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Practical cross-border insights into pharmaceutical advertising

Pharmaceutical Advertising 2022

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Expert Analysis Chapters

Q&A Chapters

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in your jurisdiction?

Legal provisions pertaining to the advertising and promotion of medicinal products can be found in various laws, regulations and administrative acts (e.g. Circulars), the most important of which are:

- Legislative Decree 96/1973 on the trading of pharmaceutical and cosmetic products (article 16 par. 1-2).
- Law 1316/1983 on the establishment, organisation and competence of the National Organisation for Medicines (EOF, as per its Greek acronym).
- Ministerial Decision Y6a/22261/2002 on the advertising of medicinal products that may be administered without prescription (over-the-counter (OTC) medicinal products).
- Ministerial Decision DYC3a/32221/29.04.2013 on the implementation of Directive 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 G5a/59676/2016 on the transposition of Regulation (EU) 536/2014 on clinical trials on medicinal products for human use.
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- Doctors' Code of Medical Ethics (Law 3418/2005).
- Pharmacists' Code of Pharmaceutical Ethics (Presidential Decree 340/1993).
- Law 2251/1994 on Consumer Protection.
- Circular Nr. 16251/13.02.2019 issued by EOF.
- Circular Nr. 37201/23.3.2020 concerning scientific events issued by EOF.
- EOF has recently issued a relevant Notice dated 24.05.2021 regarding advertising/informational material accompanied by a relevant Q&A memo.
- The Code of Ethics of the Hellenic Association of Pharmaceutical Companies (SFEE, as per its Greek acronym), which regulates, *inter alia*, the promotion of pharmaceutical products by its members, also provides the principles that govern promotional and advertising activities. The SFEE Code of Ethics is a self-regulation code with rules relating to the promotion of pharmaceutical products for human use, based on professional responsibility, ethics and transparency and addressed to pharmaceutical companies – members of SFEE and non-members who wish to follow it. It is aligned with the relevant legislation and regulatory framework and the Code of the European Federation of Pharmaceutical Associations (EFPIA). An updated version of the SFEE Code of Ethics was released in 2020.
- The Greek Code of Advertising and Communication, which is implemented by the Greek Advertising Self-Regulation Council (SEE, as per its Greek acronym).
- SEE's Best Practices Guidance for the Substantiation of Advertising Claims.
- The Code of Ethics and Self-Regulation of the Greek Association of Self-Medication Industry (EFEX, as per its Greek acronym).

1.2 How is "advertising" defined?

According to the definition provided in article 118 par. 1 of Ministerial Decision 32221/2013 (MD): "the advertising of medicinal products means any form of dissemination of door-to-door information, act of customer attraction, or provision of incentives aimed at promoting the prescription, supply, sale or consumption of medicinal products. In particular, it includes - among others:

- The advertising of medicinal products, which is aimed at the general public. It is worth noting that this is allowed only in the case of over the counter medicines ("OTCs");
- The advertising of medicinal products to persons authorised to prescribe or supply medicinal products;
- The advertising of medical sales representatives to persons authorised to administer prescriptions;
- The sponsorship of promotional events attended by persons authorised to distribute medicinal products or to administer prescriptions;
- 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."

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

Pharmaceutical companies must establish and operate at all times a "Scientific Committee", which is provided in article 130 par. 1 of the MD. As per the SFEE Code of Ethics, it is recommended that said Committee be integrated into the medical affairs department of pharmaceutical companies, depending on the organisational structure of each company. The SFEE Code of Ethics also provides that the Scientific Committee should preferably be

composed of at least one medical doctor or pharmacist or other properly qualified healthcare professional (HCP). The Scientific Committee's purpose is – among others – to provide information on the company's medicinal products, to train the company's medical sales representatives on the applicable laws and regulations regarding the promotion of pharmaceutical products, and to provide answers regarding all questions, either by medical sales representatives, patients or other sources. The Committee also ensures compliance with internal and legal procedures by following review and assessment thereof, verifying that the promotional material of the company is in compliance with the applicable rules and regulations, as well as providing the final "sign off" prior to the dissemination of the material to the public.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

The compliance of pharmaceutical companies to the rules governing advertising is typically ensured through the compulsory establishment and operation of the Scientific Committee mentioned in the answer to question 1.3 above. The adoption of SOPs is optional. In practice, however, pharmaceutical companies opt for such written guidelines in order to have concise manuals outlining the applicable rules and any internal procedures that must be adhered to. SOPs typically cover all matters relating to the operation of pharmaceutical companies, yet they do so in a simple and comprehensive manner, since the applicable provisions are largely scattered in various legislative texts, codes and Circulars.

As mentioned in the answer to question 1.3 above, the Scientific Committee should preferably include a physician, or pharmacist or other properly qualified HCP (see section 19.1 of the SFEE Code of Ethics). The person in question must only report to the medical/scientific department and not to the promotion department of the pharmaceutical company, and no conflict of interest should exist. There is, however, no obligation for pharmaceutical companies to employ personnel charged exclusively with the role of monitoring advertising activities.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

According to the MD, pharmaceutical companies must notify to EOF a copy of every advertisement they produce along with a memorandum mentioning the recipients of the advertisement as well as the method and date of dissemination, registration or circulation thereof. This notification takes place in parallel with the dissemination of the advertisement. EOF, however, has the authority to forbid a misleading advertisement at any time, either preventively or repressively, especially in cases where the public interest is at stake. Circular Nr. 16251/2019 has not altered the regulatory framework significantly, since EOF's control remains at an *ex post* basis and EOF does not provide an *ex ante* approval of advertisements.

Said Circular, however, provides an exception for vaccination campaigns, which by law must be approved by EOF.

