The Pharma Legal Handbook

Greece

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs

PHARMA BOARDROOM

Greece

The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Greece.
It is a must have for any company operating in the country or looking to enter the market.

Prepared in association with CALAVROS LAW FIRM, a leading greek law firm. It should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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CALAVROS LAW FIRM
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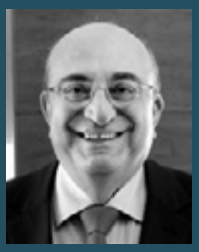
Established in 1980 Calavros Law Firm – Filios – Babiniotis – Kloukinas is a leading and one of the most esteemed law firms in Greece. Managed by a forward-thinking team of partners under the leadership of Professor Constantin Calavros, with offices in Athens, Thessaloniki and Corfu, the Firm enjoys a widely established reputation for its commitment to providing top quality, comprehensive and business-oriented legal services.

The Firm currently employs 45 exceptional, highly qualified professionals including lawyers, academic consultants, trainee lawyers, paralegal assistants, computer experts and administration staff, all dedicated to providing full, tailor-made services that meet all of our clients' needs. Most of the lawyers we employ have postgraduate degrees from foreign universities or hold academic positions in law schools. They all have long experience in a wide range of practice areas.
To achieve excellence in results we take extra care in keeping close, personal contact with our clients. We strive to be proactive, anticipate their needs and provide them with timely and reasonable solutions, ensuring that the work we do and the services we deliver are consistently of the highest quality: commercial acumen, meticulous attention to detail, responsiveness and 360 quality services are the cornerstones of our law practice.

Due to this mentality we have structured the Firm in such a way as to enable us to cooperate effectively with the very best law firms in the world and maintain a solid pan-European co-operation network. For the past thirty years we have been successfully representing private clients, large multinational companies, public bodies and the Greek State in numerous significant law cases. The fact that today our company ranks among the top law firms in Greece is in line with our outstanding level of performance and consistently exceptional results.

THE AUTHORS



CONSTANTIN CALAVROS

FOUNDER AND MANAGING PARTNER

Professor Constantin Calavros is the founder and managing partner of Calavros Law Firm - Filios - Babiniotis - Kloukinas.

He is a Professor of Civil Procedure and International Arbitration Law at the Democrition University of Thrace. Professor Calavros heads the litigation and dispute resolution department of the Firm. He specializes in national and international litigation and arbitration. He has represented numerous clients before national courts of all degrees, the European Union Court in Luxembourg and the International Chamber of Commerce (ICC).

Professor Calavros also deals with restructuring and companies' reorganisation, outsourcing and insolvency procedures. He has supervised and advised on some of the largest and most high-profile deals in the Greek market that range from corporate reorganisations to debt restructuring (including distressed debt and NPLs), and formal insolvency such as bankruptcy, judicial composition or liquidation. In this regard, he has acted as an advisor to Greek state controlled companies, Greek Government and ministers, especially in relation to privatization initiatives.

Professor Calavros acting as an external advisor to the Greek Association of Pharmaceutical Companies (SFEE) has also obtained in depth experience in pharmaceutical law and competition law matters.

Professor Calavros has been a member of various drafting committees which have revised Greek Civil Procedure Code.

CHRISTIAN FILIOS

PARTNER

Christian P. Filios has been a partner at Calavros Law Firm - Filios - Babiniotis - Kloukinas since 2007.

He is an Associate Professor of Civil Law (Law of successions and Law of obligations) at the Democritus University of Thrace. He heads the civil and commercial litigation department of the Firm. He specializes in domestic and international litigation and arbitration with particular focus on bank related matters. He has represented individual clients and companies before domestic courts up to the Supreme Court level, and the International Chamber of Commerce (ICC). He is also highly experienced in matters of collection of debts from public entities and private companies, distribution and agency agreements, competition law matters and matters of unfair practices. He has acted as external counsel to major national and multinational constructions and wind energy companies.

