COUNTRY COMPARATIVE GUIDES 2022

The Legal 500 Country Comparative Guides

Greece

PHARMACEUTICAL ADVERTISING

Contributor

Koutalidis Law Firm

Nikitas Fortsakis

Partner | nfortsakis@koutalidis.gr

Evans Courakis

Partner | encourakis@koutalidis.gr

Lambros Fakitsas

Associate | lfakitsas@koutalidis.gr

Sofia Vestaki

Associate | svestaki@koutalidis.gr

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

For a full list of jurisdictional Q&As visit **legal500.com/guides**

GREECE
PHARMACEUTICAL ADVERTISING

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

The legal framework includes the following key legislation:

- Legislative Decree No.96/1973;
- Law No.1316/1983;
- Ministerial Decision No.Υ6α/οικ.22261/2002;
- Ministerial Decision No.Δ.ΥΓ3α/Γ.Π.32221/29.4.2013 ("**MD**") ;
- Ministerial Decision No.Α6/10983/84;
- Doctors' Code of Conduct (Law No.3418/2005);
- Pharmacists' Code of Conduct (Presidential Decree No.340/1993);
- Law No.2251/1994 on Consumer Protection;
- National Organisation For Medicines ("**EOF**") Circular No.16251/13.02.2019; and
- EOF Circular No.37201/23.03.2020.

Moreover, EOF issued a Q&A in relation to advertising of pharmaceutical products dated 31.05.2021("**EOF Q&A**").

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) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The codes that apply specifically to the pharmaceutical industry are the following:

- Code of Conduct of Hellenic Association of Pharmaceutical Companies ("**SFEE Code**"), applies to the pharmaceutical companies that are members of the Hellenic Association of Pharmaceutical Companies; non-members have the right to submit a statement expressing their will to comply with it. SFEE Code provisions are in alignment with the provisions of the EFPIA Code.
- Code of Conduct in relation to advertising non-prescription medicines ("**Code of EFEX**") issued by the Association of Greek Self Medication Industry.
- Code of Ethics and Conduct of the Executives of pharmaceutical Management adopted by the Hellenic Society for Pharmaceutical Managements regulating the activities of the marketing executives in the pharmaceutical field.

b) What is the legal status of the self-regulatory codes?

Self-regulatory codes are soft law instruments introducing guidelines and setting up the rules of conduct and good practice in a particular industry, containing though disciplinary provisions for their members.

Self-regulatory codes' provisions are not binding for EOF or other competent authorities.

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) What does the definition cover? – does it include patient information leaflets, for example,

catalogues, disease awareness campaigns or correspondence, for example?

Advertising of medicinal products shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular: a) the advertising of medicinal products to the general public and healthcare professionals ("**HCP**s"), b) visits by medical sales representatives to HCPs, c) supply of samples, d) the provision of inducements to HCPs and e) sponsorship of promotional meetings and scientific congresses attended by HCPs.

b) Does the definition apply equally to all target audiences?

The definition of advertising remains the same regardless the target audience. However, stricter rules apply to advertising for general public.

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)?

There are no specific provisions regarding press-releases. Any press release is subject to the restrictions regarding advertising. Given that any documents released by pharmaceutical companies that refer to active substances and/or trade names are presumed promotional, press releases including such data have to balance the advertising rules restrictions based on prevailing public interest reasons.

EOF Q&A provides that announcements of pharmaceutical companies aiming to protect public health cannot be considered as advertisements.

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

SFEE Code has specific provisions in relation to the internal control procedures that pharmaceutical companies shall have in place in order to examine the compliance of the advertising materials with the applicable legislation and SFEE Code.

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

MAH are obliged to provide EOF with a copy of any advertising/informative material to be released from the pharmaceutical company. Such copy must be accompanied by a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination. SmPC must be submitted together with the copy of the materials. Materials notified to EOF are subject to repressive controls.

Vaccination campaigns initiated by pharmaceutical companies are subject to EOF's special approval.

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

According to general legislation comparative advertising shall neither be misleading, nor create confusion between products nor denigrate a product. The comparison between products shall be made in an objective manner.

MD prohibits the advertisements of medicines suggesting that the effects of taking the advertising medicine are better than, or equivalent to, those of another treatment or medicinal product. Thus, EOF Q&A provides that EOF Committee, has opinioned that the advertising statement "No.1" highlights the superiority of a medicine compared to other medicines.

