THE LIFE SCIENCES LAW REVIEW

ELEVENTH EDITION

Editor
Peter Bogaert

THE LAWREVIEWS

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PREFACE

The eleventh edition of *The Life Sciences Law Review* covers a total of 24 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

The past year showed a transition from the covid-19 pandemic to more normal health conditions, but also an enhanced awareness of new challenges. During the two preceding years, manufacturers of healthcare products, together with healthcare professionals and services, focused on the development and testing of vaccines, other drugs, biologics, diagnostics and personal protective equipment. This was done on an expedited basis, and regulatory agencies have reviewed marketing applications with unprecedented speed and efficiency. Manufacturers and international organisations have also worked closely together in an effort to ensure equitable access to vaccines and other important healthcare products in low- and middle-income countries, but much work remains to be done. Regulators are now making preparations for later emergencies and are also drawing lessons from the experience gained during the pandemic for the development and assessment of new health products in important therapeutic areas. Efforts to support effective and equitable access to key products at a more international level also continue.

Given the constant challenges and quick developments, it is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems that govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this year's publication will be especially helpful in this respect.

All of the chapters have been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this publication.

Peter Bogaert
Covington & Burling LLP
Brussels
February 2023

Chapter 11

GREECE

Nefelie Charalabopoulou and Natalia Kapsi[1]

I INTRODUCTION

In Greece, medicines for human use are primarily regulated by the Ministerial Decision 32221/2013[2] (the MD on Medicines), which transposed Directives 2001/83/EC3 and 2011/62/EU into the Greek legal order. The MD on Medicines sets out the basic legal framework governing the lifeline of a pharmaceutical product, from authorisation stage to post-marketing activities.

With regard to medical devices, Medical Devices Regulation (EU) 2017/745[3] (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746[4] (the EU IVD Regulation) have come into effect. However, Ministerial Decision 130648/2009[5] (the Medical Devices MD) as well as Ministerial Decision 130644/2009,[6] which transposed Directive 90/385/EEC[7] in Greece, constituting the two main pieces of legislation governing medical devices in Greece, prior to the entry into force of the foregoing Regulations, have not yet been abolished or amended. Given that, at the time of writing, there is a grace period valid until 26 May 2025 in place, during which medical devices that have been approved by virtue of the former legislative regime can still be made available on the market, our analysis shall also extend to the said provisions.[8]

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1 Nefelie Charalabopoulou is a partner and Natalia Kapsi is a senior associate at Zepos & Yannopoulos.

2 Ministerial Decision YA D.YG3a/G.P.32221 (Government Gazette B 1049/2013) 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.

3 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

4 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

5 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.

6 Ministerial Decision D.Y8d/G.P.130644/2009 (Government Gazette 2197/B/2-10-2009) on Implantable Medical Devices.

7 Directive 90/385/EEC on active implantable medical devices and Directive 98/79/EC on in vitro diagnostic medical devices.

8 On 6 January 2023, the European Commission issued a legislative proposal for extending the transition period for legacy devices as follows: until (1) 31 December 2027 for higher risk devices (Class III and Class IIb implantable devices except certain devices for which the MDR provides exemptions, given that these devices are considered to be based on well-established technologies); and (2) until 31 December 2028 for medium and lower-risk devices (other Class IIb devices and Class IIa, Class Im, Is and Ir devices). Class III custom-made implantable devices shall benefit from an extension to 26 May 2026.

The National Organisation for Medicines (EOF) is the competent regulating and overseeing body for all aspects concerning pharmaceutical products as well as medical devices in Greece.

II THE REGULATORY REGIME

i Classification

Both medicines and medical devices are highly regulated in Greece, albeit the provisions covering the latter are less rigorous in comparison.

Pursuant to Article 2 of the MD on Medicines, within the definition of a medicinal product falls (1) any substance or combination of substances presented for treating or preventing a disease in human beings or (2) any substance or combination of substances that may be administered to human beings with a view to restoring, correcting or modifying the physiological functions in human beings or to making a medical diagnosis.

According to Article 2 of the Medical Devices MD, a medical device is defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of (1) diagnosis, prevention, monitoring, treatment or alleviation of disease; (2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; (3) investigation, replacement or modification of the anatomy or of a physiological process; or (4) control of conception and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means.

In terms of rules introducing a general distinction between medicines and other regulated products (e.g., food supplements, cosmetics, chemicals and general consumer products), there are no pertinent national provisions to be reported. However, with regard to medicines and medical devices, Article 2 of the Medical Devices MD transposes verbatim the borderline principles between medicines and medical devices, as laid down by both Directive 93/42 EEC and the MDR.

ii Non-clinical studies

Non-clinical studies to demonstrate health and environmental safety must be planned, conducted, archived and presented in line with the principles of good laboratory practice (GLP). In Greece, GLP is governed by MD 30/2022,[9] transposing the related European provisions.

With regard to tests conducted on animals, Presidential Decree 56/2013[10] has transposed into the Greek legal order the provisions of Directive 2010/63/EU.[11] The Presidential Decree

9 Ministerial Decision 30/004/000/153 (Government Gazette B 5991/24.11.2022) on the Implementation of the Principles of Good Laboratory Practice (GLP), control of compliance with the GLP Principles during the studies of the Controlled Substances and Inspection and Accreditation System of the Experimental Units and Test Sites of GLP.

