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The International Comparative Legal Guide to: Pharmaceutical Advertising 2011

A practical cross-border insight
into pharmaceutical advertising

Published by Global Legal Group
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Published by

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Email: info@glgroup.co.uk
URL: www.glgroup.co.uk

GLG Cover Design

F&F Studio Design

GLG Cover Image Source

iStockphoto

Printed by

Ashford Colour Press Ltd.
June 2011

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ISBN 978-1-908070-02-9
ISSN 1743-3363



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■ Preface by Tom Spencer, Counsel, GlaxoSmithKline Plc.

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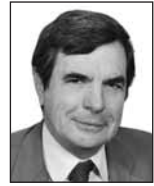
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1 General - Medicinal Products

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

Article 16 of Legislative Decree 96/1973 refers to the advertising of medicinal products. This article has been supplemented by Article 11 of Law 1316/1983. Finally, Articles 106 to 111 inclusive of Ministerial Decision DYG 3(a) 83657 (the “MD”) refer to the conditions under which advertising of medicinal products may be addressed to both the general public and health professionals. At this point, it should be mentioned that the MD transposes into Greek law EU Directive 2001/83, as amended and currently in force (the “Directive”), on the marketing of medicinal products for human use.

In parallel, the Code of Practice prepared by the Hellenic Association of Pharmaceutical Companies (“SFEE”) contains provisions relating to the advertising and the promotion of medicinal products in general. It should be noted that this Code has no legal force and is binding only on the members of SFEE. On the other hand, the Code in question is frequently updated; the last update having taken place on 28 March 2011.

1.2 How is “advertising” defined?

Article 105 of the MD provides that “advertising” is any form of provision of door-to-door services or canvassing of clientele or provision of incentives aiming at the promotion of the prescription, supply or consumption of medicinal products.

The specific article distinguishes, as is also the case under the Directive, between advertising addressed to the general public and that addressed to health professionals.

Any scientific information provided directly or indirectly by pharmaceutical companies (*inter alia* supply of samples, sponsoring of meetings and events as well as the activity of sales representatives) is considered as advertising to health professionals and should be carried out in accordance with the provisions of the above legislation.

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?

According to Article 118(2) of the MD, the holder of a marketing authorisation informs the National Medicines Organisation

(“EOF”), which is responsible for the marketing of medicinal products in Greece and is under the control of the Ministry of Health, that it has created in the company a scientific service that is entrusted with the provision of information concerning the medicinal products it distributes in the market.

The primary aim of the pharmaceutical company’s scientific service is to examine whether the advertisements and the promotional printed material of the company, before marketing of the medicines, conform to the relevant legal provisions.

In addition, Article 13 of SFEE’s Code of Practice states that the scientific service is responsible for providing information to the general public on the medicinal products they market, and must reply to all questions, regardless of whether they are received from medical sales representatives, patients or other sources. According to this Code, the scientific service must include in its staff a physician or a pharmacist or another adequately trained health professional that will be responsible for approving any promotional material before its release.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover??

As mentioned above (question 1.3), Article 118 of the MD provides that every pharmaceutical company must have created a scientific service entrusted with providing information related to the medicinal products it distributes in the market.

In parallel, in accordance with the same provision, the pharmaceutical company communicates to EOF a copy of every advertisement it publishes.

In implementing the above article of the MD, the Code of Practice of SFEE provides that the scientific service that each pharmaceutical company has created must be staffed with a physician or pharmacist or another properly trained health professional that will be responsible for approving any promotional material before its release.

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 Article 118(2) of the MD, the holder of a marketing authorisation communicates to EOF a copy of every advertisement carried out by its company, accompanied by a note indicating the

recipients, the manner of its transmission, registration or circulation and the date of first transmission, registration or circulation.

Consequently, the review of the advertisement by EOF is effected after its publication. However, the holder of the marketing authorisation certifies to EOF that the advertisement of medicinal products carried out by its pharmaceutical company conforms to the legislation on advertising.

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?

If EOF considers, following the relevant review, that an advertisement of a pharmaceutical company does not conform to the relevant legal provisions (Articles 107-116 of the MD), it commences a procedure before its public relations department for the prohibition of the advertisement, which may impose administrative sanctions. However, this department may refer the case to the civil and administrative courts, according to Article 117 of the MD.

A voluntary review of an advertisement for medicinal products may also be effected by self-regulatory bodies, on the basis of the procedures provided for by such bodies.

