PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES

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GENERAL

1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.

The advertising of pharmaceuticals and medical devices in Greece is governed and regulated by European Union legislation and a series of national laws that separately demonstrate specific provisions with regard to the advertising of medicines and medical devices. More specifically, the following laws in force at this time are applicable: (1) Legislative Decree 96/1973, as it has been amended, on the trading of pharmaceutical and cosmetic products; (2) Law No 1316/1983 on the establishment, organisation and competence of the National Organization for Medicines (Ethnikos Organismos Farmakon or EOF), the National Pharmaceutical Industry, State Pharmaceutical Warehouse and other provisions; (3) Ministerial Decision (MD) No 22261/2002 on the advertising of medicinal products that may be administered without medical prescription; (4) MD No 32221/2013 on the implementation of Directive EC 2001/83 of the European Parliament and of the European Council on the Community Code relating to medicinal products for human use; (5) MD No 59676/2016 on the transposition of Regulation 536/2014 on clinical trials; (6) MD No 130648/2009 on medical devices; the advertising of pharmaceuticals and medical devices in Greece is also governed and regulated by a series of self-regulatory and other codes, which are essentially the following: (1) Healthcare Professionals' Ethical Code; (2) Pharmacists' Ethical Code; (3) EOF's Circular No 44787/12.5.2017 with regard to the advertising of medicinal products as amended by EOF's Circular No 16251/13.2.2019; (4) the Hellenic Association for Pharmaceutical Companies (SFEE) Code of Ethics on the promotion of prescription-only medicines, which includes provisions that are binding only for its members; and (5) the Code of Ethics of the Association of Self-Medication Industry (EFEX), which also foresees respective provisions for its members with regard to the advertising and promotion of medicines and medical devices.

2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?

According to Article 118 of MD No 32221/2013, advertising of medicinal products means any form of advertising, customer engagement or incentives designed to promote the prescription, procurement, sale or consumption of medicinal products. It includes, in particular, the advertising of medicinal products to the general public; the advertising of medicinal products to persons authorised to prescribe or supply medicinal products; medical visitors to persons authorised to prescribe; the supply of samples; encouraging the supply of medicines or prescribing them by offering or promising benefits or gifts, whether in cash or in kind, unless their value is minor; the sponsorship of marketing meetings attended by persons authorised to dispense or prescribe prescriptions; the sponsorship of scientific conferences involving persons authorised to prescribe or supply medicinal products; and, in particular, the travel and subsistence expenses of participants.

The definition in question does not include information such as patient information leaflets, or catalogues, disease awareness campaigns or correspondence.

On the other hand, according to the EFEX Code of Ethics, 'promotion' means all the activities undertaken for a 'Product falling within the scope of this Code' by a marketing authorisation holder (MAH) and/or distributor, or a third party on its behalf for the promotion, supply, sale or administration of its products.

In relation to the advertising of medical devices, there is no specific definition of advertising.

3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?

EOF is responsible for enforcing the rules of advertising and rules of inducement. In addition, self-auditing organisations, such as SFEE reserve the right to perform audits regarding compliance with existing legislation and soft law provisions, and may impose various sanctions and fines.

However, the provisions of SFEE are in accordance with EOF's circular and are binding for its members only; however, many local pharmaceutical companies voluntarily comply with its provisions, which ensures compliance at the maximum level with all applicable legislation in the pharmaceutical field.

4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals for example, food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?

No other product types fall under the same regulations on promotion (and advertisement) as pharmaceuticals. Other product types, for example, food supplements, have specific legislation regarding their promotion.

CONSUMER MARKETING

5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisement) in your country and if so, which ones?

According to MD No 32221/2013, as well as SFEE's Code of Ethics provisions (Article 5.1), there are restrictions concerning the advertising of medicinal products to the public, for example, according to SFEE's Article 5.1, advertising medicinal products to the public that can only be dispensed with a prescription is prohibited.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

There are no specific legal requirements regulating internet advertising. The general rules regarding the advertising of medicinal products to the general public and healthcare professionals (HCPs) are respectively applied to all advertising actions taking place through the internet.

