (Article 5 of the CTR).

Ethical evaluation is carried out by the National Ethics Committee, which drafts an assessment report in accordance with the procedure set out in Article 7 of the CTR.

A positive scientific (by EOF) and ethical (by National Ethics Committee) assessment of the clinical trial is required for its approval (Article 3.1b of Ministerial Decision No G5α/59676/2016).

Medical Devices

According to articles 62 of the MDR and 58 of the IVDR, both clinical investigations and performance studies are subject to an authorisation by the Member State in which the clinical investigation or the performance study is to be conducted, following a scientific and ethical review, the latter being performed by an ethics committee, according to the national law. As per above, competent authorities are the EOF and the National Ethics Committee.

The Joint Ministerial Decision D3 (α) 52922/2025 (Articles 11et seq.) establishes the national legal and procedural framework for the conduct of clinical investigations with medical devices in Greece, in alignment with MDR and IVDR. For investigations outside the device's intended purpose, the principal investigator must obtain both National Ethics Committee approval and EOF authorisation; for investigations within the intended purpose, a simplified pathway requires National Ethics Committee approval and submission to the institution's Scientific Committee, which must respond within thirty working days or approval is legally presumed.

2.3 Public Availability of the Conduct of a Clinical Trial

Greece has no national database for clinical trials of medicines or medical devices. Clinical trials are registered and managed exclusively through the central European CTIS. The CTIS serves as both the single EU submission portal and a publicly accessible database of clinical trials conducted in the EU. CTIS.

Information on authorised clinical trials is published in CTIS in accordance with the transparency rules and deferral mechanisms laid down in CTR, subject to the

protection of personal data and commercially confidential information.

2.4 Use of Online Tools to Support Clinical Trials

In Greece, there are no explicit restrictions on the use of online tools in clinical trials. However, the use of these tools must comply with both national and European legislation. This includes the CTR, Ministerial Decision No G5α/59676/2016 on Clinical Trials and EU Regulation 2016/679 (General Data Protection Regulation – GDPR), as well as its implementation in Greek Law 4624/2019. Additionally, guidance from EOF must be followed to ensure the protection of clinical trial participants' data privacy rights.

More specifically, Ministerial Decision No G5α/59676/2016 (Articles 8, 13 and 24) describes the processes throughout the clinical trial course in Greece and the obligations assigned to sponsors and clinical research organisations (CROs) regarding protecting the participant's data, including using appropriate security measures.

In addition, a data protection impact assessment must be conducted; appropriate privacy-related information must be provided to the individuals concerned; and data processing agreements (DPAs) must be in place between sponsors, investigators and tool providers. The Hellenic Data Protection Authority (HDPA) oversees the enforcement of data protection regulations in Greece. While the HDPA has not issued specific guidance on the use of online tools in clinical trials, sponsors and investigators must ensure that any digital platforms used for recruitment or monitoring purposes implement appropriate technical and organisational measures.

2.5 Use of Data From Clinical Trials

Data from clinical trials is classified as sensitive health-related information regarding an individual's past, present, or future physical and mental health (Article 4 (15) GDPR).

Transferring clinical trial data to third parties or affiliates is allowed under specific conditions:

- Within the EU/EEA, it is allowed, provided that clinical trial participants have been duly informed through the informed consent form and processing is in accordance with the trial's approved protocol.
- Outside the EU/EEA (International Transfers), if data is transferred to a third country (eg, the US), additional safeguards are required:
  (a) the recipient country must have an adequacy decision from the European Commission (eg, under the EU-US Data Privacy Framework);
  (b) if no adequacy decision exists, Standard Contractual Clauses (SCCs) or Binding Corporate Rules (BCRs) must be used; and
  (c) additional security measures (eg, encryption, pseudonymisation) may be required.

To ensure compliance, before transferring clinical trial data to third parties or affiliates, the sponsor must execute a Data Processing Agreement (DPA) (along with the execution of the appropriate Standard Contractual Clauses if applicable for international transfer) with third-party vendors or enter into an intragroup data transfer agreement with its affiliates.

2.6 Personal or Sensitive Data

Below, you will find the requirements for creating a database containing personal or sensitive data (in accordance with the GDPR and Law 4624/2019).

A Data Protection Impact Assessment (DPIA) (GDPR Article 35) is mandatory if the processing of personal data is likely to result in a high risk to individuals' rights. For example, this will be the case if:

- there is large-scale processing of special categories of data;
- there is involvement of high-risk data processing; or
- there are systematic and extensive processing activities, including profiling.

Adherence to data protection principles, such as the data minimisation and purpose limitation principles, is required, as the database should contain only the minimum amount of data necessary for the specific purposes for which it was created (Articles 5-11 GDPR).

Appropriate security and access controls (eg, encryption and pseudonymisation, access restrictions, data retention policies and rules to protect data from unauthorised access, breaches or leaks) must be implemented.

The appropriate legal basis must be assessed (as per Articles 6 & 9 of the GDPR for plain and special categories of personal data, such as health-related).

It is essential to provide relevant information to the individuals involved. This information should include the purposes for processing their data, the identity and contact details of the data controller, any recipients or categories of recipients who will receive the personal data and the privacy-related rights of the individuals, among other necessary details.

If third parties access the database, data processing agreements must be executed, along with Standard Contractual Clauses (SCCs), as applicable for international transfers. If the database involves automated processing of personal data, prior consultation with the Hellenic Data Protection Authority (HDPA) may be required under Article 67 of Law 4624/2019. The HDPA may also review international data transfers or secondary uses of the data.

3. Marketing Authorisations

3.1 Product Classification

The process for classifying a product as either a pharmaceutical or a medical device depends on its intended use, primary mode of action and composition. The primary distinction is their mode of action. Pharmaceuticals exert their effects through pharmacological, immunological or metabolic means mechanisms, while medical devices primarily operate via physical or mechanical mechanisms.

Pharmaceuticals

Pharmaceuticals are governed by Directive and relevant national laws, such as Legislative Decree 96/1973 and Law 1316/1983 in Greece. The approval process for pharmaceuticals involves submitting an application to the regulatory authority (EOF in Greece), including information about composition, manufacturing standards and pharmacovigilance practices. Once approved, marketing authorisation holders (MAHs) must comply with stringent post-marketing obligations, including pharmacovigilance reporting.

Medical Devices

The MDR and the IVDR regulate medical devices. National Joint Ministerial Decisions, along with guidance issued by the EOF, provide additional oversight. Medical devices are designed to assist bodily functions and can operate mechanically, physically, or through software without producing direct pharmacological effects. Examples include surgical instruments and diagnostic software. Manufacturers must complete a conformity assessment to demonstrate compliance with safety and performance standards. The product obtains CE marking through a notified body or the national authority before it can be marketed. Devices are classified by risk level and intended purpose, with post-marketing vigilance responsibilities to ensure continued safety and effectiveness. In Greece, the responsible notified body for the conformity assessment and the CE marking (granting of CE 0653 in Greece, which shows compliance with the applicable legislation) of medical devices is the National Evaluation Centre of Quality and Technology in Health (EKAPTY).

