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COMMERCIALISATION OF HEALTHCARE

Commercialisation of healthcare in Greece: overview

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MEDICINES

1. What is the definition of medicine (or equivalent) in your jurisdiction?

"Medicine" is defined in Article 2(1) of Greek Ministerial Decision 32221/2013 (Medicines Act), which implements EU Directive 2001/83 on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) into Greek law , as either:

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings.
- Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

2. What authorities are responsible for regulating the manufacture, marketing and advertising of medicines?

The Greek National Drug Organisation (EOF), supervised by the Ministry of Health, is responsible for regulating the manufacture, marketing and advertising of medicines (*Article 2, Law 1316/1983*).

3. What notifications, registrations, approvals and licenses are required to manufacture and market medicines and their active pharmaceutical ingredients?

Manufacturing

A licence issued by the EOF is needed for the manufacturing of medicines in Greece, including for any medicines which will be exported.

For the manufacturing authorisation to be granted, the applicant manufacturer must meet the following requirements:

- Specify the medicines and their pharmaceutical forms and the place where they are to be manufactured/and or controlled.
- Have suitable and efficient premises for manufacture and technical equipment and control and storage facilities complying with the requirements of Article 32 of the Medicines Act.
- **Employ** at least one qualified person responsible for carrying out control of the manufactured medicines.

(*Article 58, Medicines Act.*)

Under domestic legislation, provisional authorisation can be granted for the early access (compassionate use) to medicines not yet available in Greece by individuals or groups of patients (*Ministerial Decision 85037/2010*) (*see below, Marketing authorisation*).

The Marketing Authorisation Holder (MAH) or the MAH's local representative is entitled to hold the required approvals and licences and undertake approved activities in Greece.

Marketing

Marketing authorisation. For the marketing of medicines a marketing authorisation is required.

The processes for the granting authorisations vary according to the type applied for as follows:

- **Centralised Marketing Authorisation**. This is granted by the European Medicines Agency (EMA), under Regulation (EC) 726/2004 on the authorisation and supervision of medicines. For a medicine authorised by the EMA to receive a price and be commercialised in Greece, a simple notification must be filed with the competent division of the EOF.
- **Mutual Recognition and Decentralised Procedure**. A medicine that has been approved in another EU member state can be recognised in Greece under the mutual recognition procedure provided by Article 45 of Medicines Act. Under this procedure, the EOF must acknowledge and recognise marketing authorisations granted in other member states.
- **National Procedure**. This relates to the national licence for medicines which are manufactured in Greece and are marketed exclusively in Greece.

A provisional marketing authorisation can be provided for medicines in the context of clinical trials, early access programmes and special individual patient use.

Either legal entities or natural persons are entitled to hold the required approvals and licences and undertake approved activities in Greece. In the case of legal entities, this activity needs to be provided for in their articles of incorporation.

4. What are the differences between the regulation of new innovative medicines and generic or biosimilar versions of those medicines?

There are several provisions in Greek legislation which support the generic and biosimilar industries:

- **Health technology assessment (HTA):** generics for the same active substances and indications are exempted from the HTA. Also exempted are the medicinal products containing active substances used in the composition of authorised medicinal products but not until now used in combination for therapeutic purposes. Biosimilars are subject to an accelerated assessment process, within one month from the application's submission.

- **Pricing**: the price of the generic medicine is set at 65% of the price of the reference product at the end of the protection period (*Article 22 (e), Law 4638/2019*).
- **Calculation of mandatory claw-backs**: 90% only of the excess of the pharmaceutical expenditure is taken into consideration for generics, while for reference products 100% of the expenditure is taken as a basis.

In addition, there are provisions setting targets for the increase of the generics' market share for outpatients and introducing incentives and obligations for pharmacists to follow the International Non-Proprietary Name (INN) system when dispensing a physician's prescription for a patient.