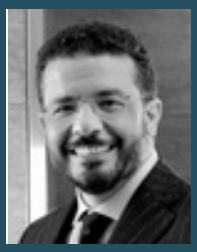
THE AUTHORS

CHRISTINA CALAVROU

PARTNER DIRECTOR

Christina C. Calavrou has been a partner at Calavros Law Firm - Filios - Babiniotis - Kloukinas since 2007.

She is active in the fields of civil and commercial litigation and pharmaceutical legislation. She heads the team of lawyers which deals with the claims of major pharmaceutical companies in Greece against public hospitals for debts and has successfully protected the claims of our clients. She also heads the team of lawyers which deals with outstanding claims of several bank institutions. Mrs. Calavrou is also acting as external advisor to pharmaceutical companies in Greece and all over the world.



DIMITRIS G. BABINIOTIS

PARTNER

Assistant Professor Dr. Dimitrios Babiniotis has been a partner at Calavros Law Firm - Filios - Babiniotis - Kloukinas since 2010.

He is an Assistant Professor of Civil Procedure Law at the Democrition University of Thrace. Dr. Babiniotis is an experienced litigator and specializes in Supreme Court (Areios Pagos) review proceedings. Dr. Babiniotis also deals with high-profile, complex litigation, appearing before state and arbitration courts at both trial and appellate levels. He has over ten years of legal experience in business disputes, family law matters, product liability cases and alternate dispute resolution by arbitration. While primarily a litigation lawyer, Dr. Babiniotis is also a keen consultant and he frequently advises clients, both companies and individuals, from the industry. He deals with commercial contracts, joint ventures, mergers, public private partnerships and structured finance, as well.

ATHANASIA GKOUMA

SENIOR ASSOCIATE

Athanasia K. Gkouma has been senior associate at Calavros Law Firm - Filios - Babiniotis - Kloukinas since 2017. She graduated from the National and Kapodestrian University of Athens Law school and holds an LL.M in Health Law from the Toulouse 1 Capitole University.

Athanasia regularly advises clients active in the field of Pharmaceuticals and Medical Devices as regards their everyday practice, while her extended litigation experience primarily involves the pre-contractual stage of public tender procedures.

IRIS NTOLAPTSI

ASSOCIATE

Iris G. Ntolaptsi has been an associate at Calavros Law Firm - Filios - Babiniotis - Kloukinas since 2018. She was admitted to the Athens Bar in 2014 and holds an LL.M. in Private International Law from the National and Kapodestrian University of Athens and an LL.M. in Commercial Law from the Université Paris 13.

Iris specializes in dispute resolution with a focus on civil, commercial and banking litigation. She represents clients on a variety of domestic and cross-border disputes, including breach of contract, product liability and disputes arising from the performance and termination of commercial agreements. Iris also regularly advises clients on real estate issues and commercial lease agreements.

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FILIOS • BABINIOTIS • KLOUKINAS

DealMakers

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2013 LEGAL AWARDS WINNER

Athens

19 Vrana Str., 115 25
Athens, Greece
+30 210 3698700
+30 210 3698750
athens@calavros.gr

Thessaloniki

2 Salaminos Str., 546 26
Thessaloniki, Greece
+30 2310 500 770
+30 2310 500 771
hessaloniki@calavros.gr

Corfu

2 Salaminos Str., 546 26
Thessaloniki, Greece
+30 2310 500 770
+30 2310 500 771
hessaloniki@calavros.gr

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01

REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

3. What are the steps to obtaining authorization to develop, test, and market a product?

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The National Organization for Medicines (hereinafter referred to as E.O.F.) which was established in 1983 as a public entity of the Ministry of Health by virtue of Law 1316/1983, constitutes the main national regulatory authority with regard to medicinal products for human and veterinary use, drugs, foodstuffs intended for particular nutritional uses and food supplements, biocides, cosmetics and medical devices in Greece.