3.2 Marketing Authorisation for Biologic Medicinal Products

In Greece, biologic medicinal products require marketing authorisation through either the national procedure (EOF) or, more commonly, the centralised procedure under Regulation (EC) No 726/2004, where approval is granted at the EMA level.

There are no differences in the approval process between pharmaceutical (chemical) and biological products.

Biosimilars, or generic biological products, must be similar but not identical to the reference product. This contrasts with traditional chemical pharmaceuticals, which require identical characteristics for approval.

3.3 Period of Validity of Marketing Authorisations

Validity and Renewal

Pharmaceuticals

Marketing authorisations are valid for five years from the date of approval. If a renewal is approved, the authorisation lasts indefinitely unless further safety monitoring is necessary, in which case the renewal is for an additional five-year period (Article 40 (4) and (5) of Joint Ministerial Decision DYG3a/32221/2013).

Medical devices

A CE certificate, necessary for the marketing of medical devices, is issued by a notified body for a five-year term (as per Article 56, paragraph 2, of the MDR). Manufacturers must provide updated clinical evaluations, performance data and post-market surveillance reports to renew the CE certificate. The said CE certificate is issued by a notified body (ie, the organisation responsible for the CE certification issuance and conformity assessment procedures as per Article 1, paragraph 2ie), Article 11 and 16 of the Joint Ministerial Decision DY8d/130648/2009 – their specific requirements are set out in Annex VII of the MDR, in Greece, Ministry of Health is responsible for their compliance as per Article 3 of the Ministerial Decision A4g/88159/2017.

Revocation, Variation, Suspension or Withdrawal

Revocation by EOF or EMA if according to Article 40 (4) of JM Decision:

- the product is not placed on the market within three years of authorisation;
- the product is not marketed for a continuous period of three years; or
- if new pharmacovigilance data show an unacceptable risk-benefit ratio.

Modification of a marketing authorisation is applicable if new data on safety or efficacy is discovered.

A temporary suspension is applied in cases of unresolved safety issues.

For medical devices, the CE marking certification can be:

- revoked if the device is not placed on the market within three years from the issuance of the certificate;
- suspended or withdrawn if there is an increase in adverse events and the risk level is high; and
- modified if additional safety measures are needed.

3.4 Procedure for Obtaining a Marketing Authorisation

Obtaining an Authorisation

Pharmaceuticals

The regulatory process for national marketing authorisation by EOF is outlined in detail in the JM Decision (Article 7 et seq.), and is fully aligned with the centralised process (marketing authorisation from EMA) provided for in Regulation (EC) No 726/2004. The application for a national marketing authorisation for a medicinal product intended for human use is submitted to the EOF.

Medical devices

The manufacturer of medical devices is required to submit all relevant data to the EOF for the identification of these products before they are marketed (including the CE marking and the instructions for use). This requirement is outlined in Article 14 of Joint Ministerial Decision DY8d/130648/2009, Article 10a of Joint Ministerial Decision DY8d/130644/2009, and Article 10 of Joint Ministerial Decision DY8d/3607/892/2001.

The rules regarding conformity assessment and CE marking of medical devices also depend on their classification as:

- category I, category IIa, category IIb or category III medical devices;
- made-on-order medical devices; or
- active implantable medical devices.

In particular, every manufacturer of category I or on-order medical devices that sells in the Greek market under its name or via an authorised representative based in Greece (when the manufacturer's registered office is outside the EU) is registered in the Register of Manufacturers of the EOF, to affix the CE marking on the medical devices (Article 14 of Joint Ministerial Decision DY8d/130648/2009).

Every manufacturer of category IIa, IIb, and III medical devices, of active implantable medical devices, as well as of in vitro diagnostic medical devices, submits a technical dossier of the products to a Notified Body within the EU, which assesses their compliance with the legal requirements and issues a CE marking certificate (Article 16 and Annex XI of Joint Ministerial Decision DY8d/130648/2009, Article 9 and Annex II of Joint Ministerial Decision DY8d/130644/2009, as well as Article 9 and Annex II of Joint Ministerial Decision DY8d/3607/892/2001).

Variation of an Authorisation

Pharmaceuticals

According to Article 43 of the JM Decision, any changes to an existing marketing authorisation are determined by the EOF. An application providing a specific form that follows the template set by the EMA must be submitted to the EOF to initiate a variation.

Variations are categorised based on their impact on safety, quality, and efficacy, and the process aligns with EU rules for minor and major variations (EU Regulation 1234/2008). Minor changes may require just EOF's notification (eg, change in labelling – such as a font size change), moderate changes require EOF's approval before implementation (eg, change of labelling which is linked with safety) and major changes necessitate an evaluation before implementation (eg, change in therapeutic indication, formulation).

Medical devices

EOF has not made publicly available a template form to be submitted for variations concerning specifically medical devices; however, based on the rules and guidance provided by EMA,the following details are expected to be requested:

- device(s) identification and classification;
- name of the device and brief description;
- intended purpose;
- classification;
- serial number;
- manufacturer details;
- notified body details;
- proof of fee paid; and
- details regarding the variation.

Transfer of an Authorisation

Pharmaceuticals

The process involves a joint transfer application to EOF, which includes:

- details about the product concerned
- details about the existing and the new MAH;
- confirmation that there are no changes to the product; and
- description of the pharmacovigilance system.

Medical devices

For medical devices, the rights regarding the CE marking can be transferred by:

- updating the CE certificate holder details with the Notified Body;
- ensuring continued compliance with the MDR and the EOF's guidance by the new holder; and
- updating EOF's registration regarding the new owner's details.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

Pharmaceuticals

Compassionate use programmes

In Greece, compassionate use programmes are regulated by the Joint Ministerial Decision DYG3 (a) 85037/10/2011, which provides early access/compassionate use of medicinal products which either constitute the subject of a marketing authorisation application before EOF or EMA or are at stage III of clinical trials and more specifically at the stage of analysis of clinical trial data. Conditions are:

- approval by EOF; and
- certification from a doctor of the respective speciality that the existing treatments do not exist.

Two types of programmes may be approved:

- a group early access; and
- an individual early access,

with a maximum duration of one year for both programmes.

In the first case, the applicant is the applicant for the marketing authorisation before the competent authority or the sponsor of the clinical trial, while in the second case, the applicant is the treating physician.

Emergency and public health exceptions

EOF can authorise a temporary supply of unapproved medicines as follows.

