Greece


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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 may be found in various legislative acts and regulations, the most important of which are the following:

- Legislative Decree 96/1973 "on the trading of pharmaceutical and cosmetic products";
- Law 1316/1983 "on the establishment, organisation and competence of the National Organisation of Medicines, the National Pharmaceutical Industry, the State Pharmaceutical Warehouse and other provisions";
- Ministerial Decision Y6a/22261/2002 "on the advertising of medicinal products that may be administered without prescription" (OTC);
- Ministerial Decision DYC3a/32221/29.4.2013 "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 536/2014 on clinical trials;
- Doctors' Code of Medical Ethics; and
- Pharmacists' Code of Pharmaceutical Ethics.

It is also worth noting that various circulars of the National Organisation for Medicines ("EOF"), which is the overseeing authority for pharmaceutical products, are operating as well, as a means of practical interpretation of the above referenced applicable legislation (e.g. EOF's Circular Nr. 16427/2017 on the promotion of medicinal products).

Finally, the Code of Ethics of the Hellenic Association of Pharmaceutical Companies ("SFEE") which regulates, inter alia, the promotion of pharmaceutical products by its members (multinational pharma companies) can be considered as a useful tool, rather than a legally binding instrument, since it adheres to the relevant legislation and incorporates concise and updated provisions in alignment to the relevant regulatory framework. In practice, the provisions of the aforesaid Code of Ethics are being respected by the majority of pharmaceutical companies in Greece, irrespective of their actual membership in SFEE.

1.2 How is "advertising" defined?

The advertising of medicinal products can be defined as any dissemination of information, either door to door, or via customer attraction or by giving incentives to the public or healthcare professionals, in order to induce prescription writing, supply, sale or consumption of medicinal products (article 118 of the Ministerial Decision DYC3a/32221/29.4.2013 –hereinafter the "MD").

Advertising may be distinguished between that addressed to the public and that which is addressed to healthcare professionals ("HCPs"), both of which are regulated and must be conducted in accordance to the applicable laws and regulations.

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" with the special purpose of providing information on the company's medicinal products, training the company's officers and sales representatives on the applicable laws and regulations regarding the promotion of pharmaceutical products and replying to all questions, either received from medical sales representatives, patients or other sources. Its role is epitomised in ensuring 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 and the final "signing-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 answer to question 1.3 above. To this end, the adoption of SOPs is only optional, yet in practise many pharma 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 the fields applicable to pharma 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. According to EOF's and SFEE's guidance, it is recommended that the scientific

service in charge of certifying the printed (promotional) material is integrated into the medical affairs department of pharmaceutical companies, depending on the organisational structure of each company. The scientific service should preferably include a medical doctor or a pharmacist or other properly qualified HCP who will be responsible for approving all promotional material before release. Such person must certify that he/she has examined the final form of the promotional material and has found it to comply with the requirements of the law and the Code. The person in question cannot be a member of and/or report to the scientific information and promotion department and no conflict of interest must exist.

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 a copy of every advertisement of a pharma company must be notified to EOF, along with a memorandum mentioning the recipients of the advertisement and the method and date of dissemination, registration or circulation thereof. This notification is hence being made in parallel with the advertisement, yet the EOF has the authority to forbid a misleading advertisement at any time, either preventively or regressively, and especially where public interest is at stake. The new Circular Nr.16427/2017 has not altered the framework significantly, since EOF's control remains at an *ex-post* basis. However, the Circular clarifies that its provisions shall not be applied to vaccine campaigns approved by EOF. The above campaigns, when conducted by the Industry, should be supported in order to increase public awareness and vaccination, which is one of the State's Public Health Policy purposes. However, vaccine campaigns must also follow certain rules. Sixty days before initiation, the duration of the campaign, its potential repetition and the inclusion of the vaccine to the National Vaccination System, should be declared to EOF.

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 on advertising and release of information by pharmaceutical companies is always subject to EOF's scrutiny. In cases of violation of the applicable provisions, especially when the public interest is infringed, EOF is usually assuming a vigilant role and puts a great effort in taking remedial action. Namely, EOF may impose a fine, while in the same time it may order the complete revocation of the advertisement either on its own initiative or following a substantive complaint from another pharma company, individual or state authority. Moreover, when an advertisement which has been found in breach of the relevant regulations is banned or otherwise retracted, but its adverse results survive, then EOF may request the publication of the enforced decision to the press (either the entire decision or part of it), as well as demanding the release of a corrective statement, on behalf of the company.

