Chapter

Portugal

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1 General - Medicinal Products

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

The applicable regime to the advertising of medicinal products in Portugal is set-forth in Decree-Law 176/2006, 30th August 2006 ("Medicines Code"), which transposed Directive 2001/83/EC, of 6th November 2001, on the Community Code relating to medicinal products for human use, as amended ("Community Code").

Briefly, the Medicines Code comprises a set of rules concerning: (i) the definition of the advertising of medicinal products; (ii) the cases in which advertising is permitted to the general public, its limitations and requirements; (iii) the requirements for the advertising of medicinal products to persons qualified to prescribe medicinal products; (iv) the obligations of the marketing authorisation holder ("MA holder") as well as the obligations of the company responsible for the promotion of the medicinal product; (v) the requirements concerning the activity of the medical sales representatives when advertising a medicinal product; (vi) the scientific and promotional events and the accommodation costs; (vii) the terms and conditions subject to which the offer of free samples is permitted; and (viii) the supervision and sanctioning powers of the Portuguese Authority for Medicinal Products ("Infarmed").

Additionally, Decree-Law 330/90, 23rd October 1990, as amended ("Advertising Code"), which sets-forth the Portuguese advertising rules in general, is subsidiary applicable to the advertising of medicinal products in all matters not specifically provided for in the Medicines Code.

Furthermore, Resolution 044/CD/2008, 7th February 2008, issued by Infarmed and which came into force on the 1st April 2008, approved the "Advertising Regulation" which establishes rules regarding: (i) the necessary elements in advertising to health professionals defining essential information compatible with the summary of product characteristics ("SPC"); (ii) distribution of free samples – number of samples that can be distributed to a health professional per year; (iii) the submission to Infarmed of the advertising materials; and (iv) the price lists and trade catalogues.

At a deontological level, the Apifarma Code of Practice for the Pharmaceutical Industry (last amended on the 1st July 2008) ("Apifarma Code"), approved by the Association of the Portuguese Pharmaceutical Industry ("Apifarma"), a member of the European Federation of Pharmaceutical Industries and Associations ("EFPIA"), must also be considered. The Apifarma Code develops the rules established in the Medicines Code and is only applicable to the associated companies.

There is also an Advisory Committee designated "*Conselho Nacional de Publicidade de Medicamentos*" ("CNPM"), composed by representatives of entities that participate in the pharmaceutical market, competent to issue opinions on the implementation and observation of rules and standards governing the advertising of medicinal products.

In addition, other rules must be taken into account, particularly in what concerns unfair competition, the protection of confidential information and unfair commercial practices. For this purpose Decree-Law 36/2003, 5th March 2003 as amended ("Industrial Property Code"), Law 18/2003, 11th June 2003 ("Competition Law") and Decree-Law 57/2008, 26th March 2008, transposing Directive 2005/29/CE ("Unfair Commercial Practices Code"), may be deemed applicable depending on the issues at stake.

1.2 How is "advertising" defined?

The advertising of medicinal products is defined in the Medicines Code as any form of information, surveying or inducement with the purpose or effect of promoting the prescription, supply, sale, purchase or consumption of such products, in any of the following situations:

(a) to the general public;

(b) to wholesale distributors and health professionals;

(c) by means of visits by medical sales representatives to the persons referred in hereabove;

(d) through the supply of samples or commercial bonuses to any of the persons referred in (b) hereabove;

(e) through the granting, offering or promising of advantages, whether in money or in kind, except for when their intrinsic value in insignificant;

(f) by sponsoring promotional meetings attended by the persons referred in (b) hereabove;

(g) by sponsoring scientific conferences or meetings attended by the persons referred in (b) hereabove, namely by direct or indirect payment of accommodation costs; or

(h) by reference to the commercial name of the medicinal product.

The advertising regime of the Medicines Code does not apply to:

(a) the labelling and the accompanying package leaflet approved in accordance with the Medicines Code and the applicable European Law;

(b) the correspondence needed to answer a specific question about a particular medicinal product, possibly accompanied by documentation, as long as it does not contain any element

of a promotional nature;

(c) factual, informative announcements and reference material relating to packaging changes, adverse reaction warnings in what concerns pharmacovigilance, trade catalogues and price lists, provided they do not include any other information regarding the medicinal product; and

(d) the information regarding human health or diseases provided that there is no reference, even indirect, to a medicinal product.

