Chapter 99

Greece

Bahas, Gramatidis & Partners

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1 General- medicinal products

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

Ministerial Decrees Y6a/776/23.6.1993 "on the harmonisation of the Greek legislation to the relevant legislation of the European Community regarding the classification of medicinal products for human use, their labelling and package leaflets, as well as of their advertising" (Official Gazette B 536/1993), A6/10983/84 "on medical information about medicines by pharmaceutical companies" (Official Gazette B 37/1985), Y6a/22261/8.3.2002 "on the advertising of medicinal products that may be given without prescription" (Official Gazette B 284/2002) are the dominant legal instruments governing the subject today, in combination with Legislative Decree 96/1973 "on the trading of pharmaceutical and cosmetic products" (Official Gazette A 172/1973) and Law 1316/1983 "on the establishment, organisation and competence of the National Organisation for Medicines, the National Pharmaceutical Industry, the State Pharmaceutical Warehouse and other provisions" (Official Gazette A 3/1983). Apart from the above legislation, relevant provisions are also interspersed in various other legislative texts, such as the Presidential Decree 301/2002 "on the adaptation of Greek legislation to the provisions of Directive 98/27/EC on the lawsuits in the sector of the protection of the consumers' interests" (Official Gazette A 267/2002), the Market Ministerial Decree 14/1989, as successively amended, Ministerial Decree DY7/oik.2480/1994 (Official Gazette B/679/1994) for medical devices, the Code of Greek Pharmaceutical Ethic (for pharmacists), the Code of Ethic for Physicians, the breach of which entails disciplinary sanctions for the professionals, the Code of Practice of the Hellenic Association of Pharmaceutical Companies regarding Medicinal Products, which is observed by the great majority of the pharmaceutical companies active in Greece, the Civil Code, Law 2251/1994 on consumers' protection (Official Gazette A 191/1994) etc.

1.2 Must advertisements be approved in advance by a regulatory or industry body before use?

There is no regulatory or industry body approving in advance advertisements of pharmaceuticals. The only restriction is that the said advertisements should observe a number or criteria explicitly specified by law. However, it should be noticed that the person(s) in charge of the product's circulation should keep at EOF's disposal or disclose to the said authority a copy of every advertisement disseminated by the pharmaceutical company, together with a document, in which the recipients, the mode of transmission and the date of the first transmission should be mentioned.

1.3 What are the penalties for failing to comply with the rules? 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 in a case where a pharmaceutical advertisement does not comply with the relevant legislation on promotion and advertising are - depending on the case - fines amounting to 1.468 Euros or even more in case of repetition of the breach, committal proceedings before the Public Prosecutor leading to an up to six months imprisonment, press announcements, and even suspension or revocation of circulation permits.

The preponderant role for the supervision and control of pharmaceutical advertising is entrusted to the National Organisation for Medicines (EOF), which ensures there is a proper and effective means of control of the advertising of pharmaceutical products and may ex officio take measures when it deems that interests are compromised and especially the public interest. Therefore, it may either initiate the proper procedures, so that a misleading advertisement is banned, or in the case where such an advertisement has already appeared, EOF may give to the media for publication the resolution by which the said organization had pronounced on the unsuitability or illegality of the advertisement. Moreover, consumers' organizations may also take action through the courts, should the public's interests be affected.

The law does not contain explicit provisions in connection with competitors and their possibility of having recourse to the law, those may take action pursuant to the provisions on unfair competition law, should the relevant requirements be met.

However, it should be pointed out that pharmaceutical companies in Greece are very responsible and respect the legislation in force, which explains why our national jurisprudence lacks any examples worth mentioning. Moreover, the members of the Hellenic Association of Pharmaceutical Companies, a vehicle that embraces 90% of these companies in Greece, have efficient internal mechanisms by which the observance of the Code of

Ethics, and by extension, the relevant legislation is controlled.

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?

Pursuant to article 20 of Ministerial Decree Y6a/776/23.6.1993 it is forbidden to advertise any medicine that does not hold a marketing authorisation granted by EOF (or by EMEA). The notion of advertising is broad and covers any form of rendering information for the promotion of prescribing, supply, sale, administration or consumption of pharmaceutical products, including scientific meetings. On the other hand, Ministerial Decree 10983/84 provides that pharmaceutical companies may supply information to health professionals for the proper use of authorised medicinal products in order to ensure the protection of public health.

Therefore, any information discussed or made available to health professionals should be limited to a purely scientific content and be within the context of sharing the scientific development. For instance, in a case where the medicinal product contains a new active ingredient or the active ingredient's method of preparation is new, or if new important indications are going to be authorised, or the administration method is new and innovatory. Any elements that could directly or indirectly give the impression that the discussion or meeting is of a promotional character are prohibited. However, since the difference between information and advertisement (and in general promotion) is not always clear, each case should be treated on its merits.