Moreover, on websites exclusively addressed to HCPs, Article 4.2.2 of SFEE's Code of Ethics highlights that measures must be adopted in order to ensure that only those professionally dealing with health issues have personal access via a username and password. The material included on such websites must be primarily approved in accordance with the internal procedures of the company, comply with the respective provisions on the promotion of medicinal products and be respectively notified to EOF. The approved Summary of Product Characteristics (SPC) of the products must be accessible, posted in a visible place on the website and updated after every revision. In addition, attention must be drawn to the following matters:

- In the case of interactive communication with HCPs and the collection of personal data, this must be performed in accordance with the applicable legislation and with prior consent of the HCPs
- In the case of accompanying questions digitally recorded with free text fields and, if these fields fall into the category of market research, they must be approved in accordance with the SFEE's Code of Ethics provisions (Article 14).
- Special care must be taken to ensure pharmacovigilance and adverse reaction reporting, within the time periods provided for by law, as appropriate through the special platform and the Yellow Card, either in printed or digital form. A clear indication of the contact details of the respective pharmacovigilance department is required.
- Copyright protection must be taken into account, when content is used whose copyrights are not owned by the person in charge of the website.
- Care must be taken if the website offers functionality that qualifies as a medical technology product.
- If links to other (third-party) websites are included, the user must be clearly informed that he/she is being led away from the company's website.
- Website cookies are permitted only with the user's consent and after he/she is properly informed according to the law in force.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

According to MD No 32221/2013, each pharmaceutical company should notify EOF of any advertising made by it, accompanied by a form indicating the transmission, mode of transmission, registration or circulation, and the date of first transmission, registration or circulation. Further on, the aforementioned decision states that the pharmaceutical company (MAH) must also ensure that the advertising of medicinal products carried out by it complies with the provisions of existing legislation, and also that its medical representatives are adequately trained and comply with their obligations under Article 125 (2) and (3) of the MD. Moreover, according to EOF's Circular No 16251/13.2.2019, which repeats the above-explained

provisions, each pharmaceutical company must also file the product's SPC. The above notification of each advertisement to be transmitted by each pharmaceutical company is not submitted for approval; however, it is required for the purpose of ex post audits on behalf of EOF. However, EOF explicitly clarified that the above provisions do not apply to vaccine campaigns that are subject to authorisation and must be submitted at least 60 days in advance to EOF.

8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?

The publication of information on unauthorised medicines and/or off-label information is strictly forbidden by existing legislation. By exemption only, the presentation of new scientific data information to HCPs on new medicines is allowed in the context of a scientific event.

Moreover, in accordance with EOF's Circular No 16251/13.2.2019, as amended, medicines that have not been approved in Greece or have been submitted for approval to EOF or European Medicines Agency (EMA) and are in the process of evaluation cannot be advertised in the medical press or promoted in scientific events. However, the presentation of new scientific data in scientific events is allowed, provided the information disclosed does not make reference to any commercial name, while it must also be explicitly noted that the active substance has not yet been approved. Finally, approved medicines that have not yet received a price may be promoted with reference to an indicative value. According to SFEE's Code of Ethics, the use of unpublished data regarding the efficacy and safety of products (data on file) for promotional purposes is prohibited. Such data may constitute the subject matter of discussions between HCPs and the scientific service of the pharmaceutical company, but cannot be included in promotional material. Only general data is acceptable, such as the total number of patients in clinical programmes where the medicinal product has been studied, the total duration of the clinical programme and financial data, that is, data that only the company possesses and can provide on request.

9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?

Comparative advertisement is only allowed if it is not misleading; compares only similar products regarding their nature and indications; compares one or more essential characteristics of the product objectively; does not in any way diminish the value of the product, trademark or brand name of the competitor; does not profit illicitly from the fame of the competitor's trademark or brand name; does not generate any confusion among the products or entities that are being compared; and must be capable of scientific substantiation. Moreover, the trade names of products of other pharmaceutical companies must not be used without the prior consent of the MAH of the respective medicinal product (Article 3.4.19 of SFEE's Code of Ethics).

DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?