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?

In what concerns the arrangements that companies are required to have in place to ensure compliance with the applicable rules to the advertisement of medicinal products, article 156 of the Medicines Code establishes that the MA holder must create and maintain a scientific service responsible for the information related to the medicinal products.

Through the abovementioned scientific service, the MA holder must: (i) keep complete and detailed records of all the advertisement made by the company, in documents that mention the recipients of the information, the means and the dates of the first disclosure; (ii) keep the mentioned records available to the competent authorities, in this case Infarmed, responsible for monitoring the advertising of medicinal products, for a minimum period of five years, counted from the date of the first disclosure; (iii) guarantee that the advertising undertaken by its company or on behalf of its company respects the requirements set-forth by applicable laws regarding advertising; (iv) ensure that the medical sales representatives that promote medicinal products in name of the company have the adequate qualifications and the necessary training to carry out their responsibilities in full respect of their obligations and the applicable laws regarding advertising; and (v) cooperate with the competent public authorities, particularly by providing information and necessary assistance in what concerns the monitoring of the advertising.

On the other hand, according to the Advertising Regulation, the MA holder must send Infarmed a description of any piece of advertising regarding medicinal products within 10 days counting from the first disclosure of the advertising material.

Companies may also request Infarmed for an opinion regarding advertising issues that may arise in what concerns certain advertising materials.

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?

In Portugal, there are no legal or deontological requirements establishing that companies must have SOPs governing their promotional activities.

Despite it not being legally or deontologically binding the fact is that several pharmaceutical companies operating in Portugal have developed and implemented SOPs which aim at ensuring the consistency of the respective advertising activities with the applicable regulatory and deontological framework.

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?

Advertising does not need to be previously approved by Infarmed or by any other public authority.

However, in what concerns the required procedures regarding this matter, as mentioned in question 1.3, the Advertising Regulation establishes that the MA holder has to send Infarmed a summarised description of each piece of advertising of the medicinal product. Note that in lieu of the summarised description Infarmed may require a copy of the original piece of advertisement.

The procedure consists of the notification to Infarmed through the submission of a form available at Infarmed's website, within 10 days from the first disclosure of the advertising material at stake.

The MA holder may, instead of sending a summarised description of each piece of advertising, submit a summarised description of a piece of advertising inserted in an advertising campaign or in an annual plan of advertising events.

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?

When Infarmed considers that a company may be in breach of the laws regarding advertising of medicinal products, it promotes a misdemeanour procedure (to which the subsidiary regime established in Decree-Law 433/82, 27th October 1982, as amended, is applicable) in order to analyse the advertisement at stake. Within said misdemeanour procedure Infarmed has the powers to decide whether or not the advertising is in compliance with the law.

If Infarmed considers that a company is in breach of the law, Infarmed may apply a fine and order the company to stop further publication of the advertising materials. Following the notification of Infarmed's decision to apply a fine, the company may appeal from said decision to the judicial courts.

In what concerns the possible breach of the Apifarma Code the disciplinary powers belong to Apifarma, which may promote a disciplinary procedure against an associated company. According to said procedure Apifarma may request the company to immediately stop the advertising at stake and compromise itself to not repeating the referred advertising. Furthermore, Apifarma may apply a sanction that may consist of: (i) a warning; (ii) a pecuniary fine; or (iii) the suspension of the company from the association for a determined period of time or even the company's expulsion.

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?

Within the misdemeanour procedure the penalties for failing to comply with the rules governing the advertising of medicines, provided in the Medicines Code, are pecuniary fines that range from € 2,000 to € 3,740.98 or from € 2,000 to € 44,891.81 respectively, whether the conduct has been undertaken by a natural

person or a company. The applicable penalties in case of breach of the rules concerning (i) the medical sales representative's access to the National Health Service ("NHS") hospitals, and (ii) free samples, are also pecuniary fines that range from € 1,000 to € 35,000. Note that the advertising agency or any other entity that undertakes the advertising activity, are also punished as authors or co-authors of the referred regulatory offences for the breach of the rules governing the advertising.