- According to Article 8 (5) of Legislative Decree 96/1973, EOF may, in case of a public health emergency, proceed with the import of any pharmaceutical product with no limitations in terms of quantity and quality.
- According to Article 8 (6) of Legislative Decree 96/1973, EOF may permit importing unapproved medicinal products in limited quantities and for specific purposes.

Medical Devices

According to Article 59 of the MDR and as per Article 11 paragraph 13 of the Joint Ministerial Decision DY8d/130648/2009, any competent authority (EOF for Greece) may authorise the import of a specific device for which the procedures for placement in the market have not been carried out but the use of which is in the interest of public health or patient safety or health.

3.6 Ongoing Obligations Imposed by Marketing Authorisations

Pharmaceuticals

MAH's ongoing obligations are described in Articles 36, 38, 39 and 40 of the JM Decision.

Article 36 of the JM Decision provides that EOF may impose on MAH the obligation to conduct either:

- a post-marketing safety study, if there are issues relating to the risks of a medicinal product; or
- a post-marketing efficacy study when the knowledge of the disease or the clinical methodology suggests that previous efficacy assessments may need a significant revision.

Furthermore, according to Article 38 of the JM Decision, the MAH immediately informs EOF of any prohibition or restriction imposed by the competent authorities of any other country and any new information that might influence the pharmaceutical product's risk-benefit balance.

Article 39 of the JM Decision provides that the MAH notifies the EOF of the exact date of the medicinal product's placement in the Greek market. The MAH notifies EOF of any discontinuation (temporary or permanent) of commercialisation of the product at least three months before discontinuation.

Article 12A of the Legislative Decree 96/1973provides that any MAH of medicinal products shall ensure the adequate and continuous supply of products to the market in order to meet the needs of patients in Greece.

The electronic submission of individual case safety reports (ICSRs) in the Eudravigilance database is mandatory for MAHs, whether through the centralised procedure under Regulation 726/2004 or the national procedure under the Directive, as well as for clinical trial sponsors.

Medical Devices

Post-marketing vigilance. The competent authority in Greece, the EOF, has adopted the White Card system. Manufacturers are obliged to report to EOF all serious adverse events taking place in Greece by submitting in English the following two types of reports:

- the Manufacturers Incident Report (MIR) form; and
- the Field Safety Corrective Action (FSCA) form. The following are reportable to EOF:
  - (a) any malfunction or deterioration in the characteristics and/or performance of a product, as well as any deficiency in the labelling or instructions for use, which may cause or have caused the death or serious deterioration in the health of a patient; and
  - (b) any technical or medical event relating to the characteristics or performance of a product which has led to the manufacturer's systematic withdrawal from the market.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations

Pending Applications

Third parties have limited access to information in pending marketing authorisation applications. The information included in the application dossier (such as proprietary formulations, clinical trial data, regulatory status or information that might reveal competitive strategies) is not publicly accessible unless there is an overriding public interest in disclosure (Article 81 (5) of the CTR).

For medical devices, there is no public registry of pending applications.

Granted Authorisations

Pharmaceuticals

The following information becomes public:

- product name & active substance;
- MAH;
- summary of product characteristics;
- public assessment report;
- approval date and therapeutic indications; and
- package leaflet & labelling.

Medical devices

EOF may release basic registration details (eg, the manufacturer's name, general device use, approval date), but full technical documentation remains confidential. Article 20 of the Joint Ministerial Decision DY8d/130648/2009 sets out what is considered non-confidential information. Moreover, the National Electronic Registry of Medical Devices (GREMDIS) can only be accessed if there are dedicated credentials and is not publicly available, while for EUDAMED (the EU medical device database), in order to check for device registration/certifications, specific fields need to be completed, such as:

- manufacturer;
- notified body;
- certificate number and status;
- risk class;
- device type.

Refused Authorisations

Pharmaceuticals

EMA publishes details of authorisations that have been refused, withdrawn or suspended, including the reasons for refusal. Information on national refusals (EOF decisions) is not published but can be obtained upon request.

Medical devices

If a CE certification is refused, the manufacturer is not obligated to disclose it.

Rules on Protecting Commercially Confidential Information and Personal Data

There are confidentiality obligations regarding commercially confidential information (eg, manufacturing processes, regulatory strategies, proprietary research) and the protection of personal data (eg, clinical trial participants' personal data and individual adverse event reports) as set out in EU legislation (eg, Regulation EU 1049/2001 – Access to EU Documents, 679/2016 GDPR, Regulation EU 1725/2018 for processing of personal data by the Union institutions, bodies, offices and agencies; Directive, etc).

4. Regulatory Reliance and Fast-Track Registration Routes

4.1 Fast-Track Registration Routes

Pharmaceuticals

EMA provides mechanisms such as accelerated assessment (Regulation 726/2004, Article 14 (9) and the Directive) and conditional marketing authorisations (Regulation 726/2004, Article 14a, in conjunction with Regulation 507/2006 and the Directive) for products that address unmet medical needs or serious conditions. For accelerated assessment, the authorisation application is assessed within 150 days instead of 210 days and the applicant submits a full set of clinical data and evidence that the medicine is of major interest to public health.

Conditional marketing authorisation allows approval of the product before full submission of the clinical trial results, provided that the benefit of immediate market availability outweighs the risk when additional data are still required.

Medical Devices

For medical devices, Article 11 (13) of the Joint Ministerial Decision DY8d/130648/2009 and Article 59 of the MDR provide expedited pathways in specific cases where any competent authority may authorise, on a duly justified request, the placing of a specific device on the market, the use of which is in the interest of public health. EOF may grant temporary emergency use authorisation or national exemption before EU-wide approval.

4.2 Regulatory Reliance

Pharmaceuticals

EU-based reliance

If a medicine has received a marketing authorisation from EMA (centralised procedure), it is automatically valid in all EU member states, including Greece.

If another EU national competent authority grants an authorisation via the Mutual Recognition Procedure or Decentralised Procedure, EOF relies on that decision and does not reassess the application dossier.

Non-EU reliance

EOF may consider World Health Organisation (WHO) pre-qualified medicines in the event of global health emergencies.

- EOF does not automatically accept non-EU approvals (eg, FDA, MHRA, etc); however, companies can submit foreign regulatory approvals as supportive data;
- EOF may expedite the local review.

Medical Devices

If a device is already CE-certified by an EU Notified Body, EOF does not conduct an additional review. Registration with EOF is still required for local market entry. In general, as per Article 20 (1) of the MDR, medical devices that comply with its requirements bear the CE marking of conformity, which means they can be marketed in all member states.

EOF does not automatically accept non-EU approvals (eg, FDA), but companies can submit foreign approvals to strengthen applications.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants

Pharmaceuticals

Manufacturing facilities must obtain a manufacturing license from EOF. According to Article 58 of the JM Decision, each manufacturing facility has to obtain a manufacturing license, which is granted under the following conditions:

- specify the medicinal products to be manufactured, as well as the place of manufacture;
- ensure suitable and adequate premises, technical equipment, and control facilities; and
- appoint at least one qualified person.

