The Life Sciences Law Review

Fourth Edition

Editor
Richard Kingham

Law Business Research

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EDITOR'S PREFACE

The fourth edition of *The Life Sciences Law Review* provides an overview of legal issues of interest to pharmaceutical, biotechnology and medical device companies in more than 30 jurisdictions. As before, each chapter contains information on legal requirements relating to the key stages in the life cycle of a regulated product, from discovery, through the clinical development process, registration, manufacturing and promotion, plus other issues of special interest, such as pricing and reimbursement, special liability regimes, competition and commercial transactions in the context of the medical products business. Each of the chapters has been prepared by a recognised expert in the relevant jurisdiction, and the resulting work product will assist industry lawyers, regulatory affairs staff and others who need to have an understanding of the issues in each major market.

There is also a chapter on international harmonisation, which plays an increasingly important role in the regulation of pharmaceuticals and medical devices. In particular, the guidelines adopted by the International Conference on Harmonisation have been incorporated into the national requirements for pharmaceuticals in the European Union, United States, Japan and most other developed countries, and are increasingly influential in developing countries. Readers may find it useful to review this chapter before consulting the national chapters, because it is often key to understanding many local requirements.

Once again, I wish to thank all of the lawyers who contributed to this reference work. It is a pleasure to be associated with them.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2016

Chapter 15

GREECE

Gregory Triantafillopoulos[1]

I INTRODUCTION

The life sciences sector in Greece is heavily regulated, with the legal framework applicable to medicines and medical devices closely following the regulatory framework applicable to the EU. However, some areas, such as pricing and reimbursement, are exclusively regulated by national legislation.

The National Organisation for Medicines (EOF) is the competent authority in Greece monitoring medicines and medical devices, as well as for conducting all relevant procedures and proposing the pricing of the product to the Minister of Health.

II THE REGULATORY REGIME

The regime applicable to granting a marketing authorisation, importing, exporting, labelling and advertising of medicines is mainly regulated by Ministerial Decision 32221 of 29 April 2013, which incorporated Directive 2001/83 as amended by Directives 2002/98, 2004/27, 2004/24, 2010/84 and 2011/62, Law No. 1316/1983 and Legislative Decree 96/1973.

Medical devices are regulated by Ministerial Decision 130648 of 2 October 2009, which incorporated Directive 93/42 as amended by Directives 98/79/EK, 2000/70, 2001/104, 2007/47 and Regulation 1882/2003.

1 Gregory Triantafillopoulos is an external associate of Bahas, Gramatidis & Partners.

i Classification

EU legislation provides the definitions of a product for human use as well as of a medical device. In addition, EU legislation provides the criteria for the distinction between a medical device and a medicinal product for human use that depends on the basis of the intended use; and the way in which this is achieved.

ii Non-clinical studies

Non-clinical studies are regulated by Presidential Decree 56/2013 that incorporated Directive 2010/63. The incorporating Decree closely follows the regime provided in the corresponding Directive, establishing several requirements that aim to regulate the use of animals for scientific purposes including the breeding, marking and killing of animals. Presidential Decree 56/2013 also provides the procedures for the evaluation and authorisation of scientific and educational projects.

iii Clinical trials

There are two basic categories of clinical studies: the interventional and non-interventional.

Ministerial Decision 89292 of 31 December 2003, which incorporated Directive 2001/20/EC provides the definition of the above categories and covers the conduct of clinical trials on medicinal products for human use in conjunction with Ministerial Decision 130648/2009, which incorporated Directive 2007/47/EC. The aforementioned legislative regime is to be significantly affected by the implementation of Regulation 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC.

In order for a clinical trial to be performed, the prior positive opinion of the Greek Ethics Committee must be established within the EOF.

For Class III medical devices as well as for implantable medical devices and long-term invasive devices falling within Classes IIa or IIb, a producer may commence a clinical study following a lapse of 60 days from the date that the EOF has been notified accordingly, under the assumption that the EOF has not issued an unfavourable opinion within the aforementioned time period.