The above do not preclude of course the voluntary audit of the advertisement by other self-auditing organisations, such as the Communication Control Council (SEE as per its Greek initials) or SFEE. In cases of violation, these bodies may impose various sanctions and fines. In addition, anyone with a lawful interest can take action before any competent civil or criminal court against an offensive advertisement. In all the aforementioned cases, a right of appeal usually exists, dependent on the chosen procedure and forum.

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, the EOF is the responsible regulating and overseeing body and in case a pharmaceutical advertisement has been deemed illegal, it may impose a fine up to 44,000€, order press releases containing corrective statements and even revoke the marketing authorisation of the pharmaceutical product in the Greek market.

As also explained in answer to question 1.6 above, any affected party may seek remedial action in other forums as well, such as SFEE, SEE, the Competition Authority and the Greek courts. However, in Greece no important examples of such enforcement actions have been recorded.

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?

Although in principle self-regulating bodies (such as SFEE) and the supervising authorities (such as the EOF or the Competition Authority) are completely separate and independent, in 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 a relevant 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?

Since the law does not stipulate single and specific measures to be taken in case of conflict but instead a variety of options are available, competitor pharmaceutical companies may also have recourse to the relevant provisions regarding unfair competition. Anyone who can establish a rightful claim may try his case in the Court, seeking 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)?

While it is not lawful to advertise medicinal products that have not been previously authorised and licensed by EOF or EMEA, independent speakers may provide scientific information to HCPs on new medicines in the context of a scientific event. These are shared as new scientific developments which would be valuable to the HCPs. Thus, whenever information is released concerning a new development as regards for example a new ingredient, a new manufacturing procedure or a new indication of a product, this cannot be defined as an advertisement and can be released within the realms of a scientific meeting or discussion, whether the meeting is sponsored by a pharmaceutical company or not.

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

The law strictly forbids the advertisement of pharmaceutical products that have not been authorised and licensed by EOF. As stated in the previous answer, information on unauthorised medicines may only be made available to HCPs, and not to the general public, as a form of new scientific developments.

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. main stream 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 being made as to the targeted audience. However, provided no reference is made to the brand name of the pertinent product, pharmaceutical companies may issue press releases in cases of important scientific developments or make presentations in Scientific Congresses.

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 previous answers, such information may be disseminated to the HCPs in the context of scientific briefing, provided that it cannot, in any way, be deemed as promotional in nature. Hence, to this end, only the active substance of the product may be stated, ensuring at all times that the brand name of the product is not mentioned anywhere or that it cannot be easily deducted from the accompanying material.

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 can be imported upon submission by the prescribing physician of a relevant request to the regulatory authorities, namely to the Institute of Pharmaceutical Research & Technology ("IFET" as per its Greek initials), following the procedure stipulated by the EOF.

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 medicines may be considered as an advertising attempt and as such 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?

No specific pharmaceutical law provisions governing this topic currently exist, yet it is generally acceptable to involve HCPs in market research exercises concerning unauthorised medicinal products, provided this activity is not misused in order to indirectly promote the unauthorised product.

3 Advertisements to Healthcare Professionals

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

Every advertisement should always include:

a) The essential information regarding the summary of the advertised product's characteristics ("SmPC").

b) The product's classification regarding its prescription requirements.

c) The product's indicative or sale price as well as the exact percentage that is covered by the country's insurance funds.

Yet, in cases where the sole purpose of the advertisement is to remind the health care practitioners of the product's name, as a deviation from the aforementioned requirements, 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 standards for advertising medicinal products either to the general public or to HCPs.

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

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

There are no explicit restrictions as far as advertising directed at HCPs is concerned, yet, according to article 122 of the MD an advertisement addressed to the public may not include endorsements by scientists, HCPs or other famous individuals who, whether physicians or not, may be in a position to influence the consumption of pharmaceutical 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?

No, there is no such requirement, yet pharmaceutical companies should always be very cautious when making comparative claims with other products. Any such claim of comparative nature should always be verified as regards its accuracy and objectiveness, as well as making sure that the comparison reflects the latest, up-to-date scientific information. Thus, such comparisons should never distort the available scientific information, either expressly or implicitly, and neither should they be based on unchecked or vague data.

Finally, any comparative claim should always be adequately documented, so as for the receiver to be able at any point to check its origin and truthfulness.

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?