It is also worth noting that EOF has issued a Notice regarding the submission of promotional materials concerning medicinal products for human use to EOF. According to the Notice, the submission of these promotional materials must be accompanied with specific submission forms (depending on whether the material constitutes an advertisement addressed to HCPs or the general public), which should be sent to EOF's dedicated website. Along with said Notice, EOF issued a Q&A document providing answers to frequently asked questions regarding the advertising of pharmaceutical products. The Q&A offers clarifications and examples on what does and what does not constitute advertising in the context of the following topics:

- The use of logos in the context of information campaigns.
- Information campaigns regarding nutrition and/or diseases, which are addressed to the general public.
- The display of pharmaceutical products on a company's website.

Finally, the Q&A document also provides guidance regarding the distinction between advertising and mere dissemination of medical information and lays down the requirements that vaccination campaigns must follow in order to meet objectivity standards.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Observance of the rules of advertising and release of information by pharmaceutical companies is always subject to EOF's scrutiny. In cases of violation of the applicable provisions, and especially when the public interest is at stake, EOF assumes a vigilant role and puts great effort into taking remedial action. More specifically, EOF may impose a fine, while at the same time it may order the complete revocation of an advertisement (either on its own initiative or following a substantive complaint from another pharmaceutical company, individual or State authority). Moreover, EOF has the authority to forbid a misleading advertisement at any time. When an advertisement, which has been found to be in breach of the relevant regulations, is banned or otherwise withdrawn but its adverse results continue to exist, EOF may request the publication of the enforced decision to the press (either the entire decision or part of it), and may also demand the release of a corrective statement on behalf of the company.

The above does not, of course, preclude the audit of the advertisement by other self-regulation organisations, such as SFEE or SEE, which handle complaints from consumers, competitors and other interested parties. In cases of violation, these bodies may impose relevant sanctions. In addition, anyone with a lawful interest can take action before any competent civil or criminal court. In all of the aforementioned cases, a right of appeal usually exists, depending on the chosen procedure and forum. For example, the SFEE Code of Ethics provides for a referral procedure to its Second Instance Committee (article 35 of the new SFEE Code of Ethics) for companies that have been sanctioned by its First Instance Committee. The referral may be submitted within 30 business days from the date of the company's notification of the First Instance Committee's decision.

Finally, SEE also provides a referral procedure. It must be noted that the appeal to the Second Instance Committee of SEE does not have a suspensive effect on the implementation of the First Instance Committee's decision. The referral may be submitted within 15 business days from the notification of the First Instance Committee's decision.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

According to the MD, EOF is the responsible regulating and overseeing body, and in case a pharmaceutical advertisement has been deemed non-compliant, it may issue a decision imposing a fine of up to €44,000, order press releases containing corrective statements and even revoke the marketing authorisation of the pharmaceutical product in the Greek market. SFEE may also impose the following sanctions (article 36 of the new SFEE Code of Ethics):

- A financial penalty of up to €25,000.
- Correction of the non-compliant promotional material and obligation of the pharmaceutical company concerned to re-send the corrected material to the same recipients, along with a letter stating the corrections.

As explained in the answer to question 1.6 above, any affected party may seek remedial action before other fora, such as SEE and the Greek courts.

More specifically, SEE may issue a decision ordering the modification of the advertisement that violates the Greek Code of Advertising and Communication. If the company does not comply, SEE may request the immediate cessation of the dissemination of the advertisement in question.

No important examples of such enforcement actions have been recorded in Greece.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

Supervising authorities (such as EOF) and self-regulating bodies (such as SFEE) are completely separate and independent. Thus, in the case of an adverse finding of a self-regulating body, it is not uncommon for the supervising authorities to also pursue the matter further, following an escalation of the matter by the complainant.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Pharmaceutical companies may take legal action against competitors that violate the rules relating to advertising by invoking provisions regarding unfair competition (article 3 of Law 146/1914). Anyone who can establish a rightful claim based on these provisions may bring his/her case before the Civil Court and seek interim measures, suspension or damages.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

In principle, the advertising of a medicinal product for which a (national or EU) marketing authorisation has not yet been granted in accordance with the MD or Regulation EC/726/2004, or of a medicinal product that has been submitted to EOF or to the EMA and is in the process of being examined, is prohibited.

Scientific information regarding recent scientific research data on new, unauthorised medicinal products, however, may be provided to HCPs in the context of scientific events, such as scientific meetings organised by the medical department of the pharmaceutical company, since this activity is not included in the concept of advertising and promotion, regardless of whether such meeting is sponsored by the company or not. The above-mentioned scientific information may only be provided on condition that a) it is made clear that the substance concerned is not authorised, b) no trade name is used, and c) the data are presented in their entirety with absolute accuracy.

As regards the provision of off-label information, the same rules apply, namely, according to the SFEE Code of Ethics, it is prohibited to promote indications that are not covered by a marketing authorisation or that have not yet been authorised. Off-label information may, however, be used in the context of scientific exchange as explained above.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

As stated in the answer to question 2.1 above, information on unauthorised medicines may only be made available to HCPs, and not to the general public, in the form of new scientific developments. It is also worth noting that, according to the SFEE Code of Ethics, the medical/scientific department is not allowed to send information concerning off-label indications of a medicinal product on the pharmaceutical company's initiative. The provision of such information is only permitted in response to a question addressed by a specific HCP to the pharmaceutical company in a documented manner and only by the department responsible for medical information or the medical/scientific department (Department of Medical Affairs).