The term 'HCP' includes any natural persons being characterised as healthcare professionals under the applicable laws, exercising their practice or having their primary establishment in Greece, and being empowered to prescribe, purchase, dispense, recommend or administer medicinal products as part of their practice, subject to chapter 1 (Promotion of Prescription-Only Medicines to HCPs) of the SFEE's Code of Ethics, where the term 'HCP' is narrower in scope, consistent with the decision transposing the Community Code on Medicinal Products (MD No 32221/2013) and includes any parties among the above being legally empowered to prescribe or dispense medicinal products. For the avoidance of doubt, the term HCP includes, subject to chapter 1 of the SFEE's Code of Ethics, the following: (1) any official or employee of a government agency or other organisation (whether in the public or in the private sector) who is empowered to prescribe, purchase, dispense or administer medicinal products; and (2) any employee of a PC being an HCP whose primary occupation is that of practising a healthcare profession (eg, physician, nurse and dentist). This excludes: (1) all other (HCP or otherwise) full-time employees of the PC under an employment contract, an agency contract or a contract for work; and (2) all wholesalers or distributors of medicinal products.

Moreover, according to Article 4 of Law No 4238/2014, the following persons are characterised as HCPs: family physicians and physicians of other specialties; and dentists and other HCPs, such as midwives,

health visitors, nurses, social workers, physiotherapists, dieticians/nutritionists, psychologists, occupational therapists, medical laboratory technologists, medical and biological laboratory assistants, and medical equipment operators.

In addition, each advertisement directed to HCPs shall contain the following:

- essential information consistent with the SPC;
- the supply classification of the medicinal product (ie, prescription-only or non-prescription);
- the Yellow Card, as required by EOF;
- the selling price or indicative price of the various presentations; and
- the reimbursement rate by social security funds may also be included. It must also be noted that medical information with respect to a medicinal product addressed to persons authorised to prescribe or supply medicinal products may include only the name of the medicinal product, or the international non-proprietary name, if applicable, or the trademark, in the case in which the communication is exclusively intended as a reminder.

11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

SFEE's Code of Ethics includes provisions regarding virtual promotional and advertising activity. For example, Article 3 of SFEE's Code of Ethics foresees, among others, the possibility of digital material advertising. In particular, in digital Scientific Information/Promotion material, it is permitted to attach the SPC as a link, provided the respective location is expressly stated, for example, 'For the Summary of Product Characteristics (SPC), please click here'. The prescribing information may be included in the same or a different link, where necessary. Moreover, regarding electronic communications, it foresees that subject to the applicable legislation, the use of faxes, emails, automatic calling systems, text messages and other electronic data communication methods is prohibited, except with the prior permission, or on the request, of the recipient. SFEE's Code of Ethics foresees also the participation of an HCP in web/virtual, hybrid scientific events and webinars.

12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how such endorsements may take place?

According to Article 122 paragraph 1f of MD 32221/2013, an advertisement addressed to the public is prohibited when it refers to the opinion of scientists, HCPs or famous people who, although not scientists or health professionals, can, due to their fame, promote the consumption of medicines.

13. Is it possible to provide healthcare professionals with samples of medicinal products? Of medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

The production, import and free distribution of medical samples, irrespective of packaging, to physicians and dentists for information purposes, is permitted only pursuant to special permission from the EOF in accordance with the provisions in force. The permission, granted in exceptional cases, determines the packaging, overall quantity, time and mode of distribution, and any other information, as necessary.
Pharmaceutical companies must also have suitable control and calculation systems for the samples they distribute and all medicinal products they handle through their representatives. Furthermore, a sample cannot be larger than the smallest presentation of the medicinal product on the market, and all samples must be marked 'free medical sample – not for resale', or words to that effect, and must be accompanied by a copy of the SPC.

The provision of sample distribution is not permitted for the following medicinal products: (1) medicinal products containing substances that are defined as psychotropic or narcotic by international conventions, such as the 1961 and 1971 United Nations Conventions; and (2) any other medicinal product for which the provision of samples is considered inappropriate by the competent authorities.

On the other hand, according to the EFEX's Code of Ethics, the distributors of medical devices may distribute samples of their products to HCPs and the general public, on the following conditions:

- the product has been assessed by EOF or a notified body and bears CE marking;
- samples must not be more sizeable than the smallest pack launched in the market;
- samples shall bear the indication 'free medical sample, no sale is permitted'; and
- samples shall be accompanied by a SPC copy.