Furthermore, according to Article 9 of both Joint Ministerial Decision DYG3a/7567/2008 and Joint Ministerial Decision YA D3 (a)/14709/2018, the manufacturer must ensure that manufacturing plants and equipment are sited, designed, constructed and maintained in such a way that they perform the functions for which they are intended. Additionally, they must be arranged and used in such a way as to minimise the risk of error and to permit effective maintenance in order to avoid direct and cross-contamination and any undesirable effect on product quality. EOF conducts on-site inspections to verify compliance with EU GMP standards.

Medical Devices

For medical devices, the decision issued by EOF 0–1016/22nd/15.12.2008 (Ministerial Decision 6209/2009) sets out the good manufacturing and control rules to ensure the appropriate implementation of a quality system. As per Article 3 of the said decision, among others, the manufacturer of a medical device must have the following in place:

- appropriately qualified and trained personnel;
- adequate facilities and premises;
- appropriate equipment and services;
- appropriate materials, containers and labels;
- approved procedures and instructions;
- appropriate storage; and

- written records of manufacture and distribution with which the history of the batch can be traced.

Upon approval of the application, EOF grants the manufacturing authorisation for the medical device in accordance with Article 2 of the Joint Ministerial Decision DY8d/130648/2009.

Manufacturing licenses for pharmaceuticals and medical devices typically remain valid indefinitely, provided that the manufacturer complies with ongoing regulatory requirements. These include:

- adherence to GMP rules and issuance of a relevant GMP certificate of compliance, which is valid for three years unless specific circumstances reduce or increase this period; and
- adherence to relevant quality management standards (eg, ISO 13485 for medical devices that must be renewed every three years).

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Wholesalers must obtain a wholesale license issued by EOF. Application to EOF includes:

- company details;
- warehouse location;
- description of storage and handling facilities;
- list of medicinal products to be handled; and
- responsible person certificate.

Upon evaluation and on-site inspection to verify GDP standards, EOF grants a wholesale license, which gives the right to procure, store, distribute and supply pharmaceuticals/devices to pharmacies and hospitals.

Pharmaceuticals

The Wholesale License is issued for a specific region and is valid for five years. If a MAH or its local representative holds a manufacturing license, no wholesale license is required to distribute or sell products.

The conditions for granting a wholesale license are outlined in Article 105 of the JM Decision and the Presidential Decrees 194/1995 and 88/2004.

According to Article 105 of JM Decision, the applicant must:

- have appropriate and sufficient premises and equipment;
- employ staff, including a qualified person (QP) who meets the requirements set forth in the applicable legislation;
- fulfil the obligations outlined in Article 106 of JM Decision; and
- satisfy the remaining conditions of Presidential Decree 88/2004, “Organisation and Operating Specifications of a Pharmaceutical Warehouse.”Medical Devices

For medical devices, the validity period is not explicitly set under MDR/IVDR, but compliance with regulations is continuously monitored, and EOF may revoke the authorisation if the wholesaler fails to comply with regulatory obligations. Any certification which verifies compliance with regulatory standards must be renewed every three years.

6.2 Different Classifications Applicable to Pharmaceuticals

The classifications are described in the Directive (Directive Title VI), national laws (3457/2006 & 3816/2010), and JM Decision (Article 95). According to Article 70 of the Directive and Article 95 of the abovementioned Decision, pharmaceuticals are classified as:

- a pharmaceutical subject to medical prescription; and
- a pharmaceutical not subject to medical prescription.

Based on the above, in Greece, the classification of pharmaceuticals is as follows.

- Prescription-only medicines (POM) require a prescription from a licensed healthcare professional and are dispensed in pharmacies. Furthermore, according to Directive Article 70 paragraph 2, EOF

has to classify further when labelling the following pharmaceuticals:
  (a) pharmaceuticals subject to a medical prescription;
  (b) pharmaceuticals subject to special medical prescription; and
  (c) pharmaceuticals subject to a "restricted" medical prescription reserved for use in hospitals.
- Over-the-counter (OTC) medicines can be purchased without a prescription. Regulated under EOF guidelines and still subject to quality and safety controls.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law and Relevant Enforcement Bodies

Pharmaceuticals

Directive 2001/83 (IV Section), along with the JM Decision and EU Directive 2011/62 and the Joint Ministerial Decision D3 (α)41169/19/8-7-2020 (for the prevention of the entry into the legal supply chain of falsified medicinal products), set out the rules for the importation and exportation of pharmaceuticals.

Medical Devices

MDR is the legal framework for importing and exporting medical devices, while IVDR is the legal framework for in vitro diagnostic medical devices.

Competent Bodies

EOF is the competent authority.

To ensure an adequate supply of products in the market, the EOF has banned the export of certain medicines. Additionally, through Circular No 66718/2011, the EOF requires wholesalers to submit monthly intra-EU export data. In line with this, the Greek Customs Code (Law 2960/2001) and the EU Customs Code (Regulation (EU) No 952/2013) have introduced a monitoring system, as outlined in Circular No 24151/2012, to track the domestic distribution of pharmaceuticals at the customer level for all wholesalers.

In response to COVID-19 supply chain challenges, EOF, in coordination with EMA, imposed temporary bans on parallel exports and intra-EU distribution.

Greek Customs Authority (Independent Authority for Public Revenue – AADE):

- controls import duties, VAT, and customs clearance;
- works with the EOF to intercept counterfeit or illegal imports; and
- ensures compliance with tariff codes and EU single market rules.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

In Greece, an importer can be:

- a MAH;
- manufacturers with import licenses (if importing their own products); and
- licensed wholesale distributors of medicines and medical devices.

IFET (the national Greek public wholesaler) handles the import of medicines that are not commercially available in Greece and require special approval for pharmacies and hospitals

Pharmaceuticals

According to the JM Decision (Government Gazette B' 1049/29-04-2013), which aligns Greek law with the Directive, an importation licence from EOF is required. Obtaining the licence requires filing an application that must include the specific medicines to be imported, the place of their production, the relevant premises, the technical equipment and the control capabilities for the importation process. Additionally, the application must designate at least one qualified individual responsible for these activities, as outlined in the aforementioned Ministerial Decision.

Key requirements:

- Import Permit by EOF for controlled substances (pharmaceuticals containing narcotics);
- Wholesale Distribution Authorisation from EOF;

- Marketing Authorisation or Parallel Import License; and
- Customs Registration & VAT Compliance (AADE & Greek Customs Authority).

Medical Devices

According to guidance issued by EOF, importers of medical devices are required to notify their details to the National Electronic Registry of Medical Devices GREMDIS. Required documents are:

- CE Marking Certificate (for high-risk medical devices) or certificate of the competent authority of the EU Member State where the products were registered (for low-risk Categories);
- manufacturer's Declaration of Conformity;
- outer packaging; and
- instructions for use.