10 Presidential Decree 56/2013 (Government Gazette A 106/30.04.2013) on Harmonisation of Greek legislation with the Directive 2010/63 /EU of the European Parliament and of the Council of 22 September 2010 (L 276/33/20.10.2010) on the protection of animals used for scientific purposes.

11 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

establishes the three fundamental principles underlying all animal tests on a European level and in particular the principles of replacement, reduction and improvement, as defined in the pertinent European provisions.

iii Clinical trials

Medicines

Clinical trials in Greece are governed by the provisions of Ministerial Decision 59676/2016,[12] as amended and in force (the Clinical Trials MD), along with the EOF's pertinent circulars. The Clinical Trials MD introduces a series of provisions for the implementation of the Clinical Trial Regulation (EU) No. 536/2014.[13]

Clinical trials to be conducted in Greece are subject to the EOF's regulatory approval. Submission and authorisation thereof shall be in accordance with provisions of Article 5 of Regulation 536/2014. With regard to clinical trials' funding, this may be undertaken either by private entities, including pharmaceutical companies, or by entities not acting, directly or indirectly, on behalf of the pharmaceutical industry. In the latter case, the clinical trial is classified as non-commercial. The prior ethical assessment of the trial in question by the National Ethics Committee is a prerequisite for the initiation of clinical trials in Greece.

Medical devices

On a European level, clinical investigations of medical devices are governed by the provisions of the MDR. On a national level, clinical investigations of medical are governed by Article 15 of the Medical Devices MD. According to Article 15, in conjunction with the EOF's Circular No. 42353/2011,[14] applications for the initiation of clinical investigations of medical devices shall be submitted to the EOF in case the contemplated medical device does not bear the CE mark or if the device, despite bearing the CE mark, is to be tested for new uses not covered by the CE mark. Clinical investigations on in vitro diagnostic medical devices, if the product is intended to come into direct or indirect contact with the human body, must also be submitted to the EOF.

iv Named patient and compassionate use procedures

Medicines

In principle, no medicinal product may be circulated in Greece without a marketing authorisation (MA). However, a medicinal product that has not yet obtained an MA can be brought in Greece through early access schemes, according to Article 2 of Ministerial Decision 85037/2011,[15] as amended and currently in force, which provides for the early access to pharmaceutical products in groups of patients or individuals.

12 Ministerial Decision G5a/59676/2016 (Government Gazette B 4131/22.12.2016) on the Provisions for the implementation of 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, and repealing Directive 2001/20/ EC.

13 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, and repealing Directive 2001/20/EC.

14 EOF Circular No. 42353/9-6-2011, Subject: Clinical Research with Medical Devices.

15 Ministerial Decision DYG3a/G.P. 85037/10 (Government Gazette B 558/2011) on Terms, conditions and procedure for granting temporary approval for early access to medicines for human use ('compassionate use').

In particular, a personal or individual licence for early access to medicinal products (the Named Patient Programme (NPP)) applies under the terms and conditions defined in detail in the aforesaid Ministerial Decision (i.e., in specifically justified cases, for a specific patient, upon the request of the treating doctor and under the doctor's exclusive and unlimited liability, and provided that it is ascertained, based on the available data, that the benefit–risk ratio is in favour of the anticipated benefit).

The same Ministerial Decision provides for the 'group scheme for early access to the medicinal product' (the Group Scheme). This scheme applies for a specific group or subgroup of patients who are included in a general group treatment and follow-up scheme. This scheme is based on the analytical criteria that are included in an approved therapeutic protocol for the administration of an 'early access' medicinal product. In both schemes, what must be established is that, based on the available scientific data, the existing and in-use product for the clinical need in question (if any) is not appropriate from a medical perspective for the particular patient or patients.

Both schemes need the EOF's prior approval, which is valid for a maximum of one year and can be renewed, provided that the approval's conditions are still applicable. The early access licence is terminated as soon as the medicine in scope obtains an MA or if the application for the granting of an MA is rejected on substantial grounds. Last, the pharmaceutical company concerned undertakes to provide the unlicensed product free of charge, unless specific reimbursement has been introduced, whereupon the relevant decision of the competent social security fund must be provided.

Medical devices

There is no equivalent to medicines early access schemes with regard to medical devices. As a general rule, only medical devices approved pursuant to the provisions of the MDR or EU IVD Regulation, bearing the CE mark of conformity may be placed on the Greek market. As already mentioned, until 26 May 2025, medical devices approved and marketed under the previous legislative framework can be still marketed; therefore, custom-made devices approved by way of derogation, according to Article 4 of the Medical Devices MD, from the aforementioned principal of CE-marked devices, can still be placed on the Greek market.

v Pre-market clearance

Medicines

Medicines may be placed on the Greek market only following the granting of an MA. Apart from the centralised and decentralised procedures operating at the EU level, the EOF is the competent authority in Greece for granting MAs for pharmaceutical products according to the provisions of the MD on Medicines.