According to Article 66 of Law No 4316/2014 and Article 18 of SFEE's Code of Ethics, offering a medical/educational device/application item of insignificant value is permitted to up to €15 (per item), including VAT, that is closely associated with daily HCP practice such as:

- applications for mobile phones/computers which, due to their nature, are not characterised as medical technology products (eg, they do not serve diagnostic or dosing purposes);
- anatomy and/or physiology models (physical or electronic, eg, CD/DVD/locked USB);
- anatomy maps (physical or electronic, eg, CD/DVD/ locked USB);
- educational material for patients via the HCP in the form of supporting material, for example, nutrition/exercise advice, or in the context of a disease awareness campaign approved by the competent authorities;
- printed or digital publications, including guidelines from scientific societies, provided they do not describe outside the approved indications and dosage; or
- printed or digital publications of therapeutic protocols.

All the above materials must be notified to EOF. Any other donation, sponsorship or benefit in kind to HCPs is prohibited.

In the same context, Article 126 of MD 32221/2013 describes that pharmaceutical companies are not allowed to provide HCPs with gifts or benefits of any kind, unless they are inexpensive and relevant to the practice of medicine or pharmacy.

14. What rules govern the offering of hospitality to healthcare professionals?

According to the most recent circular issued by EOF with Protocol No 37201/2020, any company falling under the scope of EOF may cover the accommodation costs of an HCP participating in a scientific event, under the circumstance that the HCP has properly acquired sabbatical leave from his/her employer beforehand. The daily costs may not exceed €70 for meals, including VAT, and €150 for accommodation, including VAT. If the scientific event takes place abroad, the daily cost for meals may not exceed €150, including VAT, for meals and €400, including VAT, for accommodation.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

SFEE's Code of Ethics includes special provisions regarding donations. In particular, according to Article 11 of SFEE's Code of Ethics, donations, grants and benefits in kind to foundations, healthcare institutions, organisations or associations that are comprised of HCPs, as well as hospitals, are only allowed if: (1) they are made for the purpose of supporting healthcare, research and training; (2) they are documented and kept on record by the company; and (3) they do not constitute an inducement to prescribe, sell or purchase specific medicinal products. Donations, where allowed, may be in kind or in money. Pharmaceutical companies are required, on an annual basis and on SFEE's website, to disclose information about their donations, sponsorships or benefits in kind. Such donations may not exceed one per cent of the total annual turnover of a pharmaceutical company.

16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?

There is no specific provision in the Greek legal framework regarding pharmaceutical laboratories. On the contrary, EOF's Circular No 37201/23.03.2020 regarding scientific events, the EFEX Code of Ethics, and the Association for Medical & Biotechnology Products (SEIV) Code of Ethics and Professional Conduct contain provisions regarding the possibility for medical device companies to support scientific events. Medical device companies are subject to similar rules on scientific events to pharmaceutical companies.

17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.

First, according to SFEE's Code of Ethics (chapter 4), any form of cooperation of pharmaceutical companies with patient organisations, as well as the support of patient organisations by pharmaceutical companies, must be in accordance with the principles set out in Article 21 of SFEE's Code of Ethics.

Moreover, any financial support (grant or donation) provided on behalf of a pharmaceutical company to a patient organisation must be covered by a written agreement. The agreement must foresee the exact amount of grant or donation, as well as its purpose being always related to the patient organisation's activity. Each pharmaceutical company must apply a contract approval procedure of this type and keep an archive of such donations. It is crucial that such benefits are granted in order to support the patient's

needs and interests, and not promote or advertise the company's products. It is also prohibited for pharmaceutical companies, which may support a patient organisation, to influence the text of the material, which they financially support in a way that is favourable to their commercial interests. In addition, a pharmaceutical company cannot be the exclusive sponsor of a patient organisation and of all actions organised on such an annual basis, with the exception of diseases for which no other funding is available. Patient organisations for rare diseases are excluded.

18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?