5. What are the differences between the regulation of prescription and over-the-counter medicines?

There are differences between the regulation of prescription and over-the-counter medicines (OTCs) in terms of:

- Pricing process, as the price for OTCs is calculated based on the average of the three lowest prices in the Eurozone, while for prescription medicines the two lowest prices in the Eurozone is taken into consideration.
- Price, as the retail price for OTCs is freely determined as opposed to prescription medicines' prices which are set by the state.
- Reimbursement, since OTCs are not reimbursed.
- Promotion, as the promotion of prescription medicines to the general public is not allowed, while promotion of OTCs is permitted.
- Channels of distribution: a specific category of OTCs (common medicines sold for common symptoms that can be easily self-diagnosed such as headaches) (General Sale Medicines)) (GEDIFA) can be sold in places other than pharmacies, such as supermarkets or e-pharmacies. GEDIFA are marketed OTCs in smaller packets which do not require specific preservation conditions.

6. Are there fewer or different requirements for the approval of medicines that have already been licensed or approved in another jurisdiction?

For medicines which have already been approved by the jurisdiction of another EU member state, the requirements for approval are the same for all EU member states based on the Code for Human Medicines Directive, implemented in Greece by the Medicines Act.

A marketing authorisation in Greece can only be granted to an applicant who is established in the EU (*Article 9(2), Medicines Act*).

The requirements for approval of a medicine in Greece, regardless of whether the applicant is in the EU or in a third country, are those provided by Medicines Act, in line with the Code for Human Medicines.

7. Is it possible to sell medicines to or buy medicines from other jurisdictions?

It is possible to sell or buy medicines from other jurisdictions. A pharmaceutical company or a wholesaler of medicines can freely import medicines from another EU member state provided that a relevant application for the issuance of a parallel import licence is submitted to the EOF (*Ministerial Decision No. 4171/1987 on the Parallel Import of medicines*).

Unless revoked earlier, the parallel import lasts for five years.

Importers wishing to import medicines from a third (non-EU) country must file a relevant application with the EOF. Before granting its approval, the EOF will examine whether the specifications of the medicine comply with the provisions of Part V of the Medicines Act relating to labelling and the summary of the product's characteristics. The prerequisites for the import of medicines from third countries are set out in the EOF's Circular 18013/2013 on the Import of Drugs from third countries.

Exporting medicines from Greece is possible, to the extent the regular supply of the local market is not put at risk. The conditions for the export of medicines are set out in detail in the EOF's Circular 66180/2005 on the Export of Medicines from Greece.

The exporter of medicines must obtain a free sale certificate from the EOF, which must be issued in accordance with the World Health Organization format. The EOF has the authority to impose export bans, where shortages are anticipated, to safeguard the regular supply of the market and public health in general.

8. How is medicine promotion and advertising activity regulated, and what are the general requirements to advertise medicines?

The promotion of prescription medicines to consumers is not allowed. Only OTCs can be advertised to the general public.

Promotion to healthcare professionals (HCPs) is regulated by the Medicines Act, various circulars of the EOF and the local Industry Association for Medicines (SFEE) Code of Ethics.

In principle, advertising material that is addressed and distributed to HCPs must be notified to the competent ,department of the EOF before being distributed (*Article 123. Medicines Act*). Restrictions in promotion are the same regardless of whether the promotion is made over the internet, through social media channels or by traditional means of advertising.

Pharmaceutical companies are allowed to distribute a small number of samples to HCPs yearly, subject to approval by the competent division of the OF (*Article 128, Medicines Act*). Pharmaceutical companies that distribute samples must maintain a system of control (track record) of the samples distributed.

9. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

Health technology assessment (HTA): Patent medicines with a marketing authorisation granted under any of the required procedures (*see Question 3, Marketing authorisation*) must be evaluated to be included in the reimbursement list. Such medicines must be reimbursed in at least five of the following EU countries, which also apply an HTA: Austria, Belgium, France, Germany, Denmark, Spain, The Netherlands, Italy, Portugal, Sweden and Finland.

Exemptions from the above requirement are:

- Orphan medicines to the extent they are covered by international protocols.
- Medicines for Mediterranean anemia (thalassemia).
- Vaccines in the context of immunological medicinal products.
- Medicines derived from human blood or human plasma.
- Medicines which are based on a combination of well-known active substances, for which the protection period has expired.

- Clone medicines.
- Biosimilars.
- Medicines with active substances of already approved medicines.

Promotion: The general prohibition for advertising to the general public is lifted for vaccine campaigns that are conducted by pharmaceutical companies following EOF approval, for the purpose of creating awareness for the disease and increasing the vaccination rate in the population.

