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Greece

PHARMACEUTICAL ADVERTISING

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

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GREECE
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

The legal framework governing the advertising of medicines in Greece consists mainly of the following:

• Legislative Decree 96/1973 on the trading of pharmaceutical and cosmetic products • Law 1316/1983 on the establishment, organization and competence of National Organization for Medicines ("EOF") • Ministerial Decision Υ6α/οικ.22261/2002 on the advertising of over-the-counter medicinal products (OTC) • Ministerial Decision DYC 3α/CP.32221/29.4.2013 on the implementation of Directive EC 2001/83/EC of the European Parliament and of the European Council on the "Community Code relating to medicinal products for human use" • Ministerial Decision YA6/10983/84/1985 on Medical Information on Medicines from Pharmaceutical Companies • Law 2251/1994 on Consumer Protection • Ministerial Decision G5a/59676/2016 on the implementation of Regulation 536/2014 of the European Parliament and of the European Council on Clinical Trials for Human Subjects • Presidential Decree 340/1993 (Greek Code of Pharmaceutical Ethics) • Law 3418/2005 (Greek Code of Medical Ethics) • EOF Circulars 16427/24.2.2017, 44787/12.5.2017, 16251/13.2.2019, 37201/23.03.2020 and Q&A 47384/31.05.2021

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

a.

• Hellenic Association of Pharmaceutical Companies (**SFEE**) Code of Ethics (2023 edition), aligned with EFPIA CODE, is an instrument of self-regulation of the pharmaceutical companies, regularly updated and relating to the promotion of pharmaceutical products for human use, based on professional responsibility, ethics and transparency – applicable to its members. • Greek Association of Self-Medication Industry (**EFEX**) Code of Ethics and Self-Regulation (medical devices, OTCs, etc.) – applicable to its members. • Hellenic Society for Pharmaceutical Management Code of Ethics and Conduct – applicable to Pharma Executives. • Greek Advertising Self-Regulation Council (**SEE**) Advertising and Communication Code – regulates promotional communication of businesses in general.

b. The self-regulatory codes, SFEE's Code being predominant, are soft law instruments containing guidelines for members of respective associations. To be noted that SFEE's Code is stricter than respective provisions. Non-members may adhere to the code voluntarily.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

a. '**Advertising of medicinal products**' means any form of door-to-door information, solicitation or incentive aimed at encouraging the prescription, supply, sale and/or consumption of medicinal products and particularly (Art. 118 par. 1 of MD32221/2013):

• The advertising of medicinal products to healthcare professionals ("HCPs") and to the public (allowed only for non-prescription products), • the visiting of medical sales representatives to HCPs, • the supply of samples, • the solicitation of the supply of medicinal products or

their prescription by the offer or promise of advantages or gifts, whether in cash or in kind, • the sponsorship of promotional meetings or scientific conferences attended by persons delegated to dispense prescriptions or supply medicinal products.

b. The definition of advertising applies equally to all target audiences but rules vary according to the category of addressee.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases are allowed subject to the relevant general advertising provisions. A press release can be characterized as promotional if it refers to a specific medicinal product, directly (by trade name) or indirectly (e.g. referring to active substance of a patented drug in such a way as to “photograph” it).

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Pharmaceutical companies are required to establish a Scientific Committee comprising of at least one healthcare professional, which – among others – provides full range information to patients and sales representatives on the company’s medicinal products and verifies the compliance of promotional material or initiatives with the law (Art. 130 of MD 32221/2013) and guidelines. SFEE Code contains very strict provisions regarding internal procedures to ensure compliance of their promotional material.

6. Do companies have to have material approved by regulatory bodies prior to release?

Marketing Authorization Holders are obliged to submit to EOF a copy of any promotional material to be released, accompanied by a statement indicating the recipients, method and date of first dissemination, as well as a Summary of Product Characteristics (SPC) (Art. 130 MD 32221/2013 and Circular 44787). The abovementioned notification does not constitute a submission for approval save vaccination campaigns that need special approval; EOF can forbid any advertisement when public health is at stake though.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

L. 2251/1994 allows for comparative advertising between products meeting the same needs and objectives, under the condition that such advertising shall neither be misleading or defamatory, does not profit illegally of competitor’s distinctive trademark, does not create confusion between products nor present a product as an imitation of another.

Art. 122 of MD 32221/2013 prohibits the advertisements of medicines suggesting that the effects of the advertised medicine are better than, or equivalent to, those of another product. EOF has the opinion that the phrase “No.1”, regardless of its justification, suggests unacceptable statement of superiority of a medicinal product.