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

As explained above, the advertisement of pharmaceutical products that have not yet been authorised is, in principle, prohibited,

without any differentiation as to the targeted audience. Important scientific developments about unauthorised medicines and/or off-label information may, however, be presented in the context of a scientific briefing as long as a) it is made clear that the substance concerned is not authorised, b) no trade name is used, and c) the data are presented in their entirety with absolute accuracy.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

As stated in the answer to question 2.2 above, information regarding unauthorised medicinal products and/or off-label information may only be sent in the context of a question posed by a specific HCP in a documented manner. Pharmaceutical companies are not allowed to send off-label information to HCPs on their own initiative.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in your jurisdiction?

There has been no explicit impact on the legislation or practical guidance following the *Ludwigs* case in Greece. Non-approved medicinal products in Greece may be imported upon submission of a relevant request by the prescribing physician to the Institute of Pharmaceutical Research & Technology (IFET, as per its Greek acronym) after a relevant authorisation is granted by EOF. Such authorisation shall always be granted for a specific indication, for specific patients, and for a limited period of time.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

Although there are no specific legal provisions governing this topic, the general rule is that the advertisement of pharmaceutical products that have not been authorised is strictly prohibited. Therefore, proactively sending unsolicited information to institutions regarding unauthorised medicinal products may be considered an advertising attempt and should be treated with caution.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products or indications as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

It is generally acceptable to involve HCPs in market research exercises concerning unauthorised medicinal products, provided that this activity is not misused in order to indirectly promote the unauthorised product. It is worth noting that, according to the SFEE Code of Ethics, in cases where the data collection in the context of market research is conducted by a pharmaceutical company without the contribution of a market research company, the principles of the European Pharmaceutical Market Research Association (EphMRA) Code of Conduct as well as the principles of the European Society for Opinion and Market Research (ESOMAR) Code of Marketing and Social Research Practice must be respected. In this case, no remuneration may be provided to the HCPs involved in the market research. Moreover, scientific information associates and/or the commercial departments of pharmaceutical companies cannot be involved in the conduct of the market research.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

Pursuant to the MD, any advertisement for a medicinal product that is directed to HCPs must include:

a) The essential information corresponding to the summary of the advertised product's characteristics (SmPC).
b) The product's classification with regard to its prescription requirements.
c) The product's selling price or the indicative price of the various packages.
d) A clear and legible prompt to report any suspected adverse reaction to EOF.

It must be noted that where the sole purpose of the advertisement is to remind HCPs of the medicinal product's name, the advertisement may contain either only the brand name of the product or its trademark.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

Articles 121 *et seq.* of the MD provide the rules for advertising medicinal products either to the general public or to HCPs.

An advertisement directed to HCPs may refer to scientific studies not mentioned in the SmPC, provided that all data and quotations are faithfully reproduced, mention the precise source from which they have been derived, and reflect the current state of scientific and technological affairs.

As regards advertisements of medicinal products that are addressed to the general public (i.e. OTCs), all elements of the advertising of a medicinal product must correspond to the information contained in the SmPC.

Moreover, according to article 122 of the MD, advertisements of OTCs must not, among others:

- imply that the effect of the medicinal product is guaranteed, does not entail adverse reactions or is better than or equivalent to another treatment or medicinal product;
- imply that the health of the person may be improved by the use of the medicinal product;
- suggest that the person's health may be impaired if he or she does not use the medicinal product;
- imply that the safety or efficacy of the medicinal product is due to the fact that it is a natural product; or
- cause an incorrect self-diagnosis by describing or detailing the symptoms of an individual case.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

According to article 122 of the MD, an advertisement addressed to the public (regarding OTC medicines) may not include

endorsements by scientists, HCPs or other reputable individuals, who – even though they are not scientists or HCPs – may, by virtue of their reputation, promote the consumption of medicinal products.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

According to the SFEE Code of Ethics, 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, designed to compare safety/efficacy parameters and other characteristics of the medicinal products.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

The rules regarding comparative advertisements are provided in Law 2251/1994 on consumer protection. According to said Law, a comparative advertisement is an advertisement that defines implicitly or explicitly or suggests the identity of a defined competitor or their products and/or services. In order to use another company's brand name or trademark, that company's brand name should first be obtained. This kind of advertisement is only allowed if a) it is not misleading, b) compares only similar products as regards their nature and indications, c) compares objectively one or more essential characteristics of the product, d) does not in any way diminish the value of the product, trademark or brand name of the competitor, e) does not profit illicitly from the fame of the competitor's trademark or brand name, and f) does not generate any confusion among the products or entities that are being compared.

As regards references to a competitor's unauthorised product or indication, as explained above, it would not be possible to promote a product that has not yet been authorised in Greece. Such references are, therefore, not allowed.

Rules regarding comparative claims can be found in the SFEE Code of Ethics and the Code of EFEX, which refer to comparative claims concerning OTC medicines.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

The basic rule is for this release of information to have a purely scientific goal and not have the aim of promoting sales or inducing prescription writing. Thus, any informative document, including scientific papers and proceedings of congresses, should always be checked as to their scientific accuracy and integrity before their distribution. References to scientific literature must also be precise and sufficient.

3.7 Are "teaser" advertisements (i.e. advertisements that alert a reader to the fact that information on something new will follow, without specifying the nature of what will follow) permitted?