Both the sponsor and the investigator are jointly and severally liable for material and non-material damage suffered by the participants to the clinical trial, and their liability must be covered by insurance of any possible damage or disability that may occur. In case of death or permanent incapacity for work, the amount to be covered by insurance must be at least €200,000.

There are alternative means of classifying clinical trials, which are in accordance with the purpose the trials serve. Usually, the following are distinguished as types of studies:

a assessment therapies, composed of:
- new approaches (surgery, radiotherapy, etc.); and
- new drug combinations;

b methods of disease prevention;

c diagnostic; and

d quality of life (especially for chronic diseases or postoperative or post-treatment).

iv Named-patient and compassionate use procedures

In principle, unlicensed medicinal products may not be placed on the market, therefore manufacturers may not charge for supplying an unlicensed medicinal product.[2]

In exceptional cases, for the possibility of named-patient supply, the EOF may follow a special decision that allows for the import of unlicensed medicinal products if there is no therapeutic alternative among authorised products.[3]

v Pre-market clearance

The applicable regulatory regime reflects EU rules, thus medicinal products may only be put on the market following the granting of a marketing authorisation by the EOF for products to be authorised according to national procedures.

As regards medical devices, there is no need for the EOF's prior approval in order for a medical device to be placed on the market as long as there is an EU representative appointed and the medical device bears the CE marking. Although, the EOF needs to be notified accordingly before a medical device is placed on the market.

vi Regulatory incentives

As regulated by Directive 2001/83, marketing authorisations for generic products may not be granted for eight years, following the authorisation of the reference product. Following the lapse of this eight-year period, a generic product may not be placed on the market for an additional two years.

Patent-linkage is considered unlawful under Regulation (EC) No. 726/2004 and Directive No. 2001/83/EC. Since the status of a patent (application) is not included in the grounds set out in Regulation 726/2004 and in Directive 2001/83, it cannot be used as an argument for refusing, suspending or revoking a marketing authorisation.

There are currently no special provisions encouraging the development of innovative products, although there are ongoing discussions concerning a new regime that aims to facilitate the conduct of clinical trials and to encourage development of products for rare diseases.

vii Post-approval controls

The holder of the manufacturing authorisation needs to have permanently and continuously at his or her disposal the services of at least one qualified person, in accordance with the conditions laid down in Directive 2001/83.

As regards pharmacovigilance, the rules of the regulatory regime follow EU legislation, especially following the incorporation of Directives 2012/26 and 2011/62 concerning the prevention of falsified medicinal products from entering the supply chain.

As regards medical devices, the vigilance regime closely follows the relevant EU Directives.

2 Article 7 paragraph 1 of Ministerial Decision 32221.

3 Article 6 paragraphs 1 and 2 of 32221; Article 8 paragraph 6 of Legislative Decree 96/1973.

viii Manufacturing controls

Production of medicinal products in Greece demands the EOF's approval, following the submission of a relevant petition by the interested party. A production licence is needed in order for a medicinal product, including products intended exclusively for export, to be produced fully or partially in Greece, as well as for packaging and presentation of the product.

Moreover, in order for the EOF to issue said licence, the applicant needs to have adequate facilities and comply with the Guidelines provided by the EU on Good Manufacturing Practices. Permanent presence of a qualified person, bearing all qualifications provided by Directive 2001/83, is needed. Lastly, it should be noted that manufacturers of active substances established in Greece need to register with the EOF prior to commencing any activity.

As regards medical devices, for activities including but not limited to assembling, packaging and labelling, a prior notification to the EOF is needed. The applicant needs to be equipped with a quality certificate (e.g., an ISO) and be able to ensure the quality of all activities related to manufacture, storage, etc., of medical devices.

ix Advertising and promotion

Advertising of medicinal products includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products, including in particular:

a the advertising of medicinal products to the general public;
b advertising of medicinal products to persons qualified to prescribe or supply them;
c visits by medical sales representatives to persons qualified to prescribe medicinal products;
d the supply of samples;
e the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal;
f sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and
g sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.