Key requirements:

- registration with EOF as an importer;
- CE Marking & Declaration of Conformity from the manufacturer
- quality compliance certification (eg, ISO 13485); and
- Customs and VAT Registration (AADE & Greek Customs Authority).

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

In Greece, the importation of pharmaceuticals and medical devices requires prior authorisation from EOF. Import licenses are required only for products imported from non-EU countries. This is in accordance with the EOF Circular on the Import and Distribution of Pharmaceuticals (EG-18013-2013) and the regulation allowing the free movement of goods within the EU (DYG 3a 82161/12, Article 40).

Importation of Pharmaceuticals

According to the JM Decision (Government Gazette B' 1049/29-04-2013), an importation license from EOF is required as follows.

- Import Capability License:
  (a) company application with requested forms;
  (b) operating license from the authorities;
  (c) layout of required spaces; and
  (d) list of microbiological/chemical lab instruments (if self-testing).
- Pharmaceutical Product Import License:
  (a) application specifying manufacturer, packaging, control site, origin, formulation, strength, and packaging;
  (b) Import Capability License for the requested form;
  (c) marketing authorisation; and
  (d) GMP Certificate issued by an EU/EEA Authority for the product or manufacturer.

Importation of Medical Devices

Distinction based on the CE mark:

- CE-Marked Medical/In Vitro Diagnostic Devices (MDR/IVDR compliant); the importer must be registered with EOF; and
- Non-CE-Marked Devices (not registered in Greece): EOF must provide specific import approval.

Custom-made medical devices (eg, prosthetics) may be exempted from standard import requirements but must still be registered with EOF.

In order to place their products on the Greek market, medical device importers are required to notify the National Electronic Registry of Medical Devices GREMDIS of their details. Required documents are:

- CE Marking Certificate (for higher-risk medical devices) or Certificate of the competent authority of the EU Member State where the products were registered (for low-risk medical devices);
- Manufacturer's Declaration of Conformity;
- outer packaging; and
- instructions for use.

Exceptions

Personal use

Patients can import small quantities of prescription medicines for personal use, but a doctor's prescription and a patient declaration to customs are mandatory.

Emergency public health situations
During pandemics, disasters, or shortages, pharmaceutical products may be imported following a decision of the EOF (Paragraph 5 of Article 8 of Legislative Decree 96/1973)

Named patient programmes & compassionate use
Importation of unapproved medicines for individual patients or for a group of patients following the EOF decision. For individual patients, the treating physician proposes (and EOF issues) an individual decision.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

In Greece, non-tariff regulations and restrictions on the importation of pharmaceuticals and medical devices are imposed based on their regulatory category and classification under the Combined Nomenclature (CN) Code, which is based on the Harmonised System (HS) Code.

The Greek Customs Code (Law 2960/2001), in alignment with the EU Customs Code (Regulation (EU) No 952/2013), provides that if the pharmaceutical product or the medical device meets the requirements of the applicable legislation for its manufacturing and production, it may be imported into Greece or any other European jurisdiction.

Pharmaceuticals, governed by Directive, implemented in Greece through JM Decision, require authorisation from the EOF. Products must meet the provided qualitative and quantitative composition standards, and batch testing may be required upon their termination.

Medical devices are regulated under MDR and IVDR for in vitro diagnostic devices. All imported devices must bear the CE mark and be registered in the EUDAMED database. Customs authorities check for technical documentation, conformity assessments, and labelling compliance.

Additionally, country-specific restrictions on products may be available in the EU TARIC database, which provides information on additional requirements, restrictions, or prohibitions.

Laws and Regulations governing these restrictions are outlined below.

- Greek Customs Code (Law 2960/2001) – Establishes the general import framework.
- EU Customs Code (Regulation (EU) No 952/2013) – Sets import procedures across the EU.
- Directive & JM Decision – Regulates pharmaceutical imports.
- MDR & IVDR – control medical device imports.

7.5 Trade Blocs and Free Trade Agreements

Greece is a member of the European Union (EU), which operates as a trade bloc and has established multiple Free Trade Agreements (FTAs) and Mutual Recognition Agreements (MRAs) with third countries.

The EU's FTAs with Japan (EPA), South Korea, and the UK (TCA) provide duty-free access for pharmaceutical exports, eliminating tariffs entirely. Under the FTA with Canada (CETA), 99% of tariffs on pharmaceuticals have been abolished. The EU also has an FTA with Switzerland, where pharmaceutical trade benefits from tariff-free movement due to Switzerland's participation in the EU Single Market. Once ratified, the pending EU-MERCOSUR trade agreement is expected to lead to tariff reductions on pharmaceutical exports.

As a member of the World Trade Organisation (WTO) since 1995, Greece adheres to global trade rules that promote transparency, fair market access, and lower trade restrictions. Its participation in the WTO FTA reduces shipping times and administrative costs, which benefits pharmaceutical exports.

Mutual Recognition Agreements (MRAs) with Canada, Switzerland and the UK facilitate market access by eliminating duplicate testing, expediting regulatory approvals, and accelerating entry into highly regulated markets.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Pharmaceuticals

According to Legislative Decree 96/1973 and Ministerial Decisions D3 (a)/6295/2024 and D3 (a) 59308/2024, the maximum prices for prescription-only medicinal products – specifically the retail price, wholesale price, hospital sale price, and ex-factory price – are determined through Price Bulletins issued by the Minister of Health. This process follows a proposal by the EOF, as stated in Article 17 of Legislative Decree 96/1973, and requires an application from the MAH. OTC medicinal products are excluded from this pricing structure.

Original medicinal products are priced in accordance with the median of the two lowest prices of the two Member States of the Eurozone. The same applies to off-patent medicinal products (original products following the expiration of their market exclusivity). Generic products are priced at 65% of the original product's price, while biosimilars are priced using the same method as their originals (the two lowest prices in the Eurozone). Non-prescribed pharmaceutical products (OTC) are priced according to the median of the three lowest prices across three EU Member States and this price is indicative for pharmacies but mandatory for sales to hospitals. The final price for all the above product categories is the ex-factory price, to which the wholesale and retail margins are added when the product is sold through a pharmacy. When the products are sold to a hospital, the ex-factory price is reduced by 8.74%.

Medical Devices

There is no legislation in Greece controlling their prices. EOPYY (National Organisation for Health Care Services) sets maximum reimbursement limits for certain device categories. Prices are primarily controlled through hospital tenders and reimbursement policies rather than direct price caps.

8.2 Price Levels of Pharmaceuticals or Medical Devices

Pharmaceuticals

Original medicinal products are priced in accordance with the median of the two lowest prices of the two Member States of the Eurozone.