Code of SFEE and Code of EFEX permit the usage of comparative claims of superiority or non-inferiority only if they are supported by comparative trials or any other materials of evidence.

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?

The provision of information on medicines is not regulated; to the extent that such information is considered advertising, it is prohibited.

Unauthorised medicines cannot be advertised in medical press nor promoted during scientific events. However, most recent scientific-research data are shared during scientific events, on the condition that:

i. it is rendered clear that the relevant active substance has not been approved by competent regulatory authorities; and
ii. no references about trade names are made.

Moreover, pursuant to the SFEE Code pharmaceutical companies may provide information about unauthorised indications to HCPs, upon relevant request.

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.

General public must not access advertisements of medicinal products which:

a. are available on medical prescription only,
b. contain psychotropic or narcotic substances,
c. are reimbursed by the competent bodies of social security.

Over the counter medicinal products may be advertised to the general public, under the following conditions:

i. they are set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;
ii. they include the following minimum information:
    - the name of the medicinal product,
    - the information necessary for correct use of the medicinal product,
    - an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

If the purpose of the advertisement is to be used solely as a reminder of the name of a medicinal product the above information may be omitted.

Statements implying that medical consultations are unnecessary or guarantying the efficacy of the medicine or leading to self-diagnosis shall be avoided.

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 interaction between patient/patient organisations is not regulated by law.

SFEE Code imposes the obligation to pharmaceutical companies to establish within their undertaking Scientific Service to respond to any queries by the patients/consumers. This activity shall not replace medical consultation.

SFEE Code has introduced guidelines in respect of the following activities (it should be assumed that unregulated activities may not be permitted under SFEE):

1. **Patient awareness events:** to be organised only by Patients' Organizations or Healthcare Organisations. Pharmaceutical companies are only permitted to provide their financial support.
2. **Patient Education and Support ProgMrams** ("**PESPs**"): to support the patients and their caregivers under the directions of the treating doctor. Companies providing health services that are usually contracted by pharmaceutical companies-sponsors initiate PESPs. Any direct or indirect interactions between patients, their relatives and pharmaceutical companies, is not permitted.
3. **Market Research:** Market research are conducted: a) either through questionnaires completed by patients; b) or through discussions with patients. The aim of market research is to collect data referring to the market of a medicine. This initiative is performed by Market Research Companies certified by ESOMAR. Pharmaceutical companies do not interact with patients, all patient data are collected by the HCPs and pharma companies may have access only to aggregated data.
4. Representatives of patient organisations may provide services to pharmaceutical companies only for the purposes of supporting healthcare or research.
5. **Sponsorships** by pharmaceutical companies to patient organisations.

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?

Any advertising material of medicinal products addressed to HCPs shall include

a. essential information compatible with the SmPC;
b. the supply classification of the medicinal product in relation to the use of the medicine;
c. the selling price or indicative price; and
d. an express and legible invitation to report any potential adverse event directly to EOF.

The date of editing and the date of advertisement's last update must be referenced.

According to SFEE Code, pharmaceutical companies are permitted to distribute scientific bibliographic materials only upon HCP's relevant request and only for the purposes of enhancing HCP's scientific training and expertise.

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

Pharmaceutical companies shall refrain from offering or promising to offer any monetary or non-monetary benefits to HCPs.

SFEE Code prohibits the supply of educational material to healthcare professionals.

By way of exception, pharmaceutical companies are allowed to offer to HCPs devices/applications of insignificant value, which are linked to their daily practice, including but not limited to:

a. Applications for mobile phones/computers which, are not considered as medical devices;
b. Anatomy and/or physiology models;
c. Anatomy maps;
d. Educational material for patients (through HCP) in the form of supporting material;
e. Printed or digital publications including guidelines from Scientific Societies; and
f. Printed or digital publications including therapeutic protocols.

Any informative or educational material for medical use is considered as promotional and EOF must be notified accordingly.

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

Pharmaceutical companies may provide free medical samples to HCPs on the following conditions:

a. the number of samples for each medicinal product and for each HCP on an annual basis shall be limited;
b. any supply of samples shall be in response to a written request of the HCP;
c. samples' suppliers shall maintain a system of control;
d. each sample shall be identical with the smallest presentation on the market, marked "free medical sample-not for sale" and accompanied by a copy of the SmPC; and
e. no samples of medicinal products containing psychotropic or narcotic substances may be supplied.