According to Article 111 of the MD, any advertisement of a medicinal product addressed to health professionals, i.e. to persons authorised to prescribe or supply medicinal products, should include:

- the essential information corresponding to the summary of product characteristics (SPC);
- the classification of the medicinal product as regards the terms and conditions of its administration; and
- its sale price as well as the percentage of subsidy granted by the social security funds.

All the above information which is included in the documentation supplied to health professionals must be up to date, verifiable and sufficiently complete to enable the health professionals to form their own opinion.

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? To what extent may competitors take direct action through the courts?

The sanctions imposed on pharmaceutical companies in Greece by EOF for non-compliance with the provisions on the advertising of medicinal products are provided for by Article 152 of the MD.

Those sanctions are limited to administrative fines which, according to the provisions of this article, do not exceed €22,000 and, in case of repeat offences by the pharmaceutical company, may reach up to €44,000. If the case is referred to the administrative courts (see question 1.6), the penalties vary depending on the importance of the matter.

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?

No relationship exists between any self regulatory process and the supervisory and enforcement function of the competent authorities. The competent authorities can investigate matters drawn to their attention that may constitute a breach of the law. The authorities do not control the decisions of the self-regulatory bodies.

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?

If a matter of unfair competition arises between two competitive pharmaceutical companies, the affected pharmaceutical company may resort to the civil courts requesting the restitution of the damage. In parallel, pending the hearing of the case and the issuance of the court's judgment, the latter may immediately request, by filing an application for interim measures to the same court, the suspension of the advertisement affecting it negatively.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health 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's variants not authorised)?

Article 107 of the MD provides that the advertising of a medicinal product is prohibited for unauthorised products or for products for which the price has not yet been published. The same provision is included in SFEE's Code of Practice.

However, based on the provision of the Constitution concerning the free expression of scientific knowledge, at scientific meetings, it is possible for independent speakers belonging to the scientific community to provide information regarding new active ingredients or new off-label indications, and present or discuss recent developments in clinical trials regarding unauthorised products or indications.

This also applies for information or reports on scientific studies concerning a product not yet authorised in Greece, provided by a speaker belonging to the scientific community.

2.2 May information on unauthorised medicines be published? If so, in what circumstances?

Information which is based on clinical trials concerning an unauthorised product may be published in the scientific press, or if the information is of interest to the general public, it may also be published in the ordinary press, provided that the commercial name

of the product is not mentioned. This also applies to off-label information.

2.3 Is it possible for companies to issue press releases about medicinal products which are not yet authorised? If so, what limitations apply?

As mentioned above (question 2.1) the advertising of unauthorised products is prohibited.

However, the diffusion of information when it is related to an important scientific development concerning a specific disease is common practice, provided that the name of the product is not published and it is indicated that the product is not yet available in Greece.

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

There is no provision under Greek pharmaceutical law prohibiting the communication of information, comparable to that referred to in question 2.3, to health professionals. However, such information should not be provided in the form of an advertisement, but as a scientific briefing.

2.5 May information be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

No specific rules cover this issue. However, the institutions may request such information only for scientific purposes. In addition to the above, it will not be possible for the institutions to calculate the influence that the authorised products will have on their budgets, since the price of those products will not be known until they are actually marketed.

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

There is no provision covering the market research issue in Greek pharmaceutical law.

However, SFEE's Code of Practice introduced a relevant article (Article 27), according to which health professionals may participate in market research exercises.

According to the Code in question, market research must not explicitly aim at the promotion of sales and must not aim to influence the opinion of the participating health professionals.

Market research is usually effected for medicinal products that have not yet been authorised in the country.

3 Advertisements to Health Professionals

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

According to Article 111 of the MD (which corresponds to Article 90 of the Directive), any advertisement for a medicinal product addressed to health professionals, i.e. to persons authorised to

prescribe or to supply medicinal products, must include:

- the essential information corresponding to the summary of product characteristics (SPC);
- the classification of the medicinal product with regard to the terms and conditions of its administration; and
- its sale price and the percentage of reimbursement granted by the social security funds.

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

The restrictions that apply on the information that may appear on an advertisement are those provided for by Article 89 of the Directive, as transposed into Greek law by Article 108 of the MD.

In this regard, a distinction should be made between advertisements to the general public and advertisements to health professionals.

Articles 109 and 110 of the MD, which correspond respectively to Articles 89 and 90 of the Directive, provide for the information that may be disclosed to the general public, whereas Articles 111 and 112 of the MD (corresponding to Articles 91 and 92 of the Directive) provide for the information which can be disclosed to health professionals.