Although there is no specific provision banning it, and since there are explicit directions as to the way in which a medicinal product may be advertised, whether it be to the public or to HCPs, arguably, an attempt to use a "teaser" advertisement could be deemed unlawful, since, *inter alia*, by default it will not include the minimum information provided for in the MD.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

As explained above, the promotion of off-label use is not allowed. It would, therefore, be necessary for Product B to vary its SmPC despite the fact that the approved SmPC for Product A is authorised for a particular indication to be used in combination with Product B. This is because the SmPC of Product B does not refer expressly to the use of Product A. Since use of Product B for Product A's indication would be off-label, the MA of Product B cannot promote the combination.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

According to article 31 par. 6 of Law 1316/1983 and article 128 of the MD, samples may be provided *gratis* to HCPs only exceptionally, on the following conditions:

a) only a minimum amount of samples is given per year per HCP;
b) any offering of samples must be effected only after the relevant written dated and signed request of the HCP;
c) the providers of the samples must have an adequate auditing (control and calculation) system in place;
d) the samples must not be larger than the smallest available packaging that is circulated in the market;
e) the samples must bear the following or similar disclaimer: "Free medical sample not for sale";
f) the samples must be accompanied by their SmPC; and
g) the samples must not contain psychotropic or narcotic substances.

Notwithstanding the above, it is at EOF's absolute discretion to further restrict the provision of samples.

It must also be noted that, according to section 17.5. of the SFEE Code of Ethics, samples are not permitted for medicinal products for which such provision of samples is considered inappropriate by the competent authorities.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

As a basic rule and in accordance with article 126 of the MD, it is not permitted for a pharmaceutical company to give away/provide, offer or promise gifts, benefits or promises of any kind

(financial or *in rem*) to an HCP as an incentive to prescribe or otherwise promote the supply of a medicinal product, except for items of insignificant value that are related to the profession of a physician or pharmacist.

This same restriction has been incorporated in article 10 of the SFEE Code of Ethics and article 66(7) of Law 4316/2014, which sets the aforementioned insignificant value at €15 (including VAT).

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply? If monetary limits apply, please specify.

The law permits pharmaceutical companies to donate to (a) hospitals established as legal entities of public law, NHS Health Centres and, in general, hospital institutions of the public sector supervised by the Ministry of Health or any other competent Ministry, (b) medical societies/institutions/associations/organisations/unions and non-profit civil societies established by HCPs, and (c) philanthropic organisations (POs), not only equipment, but money as well, provided that the donation does not aim at inducing prescription writing or at supplying, approving, pricing or reimbursing a medicinal product; but, instead, serves a specific purpose, i.e. promotion of a scientific or educative purpose and should, therefore, always be documented. Therefore, healthcare organisations (HCOs) and other non-profit organisations can be the recipients of various medical and diagnostic equipment, scientific books and electronic aids, computers, etc. Moreover, they can receive financial support in the form of grants for awards and scholarships to HCPs and other beneficiaries to support the economic development of independent educational scientific programmes (educational grants) and to financially support research programmes (research grants) conducted by Hospital or University Institutions and other organisations. Any donation should not constitute an incentive for prescribing the medicinal products and, to this end, nothing more than the company's name should be mentioned.

According to specific provisions, medicines, hospital medical equipment and personal protection and hygiene products may be donated to public and private hospitals, Regional Hospitals (DYPEs) and institutions supervised by the Ministry of Health, as well as public health services (to assist in the effort to combat COVID-19).

In any case, donations/grants must not exceed 1% of the pharmaceutical company's total annual turnover. In case such donations/grants are conducted on the initiative of the parent company of a multinational group, they shall be calculated in the expenses of the local subsidiary.

Kindly note that pharmaceutical companies may also donate medicinal products, within the context of corporate social responsibility, to be considered humanitarian aid, upon EOF's notification and/or approval (EOF Circular Nr. 57386/17.07.2013).

Pursuant to article 66(7) of Law 4316/2014, the provisions of EOF Circular Nr. 37201/23.03.2020 and Chapter 5 on the disclosure of transfers to HCPs and HCOs of the SFEE Code of Ethics, each and every pharmaceutical company is obliged to disclose by name on its website and at the designated EOF's website, not later than six months from the end of each calendar year, any benefit it grants to HCPs and HCOs, including, but not limited to, grants, donations, entry cost in conferences and events, travelling and accommodation expenses, as well as any other benefit based on an agreement or at its free will, in relation to the promotion of the prescribed medicinal products. The supervision for the observance of the disclosure obligation lies with EOF. Any violation may incur sanctions ranging from €30,000 to €100,000.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

As explained above, pharmaceutical companies are strictly prohibited from exerting any kind of influence on HCPs, or luring them, either directly or indirectly, into changing their prescribing patterns.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

Commercial practices with regard to discounts and profit margins are not considered advertising as per Greek law. Generally, it is possible for pharmaceutical companies that supply public or private sector healthcare institutions to offer discounts on the products purchased but always within the limits defined by the applicable Ministerial Decisions governing the pricing of pharmaceutical products (currently, Ministerial Decision D3(a)oik.82331 (GG B' 4274/22.11.2019) as amended by Ministerial Decision D3(a)oik.79525 (GG B' 5511/15.12.2020)), which include, *inter alia*, provisions on discounts and profit margins. Competition law considerations must also be assessed before deciding on the offering of discounts, in addition to any public procurement rules.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

No, such practices are not encouraged, since these kinds of arrangements should only have the aim of promoting public health and the patients' interests, and not inducing sales and prescription writing.

It must be noted, however, that for medical devices intended to administer a medicinal product, the medicinal product may be placed on the market in such a way so that both the medical device and medicinal product constitute a single integrated product intended exclusively for use in the given combination and not reusable.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

Refund schemes for unsatisfied costumers pertaining to pharmaceutical products are not expressly addressed by Greek law. We are of the opinion that having in place a refund scheme for

unsatisfied customers would most likely imply that a treatment's success can be expected or that no adverse effects will arise and would therefore be likely to be deemed a violation of the applicable laws on advertising.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply?

Complex patient access schemes and/or managed access agreements are focused mainly on the patients' best interests and needs rather than the favourable financial terms for supplying products.

