# Legal 500
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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 advertising of medicines in Greece is primarily governed by the following legal provisions:

- Legislative Decree 96/1973 on the trading of pharmaceutical and cosmetic products;
- Law 1316/1983 on the establishment, organization and competence of the National Organization for Medicines ("EOF", as per its Greek acronym);
- Ministerial Decision Y6a/22261/2002 on the advertising of over-the-counter ("OTC") medicinal products;
- Ministerial Decision DYC 3α/CP.32221/29.4.2013 ("MD") 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 (Pharmacists' Code of Pharmaceutical Ethics);
- Law 3418/2005 (Doctor's Code of Medical Ethics); and
- 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) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The following Codes of Practice apply to the advertising of medicines in Greece:

- The Code of Ethics of the Hellenic Association of Pharmaceutical Companies ("SFEE Code of Ethics"), aligned with the Code of the European Federation of Pharmaceutical Associations ("EFPIA"). An updated version of the SFEE Code of Ethics was released in 2024;
- The Code of Ethics and Self-Regulation of the Greek Association of Self-Medication Industry ("Code of EFEX") in relation to the marketing and promotion of OTC medicines; and
- The 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.

These self-regulatory Codes of Practice primarily apply to:

- Pharmaceuticals companies that are Members of these Associations. Non-member pharmaceuticals companies may adhere to these codes voluntarily by submitting a declaration to the President of SFEE.
- Healthcare professionals ("HCPs") and stakeholders, especially in cases where promotional interactions between pharmaceutical companies and HCPs are involved.

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

These self-regulatory codes, such as the SFEE Code of Ethics, are considered soft law. While they are not legally binding, they set industry standards that pharmaceutical companies voluntarily adopt.

Compliance with these self-regulatory codes is not enforced by law, but violations can lead to sanctions from industry associations to member companies, including fines, or exclusion from membership.

## 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?

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According to Article 118 par. 1 of the MD, "Advertising of medicinal products" means any form of door-to-door information, solicitation or incentive aimed at promoting the prescription, supply, sale or consumption of medicinal products.

Advertising of medicinal products shall include in particular:

- the advertising of medicinal products aimed at the general public;
- the advertising of medicinal products aimed at persons authorised to prescribe or supply medicinal products;
- the visits of medical sales representatives to persons authorised to administer prescriptions;
- the supply of samples;
- the solicitation of the supply of medicinal products or their prescription through the provision, offer or promise of advantages or gifts, whether in cash or in kind;
- the sponsorship of promotional events attended by persons authorised to distribute medicinal products or to administer prescriptions; and
- the sponsorship of scientific conferences attended by persons authorised to administer prescriptions or supply medicinal products, in particular the reimbursement of travel and subsistence expenses of participants.

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

The definition of advertising applies equally to all target audiences. However, the specific rules governing advertising vary depending on whether it is directed at the general public or HCPs. The above-described marketing actions apply mainly to HCPs (bullets 3 to 6).

## 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 within the limits of advertising towards HCPs or the general public.

Press releases are considered promotional when they mention the trade name or the active substance of the medicinal product.

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

Marketing Authorisation Holders ("MAH") are required by law to establish a Scientific Committee within their organization, responsible for providing information about the medicinal products available on the market (Article 130 par. 1 of the MD).

The SFEE Code of Ethics recommends that the Scientific Committee be part of the pharmaceutical company's medical department. It also suggests that the Scientific Committee includes at least one physician, pharmacist, or other appropriately trained healthcare scientist, who will be responsible for approving each promotional material before its release (Section 3.14.4. SFEE Code of Ethics).

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

The MAH (or local representative) must submit to EOF a copy of each advertisement they produce, along with a statement specifying the recipients, the method and date of dissemination, registration or circulation (Article 130 of the MD). Additionally, a copy of the approved Summary of Product Characteristics ("SmPC") must also be submitted to EOF (EOF Circular 44787/2017).

