

# Legal 500

## Country Comparative Guides 2024

Greece

Life Sciences

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This country-specific Q&A provides an overview of life sciences laws and regulations applicable in Greece.

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## Greece: Life Sciences

### 1. Please briefly summarize your country's legislative framework for medicinal products (including biologicals), medical devices, food, and food supplements

#### Medicinal products

##### European Legislation

- 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 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, organization and competence of the National Organization for Medicines (EOF, as per its Greek acronym), as amended and in force.
- Ministerial Decision DYG 3a/32221/2013 (Government Gazette B' 1049/29.04.2013) on the implementation of Directive 2001/83/EC of the European Parliament and of the European Council on the Community Code relating to medicinal products for human use, as amended and in force.

#### 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 harmonization 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 harmonization 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 harmonization 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".

#### Food supplements and Special Dietary Foods

##### European Legislation

- Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, as amended and in force;
- Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, as amended and in force.

##### National Legislation

- Food and Beverage Code: Ministerial Decision

- 1100/1987 (Government Gazette B' 788/31.12.1987), as amended and in force.
- Ministerial Decision G5a/53625/2017 (Government Gazette B' 3328/21.09.2017) on the harmonization of national legislation with the provisions of Directive 2002/46/EC "on the approximation of the laws of the Member States relating to food supplements";
  - Circular of EOF No 55220/2009 on Health and Nutrition Statements.

## 2. With regards to medicinal products and medical devices, how is the regulatory process structured in your jurisdiction from R&D through market approval until post-marketing vigilance, and what rules does it follow? Please briefly describe.

### Medicinal Products

The regulatory process applicable for clinical trials on medicinal products in Greece is described in the Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, the provisions of which were transposed in the Greek legal system by the Joint Ministerial Decision G5a/59676/2016 (Government Gazette B' 4131/22.12.2016) as amended by the Ministerial Decision D3(a)/36809/2019 (Government Gazette B' 2015/03.06.2019).

To conduct a clinical trial in Greece, prior approval from the National Organization for Medicines (EOF) is required, following an application file submitted in Greek via the EU portal, referred to in article 80 of EU Regulation 536/2014. For all the other aspects, the application submission and the validation procedure are carried out in accordance with article 5 of EU Regulation 536/2014.

The clinical trial is subject to scientific and ethical evaluation and is approved in accordance with article 8 of EU Regulation 536/2014. The scientific evaluation of the clinical trial is carried out by EOF, which acts depending on whether it has been granted the status of "reporting" or "concerned" member state. If EOF has been granted the status of 'reporting' member state, it shall notify the sponsor and the other member states concerned of its status via the EU portal within six days of the submission of the application file (art. 5 of EU Regulation 536/2014).

Furthermore, EOF shall notify sponsor of the conducted scientific evaluation of the issues covered by part I of the assessment report, in accordance with the procedure referred to in article 6 of EU Regulation 536/2014.

As far as the ethical evaluation of the issues covered by the part II of the assessment report is concerned, it is carried out by the National Ethics Committee which drafts an assessment report on the part II in accordance with the procedure laid down in article 7 of EU Regulation 536/2014 and submits it to EOF 5 days before the expiry of the deadlines set.

A positive scientific (by the EOF) and ethical (by the National Ethics Committee) assessment of the clinical trial is required for its approval. In case of a negative opinion by the National Ethics Committee, EOF rejects the application. In any case, EOF informs the sponsor via the EU portal on whether the clinical trial has been approved, whether its approval is subject to conditions or whether it has been rejected.

The regulatory process for a national marketing authorization by the National Organization for Medicines (EOF) is outlined in detail in the Joint Ministerial Decision DYG 3a/32221/2013 (Government Gazette B' 1049/29.04.2013) (art. 7 et seq.) and it is fully aligned with the centralized process provided for in the Regulation (EC) No 726/2004. The application for a national marketing authorization for a medicinal product intended for human use shall be submitted to EOF and shall include information on (i) the qualitative and quantitative composition of the medicinal product and evidence that the manufacturer is able to comply with the rules of Good Manufacturing Practice and the performance of relevant controls and (ii) the applicant's pharmacovigilance system.

After the marketing authorization has been granted, the MAH is responsible for placing the medicinal product on the market. The appointment of a representative shall not relieve the MAH of such legal responsibility.

The regulatory process with respect to the post – marketing vigilance system is also described in the Joint Ministerial Decision DYG3a/32221/2013 (art. 133 et seq.) and it is articulated by a system of reporting the adverse events, by a set of obligations to be performed by the MAH, and by a system of control, supervision and cooperation activities of EOF with the competent EU bodies as well.

In order to achieve the post – marketing vigilance objectives, the EudraVigilance database has been established for the management and analysis of information on adverse events of authorized or investigational medicinal products undergoing clinical trials. In particular, the EudraVigilance database ensures the safe and effective use of medicinal products through the electronic exchange of individual case safety reports

(ICSRs) between the EMA, national competent authorities, MAHs and clinical trial sponsors. In addition, the system is used to detect and assess signals of changed risks or changes in the risk-benefit balance of medicinal products. To be noted that the electronic submission of ICSRs is mandatory for MAHs either through the centralized procedure of Regulation 726/2004 or through the national procedure of Directive 2001/83/EC, as well as for clinical trial sponsors.

The competent authority for pharmacovigilance in Greece is EOF that, in compliance with the harmonized rules on pharmacovigilance within the EU, has adopted the Yellow Card system. The Yellow Card is a tool for collecting information on adverse events from the use of medicinal products, including vaccines. In particular, HCPs have the obligation and patients have the right to complete the Yellow Card whenever they suspect that a medicinal product (or a vaccine) may have caused an adverse event. Upon receipt, adverse event reports are evaluated by HCPs, entered into the national database and forwarded to the EudraVigilance database. It should be noted that Patients can also report adverse reactions directly to MAHs, who are obliged to submit the information they receive directly to EudraVigilance.

### **Medical Devices**

The regulatory process applicable to clinical investigations (or performance studies in the case of in vitro diagnostic medical devices) is set out in Section VI of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices ("MDR"), as well as in Section VI of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices ("IVDR"), as the case may be.