As a general rule, an MA is valid for five years. It may be renewed after five years on the basis of a re-evaluation by the EOF of the risk–benefit analysis, and once renewed, the MA is valid for an unlimited period, unless the EOF decides to revoke it, under the special circumstances foreseen in the law. In any granting of an MA that is not followed by the actual placing of the product on the market within three years of the issuance of the MA, the MA ceases to be valid (the Sunset Clause). The granting of authorisation does not affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder (MAH) or, as the case may be, of its local representative and producer.

Medical devices

Without prejudice to any amendments as to the notification procedure that have been introduced by the MDR and the EU IVD Regulation, according to the provisions of the Medical Devices MD, any medical device placed on the Greek market is subject to a notification obligation to the EOF. In particular, manufacturers or their authorised representatives are required to submit to the EOF all data allowing for the identification of the medical device together with its labelling and its instructions for use, when such device is placed on the market and is put into use in Greece. Notification of said products is effected through the EOF's National Electronic Medical Device Registry.

A registration procedure to the aforementioned National EOF's Registry is also in place for IVDs, according to the provisions of the Ministerial Decision 3607/2001[16] combined with the EOF's Circular No. 62701/2003,[17] as well as for Class I medical devices and custom-made devices.

vi Regulatory incentives

Although incentives to producers of originator products such as data exclusivity, provisions on orphan drugs or drugs targeting neglected diseases have been adopted at a European level, at a national level, Ministerial Decision 80277/2021[18] for offsetting R&D and investment project-related expenses with clawback introduced one of the most attractive and long-awaited R&D and clinical trials incentive schemes for the pharmaceutical sector.

Moreover, a landmark decision may be of some relevance, namely Decision No. 1785/2019 of the Council of State, which basically annulled the imposition of clawbacks on orphan drugs, which may be considered overall as an incentive for them to be marketed in Greece.

vii Post-approval controls

The MAH is required to monitor the safety of its marketed products and immediately notify the EOF of any prohibition or restriction imposed by the competent authorities of any state on the market of which the medicinal product has been placed.

Pursuant to Article 162 et seq. of the MD on Medicines, the EOF, in collaboration with the European Medicines Agency, ensures that the legal requirements governing medicines are met through inspections that it is entitled and under its sole discretion to perform, such as, indicatively, inspection of manufacturing or commercial facilities, or taking of samples.

Article 133 of the MD on Medicines sets out the EOF's obligation to maintain a pharmacovigilance system, while Article 136 of the same MD provides for relevant obligations of the MAH itself.

16 Ministerial Decision DY8d/oik. 3607/892/2001 (Government's Gazette B 1060/2001) on 'In vitro diagnostic medical devices'.

17 EOF's Circular No. 62701/2003 'In vitro diagnostic medical devices – implementation of the MD 3607/892/2001'.

18 Ministerial Decision 80277/2021 (Governmental Gazette B 6247/27.12.20210) 'On the Procedure, terms and conditions for offsetting clawback with percentages on research and development costs and the costs of product or service development investment plans or production lines'.

Medical devices

Under the applicable legislative regime on medical devices, similar pharmacovigilance requirements as above apply to medical devices, and it is within the EOF's competence to take all appropriate interim measures to withdraw from or prohibit or restrict their circulation on the market in case it ascertains that a device may compromise users' health and safety.

viii Manufacturing controls

Medicines

The manufacturing of medicinal products is subject to the holding of an authorisation or licence, issued at the national level by the EOF; authorisation is also required even when the medicinal products manufactured are designated for export. Importation of medicinal products coming from third countries is permissible subject to authorisation granted by the EOF and is required for both complete and partial manufacture as well as for the various processes of dividing up, packaging or presentation.

Pursuant to the MD on Medicines, the MAH must adhere to all the statutorily provided obligations, including the obligation to have in place, on a permanent and continuous basis, at least one qualified person responsible in particular for carrying out the duties specified in said legislation, give prior notice to the EOF of any modification as to any of the particulars supplied within the context of the authorisation application and comply with the entirety of the principles and guidelines of good manufacturing practice, as issued by the EOF and as laid down by EU law, and to make use solely of substances manufactured in accordance with said principles and guidelines.

Any transfer of ownership of manufacturing facilities must be disclosed to the EOF, according to the requirements laid down by applicable legislative provisions as well as the EOF's pertinent circulars.

Medical devices

The EOF, among its competences, is also entrusted with the power of granting authorisation for the production of medical devices.

ix Advertising and promotion

Advertising and promotion of medicines is strictly regulated, and the rules mainly depend on the type of medicine (prescription-only or over-the-counter (OTC)) and the addressee (healthcare professionals (HCPs) or the general public) as regards prescription-only medicines. Any advertising or promotion of medicinal products without a valid MA is prohibited.

As a general principle, any advertising of medicinal products must encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, and must not be misleading.

Advertising of OTC products is generally permitted subject to the relevant rules, while prescription-only pharmaceutical products may only be promoted to healthcare professionals and not to the general public, the latter is strictly prohibited.

No gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply medicines, unless they are inexpensive and relevant to the healthcare practice.