The same applies to off-patent medicinal products (original products following the expiration of their market exclusivity).

Generic products are priced at 65% of the corresponding original product's price, while biosimilars are priced with the same method as their originals (the two lowest prices in the Eurozone).

OTCs are priced in accordance with the median of the three lowest prices of the three EU Member States. This price is not obligatory for the retail channel (pharmacies) but is mandatory when sales are made to public hospitals.

Medical Devices

For medical devices, Greek legislation does not explicitly tie their price to other countries under general pricing rules but relies on EOPYY reimbursement rules, considering costs across the EU.

8.3 Reimbursement From Public Funds

Pharmaceuticals

According to Article 1 (2) of Law 3457/2006 (Government Gazette A 93/8.5.2006), the medicinal products that are classified as OTC are not reimbursed by social security funds. The reimbursement rules regarding prescription-only products are contained in Article 12 of Law 3816/2010 (Government Gazette A' 6/26.01.2010), as well as in Article 247 et seq of Law 4512/2018 (Government Gazette A' 5/17.01.2018).

For the latter products to be reimbursed, they need to be approved on the positive list of reimbursed products (Article 12 of Law 3816/2010). The inclusion of a medicinal product requires a Decision of the Minister of Health, following the opinion of the Committee for the Evaluation and Reimbursement of Medicinal Products for Human Use (Evaluation Committee – Article 247 of Law 4512/2018), which opinion is issued following an application from the MAH.

The Evaluation Committee, in order to evaluate the cost-effectiveness ratio and the impact on the state budget, refers for an opinion to the Drug Price Negotiation Committee (Negotiation Committee) and is responsible for negotiating the prices or discounts of medicinal products which are going to be reimbursed (and often concludes separate agreements including further discounts).

The Negotiation Committee initiates and concludes the negotiation process for the medicinal product by issuing a justified opinion. The Evaluation Committee takes into account the justified opinion of the Negotiation Committee for its final opinion.

Medical Devices

The reimbursement of medical devices is regulated under Article 108 of Law 4461/2017 (Government Gazette A' 38/28.03.2017). In particular, for the reimbursement of medical devices for special medical purposes (FSMPs), the importer/manufacturer/representative of these products must submit to EOPYY a declaration stating that:

- the items are registered in the registers of EOF and in the registers of reimbursable products of EOPYY if the product is registered in the latter; and
- that the product is marketed in at least three countries of the European Union.

The product's reimbursement price is determined by the maximum of the average of the three lowest EU market prices.

8.4 Cost-Benefit Analyses

In Greece, Health Technology Assessment (HTA) plays a significant role in the reimbursement of pharmaceuticals and medical devices.

Currently, the country has established the Committee for Assessment and Reimbursement of Medicines for Human Use, effectively functioning as an HTA body, which evaluates new products as follows (Article 245 of Law 4512/2018):

- clinical benefit – assessing the therapeutic value and efficacy of the medicine;
- comparison with existing therapies – evaluating how the new medicine compares to treatments already available and reimbursed;
- data reliability – ensuring the robustness and credibility of the submitted clinical and economic data;
- cost-effectiveness – analysing the economic value of the medicine in relation to its therapeutic benefits; and
- budget impact – estimating the financial implications of including the medicine in the reimbursement list.

The assessment process begins with the MAH submitting a dossier. For products that receive a positive initial assessment, the Pricing Negotiation Committee (as per Article 254 of Law 4512/2018) evaluates their budgetary impact and negotiates pricing and discounts with the MAH.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Prescription and Dispensing by Physicians

According to Law 3892/2010, physicians are required to issue prescriptions through the Electronic Prescription System, a centralised platform managed by IDIKA SA (e-Government Centre for Social Security Services). IDIKA S.A. maintains a database of all insured individuals in all social insurance funds based on the unified Social Security Registry Number (AMKA Registry). This system monitors prescribing practices and ensures compliance with national guidelines.

According to the provisions of Laws 4052/2012 and 4093/2012, doctors must prescribe exclusively based on the active substance's International Non-proprietary Name (INN). Doctors are required to select the appropriate medication in compliance with the therapeutic protocols of EOF. Also, physicians are legally obligated not to exceed prescription limits for patients.

Pharmacy Sales

Pharmacies, according to law 4316/2014, are required to dispense the pharmaceutical product with the lowest retail price for each active substance from the drugs listed in the positive list unless the consumer insists on a brand-name drug and pays the price difference in addition to a co-payment, which is typically 0%-25% of the drug cost.

Also, pharmacies are linked to the national e-prescription system, ensuring real-time tracking.

Law 4052/2012, as amended, provides for a clawback mechanism imposing a specific budget for pharmaceutical sales to public healthcare entities. As a result, any amount exceeding the budget is recovered from the MAHs of pharmaceutical products by the payors.

Trends and Developments

Contributed by:
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ALG Manousakis Law Firm is a law firm established in 2011 by Ioannis and Alexandros Manousakis. Based in Athens, ALG is an international law firm with lawyers qualified in 6 EU jurisdictions and Switzerland. ALG's team consists of 50 lawyers and 25 paralegals. With deep expertise in corporate and commercial law, the firm offers tailored solutions across various industries. Their client base includes 30 pharmaceutical/biotech and five medical device companies, supported by the firm's lawyers in contracting negotiation, ensuring compliance, and developing robust data privacy frameworks. The firm has a proven commercial and administrative litigation track record, with a high rate of success, especially in commercial claims and tax and administrative litigation.

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Key Changes to the Regulatory Framework for Clinical Trials in Greece under the 2026 Ministerial Decision

A comprehensively revised and modernized regulatory framework for clinical research and related studies in Greece was issued through Ministerial Decision D3 (α)/52922/2025 (Government Gazette B' 230), published on 22 January 2026 (the "Decision"), introducing a substantially enhanced, efficient, and streamlined approach to the administrative procedures, formalities and contractual mechanisms involved in clinical research. In particular, the Decision is designed to achieve the simplification and rationalisation of procedures for contract execution and financial management of clinical trials with medicinal products, non-interventional studies with medicinal products, clinical research with medical devices, clinical performance studies with in vitro diagnostic products, and research projects without medicinal products, medical devices or in vitro diagnostic products.

Repealing the Joint Ministerial Decision G5α/59676/22.12.2016 (Government Gazette B' 4131), the new regime modernises Greece's clinical trial procedures by:

- introducing mandatory use of standardised national contract templates;
- enabling digital submissions and electronic signatures; and
- establishing strict and explicit timelines and responsibilities for approvals and financial oversight.

It aligns with Regulation (EU) No 536/2014 on clinical trials while significantly expanding the scope of the superseded 2016 Ministerial Decision, providing a unified operational workflow for contracting and budget management across pharmaceutical products, non-interventional studies and medical devices. With the framework now in force, study teams, sponsors and institutions must promptly adapt and align their procedures to comply with the Decision's requirements.