10. What controls apply to medicines or components of medicines that derive from humans or animals or incorporate modified genetic material?

Commission Directive 2009/120/EC amending and supplementing the Code for Human Medicines Directive as regards advanced therapy medicinal products was adopted by Greece through Ministerial Decision 29292/2010.

Relevant controls provided for in the EU legislation are locally monitored by the EOF.

BIOLOGICAL MEDICINES

11. What is the definition of biological medicines in your jurisdiction and what are the main laws that specifically apply to them (if any)?

The definition of a biological medicine that applies in Greece is that provided by the EMA as follows:

- Biological medicine is a medicine whose active substance is made by a living organism.
- Biological product is a product the active substance of which is a biological substance.
- Biological substance is a substance that is produced by, or extracted from, a biological source and which requires a combination of natural, chemical and biological tests for its characterisation and the determination of its quality.

The main law that applies to these medicines is the Medicines Act.

The same rules apply for biological medicines as for medicines in terms of manufacturing, advertising or sale.

12. Are there any additional or alternative regulations that apply specifically to biological medicines?

The rules and requirements set out in *Question 2 to 10* relating to non-biological medicines generally apply to the commercialisation of biological medicines, and there are no key differences in the regulation of biological medicines.

MEDICAL DEVICES

13. What is the definition of medical device (or equivalent) in your jurisdiction? What is the significance of any legal classifications?

A medical device is defined as an instrument, material or other item that is used, alone or in combination with others, for diagnostic and/or therapeutic purposes and which complies with the security measures for its use (*Article 1, Ministerial Decision No 130648/2009 on Medical Devices (Medical Devices Act)*).

There is no mechanism for obtaining a decision from the EOF as to whether a product is a medicine or a medical device. However, if the EOF considers that the product in scope is in a grey area and it cannot be clarified whether it is a medicine or a medical device, the case will be referred to the Scientific Committee of EOF, on which rests the final decision.

Currently medical devices are divided into the following classes:

- Class I: non-invasive devices.
- Class IIa: non-invasive devices intended for channelling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion.
- Class IIb: non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion, administration or infusion into the body.
- Class III: all invasive devices.

The Medical Devices Regulation *((EU) 2017/745)* (MDR) is expected to enter into force on 26 May 2021. Under the Regulation, the definition of a medical device is expanded and new rules are created for determining risk classification, including Rule 11, which specifically addresses software. Based on this, a software or mobile application intended to provide information that is used to make decisions with diagnostic or therapeutic purposes is a medical device, which will be classified in Class IIa as defined in the MDR.

14. What authorities are responsible for regulating the manufacture, marketing and advertising of medical devices?

According to Greek Ministerial Decision 1348/2004, the EOF is responsible for regulating the manufacture, marketing and advertising of medical devices.

15. What notifications, registrations, approvals and licences are required to manufacture and market medicinal devices?

If the medical device is approved in and imported from an EU member state, and already bears the CE mark, the only requirement with which the manufacturer of the medical device or the distributor in Greece has to comply is a notification before the EOF of the intention to market the product on the Greek market.

If the medical device is manufactured in Greece, an approval is required by the competent Greek certified body, which is responsible for examining whether the qualifications of the medical device are in line with the EU and domestic legislation on medical devices.

To be eligible for commercialisation, a medical device must bear a CE mark. However, this requirement does not apply where the medical device is manufactured following a special order or intended for use only within the context of clinical studies (*Article 4, Medical Devices Act*).

All approvals and licences that are required must be held by the manufacturer of the medical device and/or the distributor in Greece, the two parties that are entitled to undertake all relevant approved activities in Greece.

Manufacturing

The manufacture of medical devices in Greece must meet the requirements of Annex I of the Medical Devices Act.

Where a medical device is manufactured locally or is imported from a non-EU member state, the manufacturer/importer must apply for

the CE mark, which is granted by a recognised notified body accredited by the Greek state (*Article 117, Medical Devices Act; Article 4, Ministerial Decision No 130644/2009 on Implantable Medical Devices (Implantable Medical Devices Act)*).