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

Pursuant to the analysis stated above under 2.1, it is not possible to publish information on medicines unless they have been authorised by EOF (or EMEA) in conformity with the relevant legal provisions. Since information published on a medicine necessarily means reference to it, such a publication could not be acceptable under the current legal system.

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

In light of the above remarks (under 2.1 and 2.2), a press release may be excluded from the general prohibition only provided its content is not directly or indirectly promotional, but purely informative and does not make any reference to a specific medicinal product.

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

Pharmaceutical companies may make further information available to health professionals on their own initiative provided they do not aim directly or indirectly to promote medicinal products. It is also possible that health professionals themselves require information or clarification. In the last case, the information given could be considered to be of a non-advertising nature. However, the frequency and the volume of the communicated documentation should correspond to the actual need for effective information and remain within a proper and ethical framework, and the supply of such information should not be contingent upon any returns. It should be noticed that pharmaceutical companies should have a scientific service responsible for giving information on medicines that are in the market, able to answer all queries that health professionals or patients may have. These questions may also be registered and filed.

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?

It is not unusual for information to be sent to the policy decision making centres, so that social security organisations may map out their budget.

3 Advertisements to health professionals

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

Pursuant to article 24 of Ministerial Decree Y6a/776/23.6.1993 advertisements directed at health professionals should include the substantial information that corresponds to the brief description of the product's characteristics, the product's classification in connection to the provision requirements, the sale price or an indicative sale price, as well as the percentage of their subvention by social security funds. In some cases however it is possible that such an advertisement only mentions the name of the medicine, and its sole purpose is to promote the name.

3.2 What rules govern comparator advertisements? Is it possible to use another company's brand name as part of that comparison?

According to Law 2251/1994 an advertisement is considered a comparator when it defines directly or indirectly the identity of a specific competitor or of the same products or services. Such an advertisement is only allowed when it compares in an objective manner the substantial, pertinent, confirmable and impartially chosen characteristics of the competitive products or services and provided this advertisement a) is not misleading, b) does not cause confusion in the market between the advertised company and a competitor or between the competitors of the advertised company or between the trademarks, features, products or services of the advertised company and its competitor or between the competitors, c) is not degrading, derogatory, slanderous or defamatory of a competitor, its products, services or activities and d) does not essentially intend to benefit from the reputation of the competitor's trademark or other feature.

3.3 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)?

It is incontestable that due to the sensitive nature of pharmaceutical advertisements and their importance, the same could be described as "sui generis" advertisements. A "teaser" message, which is highly likely to create a quite striking image of the product, is alien to the mission and role of pharmaceutical advertising and therefore it should be avoided.

4 Gifts and financial incentives

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

The said subject matter is regulated by article 5 of Ministerial Decree YA A6/10983/84 in combination with article 29 of Ministerial Decree Y6a/776/23.6.1993 and Legislative Decree 96/1973. Free samples must be samples of authorised medicines only, and under no circumstances does the law allow the supply of samples of psychotropic and narcotic medicines.

Samples may be provided to health professionals qualified to prescribe them only following relevant special authorisation from EOF according to the law. The said authorisation also specifies the package, total quantity, the time and place of disposal of the samples, as well as any other necessary element. Selling and supplying for any exchange products that have been supplied to health professionals free of charge are absolutely prohibited.

Samples should not be provided by post. On the contrary only medical sales representatives or other individuals especially and exclusively authorised by pharmaceutical companies may provide health professionals with samples, always followed by a receipt on which the following should figure: the quantity of samples provided, the date of their delivery, as well as the name, address and signature of the recipient. Pharmaceutical companies should keep these receipts for at least five years.

Only a limited number of samples is justified each year for each individual qualified to prescribe medicines and a written, signed and dated request should always precede the supply of samples. The latter should have an identical form with the actual smallest package that is on the market and should bear the indication "Free Medical Sample – Sale is prohibited" in capital letters. All samples must also indicate the lot number and the expiration date, as well as a copy of the summary of the medicine's characteristics and the leaflet of instructions of use, as the same has been accepted by EOF. Finally, the supplier should ensure that an adequate system of control and accountability exists.

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

Article 27 of Ministerial Decree Y6a/776/23.6.1993 provides that within the framework of promoting a medicinal product, it is prohibited to supply, grant or promise gifts, financial benefits or benefits in kind to people authorised to prescribe or supply medicinal products, with the exception of gifts of negligible value related to the profession of physicians or pharmacists. However, it is accepted that it is possible that gifts under the form of promotional aids may be distributed to health professionals, as well as to proper administrative executives in connection with a specific product of general utility under the condition that the said gifts are of low value and relevant to their professional practice.