According to articles 62 of the MDR and 58 of the IVDR, both clinical investigations and performance studies are the subjected to an authorization 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. The Greek legislator has not yet enacted any national legislation for the purpose of implementing the aforesaid Regulations.

In terms of national legislation, the current legislative framework in force governing medical devices varies depending on their classification as medical devices [Joint Ministerial Decision DY8d/130648/2009 (Government Gazette B' 2198/02.10.2009)], as active implantable medical devices [Joint Ministerial Decision DY8d/130644/2009 (Government Gazette B'

2197/2.10.2009)] or as in vitro medical devices [Joint Ministerial Decision DY8d/3607/892/2001 (Government Gazette B' 1060/10.8.2001)].

First, it should be noted that medical devices are not subject to the same approval procedure as medicinal products. On the contrary, instead of the pre-approval and authorization regime by EOF, the manufacturer of medical devices of all categories, or its authorized representative, submits to EOF all the data that allow the identification of these products as well as the CE marking and the instructions for use, before the start of use of these products in the Greek territory (art. 14 of Joint Ministerial Decision DY8d/130648/2009, article 10a of Joint Ministerial Decision DY8d/130644/2009, art. 10 of Joint Ministerial Decision DY8d/3607/892/2001).

The rules regarding conformity assessment and CE marking of medical devices are also depending to their classification as category I, category IIa, category IIb and 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 own name or via an authorized representative based in Greece (when the manufacturer's registered office is outside the EU), is registered in the Register of Manufacturers of the EOF, in order to affix the CE marking on the medical devices (art. 14 of Joint Ministerial Decision DY8d/130648/2009).

On the other hand, every manufacturer of category IIa, IIb, 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 of the EU, which assesses their compliance with the legal requirements and issues a CE marking certificate (art. 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).

Consequently, medical devices that, in accordance with the above, bear the CE marking by the competent authority or a Notified Body of the EU are freely marketed in all countries of the European Union (points 40 and 37 of the MDR and IVDR preamble respectively, in conjunction with articles 4 of Joint Ministerial Decisions DY8d/130648/2009, DY8d/130644/02.10.2009 and Joint Ministerial Decision DY8d/3607/892/2001).

With regard to the post – marketing vigilance, the competent authority in Greece is EOF that has adopted the White Card system. The White Card is a tool for

collecting information on adverse events from the use of medical devices. In particular, HCPs have the obligation and patients – users have the right to complete the White Card whenever they suspect that a medical may have caused an adverse event. On the other hand, as far as the manufacturers are concerned, they are also obliged to report to EOF all serious incidents taking place within the Greek territory and for which they have been informed in every possible way, by submitting in English the following two types of reports: i) the Manufacturers Incident Report (MIR) form and ii) the Field Safety Corrective Action (FSCA) form. In particular, according to the abovementioned legislation on medical devices and in vitro diagnostic medical devices, the following data are reported 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 or user; and

(b) any technical or medical event relating to the characteristics or performance of a product which has led to the systematic withdrawal from the market by the manufacturer of products of the same type.

### 3. What is the regulatory process for food supplements, from first notification to the competent authorities until post-marketing vigilance in your country, and what regulations are applicable here? Please briefly describe.

#### Food Supplements

The regulatory process for food supplements is outlined in the Ministerial Decision G5a/53625/2017 (Government Gazette B' 3328/21.09.2017) on the Harmonization with Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements. Food supplements are not subject to a pre-approval and authorization regime by the competent regulatory authority but are only subject to a notification of their placing on the market to the EOF. For imported food supplements outside EU, the composition and the certificate of analysis of the producer are also notified (art. 10). According to EOF Circular No 55220/2009 on Health and Nutrition Statements, any reference to the product as 'approved' by EOF is unlawful and misleading.

With regard to post-marketing vigilance, if EOF, on the basis of new data or re-evaluation of existing data, concludes that the product poses a risk to human health, it may suspend or temporarily restrict distribution in

Greece, notifying its decision to the Member States and the European Commission (Article 12 of Ministerial Decision G5a/53625/2017).

### 4. What are the ongoing obligations in your country after a marketing authorization for medicinal products has been obtained or a conformity assessment been carried out for medical devices?

#### Medicinal products

As far as the MAH's ongoing obligations after the granting of the marketing authorization are concerned, they are described in detail in (art. 36, 38, 39 and 40).

Article 36 of the Joint Ministerial Decision DYG3a/32221/2013 (Government Gazette B' 1049/29.04.2013) provides that the National Organization for Medicines (EOF) may impose on MAH the obligation to conduct either a) a post-marketing **safety** study, if there are issues relating to the risks of an authorized medicinal product, or b) a post-marketing **efficacy** study when the knowledge on the disease or the clinical methodology suggest that previous efficacy assessments may need a significant revision.

Furthermore, according to article 38 of the abovementioned Ministerial Decision, the MAH shall also immediately inform EOF of any prohibition or restriction imposed by the competent authorities of any other country in which the medicinal product is marketed and of any new information which might influence the risk – benefit balance of the medicinal product concerned.

Article 39 of the abovementioned Joint Ministerial Decision provides that the MAH shall notify EOF of the exact date of the placement of the medicinal product in the Greek market. The MAH shall also notify EOF of any discontinuation (temporary or permanent), of commercialization of the product at least 3 months before discontinuation, unless there are exceptional circumstances justified by the MAH.

Moreover, in accordance with par. 4 and 5 of Article 40 of the above Ministerial Decision, if three (3) years after the issuance of the marketing authorization of the medicinal product, such product is not commercialized, or such commercialization is interrupted for three (3) consecutive years the marketing authorization is automatically invalid and may be revoked by EOF.

In order to ensure the continuous supply of the Greek market, the Greek legislator has enacted an additional

article 12A in the Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973), according to which any MAH of medicinal products, shall ensure the adequate and continuous supply of medicinal products to the market in order to meet the needs of patients in Greece.

The EudraVigilance database ensures the safe and effective use of medicinal products through the electronic exchange of individual case safety reports (ICSRs) between the EMA, national competent authorities, MAHs and clinical trial sponsors. The electronic submission of ICSRs is mandatory for MAHs either through either the centralized procedure of Regulation 726/2004 or through the national procedure of Directive 2001/83/EC, as well as for clinical trial sponsors.