Any advertising of a medicinal product in respect of which a marketing authorisation has not been granted is prohibited. Moreover, any advertising of prescription only products, or products that contain substances defined as psychotropic or narcotic by an international convention, such as the United Nations Conventions of 1961 and 1971, or products reimbursed by social security organisations is prohibited.

The regulatory regime prohibits granting of gifts or benefits in kind or discounts in kind by pharmaceutical companies to health-care professionals (HCPs) and patients. Such prohibitions have also been included in the Pharmaceutical Companies' Code of Ethics on the promotion of prescription-only medicinal products. It is, however,

permitted to offer medical items and educational devices and applications of insignificant value (up to €15 per item, VAT included) that are closely associated with daily health-care professionals' practice, such as applications for mobile phones or computers which, because of their nature, are not characterised as medical technology products (e.g., they do not serve diagnostic or dosing purposes).

Pharmaceutical companies are also obliged to provide the EOF with a description of all advertising materials and notify the EOF in advance of their sponsorship of any event (e.g., congress, symposia).

x Distributors and wholesalers

Wholesale distribution and warehousing of medicinal products is allowed only for medicinal products in respect of which a marketing authorisation has been granted. Wholesale distribution is subject to the EOF's prior authorisation. Granting of such authorisation requires the applicant to have adequate facilities ensuring proper conservation and distribution of medicines. Moreover, the applicant needs to employ adequate personnel and at least one responsible person with the qualifications set by Ministerial Decision 32221/2013. The authorisation is provided by the EOF within 90 days from the date that an application, accompanied with all the necessary certificates, is filed.

Wholesalers need to ensure that they are in position to supply the market with medicinal products that are adequate to cover patients' needs, and are obliged to notify the EOF of any alteration they become aware of that may affect the supply three months prior to such alteration occurring.

From time to time, the EOF issues certain circulars regulating wholesalers' obligation in respect of the products that need to be maintained in stock to cover patients' needs.

Wholesale distribution of medical devices is not subject to authorisation from the EOF but a notification must be made by the party interested in performing such activities. Similar to the regime applicable to wholesale distribution of medicinal products, a wholesale distributor of medical devices needs to have adequate facilities and personnel to safeguard the quality of distribution activities.

xi Classification of products

When a marketing authorisation is granted, the EOF specifies the classification of the medicinal product as a medicinal product subject to medical prescription or a medicinal product not subject to medical prescription.

The EOF may fix subcategories for medicinal products that are available on medical prescription only. In that case, they shall refer to the following classification:

a medicinal products on medical prescription for renewable or non-renewable delivery;

b medicinal products subject to special medical prescription; or

c medicinal products on 'restricted' medical prescription, reserved for use in certain specialised areas.

Classification is very important as regards the regime applicable to products' advertising, pricing and reimbursement by social security organisations.

Dispensing of prescription-only medicinal products may only be done through pharmacies (for those that are not only for hospital use), while medicinal products not subject to medical prescription may be sold to other points of sale as specified in the applicable legislation.

xii Imports and exports

The applicable regulatory regime follows the regime set by Directive 2001/83 so that importation of medicinal products is subject to the EOF's authorisation. Export of medicinal products is not subject to authorisation from the EOF; a company manufacturing medicinal products for export needs only to be equipped with a production licence.

There are no special requirements as regards imports and exports of medical devices.

xiii Controlled substances

The EOF is the entity responsible for authorising activities relating to the manufacture, use, distribution and possession of narcotics and psychotropic substances. Specific requirements also exist for the prescription of products when controlled substances are contained in medicinal products. Engagement in activities concerning narcotics and psychotropic substances without relevant authorisation may result in the imposition of administrative fines, while penal proceedings may also be commenced.

xiv Enforcement

The EOF is the competent authority for supervising and enforcing the regulatory provisions relating to medicinal products and medical devices. Breach of relevant provisions is punishable with administrative sanctions including monetary fines, prohibition on exercising certain activities and suspension of authorisations and licences.