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 attended by HCPs constitutes an advertising activity. The restrictions applying to this type of scientific events organised in Greece are relevant with a) their duration, b) the number of scientific events held by the same pharmaceutical company, c) the amount of sponsorship. In addition to this, congresses shall not be held in tourism destinations. Hospitals or universities must not be used as venues for holding events organised by pharmaceutical companies. HCPs' passive participation in local events is not subject to restrictions. However, pharmaceutical companies must respect the restrictions set by EOF with regards to the limit of the times that the same HCPs' active participation (i.e. speakers) may be sponsored. The detailed agenda of the congress is submitted before EOF.

Pharmaceutical companies may cover the nutrition and hospitality costs of HCPs participating in scientific events both in Greece and abroad, but they have to respect the applicable monetary limits for each event category.

Pharmaceutical companies are not allowed to submit requests for organising scientific events abroad, but they are allowed to sponsor HCPs' participation, who practice in Greece. The number of HCPs participating in events

held abroad changes depending on the country where the event is held. Less restrictions apply to the scientific events organised abroad. Retired HCPs are sponsored only if they are active participants.

Webinars organised locally or abroad are not strictly regulated. Pharmaceutical companies only notify EOF about HCPs' participation.

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 obliged to refrain from sponsoring or participating in entertainment events (i.e. excursions).

SFEE Code provides that pharmaceutical companies must not organise or support financially events organised by third-party entities which are held in venues other than educational/business purposes. Organising cultural, sports or other entertainment events (including, but not limited to city-tours, museum visits, attending sports games and other spectacles) is prohibited.

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

National healthcare systems' ("**NHS**") HCPs are allowed to provide restrictively the services that are explicitly provided in the competent legislation. NHS HCPs and University HCPs need to be paid solely through special funds.

Competent legislation provides that pharmaceutical companies may engage HCPs for the following activities:

1. Participation to scientific events (honoraria); participation as speakers or panel's chairman or members of the organising committee or authors of materials presented in scientific events. NHS HCPs and University HCPs practicing in NHS and University clinics are not allowed to participate in events organised by pharmaceutical companies for the purposes of promoting medicinal products.
2. Advisory Boards; participation in working groups called "Advisory Boards" regarding medicines and therapies. NHS HCPs and University HCPs practicing in NHS and University clinics may participate in these working groups organised by pharmaceutical companies as long as the content is strictly scientific.
3. Clinical trials; participating as principal investigators or members of the project team.

SFEE code provides the following categories of engagement:

1. Training seminars for personnel of pharmaceutical companies (restricted to NHS HCPs and University HCPs practicing in NHS and University clinics).
2. Preparation of training materials/presentations for educational purposes(restricted to NHS HCPs and University HCPs practicing in NHS and University clinics).
3. Market Research; HCPs participating in market research organised by pharmaceutical companies and assisted by market research companies. The occupation time shall not last more than two (2) hours.

SFEE Code has established limits to the renumeration amount that HCPs receive from pharmaceutical companies when providing the services, which depending on their level experience, range from 130.00 to 190.00€.

HCPs shall not receive more than 5,000€ from the same pharmaceutical company as remuneration within a year. Remuneration amounts received in the context of clinical trials are not added during the calculation of the aforementioned amounts.

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?

HCPs who are authorised to prescribe medicines shall not receive or accept any promise for receipt of any gifts, monetary benefits, or benefits in kind. Objects of minor value are exempted (see reply to Q.12).

While there are no other legal provisions regarding donations/grants, SFEE Code provides that donations/grants are permitted to scientific healthcare organisations including public hospitals, medical companies, and other relevant institutions. if their main purpose, which shall be proven, is to support healthcare, research, education and the achievement of better

health services relevant records are kept by the donor and if they do not constitute an inducement for prescription.

Monetary donations must serve a specific purpose and, e.g., financing a research programme, education for HCPs, patients and their caregivers, purchase of medical equipment.

Donations in kind may involve medical equipment, such objects should not be donated on a regular basis.

All donations shall not exceed the 1% of the pharmaceutical company's turnover.

Medicines shall not be donated without EOF's prior approval.

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?