### **Medical Devices**

After the conformity assessment of medical devices, the main ongoing obligation consists in the post – marketing vigilance. The competent authority in Greece is EOF that has adopted the White Card system. HCPs have the obligation and patients – users have the right to complete the White Card whenever they suspect that a medical device may have caused an adverse event. Manufacturers are also obliged to report to EOF all serious adverse events taking place in Greece by submitting in English the following two types of reports: a) the Manufacturers Incident Report (MIR) form and b) 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 or user; and
- b. any technical or medical event relating to the characteristics or performance of a product which has led to the systematic withdrawal from the market by the manufacturer of products of the same type.

### **5. Which are the competent national authorities having the regulatory oversight over medicinal products, medical devices, food, and food supplements and what are their respective responsibilities?**

The competent national authority having the regulatory oversight over medicinal products, medical devices,

special dietary foods, and food supplements is the National Organization for Medicines (EOF), established by Law 1316/1983 (Government Gazette A' 3/11/11.1.83) as an entity of public law subject to the Ministry of Health.

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

- receiving and approving applications for clinical trials and monitoring clinical trials in order to ensure compliance with GCP requirements;
- evaluating and approving products or acting as recipient of notifications concerning the placing on the market of products not subject to its authorization ;
- monitoring the manufacturing of products in order to ensure compliance with GMP, as well as with the legislation in force regarding their marketing;
- monitoring the quality, safety and efficacy of products falling within its scope of competence; and
- providing HCPs, HCOs, other stakeholders, and the general public with objective and useful information on products falling within its scope of competence.

### **6. Please briefly describe the procedure of challenging regulatory decisions (e.g., denial of marketing authorization) made by the competent regulatory authority in relation to medicinal products, medical devices, and food supplements.**

#### **Medicinal Products**

- a. When a marketing authorization for a medicinal product is rejected, the applicant appeals to the Committee for Medicinal Products for Human Use [article 49 of Joint Ministerial Decision DYG3a/32221/2013 Government Gazette B' 1049/29.04.2013)]. The Committee issues a decision on the petition within 60 days from filing. If the applicant's petition is rejected, the applicant may appeal to the Administrative Court of First Instance.
- b. Objections against the price bulletin issued by the Ministry of Health , may be raised by a petition of annulment before the Conseil D' Etat (ΣΤΕ), in accordance with the provisions of Presidential Decree 18/1989 (Government

Gazette A' 8/09.01.1989).

- c. Objections against the decision of the Ministry of Health for inclusion/non-inclusion in the Reimbursement List, may be raised by a petition of annulment before the Three-Member Administrative Court of Appeal, in accordance with the provisions of Presidential Decree 18/1989 and Law 702/1977 (Government Gazette A' 268/19/19.09.1977).

### **Medical Devices**

In Greece, EOF has the oversight of marketing, i.e. if the medical devices meet or not the legal requirements [article 2 par. 2, article 3 par. 1, I, article 6 par. 2 of Law 1316/1983 (Government Gazette A' 3/11/11.1.83) and the applicable MDR and IVDR provisions]. As such EOF may withdraw a medical device from the market, in which case the manufacturer may appeal to the Administrative Court of First Instance for the annulment of the EOF decision.

### **Food Supplements**

EOF is the designated and responsible authority for food supplements. If EOF decides that a food supplement does not meet the requirements set out in the law or is defective so that it cannot be placed on the market, the EOF may issue a withdrawal decision from the market [Articles 12 and 13 of the Ministerial Decision G5a/53625/2017 (Government Gazette B' 3328/21.09.2017)], in which case the producer/distributor may appeal to the Administrative Court of First Instance for the annulment of the EOF decision.

### **Administrative Fines**

For all the products (medicinal, medical devices and food supplements) for any fines imposed by virtue of Article 19 of the Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973), by EOF, the appeal is addressed to the Administrative Court of First Instance for the annulment of the EOF decision.

## **7. Please briefly describe the legal framework and the relevant regulatory procedure (e.g., application process, requirements, approval, denial) that applies in your jurisdiction to clinical trials for medicinal products and medical devices.**

### **Medicinal Products**

The legal framework applicable to clinical trials in Greece is laid down in the Regulation (EU) No 536/2014 of the

European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.

The provisions of the Regulation (EU) No 536/2014 were transposed in the Greek legal system by the Joint Ministerial Decision G5a/59676/2016 (Government Gazette B' 4131/22.12.2016) as amended.

In order to conduct a clinical trial in Greece, prior approval from the National Organization for Medicines (EOF) is required (art. 3) following an application file submitted in Greek via the EU portal, referred to in article 80 of EU Regulation 536/2014. For all other aspects, the application submission and the validation procedure are carried out in accordance with article 5 of EU Regulation 536/2014.

The application, the protocol of the clinical trial, the information material addressed to patients, the informed consent form, the labelling, the patient cards and the insurance contract have to be submitted in Greek. The other documentation of the file may be submitted in English but will be provided in an official translation into Greek, if requested by EOF.

The clinical trial is subject to scientific and ethical evaluation and is approved in accordance with article 8 of EU Regulation 536/2014. The scientific evaluation of the clinical trial is carried out by the EOF. If EOF has been granted the status of 'reporting' member state, it shall notify the sponsor and the other member states concerned of its status via the EU portal within six days of the submission of the application file (art. 5 of EU Regulation 536/2014).

As far as the ethical evaluation is concerned, it is carried out by the National Ethics Committee which drafts an assessment report on the part II in accordance with the procedure laid down in article 7 of EU Regulation 536/2014.

A positive scientific (by the EOF) and ethical (by the National Ethics Committee) assessment of the clinical trial is required for its approval. In case of a negative opinion by the National Ethics Committee, EOF rejects the application. In any case, EOF informs the sponsor on whether the clinical trial has been approved, whether its approval is subject to conditions or whether it has been rejected.

### **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 Regulation (EU) 2017/745 of the European Parliament and of the

Council of 5 April 2017 on medical devices ("MDR"), as well as in Section VI of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices ("IVDR"), as the case may be.