All medical devices imported from an EU member state must bear a CE mark. These medical devices can be marketed in Greece without any additional registration or regulatory approval. The importer only needs to make a simple notification to the EOF. Information concerning the use of a medical device marketed in Greece must be provided in Greek.

Advertising

The advertising and promotion of medical devices in Greece is subject to approval by the EOF, and promotional materials must not be misleading (*Article 22, Medical Devices Act; Article 16, Implantable Medical Devices Act*). The advertising of medical devices to consumers is not expressly prohibited. Therefore, the authors consider that such advertising is allowed.

Sale

To be eligible for commercialisation, a medical device must bear a CE mark. However, this requirement does not apply to medical devices manufactured following a special order or for medical devices intended for use in clinical trials (*Article 4, Medical Devices Act*).

The CE mark on medical devices is recognised by all EU member states. There are no further requirements for the commercialisation of medical devices imported from other EU member states, except that usage information must be in Greek.

To import a medical device which does not bear the CE mark, the importer must apply to the competent body for the certification of medical devices in Greece, which will examine the specifications of the product and if its approval for the CE mark is granted, the product can be launched on the Greek market.

16. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

The CE mark on medical devices is recognised by all EU member states. There are no further requirements for the commercialisation of medical devices imported from other EU member states and bearing the CE mark. However, the information leaflet must be in Greek and a notification to the EOF of the intention to market the product in Greece must be made by the manufacturer or the distributor.

In the case of import of a medical device which does not bear the CE mark, the importer must apply for the issuance of a CE mark.

17. Is it possible to sell devices to or buy devices from other jurisdictions?

Medical devices can be bought from or sold to all EU member states, provided that the importer or exporter of the products has a CE mark granted by a certified body recognised in the relevant state.

As an EU member state, Greece also follows the agreements that have been put in place between EU and third countries such as Switzerland, China and the US, which aim to reinforce the mutual recognition and parallel trade of medical devices.

18. What are the general requirements to advertise medical devices?

A medical device can be advertised in Greece without any restrictions, provided that its information leaflet is written in Greek. Advertising over the internet is not treated differently or specifically regulated.

The advertising and promotion material of medical devices in Greece must not be misleading (*Article 22, Medical Devices Act; Article 16, Implantable Medical Devices Act*).

In the case of non-compliance with the rules on promotion, the EOF has the power to impose fines of between EUR22,000 and EUR44,000 in the case of repeated infringements of the same rules on promotion.

19. What product marking is required for authorised medical devices?

Authorised medical devices must bear the CE mark. Medical devices imported from an EU member state already bearing a CE mark can be marketed in Greece without any additional registration or regulatory approval. The importer only needs to make a simple notification to the EOF. Information concerning the use of a medical device marketed in Greece must be provided in the Greek language.

Where a medical device is manufactured in Greece or is imported from a non-EU member state, the manufacturer/importer must apply for a CE mark, which is granted by a recognised certified body accredited by the Greek State (*Article 117, Medical Devices Act and Article 4, Implantable Medical Devices Act*).

COMBINATION PRODUCTS

20. Does your jurisdiction recognise combination products? What are the main laws that specifically apply to them (if any)?

Greek laws and regulations recognise combination products under Greek laws implementing the relevant EU legislation which define such products. Combination products are mainly regulated by the Medical Devices Act, in particular Article 1, paragraphs 3, 4 and 4a and Article 12, Appendix II, point 9.

21. Are there any additional or alternative regulations that apply specifically to combination products?

There are no additional or alternative regulations that apply specifically to combination products and the rules and requirements set out in *Question 2 to 10* relating to medicines generally apply to the commercialisation of combination products.

NATURAL HEALTH PRODUCTS

22. Is there a category for natural health products (or equivalent) (including, for example, traditional medicines, homeopathic medicines, supplements, vitamins and minerals)?

Under Greek law, natural health products or herbal products and homeopathic medicines are regulated by the Medicines Act. A distinction is used in the Medicines Act, in line with EU legislation,

for natural health products between those for "traditional" use and those of "well-established" use.

Food supplements, vitamins and minerals are categorised by the EOF in the "various" products category and regulated by other Ministerial Decisions.