Pharmaceutical companies may sponsor and/or be responsible for early access programmes enabling early patient access to new medicines by submitting to EOF the necessary documentation pursuant to the provisions of Ministerial Decision DYG3a/G.P. 85037/10 (GG B' 558/8.4.2011), including, *inter alia*, a description of the early access group programme, consent forms, a copy of the submitted petition to obtain the marketing authorisation along with the SmPC and the instructions for use, labelling samples, etc. In such schemes, pharmaceutical companies undertake the provision of the early access medicine free of charge, hence without charge to patients, to the State budget or to the insurance funds, unless special relevant coverages have been established.

Moreover, pharmaceutical companies as manufacturers and/or distributors may also cooperate with IFET for the importation and supply of specific medicinal products, either according to an individual patient's needs or in order to cover emergency and market shortage needs following an order from EOF or the Ministry of Health. The medicinal products should fall within one of the following categories:

- Innovative high-tech products.
- Medicinal products necessary for public health.
- Medicinal products not available in Greece from pharmaceutical companies (either because they are not of commercial interest or because they are new medicines that have not yet been authorised, released or marketed in Greece).
- Orphan medicines.

The terms and conditions of cooperation with IFET may be found at the following link: https://www.ifet.gr/186/en. Each interested company has to submit the Supplier Approval Form along with a Cover Letter describing the product(s), its/their prices and the proposed terms and conditions of the cooperation, as well as all the requested documentation. Upon receipt of the aforementioned documents, IFET will evaluate the submitted documentation in order to decide whether it shall include the supplier in the list of IFET's approved suppliers for this/those specific medicinal product(s). Each time IFET receives a request to supply a specific product to cover patients' needs, it conducts market research amongst its approved suppliers to identify the most cost-effective product, taking also into consideration the suggested terms and conditions of cooperation with any given approved supplier. When a supplier qualifies as the best cost-effective option for a specific medicine in the market, IFET will place an order with said supplier.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

Pharmaceutical companies may only cooperate with NHS Clinics/Hospitals and/or NHS HCPs for the conduct of clinical trials and/or studies as well as in the context of non-promotional scientific events and purely scientific advisory boards. All fees and amounts payable to either NHS Clinics/Hospitals or NHS HCPs shall be submitted via the Special Account for Research and Development Funds (ELKEA, as per its Greek acronym) of the relevant Health District of Greece.

4.10 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Pharmaceutical companies may sponsor continuing medical education either through scientific events organised in accordance with the procedures provided by EOF or through the provision of scholarships and educational grants via HCOs and, in particular, non-profit organisations and institutions. Likewise, one of SFEE's principles is to support continuing medical education, information and lifelong learning. Any such grants, donations or benefits offered for medical education must be adequately documented and disclosed and must not constitute an inducement to prescribe, sell or purchase specific medicinal products.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

Over the last few years, the Hellenic State, the competent authorities, the self-regulating bodies, pharmaceutical companies, as well as other key players of the industry, have adopted rules and internal policies in order to ensure that no prohibited interactions are taking place between the pharmaceutical industry and HCPs and/or HCOs. Pharmaceutical companies have adopted internal policies and procedures (such as Due Diligence Questionnaires prior to contracting) and include extensive anti-bribery and anti-corruption terms in their agreements with HCPs and HCOs; while the State has introduced the General Secretariat for the Fight Against Corruption, which, along with other State authorities (e.g. EOF), aims to prevent the abuse of public power for private gain and has established relevant legislation, including, but not limited to, Law 2957/2001 on corruption, Law 3666/2008 ratifying and implementing the United Nations Convention against Corruption and Law 4557/2018 on money laundering. The competent authorities are able to and do in fact collaborate with one another, depending on the circumstances and infringement in question.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

In accordance with the most recent EOF Circular Nr. 37201/23.03.2020, the hospitality costs (accommodation and

meals) of HCPs in relation to scientific events taking place in Greece may not exceed a daily amount of €150 including VAT for accommodation and €70 including VAT for meals. The hospitality costs for scientific events taking place outside Greece are set at the daily rate of €400 including VAT for accommodation and €150 including VAT for meals (including breakfast).

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 outside Greece by HCOs.

The aforementioned 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.

For any scientific events organised in Greece by foreign entities (with or without collaboration with a Greek entity), at least 50% of the budget and 50% of the speakers' expenses must be covered by the foreign entity. The total sponsorship to the Greek entity may not exceed €30,000 per company/sponsor.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

No, it is not possible to remunerate an HCP for attending a scientific meeting or to compensate for his time. However, as per EOF's Circular Nr. 37201/23.03.2020, hospitality expenses (see the answer to question 5.1 above), travel expenses and registration fees as well as passwords for online scientific events may be covered by pharmaceutical companies, provided EOF and the employer of the HCP, where applicable, have given their prior approval.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

In principle, it is the entity organising or sponsoring a scientific meeting that is responsible for the content and the other elements of the meeting, such as hospitality granted to HCPs. In cases where a pharmaceutical company organises a scientific event with the help of an independent third party (i.e. private conference organiser (PCO)), the company remains responsible for the content and the hospitality, and it must obtain the necessary EOF approval and report the relevant costs for holding the event.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

The payment of honoraria by pharmaceutical companies to HCPs for their participation in advisory boards, expert input forums, etc. inside or outside Greece is permitted in accordance with article 36 of Law 4272/2014 (which amends article 11 of Law 2889/2001) and EOF's Circular Nr. 37201/23.03.2020.

HCPs shall obtain any licence, approval, consent and/or leave from their supervising entity, while pharmaceutical companies have to submit electronically to EOF's platform the relevant request for the participation of those HCPs.