According to articles 62 of the MDR and 58 of the IVDR, both clinical investigations and performance studies are the subjected to an authorization 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. The Greek legislator has not yet enacted any national legislation for the purpose of implementing the aforesaid Regulations.

### **8. Is there a public database for clinical trials in your country, and what are the rules for publication?**

There is no national database for clinical trials in Greece. Only the central European EudraCT database provided for in article 80 EU Regulation 536/2014. In particular, in cases where clinical trials are to be conducted in Greece, prior approval from EOF is required following an application file submitted in Greek via the EudraCT database.

### **9. Please briefly summarize the rules that must be observed in your jurisdiction when using data from clinical trials?**

The use of medical and genetic data of individuals is mainly regulated by Regulation (EU) 2016/679 and its implementing Law 4624/2019 (Government Gazette A' 137/29.8.2019) which protects all personal data, especially sensitive data, such as medical and genetic data. The protection of genetic data processed for medical purposes is provided for by Law 2619/1998 (Government Gazette A'132/19.6.98) which ratified the Oviedo Convention and an important, non-binding, text that refers specifically to genetic data is the UNESCO Declaration on Genetic Data.

More specifically, the personal data from a clinical trial must be physically and technically secured to prevent any unlawful incident such as unauthorized access in the filing systems kept and to maintain the confidentiality of the information on the health status and medication of the participants. In addition, participants must be appropriately informed regarding the purpose, collection and any other processing of their personal data, must be able to exercise their data privacy rights and must have

provided their explicit consent to the use of their personal data.

### **10. Are there any trends and/or legislative proposals in your country on digitizing the process of conducting clinical trials (e.g., digitalization of the application process, decentralization of clinical trials)?**

A notable advancement is the digitization of the approval process for project funding and reimbursement overseen by the national Special Account for Research Grants (SARG), which approves the contract for the clinical trial, budget and other related documents. Through SARG website an electronic application seeking approval from SARG is filed for clinical trials conducted in university hospitals, enabling the automatic approval of the clinical trial related documents.

An important step towards decentralization is the adoption of a country clinical trial agreement template which is used by both public and private hospitals.

### **11. What are your country's legal requirements for the authorization of manufacturing plants for medicinal products, medical devices, food, and food supplements? Please briefly describe.**

#### **Medicinal Products**

According to article 58 of the Joint Ministerial Decision DYG3a/32221/2013 (Government Gazette B' 1049/29.04.2013), each manufacturing facility of medicinal products has to obtain a manufacturing license which is granted, under the following conditions: i) specify the medicinal products and pharmaceutical forms to be manufactured or imported, as well as the place of manufacture, ii) suitable and adequate premises, technical equipment, and control facilities and iii) at least one qualified person.

These requirements are further outlined in the Joint Ministerial Decisions DYG3a/7567/2008 (Government Gazette B' 1562 6.8.2008) and YA D3(a)/14709/2018 (Government Gazette B' 1152/29.3.2018), which had respectively implemented in the Greek legal order the EU Directive 2003/94/EC and the EU Directive (EU) 2017/1572 on Good Manufacturing Practices.

According to articles 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 minimize the risk of error and to permit effective maintenance in order to avoid both direct and cross-contamination and any undesirable effect on product quality.

#### **Medical Devices**

With regard to medical devices, there are no specific national legal requirements for the authorization of manufacturing plants and the provisions of the Annex XI – Part A of the MDR apply. In particular, the manufacturer shall ensure that the quality management system (ISO 13485: 2016) which is approved for the manufacture of the medical devices concerned is implemented.

Infrastructure includes, as appropriate:

- a. buildings, workspace, and associated utilities;
- b. process equipment (both hardware and software);
- c. supporting services (such as transport, communication, or information systems).

#### **Food supplements**

Article 10 of the Ministerial Decision G5a/53625/21.09.2017 provides that the manufacturers of food supplements in Greece must have been granted an establishment and operating license by the competent authorities following a positive opinion by EOF as set out in Article 3 of Law 1316/1983. For food manufacturing facilities, Annex II Chapter I of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs is applicable, according to which food the layout, design, construction, siting, and size of food premises shall:

- permit adequate maintenance, cleaning and/or disinfection, avoid or minimize air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
- be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
- permit good food hygiene practices, including protection against contamination and, in particular, pest control; and
- where necessary, provide suitable temperature-controlled handling and storage

conditions of sufficient capacity for maintaining foodstuffs at appropriate temperatures and designed to allow those temperatures to be monitored and, where necessary, recorded.

### **12. Please briefly describe the typical process of distributing medicinal products, medical devices, and food supplements in your country, encompassing, if applicable, the wholesale distribution of products.**

#### **Medicinal Products**

The supply chain of medicinal products in Greece starts from the MAH or local representative, and is divided into the two following distribution channels:

The first channel is that of hospital distribution, through which medicinal products are made available to patients in public hospitals and private clinics directly by the MAH/local representative, which is selling directly to public hospitals and private clinics, without the intermediation of any other link in the supply chain (due to the fact that hospital price is lower than the wholesale price).

The second channel is that of retail distribution to the final consumer through pharmacies. In this channel the MAH/local representative sells to the wholesaler at the ex-factory price and the wholesaler sells to the pharmacy at the wholesale price. The margin of the pharmacy is added to the final (retail) price to consumer.

#### **Medical Devices**

The applicable legislation regarding the distribution of medical devices is mainly set out in the Ministerial Decision DY8d/1348/16.01.2004 (Government Gazette B'32/16.1.2004), on the guidelines of GDP for medical devices, which aims to implement in the Greek legal order EU standards seeking to ensure that all medical devices released from the manufacturer's facilities for distribution are of appropriate quality. In particular, the aforementioned Ministerial Decision includes provisions regarding the requirements for transport and storage conditions, as well as the requirements applicable for the distribution plants and equipment and all relevant applicable procedures.

#### **Food supplements**

According to the current legislation in force [art. 11 of the Ministerial Decision YA G5a/53625/2017 (Government

Gazette B' 3328/21.09.2017)), the distribution and sale of food supplements is allowed to be performed both by pharmacies and other retail stores that are allowed to sell packaged foodstuffs. In particular, the products must be placed in a special area, clearly marked 'food supplements', which must be displayed in a central and prominent place in the display case.