MAHs are required to file with the EOF all promotional material, as the latter proceeds to *ex post* controls in case the material submitted is not in line with the pertinent legislative and regulatory provisions.

The EOF's operating circular No. 37201/2020[19] is the main regulatory instrument that governs scientific events when products of the EOF's competence are concerned, including, inter alia, medicines and medical devices. In principle, all scientific events shall be registered with the EOF.

NHS and university HCPs cannot participate in commercial or promotional events, with the exception of participating as speakers or chairpersons of such events, or as advisers in the context of advisory boards. On the contrary, self-employed HCPs may freely participate in such events organised in Greece.

From a soft law perspective, the Code of Ethics of the Hellenic Association of Pharmaceutical Companies (SFEE's Code of Ethics),[20] which regulates, among other things, the promotion of pharmaceutical products by its members (mostly multinational pharma companies) can be considered as a useful tool, as it incorporates concise and updated provisions in alignment to the relevant regulatory framework. In practice, the provisions of the aforesaid Code are being respected by the majority of pharmaceutical companies in Greece, irrespective of their actual membership of the SFEE, as the SFEE is one of the most respected and influential associations in the pharmaceutical industry, wherefrom analogies may be drawn for medical devices as well.

Medical devices

On a national basis, advertising of medical devices is governed by the Medical Devices MD and the Ministerial Decision 130644/2009 in combination with EOF Circular No. 18158/2010[21] and the SEP Code,[22] which contains general principles and is the equivalent of the Eucomed Code in Greece. Apart from a couple of prohibitions (e.g., related to HIV self-testing kits), the advertising and promotion of medical devices is permitted as long as it corresponds to the intended use of the product. The direct or indirect promotion of misleading indications and the promotion of inaccurate or undocumented claims is prohibited. The pertinent material (printed, audiovisual, etc.) is subject to the monitoring powers of the EOF.

x Distributors and wholesalers

Distribution and storage of medicinal products in Greece is mainly regulated by the provisions of the MD on Medicines, Presidential Decree 88/2004[23] and the Guidelines of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use, 2013/C 343/01.[24] Additionally, the EOF has issued various interpretative circulars, the most important of which are 96870 and 5664 of 2014.

19 EOF Circular No. 37201/23.03.2020 on Scientific Events.

20 Code of Ethics of the Hellenic Association of Pharmaceutical Companies (SFEE).

21 EOF Circular No. 18158/2010 on Information on the Revision of the Legislation on Medical Devices and Active Implantable Medical Devices – Implementation of Directive 2007/47/EC'.

22 Code of Ethics of the Hellenic Association of Scientific and Medical Equipment Suppliers (SEP)

23 Presidential Decree 88/2004 (Government's Gazette 68/A/3-3-2004) on the organisation and operational standards of a pharmaceutical warehouse.

24 Guidelines of the European Commission of 5 November 2013 on Good Distribution Practice of Medicinal Products for Human Use.

Briefly, the following are the main requirements to be reported regarding wholesale distribution:

a the wholesale of medicinal products is subject to the possession of a wholesale authorisation (licence), which is valid for a specific geographical area;

b the authorisation is issued for five years and is renewable for consecutive five-year periods;

c the possession of a manufacturing authorisation includes authorisation to distribute by wholesale the medicinal products covered by that authorisation. Possession of an authorisation to engage in activity as a wholesaler in medicinal products does not, however, cover the need to possess a manufacturing authorisation, even where the manufacturing or import business is secondary;

d the wholesale of medicinal products is permissible only for those products in respect of which an MA has been granted; and

e a wholesaler, who is not the MAH and imports products in Greece from other Member States, must notify the EOF who the MAH is and its intention to import said products in Greece.

Last, the MAH itself may skip the requirement of holding a wholesale licence, as long as physical distribution of its products has been duly assigned to a third-party logistics firm pursuant to the provisions of Circular 96870/2014.

xi Classification of products

Medicines

Classification of a medicinal product is effected by the EOF. Medicines are mainly classified in two categories, prescription-only and OTC; the latter can be further subdivided into OTC products sold exclusively in pharmacies and those available in other retail stores such as supermarkets, grocery stores and health food stores. Prescription-only medicines may be further subcategorised as follows:

a medicines that require prescription, renewable or not;

b medicines subject to special prescription; and

c medicines subject to prescription for restricted use and intended for use in a certain setting (restricted prescription).

Article 95 of the MD on Medicines provides for the criteria upon which classification is effected that coincide with the principles listed in Article 70 of Directive 2001/83/EC (blue box classification).

Medical devices

Medical devices are classified as Class I, IIa, IIb or III IIb, III, depending, inter alia, on their characteristics, the duration of their use, their reusability, and the potential risk to patients as a result of their use. They are further distinguished between active implantable medical devices, in vitro diagnostic devices and other general devices. There are also other categories of medical devices, such as custom-made devices, devices intended for clinical research and medical devices for professional use.

xii Imports and exports

The MD on Medicines regulates both the import and the export of medicinal products in and outside Europe by designating the EOF as the responsible overseeing authority in Greece. Any importation or exportation from third countries is subject to a relevant licence, while parallel trading of pharmaceuticals is a lawful form of trading between EU Member States on the basis of the free movement of goods principle. Parallel exports may, however, be temporarily banned from time to time in case of shortages.

xiii Controlled substances

According to Law 4139/2013,[25] as amended and in force, the manufacture, possession, transport, storage, supply, processing and marketing, and in any way mediation in the distribution of narcotics and psychotropics (as extensively listed in the pertinent provisions), may only be undertaken by the state; this exclusive right is exercised by the EOF. The same rule applies to any imported narcotic and psychotropic substances.