In case of University or NHS HCPs, the payment of honoraria shall be submitted *via* the Special Account for Research Grants (ELKE, as per its Greek acronym) of any Greek University or ELKEA of the competent Health District of Greece.

For any other services apart from scientific advisory boards, a distinction must be made between self- and State-employed HCPs (University or NHS HCPs). Whereas the former may be paid for offering expert services to pharmaceutical companies on the basis of a written agreement, the latter, being exclusively employed by the State, are, in general, prohibited from offering their services to any private entity (article 11 of Law 2889/2001).

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

Clinical trials, including studies conducted in relation to marketed medicinal products, are conducted in accordance with Ministerial Decision G5α/59676 (GG B' 4131/22.12.2016) as amended by Ministerial Decision D3(a) oik. 36809 (GG B' 2015/03.06.2019) and article 87 of Law 4812/2021. In this context, HCPs acting as investigators in studies that are being conducted in NHS Hospitals or University clinics may be remunerated, yet any amounts to be paid will be handled through the respective Special Research and Development Accounts (ELKEA and ELKE, respectively) of the pertinent site where the study is taking place. These Special Research and Development Accounts, after withholding a percentage of the total budget of the study per site, will forward the relevant payment to the participating investigators.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

No specific legal provisions may be found in the Greek pharmaceutical law relating specifically to payments to HCPs for participating in market research.

However, pursuant to section 14.12 of the SFEE Code of Ethics, in case pharmaceutical companies enter into contracts with market research companies, they have to agree a reasonable compensation to be given to the HCPs participating in the research, where permitted under the applicable legislation, taking also into consideration the working time spent by the HCPs, which may under no circumstances exceed two hours.

As explained in the answer to question 5.4 above, there is an exception for State-employed HCPs (NHS HCPs) – they may not be remunerated for any services offered to private entities (such as pharmaceutical companies).

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

According to the MD, medicinal products that, due to their composition and aim, may be acquired by the public without a

prescription may be the subject of an advertisement. Any such advertisement should be designed in a way that its advertising intent is made explicit, easily identifiable, and that the medicine is expressly characterised and identified as such.

In addition, all advertisements must contain: a) the name of the product and its generic name, when it comprises only one ingredient; b) the necessary information for the correct usage of the product; and c) a clear and direct order in writing, inducing the public to read the instructions of use. Advertisements directed to the general public must not contain any of the following elements, namely: that a visit to a doctor or a surgical intervention is not needed, especially by giving diagnosis or suggesting treatment by correspondence, or implying in a misleading way that the action of the medicine is assured to be equal or superior to any other medical treatment or other medicine without side effects. Advertisements must not be targeted at children. Moreover, advertisements must not imply that the consumer's health may be improved by the use of the product or, on the contrary, be harmed in case the consumer does not use it, or that their effectiveness is due to "natural" substances.

Moreover, no reference can be made to endorsements by scientists or other professionals who may promote the product due to their status, or present the product as if it was a nutrition item, a cosmetic product or any other consumer product, or cause wrong self-diagnosis due to the presentation of a disease's symptoms. It must also be noted that advertisements must not provide assurance about the cure of a disease or demonstrate in an extremely alarming or misleading way what the human body looks like because of a disease or because of the effect of the product.

In addition to the above and pursuant to EOF's Circular Nr. 16251/13.05.2019, each advertising spot in any printed, audiovisual or electronic media must be accompanied by the statement: "*THE MINISTRY OF HEALTH AND THE NATIONAL ORGANISATION FOR MEDICINES RECOMMEND: READ THE INSTRUCTIONS OF USE CAREFULLY – CONSULT YOUR DOCTOR OR PHARMACIST.*"

This statement must be legible and, for that purpose, specific colours must be selected, so as to ensure the appropriate contrast.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

No, as per the MD, it is prohibited to advertise prescription-only medicines to the general public.

This prohibition does not apply, however, to vaccination campaigns conducted by pharmaceutical companies on the premise that such campaigns aim at increasing the vaccination coverage of the population and not at promoting pharmaceutical products. As already mentioned in the answer to question 1.5 above, vaccination campaigns must be approved by EOF and satisfy certain requirements provided in the Q&A memo of EOF's Notice 47384/21.05.2021 so as to meet objectivity standards. In particular:

- It must be clear to the public that vaccination concerns population groups on the basis of the National Vaccination Programme.
- It must be clear to the public that every person must consult his/her treating physician about whether he/she belongs to the population groups that must be vaccinated.
- Pharmaceutical companies must provide objective information on the basis of the SPC, the most important adverse reactions or important contraindications or medicine interactions.
- If statistical data that may contribute to the creation of a climate of concern are used, these data must correspond to the Greek reality.
- The public information material in the context of a vaccination campaign by a pharmaceutical company must be relevant to the information material for HCPs on the vaccines concerned. In the case of medical information, the above parameter is also taken into account, since the public is also informed by HCPs.
- The relevant promotional materials must be submitted to EOF as a whole and not in fragments at least 60 days before the commencement of the vaccination campaign.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Provided no reference (direct or indirect) is made to a specific medicine, the release of information regarding a disease or health issue in general is not considered advertising and, therefore, such purely informative disease awareness campaigns can be lawfully conducted and are usually encouraged. On such basis, disease awareness campaigns are not notified to EOF (Q&A memo of EOF's Notice 47384/21.05.2021).

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

As mentioned in the answer to question 6.2 above, any kind of advertisement or promotion of prescription-only medicines to the general public is forbidden. Even though the active ingredients of prescription-only medicinal products *per se* are not clearly and expressly subject to the aforementioned prohibition, any reference to them shall be permitted in exceptional cases, under the condition that they do not coincide with the medicinal product or are not associated during advertising with the prescription-only medicinal products, so that the latter are advertised or promoted.