SFEE (sect. 3.4) and EFEX (sect. 6) Codes permit the usage of comparative claims if they are supported by significant comparative trials or any other evidence, such as studies published in peer-reviewed scientific journals.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

According to the SFEE Code, unpublished data on the effectiveness and safety of medicines (data on file) cannot be used for promotional purposes. Moreover, if the marketing authorization process for a certain medicine or indication is still pending, advertising is strictly prohibited. Exceptionally, new scientific data on unauthorized medicines or indications may be shared with HCP during a scientific conference because this kind of communication does not fall within the scope of advertisement or promotion, provided that it is made clear that the active substance in question has not been yet approved, no trade name is used and shared data are absolutely accurate.

Moreover, general information such as the total duration of a clinical program may be become the subject matter of discussions between healthcare professionals and a certain pharmaceutical company upon the latter’s initiative to address a documented question to its medical department.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

The advertising of prescription-only medicines to the general public is strictly forbidden. On the contrary, the advertising of over-the-counter medicines to the public is permitted (Arts. 119 et seq of MD 32221/2013), under the following conditions:

a) The advertisement must clearly correspond to the information contained in the SPC and specify the promotional character of the message, avoiding to create the impression that medical consultation can be omitted, that the health of user can be improved through the use of said product (or respectively that it can be affected by not using it), that its safety is because of its natural origin and/or that the efficacy of the OTC is guaranteed because of the inclusion of an endorsement of a reputable person or otherwise;

b) Minimum information: name of the medicinal product, international non-proprietary name, information for correct use, invitation to read the instructions on the package leaflet or on the outer packaging.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

The scientific committee of a pharmaceutical company is responsible for replying to all queries, including those of patients (Art. 19 SFEE Code, Art. 130.1 MD).

SFEE Code poses a limitation to the interactions between patient organizations and companies:

Patient Awareness Events (Art. 6 SFEE Code): may only be organized by patient organizations or scientific healthcare institutions. Pharmaceutical companies can only provide financial support.

Patient Education and Support Programs (Art. 13 SFEE Code): Pharmaceutical companies may sponsor a program of supporting patients and caregivers by contracting with a third-party organizer, without being allowed to collect any personal data (exceptions for pharmacovigilance compliance) or contact patients and their family, directly or indirectly.

Market Research (Art. 14 SFEE Code): Conducted by Market Research Companies certified by ESOMAR, either through questionnaires (quantitative) or through focus-groups/in-depth interviews (qualitative) for marketing purposes. Pharmaceutical companies are not permitted to have access to patients' personalized data.

Contractual Services (Art. 26 SFEE Code): patient organizations may provide experts, consultants or speakers to pharmaceutical companies to support healthcare or research.

Sponsorships (Art 23 SFEE Code): any form of financial support from pharmaceutical companies to patient organizations must be covered by written agreement.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Advertising material of medicinal products addressed to HCPs (MD 32221/2013) must include:

– essential information deriving from the Summary of Product Characteristics (SPC);

– the supply classification of the medicinal product as prescription-only or non-prescription;

– the selling or indicative price of the various packages;

– an invitation to report any adverse event to EOF;

-the date of drafting and latest revision of the advertising material.

Information about clinical trials or copies of journal can be sent to HCPs, upon their request, provided that all data are faithfully reproduced, refer the exact source from which they derive and reflect the precise stage of scientific developments in order to be sufficient to allow the recipient to estimate the therapeutic value of the medicinal product.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Pharmaceutical companies are prohibited from providing or promising gifts, monies or benefits to physicians or pharmacists, except for giving items of negligible value (up to 15 Euros/item incl. VAT) that are relevant to

medical or pharmaceutical practice. (Art. 126 MD. 32221/2013, Art. 10 SFEE Code, the Greek Code of Medical Ethics, Art. 66.7 L. 4316/2014).

In the same line, the supply of educational material to healthcare professionals is prohibited except for same value devices/applications linked to their daily practice. (e.g. applications for mobile phones/computers, publications including guidelines or therapeutic protocols, etc.) (Art. 18 of SFEE Code).

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Pharmaceutical companies may provide free medical samples to HCPs upon special permission by EOF at its absolute discretion (Art. 128 MD 32221/2013, Art. 31 L. 1316/1983 and Art. 17 SFEE Code), provided that:

a. Suppliers maintain an adequate system of control (i.e. annual limit to provided samples and receiving HCPs); b. Any supply of samples shall be in response to an official written request of the HCP; c. Samples cannot be larger than the smallest vendible packaging of the product; d. Samples must be marked as “free medical sample – not for sale”; e. Samples must be accompanied by a copy of the SPC; f. Samples of medicinal products do not contain psychotropic or narcotic substances.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Sponsorship of scientific events and attendance by HCPs falls within the definition of advertising (MD 32221/2013). Hence, the organisation or sponsorship of scientific events by pharmaceutical companies requires prior approval from EOF as to its content and arrangements (Art. 31 L.1316/1983). For the participation of HCPs in webinars, which are not fully regulated yet, a mere notification to EOF suffices.