The MAH is responsible for promotional advertising activities. However, pharmaceutical companies may cooperate with advertising companies in order to properly promote their products. This cooperation should be described in a service agreement between the pharmaceutical and the advertising company with detailed provisions.

Co-promotion agreements are regulated by MD No 32221/2013. The co-promotion of a medicinal product by the MAH and one or more pharmaceutical companies, that is, companies whose objects include the manufacture and marketing of medicinal products, and which hold the relevant licences, is subject to notification to the EOF. Notification will be accepted under the following conditions:

- There must be a cooperation agreement between the MAH and the cooperating pharmaceutical companies under the terms of co-promotion for specific pharmaceutical products, which expressly states that the responsibility for the promoted product belongs exclusively to the MAH, in addition to the duration of the agreement and the procedures resulting from the obligations imposed by legislation, in particular those relating to pharmacovigilance.

- The responsibility for medical information and ensuring compliance with all the requirements of the legislation (training of medical visitors, ethics of their work etc) shall remain with the MAH.

In any case and for any violation of pharmaceutical legislation, the MAH is objectively liable to the EOF, and the partner company is also jointly and severally liable in proportion to its liability.

19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?

According to Article 66 of Law No 4316/2014, every pharmaceutical company must disclose, by name, on its website and at the designated site of EOF, within six months from the end of each calendar year, all benefits granted to HCPs and healthcare organisations (HCOs), including, but not limited to, donations, sponsorships, and registration fees for participating in conferences and scientific events of the medical community because these are specifically defined in the relevant circulars issued by EOF; travel and accommodation costs; as well as any other benefit based on an agreement or at its free will, regarding the promotion of the prescribed medicinal products. It is also worth noting that the Hellenic Data Protection Authority issued two opinions in 2016 and 2017, which concluded that Law No 4316/2014 refers only to promotional conferences, thus excluding from its scope any transparency of value (ToV) towards HCPs related to purely scientific events. However, EOF's updated circular on scientific events no longer separates events into scientific and promotional so that all events are considered scientific.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) adopted the EFPIA Disclosure Code, which all Member States, including Greece, have transposed into their national codes. As a member of EFPIA, and in line with these initiatives at the European level, SFEE adopted its own Disclosure Code, which requires all SFEE member companies to disclose details on their transfers of value to HCPs or HCOs (name of HCP/HCO, type and amount of transfer, eg, participation in conferences, fees for consultancy and other services). This information will be disclosed through a dedicated platform on the SFEE website, which will gather data from all member companies and be freely accessible to the public.

ENFORCEMENT

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

In accordance with Article 129 of the MD 32221/2013, the EOF ensures that there are adequate and effective means of controlling the advertising of medicines in the Greek territory. Hence, EOF may intervene whenever it considers that measures are required to be taken, especially for the protection of the public interest. For example, EOF may directly prohibit misleading advertising, either for preventive or

repressive purposes, even if no actual loss or damage or intention or negligence on behalf of the advertiser is proved. Moreover, in order to eliminate the long-term effects of misleading advertising that has been banned, the competent court may order the full or partial publication of that decision in the form it deems appropriate and, in addition, the publication of a corrective announcement on behalf of the company. When identifying a breach of the existing legal rules EOF may impose fines of up to €22,000, and, if the breach has been repeated, a fine up to €44,000 (Articles 131 and 175 paragraph 2 of the MD).

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

EOF is primarily competent for supervising compliance with existing legislation with regard to the advertising of medicinal products and may intervene whenever detecting any breach of the aforementioned provisions.

In many cases, and in accordance with existing legislation governing unfair competition relating to advertising, any company that has a legitimate interest and rightful claim may bring an action before the competent civil court, seeking interim measure, indemnification or any other rightful claim.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

In view of the adoption of the Medical Devices Regulations, new Greek legislation on medical devices is highly anticipated.

Over the few past years, EOF has been actively updating its respective circulars with regard to the organisation of scientific events, sponsoring of HCPs and advertising of medicinal products. In this direction, pharmaceutical companies in Greece seem to be enhancing their internal compliance procedures in order to fully comply at all times with the existing legal and regulatory framework regarding the promotion and advertising of medicinal products, as well as medical devices.