The abovementioned submission to EOF constitutes a form of "notification" and is intended solely for compliance monitoring by EOF effected by audits; it does not require EOF approval.

Exceptionally, vaccination campaigns must receive EOF approval, with a request for approval submitted at least 60 days prior to their initiation (EOF Circular 44787/2017).

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

Comparative advertising of all products, in general, is permitted, under Article 9 par. 2 of Law 2251/1994, provided that: a) is not misleading; b) compares only similar products with the same purpose or needs; c) the comparison is objective, focusing on essential, relevant, and verifiable characteristics of the products; d) does not defame or disparage a competitor's trademarks, trade names, or distinguishing marks, including products with the same designation of origin; e) does not unfairly exploit the reputation of a competitor's trademark, trade name, or indications of origin; f) does not present a

 

product as a copy or imitation of a trademarked product; and g) does not create confusion between the products or entities being compared.

Specifically for medicinal products, Article 122(b) of the MD prohibits the advertisement of a medicinal product that suggests or implies its effects are better than, or equivalent to, those of another treatment or product. Also, in accordance with EOF Q&A 47384/31.05.2021, the EOF Committee has opinioned that the advertising statement "No.1" is unacceptable, as it highlights the superiority of a medicine compared to other medicines.

The SFEE Code of Ethics (Section 3.4.12.) specifies that comparisons such as "better" or "better safety profile" are not permitted unless the specific comparative factor is clearly stated. Also, clarifies that comparative claims of superiority and/or non-inferiority are allowed only if they result from the level of statistical significance in specifically designed "head-to-head", randomised, comparative studies, published in peer-reviewed scientific journals and designed to compare safety/efficacy parameters and other characteristics of the medicinal products (Section 3.4.16.).

## 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?

It is strictly prohibited to promote any medicinal products that have not been granted a marketing authorisation, as well as to promote indications not covered by the marketing authorisation (off-label use) or those that are still awaiting approval (Article 119 par. 1 of the MD).

Furthermore, in accordance with Section 3.7. of the SFEE Code of Ethics, unpublished data on the effectiveness and safety of medicinal products (data on file) cannot be used for promotional purposes. Advertising for a medicinal product or indication still undergoing the marketing authorisation process is similarly forbidden.

However, scientific information regarding unauthorised medicines or indications may be shared with HCPs during a scientific conference. Such communication is permissible only if it is explicitly stated that the substance or indication in question has not yet been approved. Additionally, no trade names should be used, and the information presented must be completely accurate.

For published research or clinical data concerning unauthorised medicinal products, scientific information may only be provided to HCPs by qualified staff from the Medical Affairs 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, and include the information that must or must not be included.

According to Article 120 par. 1 of the MD, advertising of medicinal products to the general public is prohibited for those that:

a) require a prescription;

b) contain psychotropic or narcotic substances; and

c) are reimbursed by social security institutions.

In accordance with par. 3 of Article 120 of the MD. the prohibition on advertising prescription-only medicines to the general public does not apply to vaccination campaigns carried out by pharmaceutical companies and approved by EOF. As stated in EOF Circular 44787/12.05.2017, amended by EOF Circular 16251/13.02.2019, vaccines are exempt from this prohibition to promote public awareness and encourage higher vaccination rates.

The advertising of OTC medicines to the general public is allowed, provided the following conditions referred to Article 121 of the MD, are met:

a) The advertisement must be designed in such a way that the advertising nature of the message is obvious, and the product is clearly identified as a medicinal product; and

b) The advertisement must include at least the following details: 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.

Advertising of a medicinal product to the general public may include only the name of the medicinal product or its international non-proprietary name, if the sole purpose of the advertising is to recall that name (Article 121 par. 2 of the MD).