As far as unauthorised medicines are concerned, according to article 119 of the MD, EOF prohibits any advertising of medicinal products for which a marketing authorisation has not been granted in compliance with the MD or Regulation EC/726/2004.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

If such a description, which may concern products launched or research conducted during the past year, is purely informative and does not contain a hidden intention to advertise and promote products, then pharmaceutical companies can make such a description in their corporate brochures and/or annual reports. However, it is recommended that the Scientific Committee and/or Compliance Officer of the pharmaceutical company always certify that the information offered is in compliance with the applicable rules and regulations.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

Pharmaceutical companies are allowed to donate, sponsor or grant either financial aid or benefits in kind to various healthcare institutions and HCOs, including patient organisations, as long as the goal is the promotion of the patients' interests and not the promotion of pharmaceutical products. Pursuant to Chapter 4 of the SFEE Code of Ethics, any financial support provided by pharmaceutical companies to patient organisations must be covered by a written agreement. The agreement must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc.). It must also include a description of significant indirect support (e.g. donation of time from a public relations agency and the nature of its involvement) and significant non-financial support.

Chapter 4 of the SFEE Code of Ethics also provides for the following restrictions:

- A single pharmaceutical company shall not be the only sponsor of a patient organisation and of all the actions organised by the latter over a year. This restriction does not apply in relation to (a) any disease for which other funding is not available, and (b) any patient organisation engaged in rare diseases.
- Pharmaceutical companies are not allowed to financially support entertaining events.
- Pharmaceutical companies are not allowed to organise or sponsor a patient organisation event that takes place outside its registered seat, unless it is easier from a logistical perspective to hold the event in another country, given that (a) most of the invitees are from outside the pharmaceutical company's registered seat, or (b) the location of the installations is the object or subject matter of the event.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

No specific provisions may be found in the Greek law regulating this issue; however, any such contributions in kind may be made through patient organisations, as mentioned in the answer to question 6.6 above. Furthermore, under specific conditions, certain benefits may be provided to patients through Patient Support Programmes (PSPs). These programmes aim to support and educate patients who suffer from a particular disease through the elimination of the obstacles that arise between the patient and their therapy.

6.8 What are the rules governing company funding of patient support programmes?

No specific legal provisions may be found in the Greek pharmaceutical law relating to PSPs. However, article 13 of the SFEE Code of Ethics provides for clarifications on such programmes.

Patient Education and Support Programmes are not allowed to be conducted by companies marketing/trading/allocating/promoting medicinal products for human use. Such programmes are implemented exclusively by companies providing health services, which are contracted by the sponsoring pharmaceutical company of the PSP and observe the procedures prescribed in the relevant legislation and the applicable data protection laws, so as to ensure independent and correct provision of support and/or education services. The personnel/staff of the company implementing the PSP are not allowed to promote the sponsoring pharmaceutical company's medicinal products.

Both the sponsoring pharmaceutical company and its employees must not have access to data and files disclosing the identity of specific patients or in relation to specific patients, apart from cases reporting side effects. The company providing health services, however, should be able to inform the pharmaceutical company about the progress of the documents or possibly about other qualitative and quantitative elements of the implementation of the programme, ensuring the anonymity of these data.

Moreover, patients' participation in the programme may not include or be substituted by financial remuneration or other reward in kind. Patients' participation is not obligatory, or a prerequisite for their social security coverage, nor relevant to the level of care and the medicinal products for the relevant disease. However, the companies implementing such programmes may provide digital applications to patients (sponsored by a pharmaceutical company), classified as medical devices, enabling patients to be reminded to take their treatment, to monitor their symptoms, to access educational material about their disease and treatment and to inform their treating physician.

Patients shall be fully informed of the support of the pharmaceutical company on the services provided to them, through their written consent form. However, any direct or indirect communication between a patient and his familiars and the pharmaceutical company is forbidden, except in cases of reporting side effects.

Lastly, printed materials shall not be used for promotional reasons nor include critical judgments about competitive products.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

In accordance with article 66(7) of Law 4316/2014, pharmaceutical companies must disclose on an aggregate basis on the website of the company and the designated website of EOF any expenses incurred for research and development activities, including clinical trials. However, no specific details should be disclosed other than the amount of sponsorship and the study centre. The disclosure obligation also includes expenses for advisory boards, investigator meetings or the like, in case these are clearly connected to research and development activities.

Additionally, in accordance with SFEE's code on transparency in clinical trials, an electronic Registry of Non-Interventional Studies (RNIS) has been created and includes all registered non-interventional studies (with or without medicinal products) that are being conducted by SFEE member companies and admit study-subjects as of 1/1/2013. Specifically, the following data are recorded in the Registry and made publicly available: geographical distribution of research sites participating in the study; envisaged number of participants; compensation to the investigators; implementation timetable; and results after completion.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient

organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

In accordance with article 66(7) of Law 4316/2014, each and every pharmaceutical company is obliged to disclose by name on its website and on the designated website of EOF, not later than six months from the end of each calendar year (usually the deadline is defined by EOF to be June 30th), any benefit it grants to HCPs and HCOs, including, but not limited to, grants, donations, entry cost in conferences and events for scientific information of the medical community, as these are specifically defined in the Circulars of EOF issued from time to time, travelling and accommodation expenses, as well as any other benefit based on an agreement or at its free will, in relation to the promotion of the prescribed medicinal products. Benefits that concern research and development activities, as well as non-interventional clinical trials (with or without a medicinal product) will be cumulatively disclosed by each pharmaceutical company. Only the study centre and the sponsorship amount should be disclosed in these cases. The cost for market research, meals and drinks, as well as objects of minor value for medical application and training are expressly excluded from the disclosure obligation pursuant to article 126 par. 1 of the MD. Objects of minor value are those that do not exceed €15 (including VAT). The abovementioned obligations are applicable to every pharmaceutical company that provides Transfers of Value (ToVs) to Greek HCOs and/or HCPs that exercise their practice in Greece. The disclosure takes place via a central EOF platform to which all companies need to be registered.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