### 13. Please briefly describe the pricing and reimbursement rules, if any, for medicinal products, medical devices, and food supplements in your jurisdiction?

#### Medicinal Products

##### Pricing rules

Prescription – only medicinal products: According to the combined interpretation of the Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973) and the Ministerial Decision YA D3(a)/6295/2024 (Government Gazette B'1100/15.02.2024), the maximum prices for prescription – only medicinal products [i.e., the retail price, the wholesale price, the hospital – sale price, the manufacturer price (ex-factory)], except for over – the – counter medicinal products (OTC), are determined by means of Price Bulletins issued by the Minister of Health, following the opinion of the National Organization for Medicines (EOF) (art. 17 of the Legislative Decree 96/1973). The MAH/local representative applies before the pricing department of EOF after the granting of an EOF or EMA marketing authorization.

Original medicinal products, are priced in accordance with a median of the two lowest prices of two member States of the Eurozone (in order to be priced, the product has to have a price in at list three countries of the Eurozone).The same applies for off patent medicinal products (original products following expiration of their market exclusivity). Generic products are priced at 65% of the price of the original product, while biosimilars are priced with the same method of their originals (two lowest prices in the Eurozone).Non-prescribed pharmaceutical products (OTC) are priced in accordance with a median of three lowest prices of three EU Member States. This price is not obligatory for the retail channel (pharmacies) however it is mandatory when sales are made to hospitals. The final price of all the above categories of products is the ex-factory price on which the wholesale margin and the retail margin is 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%.

##### Reimbursement rules

According to article 1 (par. 2) of Law 3457/2006 (Government Gazette A' 93/8.5.2006), the medicinal products that, according to their marketing authorization, are classified as OTC are not reimbursed by the State or the social security institutions. On the contrary, the reimbursement rules regarding prescription – only medicinal products are found 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 a prescription – only medicinal product to be reimbursed, it first needs to be enlisted in the positive catalogue of reimbursed medicinal products provided for in the abovementioned article 12 of Law 3816/2010. The inclusion of a medicinal product in this positive catalogue requires a relevant Ministerial 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), which is based at EOF and answering to the Minister of Health (art. 247 of Law 4512/2018). It is to be noted that the Minister of Health may decide otherwise from the opinion of the Evaluation Committee, on the basis of a justified decision based on the following criteria (art. 249 of Law 4512/2018):

- a. the clinical benefit, as assessed considering the severity and burden of disease, the effect on mortality and morbidity rates, as well as safety and tolerability data;
- b. the comparison with already available reimbursed drug therapies;
- c. the level of reliability of clinical trial data;
- d. the cost-effectiveness ratio; and
- e. the impact on the State budget.

In particular, the administrative process for the evaluation of a prescription – only medicinal product, in order to be included to or removed from the positive catalogue of article 12 of Law 3816/2010, commences with an application of the MAH before the Evaluation Committee, accompanied by a complete file with the information and documents, after having paid an one – off evaluation fee, determined by a Joint Ministerial Decision of the Ministers of Finance and Health.

Before the Evaluation Committee gives its opinion to the Minister of Health and in order to evaluate the cost-effectiveness ratio and the impact on the state budget from the inclusion or exclusion of a prescription – only medicinal product to the positive catalogue of article 12 of Law 3816/2010, it must refer for an opinion to the Drug

Price Negotiation Committee (Negotiation Committee), which is also based at EOF and answering to the Minister of Health and is responsible for negotiating the prices or discounts of medicinal products reimbursed by the National Organization for Health Care Services or supplied by public hospitals.

The Negotiation Committee initiates and concludes the negotiation procedure for the medicinal product by issuing a justified opinion, based on the outcome regarding the impact on the State budget of including or removing a medicinal product from the positive catalogue of article 12 of Law 3816/2010. The Evaluation Committee shall take into account the justified opinion of the Negotiation Committee for its final justified opinion to the competent body of the Ministry of Health regarding the inclusion or removal of a prescription – only medicinal product from the positive catalogue of article 12 of Law 3816/2010.

#### **Medical Devices and Food Supplements**

The reimbursement of medical devices and food supplements is regulated under article 108 of Law 4461/2017 (Government Gazette A' 38/28.3.2017). In particular, for the reimbursement of medical devices as well as food supplements for special medical purposes (FSMPs) or special dietary foods for the treatment of metabolic diseases, it is compulsory for the importer/manufacturer/representative of these products to submit to EOPYY a solemn declaration stating (i) that the items are registered both in the registers of EOF and in the registers of reimbursable products of EOPYY, as well as their registration in the Price Observatory, if the product is registered in the latter and (ii) that the product in question is marketed in at least three countries of the European Union.

In a separate solemn declaration, submitted electronically once a year, the three lowest purchase prices at which the product in question is priced within the European Union. The reimbursement price of the product shall be determined by a maximum of the average of the three lowest market prices in the countries of the European Union.

### **14. What legislative framework applies to the advertising for medicinal products, medical devices, and food supplements in your country?**

#### **Medicinal Products**

- Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973) on the trading of

pharmaceutical and cosmetic products (Article 16 par. 1-2).

- Ministerial Decision Y6a/22261/2002 (Government Gazette B' 284/8.3.2002) on the advertising of medicinal products that may be administered without prescription (over the counter (OTC) medicinal products).
- Joint Ministerial Decision DYG3a/32221/2013 (Government Gazette B' 1049/29.04.2013) on the implementation of Directive 2001/83/EC of the European Parliament and of the European Council on the Community Code relating to medicinal products for human use (Articles 118-132).
- Circular Nr. 16251/13.02.2019 concerning the notification procedure of the advertisements of medicinal products to EOF.
- Circular Nr. 37201/23.3.2020 concerning scientific events issued by EOF.
- EOF has recently issued a relevant Notice dated 24.05.2021 regarding advertising/informational material accompanied by a relevant Q&A memo.