A comparator advertisement is every advertisement that defines implicitly or explicitly or suggests the identity of a defined competitor or his products and/or services. Yet, so as to use another company's brand name or trademark, that company's consent should firstly be obtained. This kind of advertisement is only allowed if it is a) 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, or f) does not generate any confusion among the products or entities that are being compared.

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 to be aiming at the promotion of sales or the inducement of 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.

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, it is suggested that an attempt to employ a "teaser" advertisement, could be deemed unlawful, since by default it will not include the minimum information provided for in the MD.

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 and dated request of the HCP,

c) the providers of the samples must have an adequate auditing 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) that the samples do not contain psychotropic or narcotic substances.

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

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

As a basic rule and in accordance to article 126 of the MD, it is not permitted for a pharmaceutical company to give away 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 SFEE's Code of Ethics and article 66(7) of Law 4316/2014, which provides that the aforementioned insignificant value is defined at €15 (incl. 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 health care institutions and other non profitable organisations, not only equipment, but money as well, provided the donation does not aim at inducing prescription writing, but instead, it is aimed at the promotion of a scientific or educative purpose and should therefore always be documented. Thus, healthcare organisations (HCOs) and other non profitable organisations can be the recipients of various medical and diagnostic equipment, scientific books and electronic aids, electronic links to databases and computers. Moreover they can receive financial support in the form of sponsorships for research programmes or programmes of similar scientific or educational purpose. Any donation should not constitute an incentive for prescribing the medicinal products and to this end, anything more than the company's name, should never be mentioned.

Pursuant to article 66(7) of Law 4316/2014 (and SFEE's Code on Disclosure) every pharmaceutical company is obliged to disclose by name at its website and at the designated website of EOF, 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 the 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 lure 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 Nr. 28408/ 15.4.2016 as amended by Ministerial Decision Nr. 9941/2017) which include, *inter alia*, provisions on discounts and profit margins. Competition law considerations must also be taken into account 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?

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

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?

Refunding schemes 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 arise and would therefore be likely to be deemed as violating the applicable laws on advertising.

4.8 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 non-profitable organisations and institutions. 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.

4.9 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?

The current trend, which is also apparent in Greece, is both for the State and by the self-regulating bodies and the key-players of the Industry as well, to adopt rules and internal policies in order to ensure that no prohibited interactions are taking place between the pharma industry and healthcare professionals (HCPs) and organisations (HCOs). While the pharmaceutical companies are very keen on including extensive anti-bribery and anti-corruption terms in all their agreements with HCPs and HCOs, the State has also introduced the General Secretariat for the Battle of Corruption, which, along with other State Authorities (EOF, Prosecutor, other auditing and independent authorities etc), aims at preventing the abuse of public power for private gain. These 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.17702/19.2.2016 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 incl. VAT for accommodation and €70 incl. VAT for meals. The hospitality costs for scientific events taking place outside Greece are set at the daily rate of €70 excl. VAT for meals (incl. breakfast) and €250 excl. VAT for accommodation. For any scientific events organised in Greece by foreign entities (with or without collaboration with a Greek entity) at least the 50% of the budget must be covered by the foreign entity as well as the 50% of the speakers of the event. The total sponsorship 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 compensating for his time. However, as per EOF's Circular Nr.17702/19.2.2016 hospitality expenses (see the answer to question 5.1 above), travel expenses and registration fees 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 who 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, 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 and the like is permitted in accordance to article 36 of Law 4272/2014 and EOF's Circular Nr.17702/19.2.2016. For advisory boards outside the Greek territory, the following conditions must be met: (a) the pharmaceutical company has sent a written invitation to the expert advisor; (b) any expenses shall be covered by the organiser of the board or the pharmaceutical company based abroad; and (c) a relevant report is filed with EOF depicting the scientific work of the advisor and exemplifying his expertise on the subject of the board. For any other services apart from advisory boards, distinction must be made between self and State employed 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 prohibited from offering their services to any private entity.

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, are being conducted in accordance to Ministerial Decision DYG/89292/2003, as amended and in force today, following the suggestion (positive or negative) of the National Ethics Committee to EOF. 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 as per their Greek initials) 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 researches. In practice though, HCPs do participate in market researches against reasonable and fair market value consideration. As explained in answer to question 5.4 above, however, exception must be made to State employed HCPs who 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 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's comprised of 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. To this end, advertisements directed to the general public shall 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 implies 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, or that the medicine has a circulation license. Moreover, advertisements should 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 person does not use it, nor that their effectiveness is due to "natural" substances. Moreover, no reference can be made to endorsement 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, nor cause wrong self-diagnosis due to the presentation of a disease's symptoms. It should also be noticed that advertisements should not 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.