The Decision introduces significant modifications and enhancements compared with the previous regime. While the previous framework implemented the EU Clinical Trials Regulation at a regulatory level, designating the Hellenic Organisation for Medicines (EOF) as the Competent Authority and the National Ethics Committee (EED) for ethical oversight, it did not establish a unified system for contracting or financial execution, nor did it provide national contract templates for all types of studies. The new regulatory framework systematically remedies these gaps by introducing an operational layer that spans all study types.

In addition, the Decision (Articles 11 et seq) establishes the national legal and procedural framework for the conduct of clinical investigations with medical devices in Greece, in alignment with the Medical Devices Regulation (Regulation (EU) 2017/745-MDR) and the In vitro Diagnostic Medical Devices Regulation (Regulation (EU) 2017/746 – IVDR). The framework distinguishes between investigations conducted within and outside the device's intended purpose and requires full compliance with MDR/IVDR, Good Clinical Practice (ICH-GCP), the Declaration of Helsinki and applicable national legislation. Sponsors bear

overall responsibility for regulatory compliance, safety, data integrity and insurance/indemnification. Clinical investigations may only be conducted following the execution and submission of a standardised written contract using the mandatory templates annexed to the Decision.

Where relevant, a centralised administrative pathway has been established via the Autonomous Clinical Trials Department (ATKM) and the National Register of Administrative Procedures (EMDD) "Mitos." Under this framework, submissions are channelled through ATKM's portal or the administration secretariat, with expedited handoffs to the Special Account for Research Funds (ELKE) and the Special Account for Research Funds of Higher Education Institutions (ELKEA) according to fixed deadlines. Such streamlined procedures were not available under the previous regulatory framework.

Standard agreement templates now incorporate embedded compliance measures, integrating references to International Council for Harmonisation – Good Clinical Practice (ICH-GCP) principles and ethics norms. In the case of non-interventional research, templates reference the Good Pharmacovigilance Practice (GVP) and Good Pharmacoepidemiology Practice (GPP) principles. This ensures greater consistency in obligations and oversight, which was absent from the previous regime. It is also worth noting that the Decision, for the first time in Greek clinical trial regulation, formally authorises and facilitates digitisation and the use of electronic signatures across the contract dossier.

A notable innovation under the current framework is the codification of precise and explicit timelines for institutional signatures, including, by way of example, five or eight working days at various procedural steps, and the recognition of tacit positive opinions from Scientific Councils where applicable, thereby effectively shortening the time to contract execution. Moreover, under the Decision, each contracted project or site is assigned a unique reference code for all protocol-required procedures, providing a clear basis for internal coordination and billing. Financial roles are now more precisely defined, with ELKE/ELKEA's review and signature responsibilities explicitly specified, including invoicing details, while ELKE/ELKEA's signature is not required for zero-budget studies. Importantly, enhanced accountability measures have been introduced, with explicit disciplinary provisions applying to unjustified delays in contracting or financial management.

In conclusion, building on the 2016 regime, the new framework standardises clinical trial contracts, digitises submissions and signatures and establishes clearer timelines and accountability for approvals and financial management. It does not merely align Greece with Regulation (EU) No 536/2014; it fully operationalises and implements it. Unlike the 2016 framework, which focused on roles and governance structures, the Decision transforms the system, from policy into measurable performance through:

- faster contracting;
- clearer budgeting;
- smoother site activation; and
- predictable timelines.

As a result, Greece is positioning itself as a more competitive, efficient and sponsor-friendly clinical research hub in Europe, offering pharmaceutical companies reduced administrative burden, faster study start-up, better cost control and improved reliability.

Drug Shortages and Parallel Exports in Greece in the Post-COVID-19 Era: The Regulatory Role of the EOF and the Case Law of the Conseil d' Etat

Drug shortages constitute a widespread challenge across Europe and globally, further intensified in the aftermath of the COVID-19 pandemic. The principal global causes include shortages of raw materials and active pharmaceutical ingredients (APIs), supply chain disruptions and increased seasonal demand, affecting widely used medicines containing active substances such as paracetamol, amoxicillin and respiratory inhalers.

Greece occupies a relatively favourable position compared to many EU Member States due to robust local production of off-patent medicines by approximately 50 domestic manufacturing facilities. Nevertheless, shortages persist, particularly for patented medicines. A major contributing factor is Greece's comparatively

low medicine prices, which are, on average, half the EU level and up to five times lower than in certain European countries, such as Germany or Austria. These price differentials encourage parallel exports, thereby reducing domestic availability. To safeguard public health, EOF periodically imposes temporary export bans and requires pharmaceutical companies to submit daily sales data and early warnings of supply disruptions. In addition, the Ministry of Health has implemented the Electronic System for Monitoring the Distribution of Medicines, which tracks stock levels and movement of selected critical medicines, improving transparency and control throughout the supply chain.

More specifically, in recent years, particularly following the COVID-19 pandemic, EOF has increasingly issued decisions imposing temporary bans on parallel exports in order to safeguard the domestic supply of medicines (the most recent being Decision No 142654 dated 21 November 2025). Such decisions impose temporary measures applicable for a period of three months. EOF has clarified that these measures may be fully or partially lifted, amended, extended, or replaced by subsequent decisions should market supply conditions change. Within the framework of its regulatory responsibilities, EOF continues to closely monitor the availability of medicinal products, investigating cases of limited supply and market withdrawals reported by:

- Marketing Authorisation Holders (MAHs);
- patients; and
- healthcare professionals.

The aforementioned regulatory measures were subsequently examined at the judicial level. By Decision No 125334/22.11.2022, EOF imposed a temporary ban on parallel exports and intra-Community distribution of 75 medicinal products, on the grounds that priority must be given to adequately covering the needs of patients residing in Greece. The Panhellenic Association of Pharmaceutical Wholesalers (PAPW), a public law legal entity, sought the annulment of that decision before the Council of State. However, the Fourth Chamber of the Conseil d' Etat (ΣτΕ/Supreme Administrative Court) via its Decision No 2214/2023 rejected the application filed by the PAPW.

Among its principal arguments, PAPW contended before the court that the challenged EOF decision establishes a measure that:

- is neither necessary nor appropriate for the protection of public health;
- imposes a disproportionate restriction on the free movement of goods;
- lacks the required reasoning and substantiation;
- contravenes the Constitution, national law, EU law and Article 81 of Directive 2001/83/EC; and
- fails to demonstrate the existence of a risk to public health,

thereby rendering the necessity and appropriateness of the contested measure unestablished.