#### **Medical Devices**

Legal provisions pertaining to the advertising and promotion of medical devices can mainly be found both in the MDR and the IVDR (art. 7 respectively) which define the necessary content of advertisements, as well as the basic principles to be followed when addressing the public.

#### **Food supplements**

The advertisement of food supplements is mainly regulated by the Ministerial Decision G5a/53625/2017 (Government Gazette B' 3328/21.09.2017) (art. 6 and 7) which sets out the basic rules for the necessary content of advertisements, as well as the basic principles that must be observed regarding their address to the public. Additionally, the Circular of EOF No 55220/2009 on Health and Nutrition Statements also applies with regards to the prohibition of any reference to the product as 'approved' by EOF.

### **15. What laws apply to patents and trademarks for medicinal products, medical devices, and food supplements in your country?**

The general legal provisions applicable to trademarks and patents of all products in question, are:

#### **Patents**

- Convention on the Grant of European Patent (European Patent Convention) of October 5, 1973;
- Law 1607/1986 for the ratification of the Convention on the Grant of European Patent (Government Gazette A' 85/30.06.1986), as amended;
- Law 1733/1987 on Technology transfer, patents, inventions, technological Innovation and the establishment of the Atomic Energy Commission (Government Gazette A' 171/18-22.04.1987), as amended;
- Presidential Decree 77/1988 for specific provisions on the implementation of the International Convention on European Patents, as ratified by Law 1607/1986 (Government Gazette A' 33/25.02.1988);
- Law 1883/1990 for the ratification of the International Convention on the Patent Cooperation (Government Gazette A' 45/22-29.03.1990);
- Presidential Decree 16/1991 for specific provisions on the implementation of the International Convention on the Patent Cooperation, as ratified by Law 1883/1990 (Government Gazette A' 6/7-24.01.1991);
- Law 3396/2005 for the ratification of the Revision Act of the Convention on the Grant of European Patent dated 29 November 2000 (Government Gazette A' 246/06.10.2005);
- Regulation (EU) 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection;
- Regulation (EU) 1260/2012 of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements;

#### **Trademarks**

- Directive (EU) 2015/2436 on the approximation of the laws of the Member States relating to trademarks;
- Law 4679/2020 on Trademarks – implementation of Directive (EU) 2015/2436 on the approximation of the laws of the Member States relating to trademarks and Directive 2004/48/EC on the enforcement of intellectual property rights (Government Gazette A' 71/20.03.2020), as amended;

In addition to the above generic legal framework, and

specifically with regard to medicinal products, the following are also applicable on the supplementary protection certificate for medicinal products:

- Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products;
- Ministerial Decision 33486/2020 on the procedure for notification to the Industrial Property Organization of the commencement of manufacturing in Greece of a medicinal product protected with a supplementary protection certificate, in accordance with the Regulation (EU) 2019/933 of the European Parliament concerning the supplementary protection certificate for medicinal products (Government Gazette B' 1258/09.04.2020);

#### **16. Please briefly describe how patent infringements in relation to medicinal products and medical devices are addressed in your jurisdiction, including possible defense strategies and legal proceedings against patent infringements.**

In Greece pursuant to Article 17 of Law 1733/1987 (Government Gazette A' 171/18/22.4.87), the patent owner possesses the right to demand the cessation of ongoing infringement and the prevention of future violations. This entails actions such as withdrawing, permanently removing, or destroying infringing goods from the market. Seeking injunctive relief from the competent court aims to halt the sale or distribution of infringing products. The patent owner may also pursue monetary (both direct and indirect) damages incurred due to the infringement.

Defendants of infringement claims may contest the patent's validity, challenging "novelty", "originality," and "industrial applicability". While a presumption of validity is established upon patent grant, it remains subject to challenge, allowing for disputes over its legitimacy.

#### **17. Does your jurisdiction provide for restrictions on the use of trademarks for medicinal products, medical devices, food, and food supplements?**

There are no legal provisions applying trademark restrictions for medicinal products, medical devices, and food supplements. Any general restrictions are contained

in the national law 4679/2020 (Government Gazette A' 71/20.03.2020), incorporating EU Directive 2015/2436 and Directive 2004/48/EC on intellectual property rights enforcement.

### 18. Please briefly describe the product liability regime for medicinal products, medical devices, and food supplements in your country.

Civil liability for defective medicinal products, medical devices, foods, and food supplements, falls within the general framework of liability for defective products established by Directive 85/374/EEC, which has been implemented into Greek legislation by the article 6 of Law 2251/1994 (Government Gazette A' 191/16.11.1994), and Directive 2001/95/EC on general product safety which has been implemented into Greek legislation by the Joint Ministerial Decision Z3/2810/2004 (Government Gazette B' 1885 20.12.2004).

In the context of this specific provision of article 6, the manufacturer is objectively liable, irrespectively of fault, for any damage caused by a defect in the product (paragraph 1) and is exempted if he proves the existence of certain conditions that exclude its liability (paragraph 8), including that the defect did not exist when the product was placed in the market. The plaintiff i.e., the consumer, in his action for compensation has the obligation to plead and prove a) the defect and the identity and its connection with the defendant manufacturer or with the other persons assimilated to him in terms of liability (paras. 2 – 4), b) his damage and c) the causal link between the defect and the damage, which includes damage due to death or personal injury (para. 6). On the other hand, in order to exclude the liability of the manufacturer and the other persons liable in the same way, they must plead and prove the existence of one of the below reasons for their exemption, according to para. 8:

- that the product has not been placed into the market;
- that the defect did not exist when the product placed put into the market;
- that the product was not manufactured for the purpose of distribution in the course of a commercial activity;
- that the defect is due to the fact that the product was manufactured in accordance with rules of mandatory law.

### 19. Please provide a short overview of risks of

### liability (criminal liability, serious administrative / civil liability) and enforcement practice with regards to medicinal products (including biologicals), medical devices, foods, and food supplements.

The basic legal provision for the establishment of criminal and administrative liability is Article 19 of the Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973). The administrative fines are set of Article 175 of the Joint Ministerial Decision DYG3a/32221/2013 (Government Gazette B' 1049/29.04.2013), which makes reference to the administrative and criminal violations of paragraph 11 of Article 19 of the Legislative Decree 96/1973.