In principle an HCP may attend a scientific meeting having solely registration, travelling and accommodation cost covered. On the contrary, National Health System (ESY) HCPs, University HCPs practicing in ESY are prohibited from participating in any manner in promotional events organized by pharmaceutical companies within Greece or abroad for the promotion of their products (Art. 36 L.4272/2014).

SFEE Code (Arts. 6-8), EOF Circular 37201/23.03.2020 and related announcement dated 7.11.2022, contain several provisions regarding scientific events, including guidelines and restrictions such as but not limited to:

a) Duration: 4hrs/day – max. 3 days

b) Number of scientific events held by the same pharmaceutical company: 48/year

c) Amount of sponsorship: hospitality monetary limits per person for scientific events:

– in Greece: max. 70 Euros /day for feeding and max. 180 Euros /day for accommodation, incl. VAT.

– abroad: max. 150 Euros /day for feeding (incl. breakfast) and max. 400 Euros / day for accommodation, incl. VAT.

d) Date and Location: suitable conference venues, no tourism destinations during tourist seasons or hospitals and universities.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Pharmaceutical companies are prohibited from financially supporting the organisation of recreational activities or the participation of HCPs in such activities (i.e. excursions and touristic activities in general) (Art. 7 of the SFEE Code). Additionally, pharmaceutical companies must not organise or sponsor events organised by third-parties which are held in venues intended for purposes other than those of education/business.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

HCPs may receive honoraria by pharmaceutical companies for their participation in scientific events inside or outside Greece as speakers, panel chairpersons, members of organising committees, or authors of material presented (Art. 36 L. 4272/2014, EOF Circular 37201/23.03.2020). Additionally, HCPs may be remunerated for their participation in advisory boards set up by pharmaceutical companies.

In case of University HCPs or NHS HCPs, payment of

honoraria shall be materialized through Special Account for Research Grants (ELKE or ELKEA) available to any University, while HCPs acting as members of advisory boards or research teams in studies conducted in NHS Hospitals and University Clinics shall be paid also by Special Research Accounts.

Self-employed HCPs may be paid on the basis of a written agreement, while State-employed healthcare professionals are generally prohibited from offering their services to any private entity (Art. 11 of L. 2889/2001) save participation in advisory boards. Nonetheless, by means of recent legislative amendment by L. 4999/2022, NHS HCPs are exceptionally allowed to operate a private practice or provide medical services in any private sector body under certain conditions. A relevant Ministerial Decision is expected for further clarifications.

The SFEE Code also contains guidelines (Art. 9) and indicative payment amounts and limits in accordance with EU data (Annex II). HCPs shall not receive more than 5,000 Euros from the same pharmaceutical company as remuneration per year (save extra amounts for clinical trials).

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Save gifts related to everyday HCP's practice, not exceeding the value of 15 Euros, healthcare professionals who are authorised to prescribe medicines are forbidden to receive or accept any promise for gifts or benefits of any kind. However, donations from pharmaceutical companies to scientific healthcare institutions including public hospitals, medical companies, and patient organisations, in rem or monetary, are permitted, provided they serve a specific purpose that can be proven (Art. 11 SFEE Code) if: a. such purpose is to support healthcare, research, education of healthcare professionals, patients and their caregivers, purchase of medical equipment and improvement of health services; b. they are documented and such documents are kept by the donor; c. they do not constitute incentive for the recipient to prescribe or make available or purchase specific pharmaceutical products.

It is important to note that in case of donations in rem the company's name may be displayed on the donated goods, but never the name of a medical product.

A pharmaceutical company's donations are limited to 1% of its turnover annually.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

A pharmaceutical company is required to disclose by name both on its own website and on EOF's website, no later than six months after the end of each calendar year, all benefits it provides to specified HCPs and scientific healthcare institutions, including but not limited to donations, sponsorships, registration fees for conferences and educational scientific events, travel and accommodation expenses, as defined in particular in the respective circulars of EOF (Art. 66 par. 7a of L. 4316/2014).

Explicitly excluded from the disclosure obligation are the costs of market research, meals and beverages, as well as items of negligible value of medical and educational application, while R&D activities and non-interventional studies need to be disclosed in aggregate.