Export of narcotics requires special approval by the Ministry of Health and is subject to a specific procedure, which must evidence that the country of destination allows the importation of narcotics and that these are to be used solely for medical purposes.

Moreover, it is strictly prohibited to advertise to the public any medicinal product that contains psychotropic or narcotic substances.

Under Law 4801/2021[26] and the ministerial decisions that were issued thereafter, including Joint MD 27462/2022,[27] special provisions were introduced with regard to cannabis for medical use, laying down exemptions for the production, possession, transportation, storage, supply and installation and operation of a plant for the processing and production of finished medicinal cannabis products.

xiv Enforcement

Medicines

MAHs remain liable for their pharmaceutical products at all stages of their circulation in the market and there is no way to otherwise restrict or exclude this liability. The appointment of a local representative does not exonerate the MAH from its liability, while the former is held liable independently and in parallel.

The EOF assumes a vigilant role in cases of violations and puts a great effort in being proactive as well as taking remedial action against infringement. It may impose various sanctions or order corrective actions according to its discretion, including the imposition of fines, the revocation of licences, the ban of exports, recalls, etc. Articles 162 to 178 of the MD on Medicines also provides for serious sanctions in case the applicable law is violated, from recalls to fines.

25 Law 4139/2013 (Government Gazette A-74/20-3-2013) On Substance Abuse and Other Provisions.

26 Law 4801/2021 (Government Gazette A 83/24.05.2021) On Production, export and distribution of finished medicinal cannabis products of the Cannabis Sativa L species with a tetrahydrocannabinol (THC) content of more than 0.2%.

27 Law 4801/2021 ((Government Gazette A 83/24.05.2021) On Production, export and distribution of finished medicinal cannabis products of the Cannabis Sativa L species with a tetrahydrocannabinol (THC) content of more than 0.2%.

Medical devices

Given that compliance with the rules and standards on medical devices is subject to the controls and scrutiny of the EOF, the above-mentioned sanctions in the case of violation of the legislation regarding medicines apply *mutatis mutandis* to medical devices, as per Article 23 of the Medical Devices MD.

III PRICING AND REIMBURSEMENT

Albeit the pertinent pricing legislation undergoes recurring modifications, Ministerial Decision 82331/2019,[28] as amended and in force, is currently operative in Greece.

Four major categories of prices have been formulated:

a the maximum wholesale price of medicinal products (i.e., the price at which medicinal products are sold to pharmacies, which includes the gross profit margin (mark-up) of the wholesaler);

b the maximum net producer's price (ex-factory) (i.e., the sale price at which the MAHs sell medicinal products to the wholesalers);

c the maximum retail price of medicinal products, which is the price at which medicinal products are sold by pharmacies to consumers, and is defined on the basis of the maximum wholesale price, adding the lawful profit margins of the pharmacy and the applicable VAT; and

d the maximum hospital price of medicinal products is the price at which medicinal products are sold by the MAHs or the wholesalers to the state, public hospitals, social care units, the pharmacies of EOPYY (i.e., the main health insurance fund in Greece), public law entities engaged in social care and to private clinics provided that they operate a hospital pharmacy. The maximum hospital price is determined on the basis of the ex-factory price reduced by 8.74 per cent.

The ex-factory price of reference medicinal products is based on the average of the two lowest prices in the EU, while generic products' price shall be 35 per cent lower than that of the respective reference products. Reimbursement of medicines is subject to their inclusion in EOPYY's List of Reimbursed Medicinal Products (the Positive List).[29] Inclusion (or exclusion) of medicines in the List is subject to their assessment by the Assessment and Reimbursement of Medicines for Human Use Committee. For products with an initial positive assessment, a recommendation from the Negotiation Committee (NC) concerning their budget impact is required. NC is also competent for negotiating prices and discounts of the products to be introduced in the List as well as for concluding agreements with MAHs involved in the relevant negotiation process. Last, for the products ultimately included in the List, a reimbursement price is determined, which results in the multiplication of the product's reference price by the number of daily doses of said product.[30]

28 Ministerial Decision 82331/2019 (Government Gazette B 4274/22.11.2019) on the provisions on the pricing of medicinal products.

29 Law 4512/2018 (Government Gazette A5/17.01.2018), Chapter IX: Provisions of the Ministry of Health, Part A: Assessment and Reimbursement of Medicines for Human Use.

30 Ministerial Decision D3(a) 46628 (Government Gazette B 2308/18.6.2018) On the Method of Defining the Reference Prices that Constitute Insurance Reimbursement Prices for the Social Security Institutions and EOPYY.