More specifically:

- Herbal products are regulated by Articles 21 to 28 of the Medicines Act. A simplified approval procedure is available if the conditions set out in Article 21 of the Medicines Act are met.
- Homeopathic medicines are regulated by Articles 17 to 20 of the Medicines Act. A special simplified approval procedure is available if the conditions set out in Article 18 of the Medicines Act are met.
- Food supplements, vitamins and minerals are regulated by:
  - Ministerial Decision No 53625/2017 on the Harmonization of national legislation with the corresponding Directive 2002/46/EC on the approximation of the laws of member states relating to food supplements and codification of the existing provisions in a single text; and
  - Regulation (EC) 1170/2009 as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements.

In addition, Regulation (EU) 432/2012 which establishes a list of permitted health claims made on foods, other than those referring to the reduction of risk of disease and the development and health of children, also regulates this category of products.

23. What authorities are responsible for regulating the manufacture, marketing and advertising of natural health products?

Natural health products, although not defined as a separate category of products in the EOF departmental structure are in the category of "various" products which in terms of manufacture, marketing and advertising fall within the competency of the EOF.

24. What notifications, registrations, approvals and licenses are required to manufacture and market natural health products?

Manufacturing

The provisions relating to the manufacturing of prescription medicines apply also to prescription natural health products, while the provisions regarding the manufacturing of non-prescription medicinal products (OTCs) apply to non-prescription natural health products, both set out above.

Currently, natural health products are considered non-prescription medicinal products in Greece.

Marketing

The Medicines Act (*Article 21*) provides for the establishment and application of a simplified registration procedure ("traditional-use registration") for herbal medicinal products which fulfil all the criteria listed in the article. This simplified registration procedure does not apply in cases where the EOF judges that a traditional herbal medicinal product fulfils the criteria for the standard procedure for authorisation that applies to medicinal products or registration procedure for other products that fall under the scope of the EOF, such as homeopathic medicines, as the case may be.

25. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

A notification to the EOF is required for natural health products that are sold in the Greek market if they are already licensed in another EU member state. If originating from a third country, to grant its approval, the EOF will examine whether the natural health product's composition and specifications are in line with the relevant EU requirements.

26. Is it possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically?

It is possible to sell natural health products to or buy natural health products from other jurisdictions both by ordinary mail and electronically.

27. What are the general requirements to advertise natural health products?

Advertising is allowed to the general public only to the extent that natural health products are non-prescription drugs. A statement must be included in the advertisement stating that this is a traditional medicine of herbal origin, to be used for specific indication(s) on the exclusive basis of a long-standing use. The basic rules applying for advertising OTCs apply, that is, the advertisement must not be misleading or include statements implying that the safety and efficacy of the herbal medicine are attributed to the fact that the medicine is a natural health product.

DATA

28. What data and information laws must be complied with by life sciences businesses that collect, use or otherwise deal in patient data (including through health apps)?

Greece complies with the EU General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR).

In addition, the following domestic laws must be complied with by life sciences businesses that collect, use or otherwise deal in patient data (including through health apps:

- Law 4624/2019 including provisions for the implementation of the GDPR.
- Law 3471/2006 on the Protection of Personal Data and Privacy in the Field of Electronic Communications.

RESEARCH

29. What restrictions and regulatory requirements apply to the testing of life sciences products on human and animal subjects?

Clinical research is generally heavily regulated by the relevant European legislation. Clinical trials are conducted on the basis of protocols which are approved by the local authorities of the country where the site the trial being conducted is located. Subjects' participation is similarly strictly regulated, based on their informed consent, while all material used in the context of a clinical trial is submitted to the local authorities for approval.

REFORM

30. Are there any plans to reform the rules on the development, manufacture, marketing and advertising of life sciences products and services?

There are no current relevant planned reforms in this field.

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- Representing a pharmaceutical company before the Hellenic Association of Pharmaceutical Companies in relation to alleged breaches of compliance and ongoing regulatory advice.
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- Advising Hellenic Healthcare Sàrl on operating and medical equipment licences, compliance with data protection regulations, co-operation and reimbursement agreements, and other regulatory issues arising in the context of their entry into a binding agreement to acquire 97% of the share capital in IASO General SA from IASO SA.
- Advising the local branch of a multinational pharmaceutical company on an ongoing basis.

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