Pharmaceutical companies are obliged to disclose by mentioning specific names any benefit granted to HCPs and Healthcare Institutions to its website and to EOF's website, within 6 months from the end of each calendar year. The benefits include indicatively, grants, costs for registration to congresses and events for scientific information of medical society, as defined in the EOF circulars, travel and accommodation expenses and any other benefit granted. Benefits related to Research and Development activities and non-interventional trials shall be disclosed by pharmaceutical companies in aggregate form. The obligation for disclosure does not apply to market research costs, meals and drinks and objects of minor value linked to the daily medical practice of HCPs and Healthcare institutions.

The aforementioned obligation applies only to the pharmaceutical companies subject to EOF's control.

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?

MAH submits to EOF the copy of any advertising materials released, accompanied by a statement indicating the recipients, the method of dissemination and the date of first dissemination. EOF's control is on an ex-post basis. EOF may order the cessation of a misleading advertising on an ex-ante or an ex-post basis – especially in case of public interest.

The rules of advertising of medicinal products apply to the advertising on the internet as well. According to SFEE Code pharmaceutical companies must ensure that general public will not access materials available on the advertiser's website, which are addressed to HCPs while it includes further related provisions for the use of social media.

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

Provisions of Law 4557/2018 (law against money laundering) apply. Also, Civil Convention of Corruption has been ratified in Greek legislation with Law 2957/2001, under which Greece has undertaken to adopt effective remedies for persons who have suffered damage as a result of acts of corruption.

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

Besides the anti-bribery rules provided in Q20, the following statutory and self-regulatory provisions apply:

a. Legislative Decree No.96/1973;
b. Law No.1316/1983;
c. MD;
d. Pharmacists' Code of Conduct (Presidential Decree No.340/1993); and
e. 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.

The enforcement of advertising falls under EOF's competency. Administrative fines and other sanctions are imposed with the issuance of a relevant decision by the Minister of Health, following EOF's proposal.

These sanctions can be challenged before the administrative courts.

In circumstances the provisions are violated repeatedly, such behavior may be considered criminal offense and therefore, criminal justice proceedings are competent.

For violation of rules of inducement, the fines are imposed by the Board of EOF; the suspension of HCPs licenses is imposed by EOF's director whereas the revocation of HCP's licenses by the Minister of Health following consultation by the competent disciplinary board.

The self-regulatory authority responsible for enforcing the rules of SFEE Code is the First Instance Committee.

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

Pharmaceutical companies have the right to file complaint before EOF, however EOF only takes measures for the cessation of a misleading advertising if the public interest is at stake.

Recourse to civil courts and interim proceedings on the grounds of unfair competition is not excluded depending on the nature of the dispute.

The voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies are not excluded by the MD, SFEE Code has adopted relevant provisions.

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?

Any entity violating the advertising rules can be subject to a fine amounting up to 22,000€, in some circumstances, certain repeated behavior might be punishable by fines amounting up to 44.000€. Criminal sanctions are also provided (imprisonment for up to 6 months and a penalty).

With regards to inducement, the aforementioned fines are imposed. Moreover, HCPs and pharmacists accepting any benefits may be deprived of their right to practice their profession for at least 6 months and up to one (1) year while, in case of repeated behavior, this sanction may be permanent.

In case of breach of articles of SFEE Code referring to advertising rules and rules on inducements for prescription the First Instance Committee may impose financial penalties up to 25,000€; similar provisions apply in case of non-compliance with such decision. In this case the Second Instance Committee is competent.

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 two procedures may apply concurrently.

According to SFEE Code if the provisions of SFEE Code are in conflict with the provisions of national legislation the stricter rule applies. The breach of SFEE Code provisions, does not constitute a breach of law. EOF is notified if a pharmaceutical company-member of Hellenic Association of Pharmaceutical Companies refuses to comply or does not properly comply with decisions issued by the Committees regulated in 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.

Following the examination of several issues arisen from the EOF Circular 16251/16.02.2019 on advertising, EOF, on 31.05.2021 issued EOF Q&A providing explanations on several matters in relation to advertising of medicinal products. EOF Q&A is divided in two parts: the first part clarifies issues on vaccination campaigns and the second part answers frequently asked questions about the compliance of usual practices of pharmaceutical companies with the applicable legislation on advertising of medicinal products.

Contributors

Nikitas Fortsakis
Partner
nfortsakis@koutalidis.gr

Evans Courakis
Partner
encourakis@koutalidis.gr

Lambros Fakitsas
Associate
lfakitsas@koutalidis.gr

Sofia Vestaki
Associate
svestaki@koutalidis.gr