According to Article 112(3) of the MD (which corresponds to Article 92 of the Directive), quotations taken from medical journals or other scientific works are permitted provided that these are faithfully reproduced and the precise sources are indicated.

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

There is no relevant provision under Greek law.

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 are made?

There is no published guidance in Greece on the number of "head to head" clinical studies required before comparative claims can be made. On the other hand, SFEE's Code of Practice provides in Article 7 that information, claims and comparisons must be correct, objective and must not be misleading.

3.5 What rules govern comparator 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 which had not yet been authorised in Greece?

There is no specific legal provision on comparative advertising in Greece. The matter is limited to Article 9 of Law 2251/1994, as amended, according to which comparative advertising is permissible if it is effected in an objective way and refers to characteristics of similar products that are essential, related, verifiable and impartially selected.

Based on this legislative framework, it is possible to mention the brand name of another company's product when effecting clinical trials of a medicinal product in order to highlight the effectiveness of that product.

However, in order to effect comparative advertising, the provision of SFEE's Code of Practice should be taken into consideration

which provides that the brand names of products of other pharmaceutical companies should not be used without the prior approval of the holder of the marketing authorisation of the product with which such comparison is made.

In parallel, the Code of Practice of SFEE provides that information and comparisons provided to health scientists must be correct, accurate, objective and clear.

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

The informative material that is distributed during scientific events to health professionals should be in compliance with Articles 111, 112 and 114 of the MD.

According to EOF's circular 66500 of September 2010, as supplemented by EOF's circular 82205 of December 2010, events are distinguished into Congresses of Scientific Content (Type A), Scientific Information Events (Type B) and Scientific Information for Medicinal or other Products (Type C).

National Health System (ESY) physicians may not participate in events for the promotion of medicinal products. This is expressly provided for by Article 11(18) of Law 2989/2001.

In order to realise such events, according to the above EOF circulars, the organising company must submit a month in advance an application for their approval. Moreover, one month after the realisation of the event, at the latest, the organising company must submit to EOF a financial report on the event.

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

"Teaser" advertisements are not covered by the provisions of Greek pharmaceutical law or SFEE's Code of Practice.

4 Gifts and Financial Incentives

4.1 It is possible to provide health professionals with samples of products? If so, what restrictions apply?

According to Article 31(6) of Law 1316/1983, the supply, free of charge, by pharmaceutical companies of samples of their medicinal products is prohibited. In exceptional cases, the same article permits the provision of free samples to persons authorised to prescribe, by a specially justified decision of EOF's Board of Directors that determines the terms of manufacture or importation and distribution of the samples. This provision is supplemented by Article 116 of the MD, which details the special cases for supplying samples.

According to the provision in question, the number of samples provided annually should be minimal and be limited per medicinal product and per person authorised to prescribe, without, however, defining the word "limited".

Any offer of samples must be in response to a written request, dated and signed, of the prescribing doctor.

The pharmaceutical companies providing the samples must maintain an adequate system for the control of the samples provided.

The number of samples freely supplied must not exceed the volume of medicinal products actually purchased.

The samples must bear on their packaging the indication "free medical sample - sale prohibited" and the summary of the product's

characteristics must be enclosed within the package.

Finally, no samples of medicinal products containing psychotropic or narcotic substances can be provided.

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

According to Article 114 of the MD, the provision, offer or promise of gifts to persons authorised to prescribe or procure medicinal products is prohibited, except for items of negligible value that are related to the profession of a physician or pharmacist.

This provision has also been included in SFEE's Code of Practice, in Article 18.1, which also defines the meaning of negligible value, as being equal to €25 (including VAT).

4.3 Is it possible to give gifts or donations of money to institutions 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?

Pharmaceutical companies are permitted to give gifts or study grants to public hospitals.

The procedure for acceptance of donations and grants is provided for by the by-laws of the public hospitals. The administration of a public hospital will decide whether it will accept gifts or donations granted to the hospital or even medical or technical material.

Furthermore, according to Article 20.2 of SFEE's Code of Practice, offers to hospital institutions organised as public entities (health care centres) and to general hospitals of the public sector are permitted, provided that they do not constitute an inducement to prescribe or purchase medicinal products.

However, concerning the procedure for the donation of equipment to a public hospital, according to the relevant legislation, the hospitals in question are not permitted to accept donations involving the assignment of ownership or the use of medical devices that accept reagents or consumables of only one specific company. An exception is permitted only if the donations include the reagents and consumable materials and also cover their maintenance cost.