Additionally, in accordance with Article 122 of the MD, the

 

advertising of OTC medicines to the general public must not:

a) Suggest that a doctor's visit is unnecessary or recommend treatment by correspondence;

b) Guarantee the product's effect, claim it has no side effects, or compare it to other treatments as superior;

c) Imply that health will improve by using the product or worsen by not using it;

d) Claim efficacy or safety due to its natural origin;

e) Encourage incorrect self-diagnosis or provide misleading assurances of a cure; and

f) Use overly alarming or misleading visuals of disease or the product's effect.

According to the Ministerial Decision Y6a/22261/2002, every advertisement for OTC medicines must include the following statement: *"THE MINISTRY OF HEALTH AND THE NATIONAL ORGANISATION FOR MEDICINES RECOMMEND: READ THE INSTRUCTIONS OF USE CAREFULLY – CONSULT YOUR DOCTOR OR PHARMACIST."*

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

In Greece, interactions between patients, patient organisations, and the pharmaceutical companies are only regulated by the SFEE Code of Ethics.

Pharmaceutical companies may provide financial or in-kind support to patient organisations to promote patient interests. When pharmaceutical companies provide financial support to patient organisations, they must always have in place a written agreement stating the amount of funding and the purpose (e.g. donation or grant for a specific meeting or publication, etc.). Companies must have an internal authorisation procedure in place for such agreements (Section 23 SFEE Code of Ethics).

Pharmaceutical companies are allowed to provide financial support for Patient Awareness Events, but they cannot directly organise or influence their content (Section 6 SFEE Code of Ethics).

Patient Education and Support Programs may also receive support from pharmaceutical companies. In these cases, personal patient data may not be collected, except for pharmacovigilance compliance (Section 13 SFEE Code of Ethics).

A single pharmaceutical company may not be the exclusive sponsor of a Patient Organization or any of its activities during the year, except for cases involving diseases with no other available funding. This restriction does not apply to patient organizations focused on rare diseases (Section 27 SFEE Code of Ethics).

Regarding market research, it is allowed only when conducted by ESOMAR-certified Market Research Companies (Section 14 SFEE Code of Ethics). Pharmaceutical companies cannot access personalized patient data and may only receive aggregated data collected by HCPs or research companies.

Representatives of patient organisations may provide services to pharmaceutical companies only for the purposes of supporting healthcare or research. According to the SFEE Code of Ethics, the remuneration provided for the services rendered should be reasonable and may not exceed 70€ per hour, subject to a total maximum fee of 560€ per service (Section 26 SFEE Code of Ethics).

## 11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

Advertising materials for medicinal products directed at HCPs must include the following key information, as outlined in Articles 123 and 124 of the MD:

- Essential details from the SmPC;
- The product's classification as either prescription-only or non-prescription;
- The selling price or indicative price for different product packaging options;
- A clear invitation for HCPs to report any adverse events to EOF; and
- The date when the promotional material was created or last updated.

According to the SFEE Code of Ethics (Sections 1.4., 3.4.1. and 3.4.7.), clinical trial information or copies of scientific journal articles may be provided to HCPs upon request. However, they must ensure that all data is accurately reproduced, clearly references the original source, and reflects the current stage of scientific research. This is to ensure that the information helps HCPs assess the therapeutic value of the product accurately (Section 1.3.

 

SFEE Code of Ethics).

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

In the context of promoting the sale of medicinal products to individuals authorised to prescribe or supply them, and in accordance with Article 126, par. 1 of the MD, it is not permitted for a pharmaceutical company to give, offer, or promise any gift, monetary benefit, or benefit in kind, except for items of minimal value that are related to the medical or pharmaceutical profession.

In accordance with Article 66 par. 7 of Law 4316/2014 and Section 10.1. of the SFEE Code of Ethics the value of any gift, monetary benefit or benefit in kind must be less than €15 (including VAT).