According to the Conseil d' Etat, holders of wholesale distribution authorisations, within the framework of their public service obligations, are required at all times to ensure the supply of appropriate medicinal products to pharmacies and other entities authorised to dispense medicines to the public, so that the needs of patients within the Greek territory are adequately met. The Conseil d' Etat further emphasised that the export activity of these economic operators is subject to the condition that the immediate availability of medicines in the domestic market is safeguarded, ensuring patients' access to appropriate treatment and preventing the creation of therapeutic gaps detrimental to public health.

The decision reiterates that the objective of the EOF is the protection of public health through ensuring adequate market supply of appropriate medicinal products. To this end, EOF is vested with the authority to adopt any lawful and appropriate preventive or corrective measures necessary to ensure smooth market supply and to avoid shortages, thereby preventing the risk of patients being unable to access the required pharmaceutical treatment. Moreover, EOF is entitled, following an assessment of data concerning supply conditions in Greece, to impose, for a limited period, a ban on the export of specific products from Greek territory, whether to third countries or within the framework of intra-Community trade. Such measures may be imposed where it is duly established that parallel export activity may jeopardise the stable, safe and

quality-assured supply of the population with necessary medicines, particularly where a therapeutic gap is identified. Significantly, in light of the precautionary principle enshrined in Article 191 of the Treaty on the Functioning of the European Union (TFEU), EOF may adopt such measures not only where shortages are proven or certain to occur, but also where there is substantiated evidence of a potential risk to the safety and quality of pharmaceutical supply.

In summary, drug shortages in Greece result from a combination of:

- global supply challenges;
- low domestic prices; and
- increased demand following the COVID-19 pandemic.

EOF's regulatory measures, including temporary bans on parallel exports and close market monitoring, are essential to ensure patient access and prevent therapeutic gaps. However, it must be acknowledged that a significant increase in medicine stockpiles, without adequate transparency and control in the distribution chain, will not effectively reduce shortages and may dramatically increase costs for the pharmaceutical industry.

The 2025 EOF Circular: Establishing a Comprehensive Regulatory Framework for Scientific Events in Greece

On 16 April 2025, EOF issued Circular No 45560/16.4.2025, together with its Corrigendum published on 21 May 2025, entitled "Circular of the National Medicines Agency on Scientific Events," which entered into force on 1 May 2025. The Circular introduces substantial revisions to the existing regulatory framework established by EOF Circular No 37201/23.03.2020, including amendments to terminology and updated procedural rules governing the organisation, notification and financing of scientific events, as well as the participation of healthcare professionals (HCPs) therein. It addresses pharmaceutical companies operating under EOF's regulatory supervision, as well as HCPs involved in planning or attending scientific events.

Among the key developments in the 2025 Circular, the scope of products under EOF's jurisdiction has been clarified and slightly narrowed, with cosmetic products explicitly excluded, while reaffirming most other categories, including:

- human medicinal products;
- veterinary medicinal products;
- foods for special medical purposes;
- dietary supplements;
- biocides; and
- medical devices.

Notably, for veterinary medicinal products and medical devices, the Circular provides that separate, dedicated guidance will be issued in due course, with the current Circular's provisions to apply in the meantime. Concurrently, the definition of "scientific events" has been materially broadened. In addition to congresses, one-day and two-day conferences and seminars, the Circular now explicitly includes post-graduate training programs and webinars, as well as any form of education or training related to EOF-regulated products. These requirements remain unchanged: events must have scientific content, receive financial support from companies marketing EOF-regulated products and be organised by:

- recognised public sector entities;
- scientific associations;
- private healthcare institutions; or
- relevant companies.

Additionally, the new Circular maintains the prohibition on public awareness campaigns by pharmaceutical companies under EOF's jurisdiction regarding specific formulations or products. However, the enhanced regulatory framework introduces limited exceptions and new opportunities, subject to strict conditions. Specifically, companies marketing EOF-regulated products are now permitted to organise public awareness events for patients and the general public concerning disease prevention, diagnosis and treatment, provided that a prior request is submitted through the EOF Online Application System for Scientific Conferences. Furthermore, companies marketing medical devices may conduct educational events aimed at instructing patients on the proper use of devices they

have obtained, subject to prior submission and evaluation of the event's purpose and content via the same system. Patient organisations may organise events independently without notifying or obtaining approval from EOF, provided there is no pharmaceutical company involvement. In cases where financial support is provided by companies, such support is permissible only in collaboration with recognised scientific health entities, requires EOF approval, and is subject to a maximum contribution of EUR 3,500 per company.

The 2025 Circular maintains the ability of public sector entities to organise up to three scientific events per year, while substantially increasing the overall sponsorship cap to EUR20,000 (previously EUR10,000), with a maximum contribution of EUR2,500 per pharmaceutical company/sponsor and a total maximum contribution of EUR20,000 from all pharmaceutical companies/sponsors.

Regarding such events, the 2025 Circular introduces two significant institutional innovations. First, Course Cycles may be held up to ten times per entity annually, in-person, online or in a hybrid format and may be organised by universities, hospitals or recognised scientific health entities. These courses target HCPs and aim to provide continuous, comprehensive professional education. Second, Satellite Symposia are introduced for the first time within domestic scientific events, with a strictly scientific, non-promotional character. These symposia do not require separate EOF approval when included in the official conference program. Key restrictions include a prohibition on any references to product brand names and a limit of three participations per HCP per conference as a compensated speaker or chairperson.

Furthermore, the 2025 Circular introduces substantially updated maximum allowable limits for accommodation and meal expenses of HCPs participating in scientific events or expert committees. For events held within Greece, the daily accommodation cost shall not exceed EUR320 (previously EUR150), while the daily meal allowance is capped at EUR100 (previously EUR70). For events held abroad, the daily accommodation cost may reach EUR400, with a maximum daily meal allowance of EUR150.

Of particular importance, the 2025 Circular strengthens accountability requirements by introducing enhanced reporting obligations and stricter enforcement measures. Under the 2025 framework, a specific sanction has been established for violations involving inaccurate reporting or failure to submit a final report: a prohibition on organising scientific events, convening advisory panels of experts or providing sponsorships under the Circular for a period of one year and, in the case of repeat violations, for a period of two years.

Additionally, the 2025 Circular establishes specific submission deadlines: applications for domestic events must be submitted at least eight days prior to the event, while applications for international events require a minimum of 15 days' advance notice. Sponsoring companies are further required to submit annual financial reports to EOF by 30 June of the following year.

In conclusion, by addressing previously unresolved ambiguities and longstanding interpretative uncertainties, the new framework seeks to:

- enhance regulatory clarity and transparency;
- improve compliance; and
- promote greater legal certainty for all stakeholders.

This development is anticipated to positively influence industry practices, particularly in regulatory compliance, sponsorship frameworks and reporting requirements. The 2025 Circular represents a significant step forward in Greece's pharmaceutical regulatory landscape, aligning national practices with evolving European standards while:

- maintaining robust oversight of scientific events and healthcare professional engagement;
- ensuring transparency; and
- preventing inducement.

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