It should be noted that SFEE's Code of Practice prohibits the donation or sponsorship of medical or diagnostic instruments by pharmaceutical companies to hospitals organised as private law entities (i.e. private clinics).

4.4 Is it possible to provide medical or educational goods and services to doctors 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?

Ministerial Decision A6/10983/84 of 15 January 1985 provides that the grant by a pharmaceutical company to scientists of gifts or any other benefits as well as offers or any kind of activity of similar effect is prohibited, as the scientist will feel bound or obliged to prescribe or utilise the company's medicinal products. On the other hand, Article 114 of the MD provides that physicians are not permitted to accept or require any gift or benefits, unless they are of a negligible value.

Therefore, in principle, a physician is prohibited from accepting any goods or services that could lead to changes in prescribing patterns.

However, the Code of Practice of SFEE, in its Article 19, provides that it is permitted for pharmaceutical companies to offer scientific manuscripts which promote scientific awareness, on condition that their value is reasonable and does not exceed €500 per year for each physician, and that the companies do not induce prescriptions.

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?

The rules on advertising and inducements do not provide the possibility of granting rebates to hospitals.

The supply of medicinal products to public hospitals is effected, as a rule, following orders submitted by them to the pharmaceutical companies depending on their needs. For these supplies, the hospital price, as set by law, applies, which equals the wholesale price reduced by 13%. However, the relevant legislation provides that the supplier (i.e. the pharmaceutical company) may grant an additional discount on the hospital price to public hospitals and to other institutions supervised by the Ministry of Health.

According to the recent Law 3918/2011, tenders will have to be called for the supply of public hospitals with medicinal products. The relevant provision will become effective as from 1 January 2012.

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?

It is not explicitly prohibited to offer to provide, or to pay for, additional medical or technical services or equipment if this is contingent on the purchase of medicinal products, provided that this does not excessively bind the consumer and that no breach is effected of the competition law or other provisions of law (especially the principle of business ethics).

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?

If the product does not work, i.e. if the product is defective, consumers can resort to the provisions of any laws and regulations on defective products and request a refund (indicatively Law 3587/2007 which amended and complemented Law 2551/1994 on consumer protection and implemented EU Directive 2005/29 into Greek law) and, of course, the relevant provisions of the Greek Civil Code. It does not make a difference whether the product is a prescription-only medicine or an over-the-counter medicine. It is, however, to be noted that adverse effects of medicines are not included in the ambit of the definition of defective products.

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

Pharmaceutical companies may partially or totally sponsor continuing medical education events provided that the events in question are organised in collaboration with scientific associations or scientific committees of public hospitals, which have the main responsibility for the event. Approval for the events in question is granted by EOF. The terms and conditions on the basis of which

such events take place are provided for by EOF's circular 66500 of September 2010, as supplemented by EOF's circular 82205 of December 2010 (see question 3.5).

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to health professionals? Does it make a difference if the hospitality offered to those health professionals will take place in another country?

The hospitality offered to health professionals within the framework of events for the promotion of sales is always strictly limited to the main object of the event and should not be extended to persons other than health professionals.

The payment of expenses incurred by physicians or other health professionals participating in Type A scientific events organised by pharmaceutical companies and other enterprises with products falling within EOF's competence, is allowed provided that EOF's approval is granted. In order to obtain approval for health professionals' participation in these scientific events taking place abroad, the sponsors inform EOF on the number of participants in the congress, citing the cost of participation per person and their specialisation. As part of their final accounting report, they submit the list of the participants' names, stating the total cost of participation per participant and their specialisation.

For participation in scientific events held in Greece, the sponsors submit to EOF a final accounting report within two months of holding the event, including the list of names and the specialisation of the guests and the final cost of participation per person.

Hospitality costs include only the costs of registration in the relevant event, costs of accommodation and meals during the event and travelling expenses of participants from their place of practice to the venue of the event. They must be reasonable both as regards their level and value, when compared to market prices and taking into account the main scientific objective of the event.

EOF sets limits, in cooperation with the representatives of the sponsoring companies, on the costs of participation and the number of Type A events in Greece and abroad, which a company can sponsor for each health professional in any given year.

5.2 Is it possible to pay for a doctor 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?

According to Article 114 of the MD, hospitality to health professionals in connection with their attendance at congresses and scientific meetings is limited to paying his or her expenses (travel, accommodation, enrolment fees), always taking into account the main object of these events, and no compensation is possible for time spent at such meetings.