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

Exceptionally and in accordance with Articles 31 par. 6 of Law 1316/1983 and 128 par. 1 of the MD, free samples may be provided only to HCPs under the following conditions:

a) only a small, restricted number of samples may be provided per year, per medicinal product, and per HCP;

b) any supply of samples must be provided in response to a written, signed and dated request from the HCP;

c) samples' suppliers must maintain an adequate system of control and accountability;

d) samples must not be larger than the smallest available packaging that is circulated in the market;

e) samples must be marked as "free medical specimen not for sale", or bear a similar indication;

f) samples must be accompanied by a copy of their SmPC; and

g) samples must not contain psychotropic or narcotic substances.

Despite the conditions mentioned above, EOF at its sole discretion reserves the right to impose additional restrictions on the distribution of samples (Article 128 par. 2 of the MD).

## 14. Are pharmaceutical companies permitted to sponsor 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 meetings attended by HCPs constitutes an advertising activity in accordance with Article 118 of the MD.

The maximum number of scientific events a pharmaceutical company may support per HCO, as well as the limits of sponsorships per company, vary depending on the duration and category of the event. Specific sponsorship limits are outlined in EOF Circular 37201/23.03.2020 and Annex I of the SFEE Code of Ethics.

According to EOF Circular 37201/23.03.2020, for Pan-Hellenic conferences (at least 2 days, ≥100 participants), the maximum sponsorship is 30,000€ per pharmaceutical company. For scientific seminars or workshops (1-2 days), the sponsorship can be up to 5,000€ per pharmaceutical company and for events lasting more than 8 hours, the maximum sponsorship per pharmaceutical company can be 15,000€. State entities, such as hospitals and universities, can organize up to 3 events per year with free participation, and pharmaceutical companies can provide up to 2,500€ per event, with a total cap of 10,000€ for all sponsors.

Pharmaceutical companies may sponsor the participation of HCPs in scientific events organized either by third parties (HCOs) or by the companies themselves, and they may offer hospitality.

The maximum number of HCPs a pharmaceutical company may sponsor to participate in scientific events organized by third parties, as well as the maximum number of HCPs per event, are defined in EOF Circular 37201/23.03.2020 and Annex I of the SFEE Code of Ethics.

Each pharmaceutical company may sponsor the participation of the same HCP for:

- two scientific events organised in Greece by HCOs and hospitals;
- two domestic scientific events organised in Greece by companies of EOF-regulated products; and
- two scientific events organised abroad by HCOs.

The above-mentioned restrictions do not apply in cases where the HCP participates in a scientific event in Greece

 

or abroad under the capacity of speaker, chairman at meetings, member of the organising committee, author of a work, etc. They also do not apply if the event is held virtually.

At least 10 calendar days before the launch of the scientific event, pharmaceutical companies under EOF's responsibility must submit an application to EOF's electronic platform, referencing the details of the HCP's participation in the scientific event (EOF Circular 37201/23.03.2020).

For virtual scientific events, pharmaceutical companies may financially support HCPs by sponsoring the purchase of access/registration codes necessary for attendance, individually for each HCP. If a registration fee is involved, the sponsoring pharmaceutical company must submit an application to EOF through EOF's electronic platform, indicating "Web Scientific Events" and referencing the registration fees (Section 6.1. (A7) SFEE Code of Ethics)

National Healthcare System ("NHS") physicians, other NHS scientific or nursing staff, and university doctors working in NHS or university hospitals are prohibited from participating in any promotional scientific events, whether held in Greece or abroad, that are organized by pharmaceutical companies (Section 6.1. (B1) SFEE Code of Ethics).

EOF Circular 37201/23.03.2020 and EOF's announcement dated 7/11/2022, set the following limits on meals and accommodation provided to HCPs attending scientific events:

- in Greece: max. 70 Euros/day for meals and max. 180 Euros/day for accommodation, incl. VAT and
- abroad: max. 150 Euros/day for meals (incl. breakfast) and max. 400 Euros/day for accommodation, incl. VAT.

## 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 not allowed to sponsor entertaining events or the participation of HCPs therein, e.g. excursions and tourist activities in general (Section 7.2. SFEE Code of Ethics).