In 2022, Law 4512/2018 was significantly amended; in this context, one of the most noteworthy innovations introduced relates to the new closed budget with regard to high-cost medicines (FYKs). In particular, medicines with a daily treatment cost not exceeding the amount of €0.20 that have already received a retail price by the EOF and, thus, constitute medicines to be potentially included in the Positive List following an MAH's or a pharmaceutical company's request, can be included in the Positive List without any prior assessment or negotiation. MAHs or pharmaceutical companies are entitled to request, through the Negotiation Committee, the reduction of their retail price so that the cost of daily treatment of the medicine in question becomes less than or equal to €0.20, and thus, they benefit from the foregoing provision.

Medical devices

Manufacturers of medical devices can freely determine their products' prices. However, according to Article 108 of Law 4461/2017,[31] as amended by Law 4472/2017,[32] the maximum reimbursement price by EOPYY is determined on the basis of the average of the three lowest prices in EU Member States. Last, the registration of said products in both the EOF's Registry and EOPYY's Registry of Reimbursed Products is a prerequisite for the products' reimbursement.

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Greek public authorities, such as the EOF, are subject to administrative law, their decisions being subject to various types of administrative appeals prior to any procedure before competent administrative courts.

It is possible to lodge an administrative appeal, either before the authority having issued the decision being challenged or before its superior authority, even in the absence of a specific provision referring to the particular procedure in the context of which the decision was issued. In the absence of such explicit provision addressing the possibility of administrative challenge in the context of a particular administrative procedure, both types of challenge (i.e., before the issuing authority and before its superior authority) may be filed or not at the discretion of the applicant. Even though not required in view of an admissible challenge before the administrative courts, administrative challenges before the authority superior to the issuing authority are particularly common prior to recourse before the administrative justice.

More critical are administrative appeals explicitly provided by virtue of the applicable legal framework, whether laws on public procurement or any other legal provision, which constitute an obligatory procedural step prior to recourse before the competent administrative courts. Where explicit provisions on challenge exist with respect to particular administrative procedures, the possibility of challenge and the obligation to file such challenge prior to admissibly challenging an administrative decision before the courts must be notified to the persons affected by this decision in the context of it (i.e., following the content of the decision per se).

Administrative disputes belong either with the jurisdiction of Regular Administrative Courts of Appeal and the Supreme Administrative Court or with the jurisdiction of

31 Law 4461/2017 (Government's Gazette A38 28.3.2017).

32 Law 4472/2017 (Government's Gazette A38 28.3.2017A' 74/19-5-2017).

Regular Administrative Courts, depending, respectively, on whether the court examines the administrative decision subject to challenge and the relevant proceedings from a legality perspective alone or whether it is entitled to assess the ruling and proceedings brought before it from the merits as well as the legality perspective. In the former case, which is the rule unless a specific legal framework allows for an appeal on the merits, a petition for annulment may be lodged before the competent administrative court (the Court of Appeal or Supreme Administrative Court depending on the value of the dispute or the applicable framework) seeking the annulment of the issued decision alone. Where a specific type of dispute is subject by virtue of an explicit legal provision to an appeal on merits, this may be lodged before the Regular Administrative Courts of First Instance or the Regular Administrative Courts of Appeal, depending on the specific applicable framework. The legality of the administrative act being challenged is examined in both cases. The petitioner is entitled, upon establishment of legal interest and specific protection requirements, to request interim judicial protection (i.e., the suspension of the effect of the administrative act in question). Temporary judicial protection is critical, taking into account standard significant delays in the handling of most cases and before most courts across Greece. This is particularly true of administrative acts issued in the context of public tender procedures, where interim protection, in principle granted upon filing of the application for annulment, by means of the newly introduced dual legal remedy of application for suspension and annulment, is key to ensuring that the tenderer affected by the challenged decision will be able to remain in the tender following the eventual annulment of the decision. In the context of public tenders above the threshold of €30,000, challenges against decisions of awarding authorities are addressed to the Single Authority for Public Contracts (EADISI), competent for the review of such challenges in the pre-contractual stage prior to recourse before the competent administrative courts of appeal, the burden of which has substantially been alleviated as a result of EADISI's review process.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

The MD on Medicines, in Articles 126 and 128, forbids the pharmaceutical companies from offering gifts, benefits or promises of any kind to HCPs as incentives to prescribe a medicinal product, except items of insignificant value (€10–15) strictly related to their profession. The same provision is also incorporated in Article 66 of Law 4316/2014[33] and in the SFEE's Code of Ethics.

Moreover, Paragraph 7 of Article 66 of Law 4316/2014 introduces in Greece the 'Sunshine Provisions' (i.e., the obligation of pharmaceutical companies to disclose on an annual basis within six months of the closure of each calendar year all transfers of value towards HCPs or HCOs). The disclosure involves any kind of transfer; namely, any donations, grants, sponsorships, registration costs related to congresses or scientific events of any kind, travelling and accommodation expenses as well as any other transfer, either on the basis of a contract concluded between the parties or voluntary, related to the promotion of prescription medicines. Although the provision limits the scope of the obligation solely to pharmaceutical companies, the EOF in practice imposes the same obligation on medical device companies.