For any violation of the provisions regulating the production, distribution, importation, brokerage of all products (including active substances and excipients) for which EOF is competent (medicinal products, medical devices, food supplements) an administrative fine up to One Hundred Thousand Euro (100,000.00€) may be imposed to the MAH, wholesaler or broker as the case may be, depending on the endangerment of public health and the severity of the violation. For the violation of the provisions regulating promotion of the medicinal products an administrative fine up to one Forty-Four Thousand Euro (44,000.00€) may be imposed.

If the above violations are repeated then in the first case, the responsible person for such violation faces a penalty of imprisonment of up to one (1) year and in the second a penalty of imprisonment of at least six (6) months up to five (5) years.

### 20. Does your jurisdiction provide for a specific legislative and regulatory framework for digital health applications (e.g., medical apps)? If yes, please briefly describe the relevant framework.

- Law 4670/2020 (Government Gazette A' 43/28.02.2020) (art. 11) on the issuance of medical certificates and reports via the Electronic Prescription System of IDIKA AE (e-Government Center for Social Security Services)
- Law 4655/2020 (Government Gazette A' 16/31.1.2020) (arts. 4 and 5), establishing the digital "Application for the distribution of high-cost medicines" accessible by patients entitled to high-cost medicines
- Law 4690/2020 (Government Gazette A' 104/30.05.2020) (art. 19) on the provision of

health services to patients with COVID-19 via digital infrastructure

- Law 4704/2020 (Government Gazette A' 133/14.07.2020) (art. 13) regulating the electronic prescription system.
- Law 4727/2020 (Government Gazette A' 184/23.09.2020) concerning Digital Governance and Electronic Communications, incorporates EU Directives (2016/2102, 2019/1024, 2018/1972) and focuses on digital governance aspects within the public sector. It aims to create a fundamental framework for the development of the Digital State. Article 11 of this legislation specifically governs the implementation of identification numbers for citizens in various technology systems, including the health sector.
- Law 3984/2011 (Government Gazette A' 150 27.6.2011), article 66 par. 16 specifying that telemedicine services are offered whenever feasible and within the purview of the attending physician addressing the specific case.
- Ministerial Decision DY8d/G.P.oik.130648/2009 (Government Gazette B' 2198/02.10.2009), regulates a) Robotical assisted surgical (RAS) devices, which are classified as medical devices, b) Medical apps that qualify as an accessory to medical devices for recording and managing medical data, that convert the smart device into a medical device by incorporating additional sensors, and/or form an integrated medical software system offering personalized diagnoses to aid clinical decision-making.
- Law 4753/2020 (Government Gazette A' 227/18.11.2020) in Greece addresses key issues related to digital platforms and the implementation of EU Regulation 2019/1150 on fairness and transparency in online intermediation services. It emphasizes concerns like data security, legality of processing, defining retention periods for diverse data categories, ensuring safeguards for cross-border data transfers, and protecting patients' sensitive data confidentiality. Moreover, the law highlights the importance of considering restrictions on online sales (e.g., prescription medicine) and associated advertising limitations, especially within the context of medical activity and ethics.

**21. Does your jurisdiction provide for laws or certain legal measures to ensure the supply of medicinal products and medical devices, or are such rules envisaged in the future? If yes, please briefly describe those rules.**

#### Medicinal Products

Article 39 of the Joint Ministerial Decision DYG3a/32221/2013 (Government Gazette B' 1049/29.04.2013) provides that the MAH shall notify EOF of the exact date of the placement of the medicinal product in the Greek market. The MAH shall also notify EOF of any discontinuation (temporary or permanent), of commercialization of the product at least 3 months before discontinuation, unless there are exceptional circumstances justified by the MAH.

Moreover, in accordance with par. 4 and 5 of Article 40 of the above Ministerial Decision if three (3) years after the issuance of the marketing authorization of the medicinal product, such product is not commercialized, or such commercialization is interrupted for three (3) consecutive years the marketing authorization is automatically invalid and may be revoked by EOF.

With regard to the continuous supply of the Greek market, pursuant to the par. 6 of art. 19 and par. 4 of art 8 of the Legislative Decree 96/1973 (Government Gazette A' 172/3/8.8.1973), the Greek legislator, has provided for criminal and administrative liability of the MAH. In particular, each MAH is obliged to supply the market with the products it imports or produces. In the event of his inability to do so, or before any change which may affect the market in terms of supply or price, he must notify EOF in writing at least 3 months in advance. If the MAH does not comply with this obligation, then an administrative fine of Forty-Four Thousand Euro (44,000.00€) is imposed and in case of repetition, the offence is prosecuted and punished with a monetary (criminal) penalty and imprisonment up to 6 months and revocation of the marketing authorization of the products concerned.

Finally, the Greek legislator, with the aim to limit the phenomenon of parallel exports of medicinal products, has enacted an additional Article (12A) in the Legislative Decree 96/1973, according to which any wholesaler or any MAH of medicinal products, shall ensure the adequate and continuous supply of medicinal products to the market in order to meet the needs of patients in Greece. In case of a shortage of medicinal products due to a breach of the above obligations by the wholesaler or the MAH, a fine of Thirty Thousand Euro (30,000.00€) up to One Million Euro (1,000,000.00€) may be imposed by

decision of the Minister of Health.

### **Medical Devices**

There are no specific legal provisions or regulatory decisions for the supply of medical devices in the Greek market.

## **22. Are there any specific compliance standards in your jurisdiction for the marketing of medicinal products and medical devices (e.g., codes of conducts of industry associations, etc.)? If yes, please give a brief overview of the relevant standards.**

### **Medicinal products**

Currently in Greece the following industry codes are applicable for medicinal products:

- The Code of Ethics of the Hellenic Association of Pharmaceutical Companies (SFEE, as per its Greek acronym), which regulates, inter alia, the promotion of pharmaceutical products by its members, also provides the principles that govern promotional and advertising activities. It is aligned with the EU and Greek legislation and regulatory framework and the Code of the European Federation of Pharmaceutical Associations (EFPIA). An updated version of the SFEE Code of Ethics was released during 2023.
- SFEE Disclosure Code which requires all SFEE member companies to disclose details on their transfers of value to Healthcare Professionals (HCPs) or Healthcare Organizations (HCOs);
- SFEE Code of Practice on the relationship between pharmaceutical companies and patient organizations, as amended by the resolution of the 12.9.2014 SFEE Extraordinary General Assembly with effect from 1.10.2014;
- SFEE Code of Practice for the Promotion of Prescription only Medicinal Products (latest edition 2008-2009)

### **Medical Devices**

The applicable industry codes for medical devices are provided by the Association of Enterprises of Medical & Biotechnological Products (SEIB, as per its Greek acronym) and consists in the following:

- SEIB Code of Conduct, which includes, inter alia, instructions and guidelines for the

distribution of medical devices or issues concerning events of scientific interest and clinical trials of medical devices.