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?

It is possible to give donations to institutions, as well as provide them with medical and educational goods and services (such as diagnostic equipment, computers, sponsorships for research programs etc.) for the enhancement of the patients' care and to the benefit of the National System of Health. Nevertheless, attention should be drawn to the fact that the supply of the above should under no circumstances be carried out in order to directly or indirectly promote a medicinal product, nor constitute an inducement to prescribe or purchase the products of the donating company. Actually, any gift may only bear the name of the pharmaceutical company and never that of a medicinal product.

4.4 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?

Discounts and special offers are permitted within the framework of a free economy and only for drugs sold by wholesalers to private hospitals, because in case of medicines that are prescribed at public hospitals, prices are fixed by the price-list that EOF prepares periodically. It is also possible that medicinal products are given at reduced prices in case of tenders. Any discount or offer is subject to the legislation on unfair competition.

4.5 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?

Any offers should aim at promoting the public health and the interests of the patients and should be kept within reasonable limits.

4.6 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed?

The accusation that a medicinal product "does not work" is very serious and may refer to a medicine that has many contra-indications or whose effectiveness was very poor as compared with the actually expected results. In that case there are formal procedures which involve EOF and the Ministry of Health and to a lesser extent the pharmaceutical company.

5 Hospitality and related payments

5.1 What rules govern the offering of hospitality to health professionals?

Pursuant to article 27 of Ministerial Decree Y6a/776/23.6.1993 when - within the framework of events organised for the promotion of sales - hospitality is offered to persons authorised to give relevant prescriptions or to provide pharmaceutical products, this hospitality should always be reasonable and of secondary importance in comparison to the main scope of the event and should not be offered to other persons that are not professionally involved in the health sector.

Furthermore, article 28 of the above Ministerial Decree provides that article 27 shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes and should under no circumstances be extended to persons other than health professionals. Such hospitality must always be reasonable and remain subordinate to the main scientific objective of the meeting.

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?

It is possible that a company covers the cost of travel, subsistence, accommodation and enrolment fees, as well as giving to the participants an amount as grant, provided the amount does not exceed the amount the participant would spend on his own for attending the specific meeting, because otherwise such a cover may be considered as benefit. Payments covering the attendance should also be kept subordinate to the main objective of the meeting. However, speakers (but not attendees) may be paid by pharmaceutical companies with hororaria for their time and effort.

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

It is possible to pay doctors in order to provide their services with a reasonable remuneration for services actually rendered.

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?

Under Greek legislation non-prescription medicines are the only ones subject to direct-to-consumer advertising.

The relevant advertisements must promote the sensible use of the product by presenting it in an objective manner without exaggerating the characteristics. Most importantly, the advertisements must not be misleading. The notion of a misleading advertisement could be described as an advertisement that in any way, including its form or content or display, misleads or may mislead the individuals to whom it is addressed, or to whose knowledge the advertisement came, and which due to its deceitful character is capable of influencing their financial behaviour, or the advertisement which, due to the above reasons, may harm a competitor. In order to decide on whether an advertisement is of a misleading nature, many criteria are applicable to the information given by the message (Article 9 of Law 2251/1994): the nature and composition of the drug, the method used for its creation, its specifications, scientific and technological data, the outcome of tests and controls, information on the way of payment, credit, delivery and maintenance, its distinctions etc. Under no circumstances should the advertisement's persuasiveness be based on the witness of people to whom a non-existing scientific quality, speciality or authority is attributed, or on the fact that the level of technology in the country of the product's origin indicates the quality of the advertised items. Furthermore, advertisements should not appear under the form of a coverage, reportage or press comment, let alone of a scientific announcement, unless it is explicitly and distinctly stated that this is an advertisement. Finally, an advertisement is deemed automatically misleading if it includes scientific terms, locutions, research results or quotations from scientific or technical texts, in order to add to the message a scientific basis that is not real.

Apart from these general principles, Articles 22 and 23 of Ministerial Decree Y6a/776/23.6.1993 introduce further requirements for pharmaceutical advertising directly addressed to the public. According to the above provisions, the message should be designed in a way that its advertising nature is obvious and the product is clearly distinguished as a pharmaceutical product. The message should include at least the name of the product and its generic name, when the drug has only one active substance, any necessary information for the proper use of the product, as well as an explicit and clear call to the consumer to read carefully the use instructions in the inside leaflet or on the package, whichever the case may be.

On the contrary, advertising should not include any item whatsoever, which indicates that visits to doctors or surgical interventions are redundant, especially by giving diagnosis or suggesting treatment by correspondence. It should not imply 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 drug 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. Also, pharmaceutical messages may not refer to scientists or other professionals or famous persons, who may promote the product due to their status, or present the drug 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 be also noticed that advertisements should not show in an extremely alarming or misleading way the appearance of the human body because of a disease or because of the action of the medicine.