Also, pharmaceutical companies must not organize themselves or sponsor events organised by third-party entities that take place in venues that are renowned for their entertainment facilities and/or are extravagant or special-purpose and generally considered to be intended for uses other than educational/business purposes, e.g. spas, casinos, places/venues of religious observance etc. (Section 7.1. SFEE Code of Ethics).

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

HCPs in Greece may receive honoraria from pharmaceutical companies for specific services, such as participating in scientific events (e.g., as speakers, panel chairpersons, organisers, or authors of materials) and serving on advisory boards or expert panels. These payments are regulated under Article 36 of Law 4272/2014, EOF Circular 37201/2020, and the SFEE Code of Ethics.

Self-employed HCPs can be remunerated based on written agreements, while state-employed HCPs, including those in the NHS or Universities, are generally prohibited from providing services to private entities except in specific circumstances, such as participation in advisory boards or research teams. Payments to state-employed HCPs must be processed through Special Accounts for Research Grants (ELKE/ELKEA).

Recent amendments under Law 4999/2022 permit NHS HCPs to operate private practices or provide medical services, including consulting, to private entities.

Pharmaceutical companies must comply with approval requirements, such as obtaining permissions from supervising entities and submitting requests to EOF's electronic platform.

Additionally, annual remuneration to a HCP from a single pharmaceutical company is capped at 5,000€, excluding payments 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?

HCPs are prohibited from receiving or accepting any gifts or benefits of any kind, except for gifts of minimum value, as further outlined in Q12.

In accordance with Section 11 of the SFEE Code of Ethics, pharmaceutical companies are permitted to provide

 

grants or make donations, either in-kind or monetary, to scientific healthcare institutions, including public hospitals, medical organizations, and patient associations, as long as the grants/donations' purpose is to support healthcare, research, education and the achievement of better health services.

Donations must be documented and kept on record by the donating company. The name of the donating company may be displayed on donated items, but the name of any medical product must not be included.

Additionally, a pharmaceutical company's total donations cannot exceed 1% of its annual turnover.

Donation of medicines by pharmaceutical companies is permitted upon EOF's prior approval (EOF Circular 57386/17.07.2013).

### 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?

In accordance with Article 66 par. 7 of Law 4316/2014, pharmaceutical companies are required to disclose by name, on both their own websites and the designated EOF platform, any transfers of value they provide to HCPs and HCOs in Greece. The disclosure must be done no later than six months after the end of each calendar year.

The types of transfers that must be reported include, but are not limited to, grants, donations, conference registration fees, travel and accommodation expenses, and other transfers of value related to the promotion of medicinal products.

Transfers related to research and development activities, as well as non-interventional clinical trials, must be disclosed in aggregate form.

Certain items are explicitly excluded from the disclosure obligation, including costs for market research, meals and drinks, and medical or educational items of minimal value (defined as those not exceeding €15, including VAT).

These transparency requirements apply to pharmaceutical companies with operations in Greece, regardless of whether they have products on the market. Foreign companies or those without products on the market must also comply if they provide transfers of value to Greek HCPs or HCOs.

The disclosure is made through a dedicated platform maintained by EOF, where companies must be registered.

### 19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

The general rules for advertising also apply to the promotion of medicines on social media, whether the target audience is HCPs or the general public.

SFEE Code of Ethics provides guidance on the advertising for medicines on social media. Specifically, in accordance with Section 4.5. of the SFEE Code of Ethics, pharmaceutical companies are prohibited from promoting prescription-only medicines on social media, except for authorized vaccination campaigns. Social media accounts must be used for professional purposes only and must follow an internal approval process involving all relevant departments (e.g. Medical Affairs, Pharmacovigilance, Marketing, Compliance, Legal Department, E-business, Communications). Only authorized staff can interact with consumers or HCPs through social media, and social media corporate accounts must be regularly updated, with inactive accounts deactivated after six months.