The disclosure obligation encompasses only companies having their registered office or business in Greece (Art. 66 par. 7a L.4316/2014 in combination with 31 of SFEE Code).

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

The Marketing Authorisation Holder must submit to EOF a copy of any advertising materials released followed by an announcement on the recipients and the details of dissemination (Art. 130.2 MD 32221/2013). Such notification does not constitute approval. EOF has the discretion to cease a misleading advertising on an ex-ante or an ex-post basis (Art. 129.2 MD).

The general rules on the advertising of medicinal products are applicable, mutatis mutandis, to advertising through the internet as well. According to SFEE Code (Art. 4.2), pharmaceutical companies should take measures to ensure that websites containing advertising of prescription-only medical products and other information addressed only to HCPs are accessed only by them, through the use of personalized usernames and passwords. Material uploaded on company websites, considered as promotional, must be approved internally by all departments involved, for their compliance with relevant legislation and codes of conduct, and notified to the competent body.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

UN Convention against Corruption which has been ratified by L. 3666/2008, L. 2957/2001 and L. 4557/2018 on money laundering apply to interactions between companies and HCPs or HCOs, while SFEE Code sets compliance with anti-bribery and anti-corruption policies as top priority. On the same line, pharmaceutical companies have established internal rules of conduct and transparency (i.e. Due Diligence Questionnaires prior to contracting) and implement extensive anti-bribery and anti-corruption terms in their agreements with said persons.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

In addition to the rules provided in the answer to Q20 above, the offering of benefits or inducements to healthcare professionals is governed by the following rules:

- Legislative Decree 96/1973
- Law 1316/1983
- Ministerial Decision 3221/2013 (expressly prohibits the offering of financial or in-kind benefits to HCPs)
- Greek Code of Pharmaceutical Ethics (PD 340/1993)
- SFEE Code

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

EOF is the supervising authority which enforces rules on pharmaceutical advertising (Arts. 129, 131 MD 3221/2013) and proposes the imposition of penalties, to the Minister of Health. Additionally, the General Secretariat Against Corruption and Public Prosecutors initiate penal processes against corrupted persons.

Regarding self-regulatory authorities, SFEE ensures compliance with the SFEE Code through a First and a Second-Instance Committee, as well as its Disciplinary Board (Chapter 6 SFEE Code).

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

EOF can intervene to seize alleged advertising infringements whereas pharmaceutical companies may initiate legal proceedings against competitors on the basis of the provisions regarding unfair competition before Civil Courts in pursuit of interim measures, suspension/omission or compensation for damages (Art. 3 of L. 146/1914).

Furthermore, legal action can be taken based on the provisions concerning misleading advertisements /messages (Art. 13a par. 2 and 2b of L.2251/1994 on Consumer Protection), aiming to penalties imposed by the Minister of Development and Investment (compliance deadline, fines and temporary suspension of operation).

Last but not least, the Disciplinary Board is also competent (Chapter 6 SFEE Code).

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

EOF has the authority to forbid a misleading advertisement at any time, when public interest is at stake.

Violating medicines advertising rules, among which are also the provisions regarding samples, may result in permanent revocation of Marketing Authorization.

For HCPs accepting illegal benefits imprisonment for up to 6 months, fines and deprivation of the right to practice profession for 6 months and up to 1 year are also threatened (Art. 33 of L.1316/1983), whereas in case of repeated behaviour, this sanction may be imposed in perpetuity. Fines imposed by EOF for violation of medicine advertising rules range from 22,000 up to 44,000 Euros, taking into account repeatability (Art. 175 of the MD).

Finally, SFEE may also impose corrective measures, as well as fines up to 25,000 Euros.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The procedures of supervising authorities (EOF) and self-regulatory bodies (such as SFEE) are separate and independent. According to Art. 38 of the SFEE Code, if the provisions of the Code conflict with national legislation, the stricter rule shall always apply. EOF is notified, if a pharmaceutical company member of SFEE refuses to comply with decisions issued by the Committees in the SFEE Code (Sect. 36.7 SFEE Code).

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The latest version of EOF's Circular 16251/13.2.2019, which amended Circular 44787/12-5-2017, as to the process of acknowledging advertising on medicinal products and the demolition of previous 96583/24-9-2018 amending Circular seems to be the latest amendment.

During the past two years, the field of pharmaceutical advertising in Greece has continued its journey towards alignment with the ever-changing international standards. Although not all changes have been regulated in-depth per se, competent authorities promptly provide guidelines and clarifications.

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