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 doctors to attend?

The sponsoring of scientific events by pharmaceutical companies is

subject to strict limitations concerning hospitality arrangements for the professionals attending the events (see question 5.1 above) as well as the control of these events' content.

In order to verify the compliance with the relevant rules, a company sponsoring a scientific event must obtain EOF's approval, as previously mentioned, and submit an application containing *inter alia* the details of the expenses and the scientific programme of the event.

5.4 Is it possible to pay doctors to provide expert services (e.g. participating in focus groups)? If so, what restrictions apply?

A distinction should be made between physicians working in public hospitals (ESY) that are of exclusive employment and, therefore, prohibited from providing services outside the public hospital in which they work, and freelance doctors, who may provide their services freely. Event services, therefore, can only be provided by freelance doctors.

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

Clinical trials which include post marketing surveillance trials according to Ministerial Decisions DYG 3/89292/2003 and DYG 3a/79602/2007 that harmonise Greek law with the respective EU law concerning the application of due clinical practice during clinical trials, are initially examined by EOF's relevant Clinical Trials Ethics Committee which suggests their approval or rejection by EOF.

Clinical trials are realised in public hospitals and the fee of the doctors employed by the National Health System (ESY) who participate in these is paid in the Special Research and Development Sums Account (ELKEA) in accordance with Ministerial Decision DYG OIK 75762/2005 or, in the event that the trial is conducted by a doctor who is a member of a university's graduate scientific personnel, his or her fee for participation in the trials in question is deposited in the Special Account for the utilisation of the sums of the organisation to which this personnel belongs (ELKE), in accordance with the provisions of Joint Ministerial Decision 679/22.08.1996 and Article 3(2)(a) of Law 3027/2002.

SFEE's Code of Practice, in Articles 28 and 29, refers to the conditions for the conduct of epidemiological and non-interventional clinical trials, respectively.

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

Greek pharmaceutical law does not cover the situation that concerns doctors participating in market research.

However, in practice, pharmaceutical companies do, in fact, cooperate with doctors who conduct, at the request of these companies, market research, for which they are paid. The Code of Practice of SFEE provides in Article 27 that the market research must be impartial; it must not directly aim at promoting sales and must not impair the credibility and integrity of pharmaceutical industry.

It should be noted that, pursuant to Article 18(11) of Law 2889/2001, doctors employed by public hospitals (ESY) on an exclusive basis, cannot participate in market research.

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 Article 108(2) of the MD (which corresponds to Article 88 of the Directive), only medicinal products which, due to their composition and purpose are intended for use without the intervention of a physician and the diagnosis or treatment or, if necessary, following the advice of the pharmacist, i.e. over-the-counter medicinal products can be advertised.

In addition, according to Article 110 of the MD (which corresponds to Article 90 of the Directive) an advertisement of a medicinal product addressed to the general public must be designed in such a way as to make clear that it is an advertisement and must include at least:

- the name of the medicinal product and its generic name, when the medicine contains only one active ingredient;
- the necessary information on the proper use of the medicinal product; and
- an express and legible inducement to read carefully the instructions contained in the enclosed leaflet or on the external package.

Advertising a medicinal product to the general public may also include only its brand name or its international generic name, if there is one, or the trademark, provided that the exclusive purpose of the advertisement is to market this brand name.

Finally, an advertisement of a medicinal product directed to the general public may not contain data that is referred to in Article 110 of the MD (i.e. information that makes a visit to the physician or operation seem unnecessary, etc.).

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

In accordance with Article 108 of the MD (which corresponds to Article 88 of the Directive), advertising of prescription-only medicines to the general public is prohibited. The above also applies to psychotropic or narcotic substances.

Despite this prohibition, EOF may only authorise the marketing of vaccination campaigns promoted by pharmaceutical companies.

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?

There is no express prohibition of disease awareness campaigns provided for by the relevant law in Greece. EOF has recently proposed that the running of such campaigns is made only by medical scientific institutions and independent health professionals having no professional connection with pharmaceutical companies. This proposal is still under consultation.

6.4 Is it possible to issue press releases concerning prescription only medicines to non-scientific journals? If so, what conditions apply?

As mentioned above (see question 6.2), it is not possible to advertise prescription medicinal products to the general public and, therefore, it is not possible to publish a press release on

prescription-only medicines in non-scientific journals when such press release is akin to an advertisement or has promotional content.