33 Law 4316/2014 (Government Gazette A 270/24-12-2014) on the Establishment of a dementia observatory, improvement of perinatal care, regulation of matters of competence of the Ministry of Health and other provisions.

Last, the Greek Penal Code also includes anti-bribery provisions governing both active and passive bribery. Indeed, bribery is punishable when taking place either in the public sector or in the private sector.

VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

Compensation of persons injured by medicines or medical devices stems from the general consumers' protection provisions (Law 2251/1994,[34] as amended and in force) as well as from the provisions of the Greek Civil Code[35] and Penal Code,[36] along with numerous provisions that may be found scattered in the Greek legislative and regulatory framework, which trigger potential liability of the parties engaged in the pharmaceutical sector in its broad sense.

Exceptionally, the Clinical Trials MD provides for the right to request compensation in case of personal injury or death of any participant as well as for the obligation of the sponsor to have in place an insurance policy covering such claims.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

Following the European Commission's inquiry into the pharmaceutical sector in 2009,[37] competition law enforcement and market monitoring in the life sciences sector have been a high priority across the EU.[38] In this regard, the Hellenic Competition Commission (HCC) has also been active in enforcing antitrust and merger control rules in the life sciences sector and in initiating relevant sector inquiries, thereby responding to concerns that anticompetitive practices of companies active in this sector may endanger patients' access to affordable and innovative essential medicines.

The national competition rules that prohibit anticompetitive agreements and concerted practices and the abuse of a dominant position are enshrined in Law 3959/2011 (the Greek Competition Act), and apply to business practices in all sectors of the economy, including the life sciences sector. Moreover, the HCC's decisional practice in this area is generally aligned with EU case law, taking into account all relevant EU legislation, notices and guidelines, as well as policy trends at the EU level.

Recent noteworthy antitrust enforcement by the HCC in respect of anticompetitive agreements in the life sciences sector includes, in particular, infringement Decision No. 689/2019 against Gambro (a manufacturer of artificial kidney machines) and Iatrika Proionta (Gambro's exclusive distributor in Greece) for prohibiting parallel imports of Gambro by a distributor competing with Iatrika Proionta in the Greek downstream market. Moreover, towards the end of 2020, the HCC had initiated an *ex officio* investigation for any

34 Law 2251/1994 (Government Gazette 191/A/16-11-1994) on Consumers' Protection, as amended and in force by Law 4512/2018 (Government Gazette A 17/01/2018).

35 Presidential Decree No. 456 of 17/24 October 1984 (Government Gazette A'164) Civil Code and its Introductory Law.

36 Law 4619/2019 (Government Gazette A' 95/11.06.2019) Ratification of the Penal Code.

37 European Commission's Final Report is available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

38 See European Commission's Report of 2019 on Competition Enforcement in the Pharmaceutical Sector (2009-2017), available at: https://ec.europa.eu/competition/publications/reports/kd0718081enn.pdf.

violation of the competition rules in the relevant market of production and marketing of cosmetic products, personal and baby care products, parapharmaceuticals and other related products, identifying contractual terms that restricted the mutual supplies between the authorised Greek retailers of the selective network, as well as restrictions of their wholesale export sales to selected distributors of the network in EU Member States.[39]

The HCC, which has proved in the most recent years to be one of the most vigilant authorities in the EU, has also carried out unannounced inspections (dawn raids) at the premises of companies that are active in the life sciences sector. In this regard, the HCC conducted in October 2021 a dawn raid at the premises of a company active in the production and supply of pharmaceutical products regarding potential anticompetitive practices.[40] Subsequently, in March 2022, the authority carried out dawn raids investigating suspected anticompetitive practices via the participation of certain firms in a public tender for the supply of rapid tests for covid-19.[41]

In terms of abuse of dominance enforcement, the HCC has not undertaken cases regarding price-related practices in this sector, which in principle fall under Article 2 of the Greek Competition Act and Article 102 of the Treaty on the Functioning of the European Union (TFEU). This is owing to both the understandable reluctance of the HCC to act as price regulator and the fact that medicinal products' pricing in Greece is heavily regulated.[42] However, there has been some antitrust enforcement against unilateral practices of dominant firms. Specifically, with Decision No. 608/2015, the HCC imposed a fine on GlaxoSmithKline for an abusive refusal to supply under Article 2 of the Greek Competition Act and Article 102 TFEU. While acknowledging that pharmaceutical companies should be allowed to defend their commercial interests when threatened by the extent of parallel trade of their products, the HCC held that a sudden and complete refusal goes beyond what is necessary for the protection of the company's interests and, as such, cannot be objectively justified. The decision followed a preliminary ruling by the Court of Justice of the European Union in the *Sot Lelos* case,[43] after a referral by the Athens Administrative Court of Appeals.

Quite apart from its enforcement activity, the HCC has also set up the Covid-19 Competition Task Force, which has taken a number of actions to ensure the enforcement of competition rules in the healthcare and medical equipment sector and the wider food sector, as well as to provide businesses and the general public with relevant information.[44] In this regard, the HCC has been closely observing medicinal pricing during the covid-19 pandemic

39 HCC's Press Release available at: https://www.epant.gr/en/enimerosi/press-releases/item/1251-press-release-ex-officio-investigation-and-examination-of-the-complaint-of-the-company-intermed-sa.html.