### 20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

Advertising for medicinal products on the internet is regulated under the same general rules that apply to all forms of advertising, including distinctions between advertising aimed at HCPs and the general public.

To ensure that websites containing advertising for prescription-only medicinal products and other information intended solely for HCPs are not accessible to the general public, pharmaceutical companies must implement appropriate measures, such as the use of personalized usernames and passwords to verify that only HCPs can access these platforms (Section 4.2.2.1.

 

SFEE Code of Ethics).

Additionally, any promotional material uploaded to company websites must undergo internal approval by all relevant departments to ensure compliance with applicable legislation and codes of conduct and must be notified to the competent regulatory body (Section 4.2.2.3. SFEE Code of Ethics).

## 21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

The provisions of Law 4557/2018, which addresses anti-money laundering measures, apply. Additionally, Greece has ratified the Civil Convention on Corruption through Law 2957/2001, committing to adopt effective remedies for individuals who have suffered harm as a result of corrupt acts.

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

In addition to the anti-bribery rules mentioned in Q20, the following statutory and self-regulatory provisions also apply:

- Legislative Decree No. 96/1973;
- Law No. 1316/1983;
- MD;
- the Pharmacists' Code of Conduct (Presidential Decree No. 340/1993); and
- the SFEE Code of Ethics.

## 23. 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 regulatory authority responsible for enforcing rules on pharmaceutical advertising. It has the authority to order the complete revocation of misleading advertisements and impose fines (Articles 129 and 131 of the MD).

Additionally, the General Secretariat Against Corruption and Public Prosecutors are involved in initiating criminal proceedings against individuals involved in corrupt practices.

On the self-regulatory side, SFEE ensures adherence to the SFEE Code of Ethics through its First and Second-Instance Committees, as well as its Disciplinary Board (Chapter 6 SFEE Code of Ethics).

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

Companies can challenge competitors for advertising infringements based on several legal provisions and through various bodies or courts.

In accordance with the MD, EOF has the authority to intervene in cases of suspected advertising violations and can take action to seize infringing materials or stop non-compliant activities.

Pharmaceutical companies can also initiate legal proceedings against competitors for unfair competition under Article 3 of Law 146/1914. These proceedings can be brought before Civil Courts, seeking interim measures such as injunctions to suspend or cease the infringing advertising practices, or to claim damages for any harm caused by the infringement.

Additionally, if the advertising is deemed misleading, companies may take action based on Articles 13a par. 2 and 2b of Law 2251/1994 (Consumer Protection Law).

In cases where advertising infringements relate to the ethical and professional conduct of pharmaceutical companies, the Disciplinary Board, as outlined in Chapter 6 of the SFEE Code of Ethics, may also have authority to take disciplinary action.

## 25. 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?

In accordance with Articles 131 and 175 of the MD, which refers to Article 19 of Law 96/1973, fines from 22,000.00€ up to 44,000.00€ may be imposed by EOF for violations of medicines advertising rules.

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 (Article 33 of Law 1316/1983).

 

If there is a violation of the SFEE Code's provisions regarding advertising rules and inducements for prescriptions, the First Instance Committee has the authority to impose financial penalties of up to 25,000.00€.

### 26. 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 EOF (government regulatory authority) and SFEE (self-regulatory authority) are separate and independent.

According to Section 38 of the SFEE Code of Ethics, if the provisions of the SFEE Code of Ethics conflict with national legislation, the stricter rule shall always apply.

EOF, also, is notified if a pharmaceutical company member of SFEE refuses to comply with decisions issued by the Committees in the SFEE Code of Ethics (Section 36.7. SFEE Code of Ethics).

### 27. 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.

Fines were imposed by EOF in 2020 for violations related to OTC medicines advertising, primarily concerning misleading advertising and failure to comply with the applicable laws and regulations governing such promotions. However, since 2020, there have been no major publicly known enforcement actions or fines reported by EOF related to pharmaceutical advertising.

## Contributors

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