- SEIB Guidelines for the Protection of Free Competition
- SEIB Code of Ethical Professional Practice, which mainly regulates the interactions with Healthcare Professionals (HCPs) or Healthcare Organizations (HCOs).

## **23. Please state 3-5 key decisions by courts or regulatory authorities that have been issued recently and that are relevant for the life sciences sector.**

Decision 2214/2023 of the Conseil D' Etat (ΣΤΕ) confirmed the legality of EOF's decision to impose temporary bans on exports of certain pharmaceutical products, emphasizing its responsibility to safeguard public health in this regard by ensuring the availability of approved medicinal products within the country. The Conseil D' Etat decision rejected the petition of the wholesalers union to annul a decision of EOF for a temporary ban of exports. It accepted the competence of EOF to take precautionary measures, even in the absence of confirmed shortages, to avoid potential risks to the availability, safety, and quality of medicines. Finally, the decision confirmed the compliance of the EOF's actions with both Greek legislation and EU regulations, which actions protect patients' access to essential pharmaceutical products.

Decision 162/2020 of the Conseil D' Etat (ΣΤΕ): In its decision 162/2020, the Conseil D' Etat (ΣΤΕ) ruled that the imposition of automatic claw back (proportional return of the amount invoiced by a pharmaceutical company and exceeding the yearly budget of the Ministry of Health for pharmaceutical products) for orphan drugs (rare disease pharmaceutical products), is illegal. Specifically, the Court stated in its reasoning that, under article 9 par. 1 of Regulation no. 141/2000/EC, the Member States of the European Union must encourage the marketing of orphan medicinal products. In this decision, the Court, taking into account Regulation 141/2000/EC, as well as national legislation, in particular article 5 of the Greek Constitution, ensuring the protection of economic freedom decided that orphan medicinal products should be excluded from the claw-back mechanism, as the consequences of its application to the category of orphan medicinal products are disproportionate to the legitimate aim of limiting hospital expenditure.

Decision 1019/2022 of the Conseil d'Etat (ΣΤΕ): By this decision, the Council of State addressed a petition for

annulment of the Ministerial Decision No. G5(a)/69976/2015 of the Minister of Health brought by the Hellenic Association of Pharmaceutical Companies (SFEE, as per its Greek acronym), which obliges the MAHs to refund the wholesale profit margin when the latter sell directly to pharmacies, bypassing the intermediate link in the supply chain, i.e. the wholesalers. The obligation imposed on MAHs to refund the wholesaler's mark – up profit margin to the EOPYY is justified in the case in question, since the wholesaler's profit margin is included in the price of the medicinal products as a legitimate profit for the wholesalers. Otherwise, the MAHs would end up making both their own profit and the wholesalers' profit. Therefore, the relevant obligation to refund the wholesaler's profit margin constitutes a legitimate constitutional restriction on the economic freedom of the pharmaceutical companies – MAHs.

**24. What, if any, are the key legal and regulatory trends in your jurisdiction with regards to the digitalization of the local healthcare system and with regards to the use of artificial intelligence in the life sciences sector? Please briefly describe.**

The digitalization of the local healthcare system is focused on the implementation of a digital patient record and the promotion of telemedicine. More specifically, Greece has implemented a centralized system of electronic appointments in all hospitals in the country and the digital issuance of medical examinations and hospitalization certificates obtaining for the first time a digital patient record and history. Regarding telemedicine and teleconsultations, provision of remote advice by doctors is to be extended. This initiative, is important for remote and island regions, as it puts remote doctor-patient communication in a clear framework.

The uses of artificial intelligence in the life sciences sector that are particularly interesting are the following:

- a. Clinical management support. Busy clinicians, can leverage the capabilities of Generative Artificial Intelligence to create draft clinical notes quickly and accurately.
- b. Clinical decision support. Given the advanced understanding of human language, GPT models also have the potential to support clinical decision making.

- c. Patient support. Focus is given on the patient and his/her needs with the healthcare professionals prioritizing generative AI empathy, the quality of care, compassion, and the creation of patient-friendly responses.
- d. Synthetic data generation. Utilizing productive AI to produce realistic synthetic patient records from real medical records while protecting patient privacy.

**25. Please briefly highlight 3-5 key developments or trends in your jurisdiction with regards to the life sciences sector as you consider them relevant. This may include legislative proposals, market activity, etc.**

- a. Incentives by the Greek Government to pharmaceutical companies' industries in order to invest more in clinical research. A recent legal initiative provides that pharmaceutical companies may off-set the amounts paid as automatic reimbursements to the state (amounts paid for exceeding the budget of the Ministry of Health) against their expenditure on research activities. This measure is now financed by the Recovery and Resilience Fund.
- b. The process for conducting clinical studies has been simplified, by the adoption of a country clinical trial agreement template which is used by both public and private hospitals.
- c. Greece in 2010 was one of the lowest countries in the European ranking of generic drug use, where only 15% of the medicinal products sold were generic or biosimilar products. Following extensive changes in the legislation a sustained and steady increase in the use of generic medicines has been observed since from 2010 to 2022 and the total consumption reached 32,6% in total with a rate of increase during 2022 of 8.5%.
- d. A significant number of companies (mostly Greek owned generic drug producers but also foreign manufacturing companies) have invested in building of manufacturing facilities. During the past 3 years 3 large manufacturing units have begun operating in Tripoli and in Attiki, a development not very common during the past 20 years.

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