40 HCC's Press Release available at: https://www.epant.gr/en/enimerosi/press-releases/item/1568-press-release-dawn-raid-of-the-hellenic-competition-commission-in-the-markets-for-production-and-supply-of-pharmaceutical-products.html.

41 HCC's Press Release available at: https://www.epant.gr/en/enimerosi/press-releases/item/2320-press-release-case-prioritization-and-assignment-to-a-commissioner-rapporteur-public-tender-for-the-procurement-of-medical-products.html.

42 It is worth mentioning, however, that both the European Commission and certain national competition authorities in the EU have recently intervened against excessive pricing in the pharma sector, showing a renewed interest in pursuing excessive pricing investigations in this sector.

43 Joined Cases C-468/06 and C-478/06, *Sot Lelos kai Sia EE and Others v. GlaxoSmithKline AEVE Farmakeftikon Proïonton*, ECLI:EU:C:2008:504.

44 HCC's Press Release available at: https://www.epant.gr/en/enimerosi/press-releases/item/929-press-release-hcc-initiatives-during-the-coronavirus-health-crisis.html.

in the context of its broader sector monitoring mandate. In particular, the HCC has collected and evaluated data from public and private hospitals to investigate whether the conditions for initiating an *ex officio* antitrust investigation were met, specifically regarding the supply of molecular covid-19 testing kits and covid-19 antibody testing kits. In its December 2020 preliminary findings, the HCC concluded that for the period between February and August 2020, no indications of collusion in terms of market sharing or price-fixing were identified, also announcing that it will continue to monitor this area and provide periodical updates.[45]

In a similar vein, the HCC initiated in July 2021 a sector inquiry into the provision of private health services and related insurance services, exercising the respective powers conferred on it pursuant to Article 40 of the Greek Competition Act.[46] This initiative was motivated by the rearrangements taking place in the private health services sector in the past five years and the restructuring of the regulatory framework for the provision of related insurance services. The final report regarding the sector inquiry into health services has yet to be published, but the competition issues to be considered are identified, in principle, in the competitive process between health service providers in terms of quality and prices of the services provided.

ii Transactional issues

Transactions related to medicines and medical devices fall under the scope of the Greek Competition Act. Consequently, any M&A in the relevant sectors that fulfils the turnover thresholds specified in the Greek Competition Act would require a mandatory pre-notification filing to the HCC. Moreover, any transaction that results in a change to a product's information or labelling (e.g., change of MAH) must also be notified to the EOF.

Generally, the HCC has examined and accepted narrow segments of the relevant markets, closely following the European Commission's relevant decisional practice. A recent noteworthy transaction that the HCC has reviewed is the acquisition by BC Partners of indirect sole control over the Pet City Group (Decision No. 756/2021), where the HCC found that the said concentration, which concerns the retail markets for pet food, the supply of pet health and care products, the supply of veterinary medicines and antibiotics, and the provision of veterinary care services, does not raise any serious doubts as to its compatibility with the competition rules.

Concentration in the healthcare services sector in Greece has been continuously growing in recent years. Of particular interest is the ever-increasing consolidation of the private insurance sector, as marked by the two recent HCC decisions clearing two transactions between four of the largest companies in the sector, namely: (1) the acquisition of sole control by Allianz SE over the company European Reliance General Insurance Co (Decision No. 782/2022), and (2) the acquisition of sole control by Assicurazioni Generali – Societa per Azioni over Axa Insurance SA (Decision No. 732/2021). In the same vein, the EC's unconditional clearance decision of CVC Capital's acquisition of sole control over the Hellenic General Insurance Co SA, one of the largest private insurance companies in Greece, is noteworthy, mindful of the fact that CVC controls most of the Greek private hospitals.

45 HCC's Press Release available (only in Greek) at: www.epant.gr/enimerosi/ deltia-typou/item/1217-deltio-typou-aksiologisi-syllexthenton-stoixeion-gia-ta-test-tou-koronoioy-covid-19.html.

46 HCC's Press Release available at: https://www.epant.gr/en/enimerosi/health.html.

VIII CURRENT DEVELOPMENTS

On the basis of Article16 of Law 4931/2022,[47] which amends Article 11 of Greek Law 4052/2012,[48] the clawback sharing parameter related to the comparison of the market share of each medicine with its share of the previous year (the 'growth rate' parameter) was abolished. More specifically, under the foregoing provision, each product's growth rate that was previously taken into account for calculating clawback, burdening each MAH or pharmaceutical company, is abolished given that the said criterion is balanced by a number of new provisions entered into force by virtue of the Law and, in particular: (1) the additional discount up to 3 per cent on the ex-factory price; (2) the new compulsory 5 per cent discount imposed on high-cost FYK; and (3) the new closed budget for FYK, as analysed in Sections V, VI and VII respectively.

47 Law 4931/2022 (Governmental Gazette A' 94/13.05.2022) 'Doctor for all, equal and quality access to the services of National Health Service and Primary Health Care and other provisions'.

48 Law 4052/2012 (Governmental Gazette A' 41/01/03/2012).

Appendix 1

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