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

There is no relevant provision under Greek pharmaceutical law and in SFEE's Code of Conduct. The publication of comparable information is permitted in implementation of corporate laws, when it is related to a serious development in the activity of a pharmaceutical company, and it does not indicate the name of the product to which that serious development is associated.

6.6 What, if any, rules apply to meetings with and funding of patient support groups, including any transparency requirement as regards the recording of donations and other support in corporate reports?

The applicable law in Greece does not regulate the funding of patient support groups.

As regards the relations between pharmaceutical companies and patient support groups, SFEE's Code of Practice provides that it is prohibited for pharmaceutical companies that finance, in any way, associations of patients, to influence the content of the material financed by them, in a manner that is favourable for their commercial interests. In parallel, in accordance with this Code, a pharmaceutical company may not demand to be the exclusive sponsor of a patient support group.

It is noted that the Code in question is fully in line with the EFPIA Code on patient support groups.

7 The Internet

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

EOF's guideline 39600/17.01.2000 provides that the distribution, sale and, by extension, advertising of medicinal products through the Internet is prohibited. In practice, EOF, in cooperation with the competent prosecuting authorities, has followed the procedure of arresting individuals who advertised and distributed medicinal products through the Internet.

7.2 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 health professionals?

SFEE's Code of Practice provides that SFEE's members should ensure that only health professionals, for whom a password is issued, have access to the promotional material contained in the company's website. Therefore, the general public can have no access to the website in question.

Furthermore, in order to avoid the imputation of company liability, there must be a warning on the website, which is linked to other websites (e.g. that of the parent company) that such linked website may not be in compliance with a body of law other than the relevant Greek legislation.

7.3 What rules apply to the content of independent websites that may be accessed by 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?

In practice, an informal procedure is followed by EOF for the prior approval of pharmaceutical companies' websites, since there is no relevant legislative framework in place, in this respect.

The warning referred to in reply to the immediately preceding question should be included by the pharmaceutical company on its website in order to be protected against possible third-party claims.

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

The information contained on websites of pharmaceutical companies that have been, informally, accepted until now include general details on the company or even initiatives of the company having an artistic content to which the general public may have access.

In any case, the website of a pharmaceutical company may not contain promotional material for a medicinal product that is prescribed by physicians. This prohibition does not apply to information campaigns approved by the competent authorities. Finally, in those isolated cases involving members of the public who request counselling on personal medical matters, they must be directed to consult a health professional.

8 General - Medical Devices

8.1 What laws and codes of practice govern the advertising of medical devices in Greece?

There is no provision on the advertising of medical devices in Greece. For matters of advertising, companies selling medical devices, in practice, apply by analogy the provisions relating to medicinal products.

The Hellenic Association of Medicinal and Scientific Equipment Suppliers (Hellasmes) applies a Code of Conduct that refers, in principle, to the relations of the companies with physicians. The Code in question is in line with the Eucomed Code and of that of the EDMA. Hellasmes is a member of both these European associations.

8.2 Are there any restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device?

There are no specific rules which provide for restrictions on payments or hospitality offered to physicians in connection with the promotion of medical devices.

It should be taken into consideration that medical devices are mostly purchased by public hospitals. Therefore, the general rules regarding corruption and bribery as well as fraud and other malpractices in public procurement apply to the officers responsible for placing the orders of the purchasing public entity. These rules will be applicable where the public officials received moneys or any other benefit in order to perform or omit performing his or her official duties or when any person disturbs or manipulates the regular bidding process for public procurement supplies.

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?

Other than the amendments to EOF's circulars (mentioned below), there have not been any significant developments on the rules relating to pharmaceutical advertising over the last year.

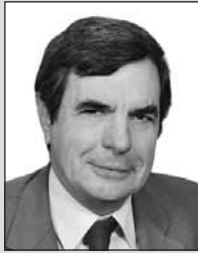
9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

Although the relevant legislation has not been amended and is not expected to change in the near future, two of EOF's circulars are expected to pass in the field of pharmaceutical advertising. In particular, a circular regarding the advertising of non-prescription

medicines to the general public and a circular regarding the information and promotion of medicinal products to health professionals from pharmaceutical companies are currently under consultation.

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

Following the first publication of SFEE's Code of Practice in March 2002 and its relevant amendment in July 2008, April 2010 and March 2011, the publication of EOF's circular on the control of promotion expenses of medicinal products in March 2004 and its amendment in January 2010 and December 2010, as well as the MD, there has been a decrease in the phenomenon of violations of the applicable legal provisions on the advertising of medicinal products, without this implying that such violations have now been totally eliminated.

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