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 not possible to advertise prescription-only medicines to the general public.

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 at all is made to a specific medicine, then 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.

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?

This might be possible, as long as the press release does not refer to the brand name of the medicinal product, is strictly informative and does not aim at promoting sales or inducing prescriptions. Yet, since advertising of prescription-only medicines is prohibited by law, pharmaceutical companies should be very cautious when releasing information to non-scientific journals and should therefore make sure that the information given does not constitute a concealed or indirect attempt to advertise. As far as unauthorised medicines are concerned, according to article 3 of SFEE's Code, it is strictly forbidden to advertise any unauthorised medicinal product or to promote unauthorised indications.

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 the products launched or research conducted during the past year, is purely informative and does not contain a hidden intention to advertise and promote the products, then pharmaceutical companies can make such a reference in their corporate brochures and/or annual reports. It is advised, however, that the Scientific Committee 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 organisations, including patient organisations, as long as the goal is the promotion of the patients' interests and not the promotion of pharmaceutical products. SFEE's Code of Conduct on the relationship between pharmaceutical companies and patient organisations provides that 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 supports (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support.

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 per 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.

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 to 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. This also includes expenses for advisory boards, investigator meetings or the like, in case these are clearly connected to research and development activities.

Additionally, according to the 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) which 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, every pharmaceutical company is obliged to disclose by name at its website and at the designated website of EOF, 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 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. The cost for market researches, 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. Minor value is the value of every object which does not exceed in total the amount of Euro fifteen (€15), including VAT. The abovementioned obligations are applicable to every pharmaceutical company which circulates its products in Greece.

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 transfers of value 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 transfers of value is provided for in the law (Law 4316/2014), the pharmaceutical company who has transferred value to an HCP must disclose it irrespective of the wishes of the HCP in question. Failure to do so may incur sanctions ranging from €30,000 to €100,000. For this reason, a written agreement must be put in place between the pharmaceutical company and the HCP prior to any transfer of value, whereby, *inter alia*, the HCP shall agree to such a disclosure taking place.

8 The Internet

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 internet as well, including the distinction between advertising to the general public and to healthcare professionals. Hence, as long as the pharmaceutical company who operates the website and the recipient of the information are both in the Greek territory, the rules concerning advertising to HCPs or the public in general provided for in above will apply.

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 to the SFEE's Code of Ethics and general practice, a strictly confidential username and password safeguards 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 should be cautious in the sense that linking and reverse linking to websites may not always be permissible, as it 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 in 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.

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 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. 16427/24-2-2017 (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 clear reference of 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 physician of the pharmaceutical company.

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

No specific legislative provisions are in place particularly for social media yet 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 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)

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?

EOF has been quite active during this year by amending and updating its applicable Circulars governing the organisation and sponsorship of scientific and promotional events, the participation of HCPs, the offering of hospitality and generally the interactions of pharmaceutical companies with HCPs and HCOs (e.g. EOF's Circ.16427/2017). Likewise, SFEE's Code of Ethics is being constantly amended in order to be in alignment with the EOF regulations.

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

Further to the previous answer in question 9.1 it is anticipated that the applicable EOF Circular and SFEE's Code of Ethics will be further amended as regards the same matters.

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

The past years have shown significant improvement in the area of monitoring and compliance with the applicable EU and national laws and regulations on the promotion of medicinal products and advertising and it is expected that this trend shall continue in order to further improve the established procedures and safeguard adherence of the pharma industry with the rules on the latter's interactions with HCPs and HCOs.

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Irene heads the Life Sciences/Pharmaceutical Practice Group as well as the Intellectual Property Practice. She has particular experience in all matters related to medicinal products, medical devices, cosmetics, homeopathic medicinal products and veterinary products and has successfully handled complex mergers and acquisitions in the pharma sector. Irene advises major pharmaceutical companies in their day-to-day operations including routine healthcare contracts, compliance programs and regulatory issues.

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Nefelie studied Law (LLB) at Queen Mary College, University of London and obtained in 2002 her LLM in Medical Law and Ethics from King's College, University of London. She was admitted to the Athens Bar Association in 2004 and she joined Kyriakides Georgopoulos Law Firm in October 2008. She is a member of KG's Life Sciences/ Pharmaceutical Practice Group and Company and Commercial Law Practice Group and has published a number of articles and reports relating to the life sciences sector. She is fluent both in English and French.

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