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 ToVs to HCPs or HCOs (name of HCP/HCO, type and amount of transfer – e.g. participation in conferences, fees for consultancy and other services, etc.). This information will be disclosed through a dedicated platform on the SFEE website, which will gather data from all member companies and will be freely accessible to the public.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Since the obligation to disclose ToVs stems from the law (article 66 of Law 4316/2014), a pharmaceutical company that has transferred value to an HCP must disclose it, irrespective of whether the HCP concerned agrees or disagrees. Failure to do so may incur sanctions ranging from €30,000 to €100,000. In order to avoid such a situation, a written agreement must be put in place between the pharmaceutical company and the HCP prior to any ToV, whereby, *inter alia*, the HCP acknowledges that such a disclosure shall take place.

8 Digital Advertising and Social Media

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

The general rules on the advertising of medicinal products, as stated above, are applicable to advertising through the internet as well, including the distinction between advertising to the general public and to HCPs. Hence, as long as the pharmaceutical company that operates the website and the recipient of the information are both in the Greek territory, the rules concerning advertising to HCPs and to the public in general provided for in the above will apply, and special access only to HCPs should be ensured when it comes to advertising of prescription-only medicinal products.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

In accordance with the SFEE Code of Ethics and general practice, a strictly confidential username and password ensures that access to internet sites and information addressed to HCPs only cannot be gained by the general public.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

Pharmaceutical companies must be cautious in the sense that linking and reverse linking to websites may not always be permissible, as such linking may raise copyright issues or breach the Terms of Use of the relevant website. For this reason, the prior consent of the relevant independent website owner must be obtained in advance. Additionally, a disclaimer must be included on the website of a pharmaceutical company to the effect that the said company has no control over and disclaims all liability with respect to the accuracy or lawfulness of the content of the linked website and that it is not affiliated in any way with the website's owner, since there have been incidents of EOF imposing fines to pharmaceutical companies for the content of an independent site.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

The main corporate website of a pharmaceutical company can include the profile, history and news on the social activity of the company, as well as a list of products with the respective approved package leaflet. It may also include texts informing the public on disease prevention and health issues, but it must not connect them with the respective medicinal products that might be offered and/or their package leaflets. The material included must be primarily approved according to the internal procedures of the company (Scientific Committee) and the same applies for any change or addition to the website. As regards websites that include exclusively informative texts on prevention and health issues, the relevant material and any future amendment must be

notified to EOF in accordance with EOF Circular Nr. 16251/13-2-2019 (and its future amendments, if any) and comply with such Circular, i.e.: (a) there will be no direct or indirect promotion of medicinal products. Therefore, there will be no references to brand names and/or names of active substances of medicinal products, nor any references to therapeutic options connected to general pharmacological groups; (b) texts and information will be quoted in a neutral and objective manner with precise reference sources; (c) a phrase to the following effect: "This is intended for general information purposes and is no substitute for advice from a physician or another competent HCP" will be included; (d) the sources of the information included will be kept on record by each pharmaceutical company and made available to EOF, upon request; (e) for reasons of transparency and responsibility, there will be a clear reference to the pharmaceutical company responsible for providing the information. No disclaimer by the pharmaceutical company is permitted for the information included in the information campaign; and (f) any texts and graphs prepared will be signed by the Medical Affairs Director of the pharmaceutical company. Furthermore, all advertising/promotional material addressed to HCPs or to the public must be submitted/notified to EOF in a specific form.

8.5 Are there specific rules, laws or guidance, controlling the use of social media by companies?

No specific legislative provisions are in place yet in relation to social media – the standard provisions on advertising and promotion are hereby applicable as well.

The SFEE Code of Ethics provides useful guidance to pharmaceutical companies as to the particularities of such social media accounts, but in every case the use of social media must be examined carefully by the company in terms of quality assurance and validity and as to the purpose of the information provided. The decision to create corporate social media pages/accounts and the approval of their content must go through the approval procedure of EOF, where applicable, and the internal approval procedure of each company by an authorised team comprising members from all departments involved (e.g. Medical Affairs, Pharmacovigilance, Marketing, Compliance, Legal Department, E-business, Communications). From a purely marketing perspective, there is also the SEE Code of Ethics, which provides general guidelines.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

No specific legislative provisions are in place for social media; therefore, there are no restrictions in relation to employees' personal accounts and interactions through "likes", "applauds", etc.

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

No specific rules governing advertising and promotional activity conducted virtually apply yet – the standard provisions on advertising and promotion are hereby applicable as well.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

In the advertising field, the most noteworthy development was in 2019, when EOF issued Circular Nr. 16251/13-2-2019 amending and updating its applicable Circular governing advertising. The SFEE Code of Ethics has also been amended (in August 2020).

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Yes, a new Ministerial Decision governing events and certain advertising activities is expected soon.

9.3 Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

Yes, in the past few years, monitoring and compliance with the applicable EU and national laws and regulations on the promotion of medicinal products and advertising has improved significantly, while at the same time, digital means and new technologies, such as podcasts, social media influencers and online open events, have come into play. These digital means and new technologies, although closely monitored by the competent authorities and subject to the general principles to the maximum applicable extent, are still not regulated *per se*.

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