Within the framework of its mission to ensure public health and safety, E.O.F., in cooperation with the European Union, is endowed with the following powers:

- Evaluates and authorizes new, safe and efficient health - related products.
- Monitors the post-marketing product quality, safety and efficacy.
- Monitors product manufacturing procedures, clinical studies and the marketing of products, in order to ensure compliance with good manufacturing, laboratory and clinical practice, as well as with the existing legislation regarding the marketing, distribution, commercialization and advertising of the products.
- Develops and promotes medical and pharmaceutical research.
- Provides health scientists, competent authorities, and the general public with objective and useful information regarding medicines (for human or veterinary use) and other products, in order to ensure their rational use and provide an assessment of their cost-effectiveness.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

The regulatory framework for the authorization of pharmaceutical products is mainly governed by Interministerial Decision D.YG3α/G.P. 32221/ Government Gazette B 1049/2013 issued in application of 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 in force and amended by Directive 2011/62/EU as regards the prevention of the entry into the legal supply chain of falsified medicinal products read together with Legislative Decree 96/1973, as currently in force.

Furthermore, pricing and reimbursement of pharmaceutical products falls within the scope of Ministerial Decision No. G5(a) 90552/Government Gazette B 3890/2016 on the setting of pharmaceutical prices, as amended by Ministerial Decisions G5(a) 97012/Government Gazette B 4215/2016 and G5(a) 11601/Government Gazette B 445/2017. It should be noted that in light of provision 17 of Legislative Decree 96/1973, the maximum retail, wholesale, hospital and ex-factory price, as well as any other special sale price of medicinal products - with the exception of non-prescription medicinal

products- are defined by the relevant Price Bulletins, issued twice a year by the Minister of Health and uploaded to the official website of the Ministry of Health, following an opinion provided by E.O.F.

The field of medical devices is mainly regulated by Interministerial Decision DY8d/G.P. 130648/Government Gazette B' 2198/2009, issued in application of Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended by Directives 98/79/EC, 2000/70/EC, 2001/104/EC, 2007/47/EC and Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003.

The general standards for the good production and control of medical devices are laid down in Decision 6209 of E.O.F.'s Board of Directors (published on Government Gazette B'/199/06.02.2009).

Several Interministerial and Ministerial Decisions in force govern specific types of Medical Devices, such as, indicatively, Interministerial Decision DY8d/130644/Government Gazette B' 2197/2009 issued in application of Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices and Interministerial Decision DY8d/G.P. 3607/Government Gazette B' 1060/2001 issued in application of Directive 98/79/EC on in vitro diagnostic medical devices.

However, it should be noted that on 5 April 2017, two new European Regulations on medical devices were adopted and entered into force on 25 May 2017. These Regulations will eventually replace the existing Directives as on medical devices. More specifically:

- **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017 on medical devices, was adopted in substitution of Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, also repealing Council Directives 90/385/EEC and 93/42/EEC and
- **Regulation (EU) 2017/746** of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices repeals Directive 98/79/EC as well as Commission Decision 2010/227/EU.

The above mentioned new European legislation will become effective after a transitional period, namely 3 years following entry into force of the Regulation on medical devices (26.05.2020) and 5 years following entry into force of the Regulation on in vitro diagnostic medical devices (26.05.2022). It may be noted that the new Regulations provide for the validity of existing certificates issued under the Directives and Interministerial Decisions currently in force for a term following the progressive entry into force of the EU Regulations, as provided therein.

3. What are the steps to obtaining authorization to develop, test, and market a product?

MANUFACTURE AUTHORIZATION

The specific procedure to be followed is mainly laid down in Interministerial Decision D.YG3α/G.P.32221/Government Gazette B' 1049/2013 on the manufacture and marketing of medicinal products for human use. More specifically, the process of manufacture of medicinal products is stipulated under section IV of the aforesaid Interministerial Decision. By virtue of article 57 thereof,

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