III PRICING AND REIMBURSEMENT

The most important recent change with regards to pricing of medicinal products is the fact that all references made in the pharmaceutical legislation to a patent shall henceforth mean the data protection period.

The price of a reference medicinal product following lapse of the data protection period will be reduced by:

a 50 per cent – the reduction will be calculated on the product's price before expiry of the data protection period; or

b the average of the three lowest prices of EU Member States depending on which price is the lowest.

Generic products, independently of their approval date, maintain 65 per cent of the price of the corresponding reference product, following the lapse of its data protection as reduced according to the aforementioned provision.

According to the most recent Ministerial Decision, the higher producer price (ex-factory) of a reference medicinal product following lapse of the data protection period and the first circulation of the first corresponding generic product in the Greek market (according to the record of sales kept by the EOF and, if needed, documented with the issuance or existence of the first invoice) is automatically reduced by 50 per cent, and such reduction will be calculated on the product's price before expiry of the data protection period (i.e., on the price that the reference medicinal product had at the time that the first generic circulated). For reference, medicinal products that do not have a corresponding generic with registered sales to the EOF for a period of 12 months prior to the beginning of the EOF's pricing procedure, or if they are only similar medicines that are priced according to the rules applying to medicines manufactured in Greece, the rule of the average of the three lowest prices in EU Member States apply.

Reimbursement for supply of medicinal products is controlled on the basis of a positive list divided in two parts. The first part includes medicinal products 'for hospital use only' and the second part for medicinal products that may first be used in a hospital and continue to be used outside the hospital. These products concern treatment of serious conditions. These products are fully reimbursed by the health-care system.

Following lapse of these products' data protection period, and if there are generic products, the health-care system may cluster same in groups or propose to reimburse new patients treated with the original product with a generic product. The NHS may as well pre-approve the use of original products with high-price or high annual therapy cost (the specific provision is subject to modification owing to the recent changes in the legislation regulating pricing).

Clustering takes place on the basis of active substance and pharmaceutical form and the reference price is determined for each cluster with identical active substance and pharmaceutical form.

From September 2015 onwards, doctors may prescribe medicines using only the active substance.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The EOF's decisions are subject to judicial review by the competent courts, administrative or civil depending on the exact claim, and may be suspended following an injunction petition. The EOF's decisions for breach of regulatory proceedings are subject to appeal before the administrative courts.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYORS

The advertising of medicinal products in Greece is controlled by a combination of legislation and codes of practice. The principal legislative provisions are Ministerial Decision 32221/2013, Legislative Decree 96/1973 and Law No. 1316/1983. The legislative provisions are supplemented by circulars issued by the EOF and guidance provided by the European Medicines Agency (EMA). In addition, the Hellenic Association

of Pharmaceutical Companies' (SFEE) Code of Ethics governs the self-regulatory system for advertising of prescription-only medicines that provides useful guidance as to the interpretation of the legal requirements.

It is permitted to offer medical items and educational devices and applications of insignificant value (up to €15 per item, VAT included) that are closely associated with daily health-care practice, such as:

a applications for mobile phones or computers which, because of their nature, are not characterised as medical technology products (e.g., they do not serve diagnostic or dosing purposes, etc.);

b anatomy or physiology models (physical or electronic (e.g., CD, DVD, locked USB));

c anatomy maps (physical or electronic (e.g., CD, DVD, locked USB));

d educational material for patients via the HCP in the form of supporting material, (e.g., nutrition or exercise advice, or in the context of a disease awareness campaign approved by the competent authorities);

e printed or digital publications including guidelines from scientific societies – provided they do not provide descriptions outside the approved indications and dosage;

f printed or digital publications of therapeutic protocols; or

g donations, grants and benefits in kind to foundations, institutions, organisations or associations that are comprised of HCPs or that conduct research are only allowed if: (1) they are made for the purpose of supporting health care, research, training or the provision of better health services; (2) they are documented and kept on record by the company; and (3) they do not constitute an inducement to prescribe, sell or purchase specific medicinal products.