Furthermore, it should be pointed out that Ministerial Decree Y6a/776/23.6.1993 prohibits the reference in an advertisement aimed at the public of any elements whatsoever that refer to the following therapeutic indications: tuberculosis, sexually infected diseases, other serious pestilent diseases, cancer and other oncomatic diseases, chronic insomnia, as well as diabetes and other metabo-

lism diseases. Finally, all pharmaceutical data mentioned in the advertisement should correspond to the information that appears in the brief description of the product's characteristics.

Ministerial Decree Y6a/OIK.22261/8.3.2002 on the other hand specifies the sine-qua-non element of the pharmaceutical advertisements, which is the following text: "*The Ministry of Health and Welfare and the National Organization for Pharmaceuticals urge: Read carefully the use instructions – Consult your doctor/or your pharmacist*".

In case of printed advertisements, i.e. in a newspaper or magazine, then the above text should cover 15% of the advertisement's surface, the letters of the part "The Ministry of Health and Welfare and the National Organization for Pharmaceuticals urge" should be semi-black and lower capital. The words "Read carefully the use instructions – Consult your doctor/or your pharmacist" should cover 50% of the advertisement's surface and be written in black capital Helvetia letters.

In addition, the colour of the background on one hand and of the frame and letters on the other should be chosen among the colours of the advertisement that have the greater contrast, and in case of technical difficulties black and white may be used to achieve this contrast. The above text should be clear and legible and under no circumstances be covered or sectioned by the interference of other indication or image.

In case that advertising takes place in television, cinema or Internet, then the above text should appear as a moving superscription or subtitle that should last for at least ten (10) seconds, cover at least 15% of the upper or lower part of the screen. This text should also be clear, legible and not covered or sectioned by the interference of other indications or messages. However, should the advertisement lasts less than 10 seconds, then a readable and stable subtitle should appear in a frame, written in three lines and with capital letters, and should cover 20% of the screen's area without the interference of any other notes.

In case of audio advertising, such as radio, the advertisements should be immediately followed by the above text, which will be red to the hearer in a very articulate and clear way.

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

Under no circumstances may a prescription only medicine be advertised 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?

Pursuant to the last section of article 19 of Ministerial Decree Y6a/776/23.6.1993, information on human health or human diseases is not considered advertising, provided no reference, not even indirect, is made to any pharmaceutical product. In this frame, the Ministry of Health and other Health Unions and relevant vehicles, governmental or non-governmental, organise in Greece campaigns aiming at informing the public on precautionary measures to be taken with regard to specific diseases, removing possible prejudices in other cases, settling the public's anxiety for a disease which may rest on false information and advising patients and their families not to experiment with their health and turn to health professionals immediately.

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

Advertising prescription only medicines to the public is absolutely prohibited by law. Therefore, even if a text is vested with the form of a press release, it may very well constitute an indirect, or camouflaged advertisement of a medicine, hence it is illegal and has legal consequences.

7 The Internet

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

Internet advertising expressly falls into the same category as television advertisements, pursuant to Ministerial Decree Y6a/OIK.22261/8.3.2002, and the same provisions described under 6.1. apply, although it is a sector much harder to monitor and control. That is why there have been violations of the relevant legislation via internet in the field of dietetic products and cosmetics.

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?

Security for websites especially addressed to health professionals or for information or advertisements that are addressed to health professionals only, but are included in websites to which the public also has access, is assured by the use of strictly confidential user names and passwords which will only be given to health professionals.

8 General- medical devices

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

Ministerial Decree DY7/oik.2480/1994 (Official Gazette B/679), Law 2955/2001 (Official Gazette A 256/2001) and Ministerial Decree DY7/3140/1997 (Official Gazette B 9/1998) are the main specialised legal texts on medical devices.

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

There are not particular provisions in relation to the above subject matter, as in regarding medicinal products.

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Professional Practice

Mrs. Eleftheria Georgopoulou joined Bahas, Gramatidis & Partners as a trainee lawyer in 2001 and as a lawyer in 2002. She specializes in Employment and Social Security Law. She is also experienced in Civil Law, Commercial law and relevant litigation, and she becomes intensively involved with pharmaceutical legislation issues.

Education – Membership

Mrs. Georgopoulou got her LLB from University of Athens Law School and her LLM in Labour Law and Social Security Law (DEA de Droit Social) from University of Strasbourg III - Robert Schuman. She performed internships in the legal Department of a Greek Bank, as well as in the Hellenic Home Department - Secretariat of Administration. She speaks English, French and German. She is a member of the Greek Commercial Lawyers' Association and the Association of Jurisprudence Study.

Bahas, Gramatidis & Partners

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