Donations or sponsorships are also allowed to medical societies, institutions, associations or unions established by HCPs as not-for-profit legal persons in private law.

Donations, where allowed, may be in kind or in money. A donation in money must serve a specific purpose (e.g., to finance a research programme, educate HCPs, patients and patient caregivers or facilitate the recipient to purchase medical equipment or part of it). Donations in kind may involve medical equipment (e.g., instruments, devices) and reagents in the context of a research programme.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Product liability claims are subject to the general legal regime concerning liability for defective products. Claimants may base their claim for remedy on the Consumers' Protection legislation and on the provisions of the Greek Civil Code.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

In Greece, antitrust law includes both EU and national provisions.

First, Article 101 of the Treaty on the Functioning of the European Union (TFEU) prohibits agreements between two or more independent market operators which restrict competition. This provision covers both horizontal agreements (between actual or potential competitors operating at the same level of the supply chain) and vertical agreements (between firms operating at different levels (i.e., an agreement between a manufacturer and its distributor)).

Second, Article 102 of the Treaty prohibits firms that hold a dominant position on a given market to abuse that position to the prejudice of consumers.

Especially for vertical agreements, national and EU competition authorities apply Regulation (EU) No. 330/2010 of 20 April 2010 on the application of Article 101(3) of the TFEU to categories of vertical agreements and concerted practices. Agreements that are deemed to fall within the scope of the Block Exemption Regulation are presumed to be lawful.

With regard to Greek antitrust law, Articles 1 and 2 of Law No. 3959/2011 establish prohibitions and legal restrictions that directly correspond to Articles 101 and 102 of the Treaty, respectively.

Owing to the fact that medicinal products' pricing is regulated by the state, the Hellenic Competition Authority has not dealt with competition issues in respect of medicinal products' pricing. However, there is an ongoing discussion relating to the procedures under which the public sector is supplied with medicinal products, so that future developments are expected that will contribute to confronting cartel policies.

ii Transactional issues

As Greece is an EU Member State, the provisions of the Greek Competition Law reflect the rules found in Articles 101 (anticompetitive agreements) and 102 (abuse of dominant market position) of the TFEU. No major transactions have been conducted recently in the pharmaceutical sector in Greece. From a legal point of view, competition law must be taken into account regarding possible M&A activities of major players in the market and a decision of the Hellenic Competition Commission may be required. Given the Greek financial situation, many developments are expected on transactional issues as the economy continues its attempts to improve the bad economic climate.

VIII CURRENT DEVELOPMENTS

Legislative provisions relating to pricing of medicinal products have been amended three times in the past six months, while the State Budget Law for 2016 requests further reductions.

Moreover, according to the latest legislative provisions, public hospitals' budgets for 2016 may not exceed €570 million (€510 million for hospitals and €60 million for social security organisations). On the assumption that public hospitals' expenses exceed the above-mentioned amounts, the exceeding amounts will have to be returned to the state through a clawback or rebate system.

Given the ongoing negotiations between the Greek state and European institutions and the IMF, further interventions are expected that will aim to reduce public expenses.

Appendix 1

ABOUT THE AUTHORS

GREGORY TRIANTAFILLOPOULOS

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Gregory has extensive experience in the life sciences sector (including pharmaceuticals, medical devices and food). He specialises in European and Greek law as it pertains to the regulation of medicinal products and devices. Gregory provides advice on market access, EU and national marketing authorisations, including issues regarding EU regulatory data protection and the implementation thereof at national level in the Member States, pricing and reimbursement, compliance matters, advertising and labelling, CRO, clinical trial and pharmacovigilance agreements. In addition, he also practises in the field of distribution and agency agreements and assisting clients in all related matters.

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