Furthermore, Infarmed may impose the publication in the media, at the expenses of the company, of the essential elements that determined the conviction, as well as the suspension of the advertising activity of the product for a period of up to two years.

Moreover, reimbursed medicines may be de-listed as a consequence of infringement of advertising rules. The process for de-listing is autonomous from the misdemeanour procedure and may run in parallel.

The responsibility for the enforcement of the present rules belongs to Infarmed and they are strictly enforced.

In what concerns examples of actions undertaken against pharmaceutical companies, according to the information disclosed by Infarmed, from January until July 2009 Infarmed's monitoring and supervising activity has resulted in the promotion of 11 misdemeanour procedures against MA holders. Said misdemeanour procedures arose mainly from the breach of rules that prohibit misleading advertising of medicinal products.

The misdemeanour procedure with the aim to apply a fine as a result of the disrespect of advertising rules must be initiated and decided by Infarmed, even if on the basis of a complaint submitted to the Infarmed by competitors. Therefore, in what concerns the misdemeanour procedure competitors may not take direct action to the courts.

However, in general terms, the misdemeanour procedure does not exclude the potential civil liability of the company, in case of which the competitors may take action through the courts by filing a civil liability lawsuit.

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?

There is no relation between the supervisory and enforcement functions of Infarmed and the self-regulatory processes within Apifarma.

Infarmed is competent to investigate matters drawn to its attention that may constitute a breach of the advertising laws. However, the breach of the rules established in the Apifarma Code is not of the competence of Infarmed but of the competence of Apifarma.

On the other hand, Infarmed may take up matters formally transmitted to Infarmed by any identified third parties.

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?

In addition to any action based specifically upon the rules relating to advertising, a company that was harmed by an advertisement may also react through a lawsuit based on unfair competition or on the infringement of the rules regarding protection of confidential information which are set-forth by the Industrial Property Code. In case of infringement of the rights to a trademark, logo or any right with legal protection, a lawsuit may be filed, claiming the compensation for damages. Said infringement may also be sanctioned within misdemeanour procedures that are investigated by the Authority for Foods and Economic Safety ("ASAE") and decided by the National Industrial Property Institute (fines may range from € 3,000 to € 30,000).

Additionally, another action that may be taken against an advertisement may be based on the Unfair Commercial Practices Code. Consumers and competitors negatively affected by an advertisement considered an unfair commercial practice may take legal action in order to prevent, correct or stop such practice. Unfair commercial practices may also be sanctioned within misdemeanour procedures that may be promoted either by Infarmed or by the Consumer's Government Department. Fines may range from € 3,000 to € 44,891.81.

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)?

The advertisement of medicinal products that do not have a valid market authorisation or registration in Portugal, or that have been authorised under special or exceptional authorisations, is not permitted. It is only possible to make information available to health professionals regarding unauthorised medicinal products if it does not qualify as advertising and therefore does not constitute an incentive to the prescription and supply of the medicinal product.

Said information may be made available at meetings of a scientific nature, whether sponsored by the company responsible for the product or a third entity. In any case, when the sponsorship of the meetings is of the company responsible for the product the risk of the information being considered advertising is increased.

The provision of off-label information is only admissible as long as it may not, in any way, be considered promotion. In essence, the rule for off-label is the same as for non-authorised products – in both cases we are dealing with unauthorised products/indications.

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

Information on unauthorised medicines may only be published if such information is not considered advertising, and hence does not have the purpose or effect of promoting the prescription, supply, sale, purchase or consumption of the product, and if the same is of a scientific and objective nature.

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

Press releases on unauthorised medicines may only be issued if

such press releases are not considered advertising and have a scientific nature. Thus, such press releases may be issued, provided that they do not have the purpose or effect of promoting the prescription, supply, sale, purchase or consumption of the products and that they cannot in any way be considered advertising of such product. When such press releases are issued by the pharmaceutical company they should only contain information regarding human health and diseases.

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

The company may send such information to health professionals, upon their request, and may be accompanied by documentation as long as it does not contain any advertising factors. This being the case, the company is addressing a specific question put forward by the health professional and not acting pro-actively.

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?

Companies may only send information to institutions provided that it is necessary to answer a specific question regarding a certain medicinal product. Otherwise, information regarding unauthorised products may not be sent to institutions.

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?

Companies may only involve health professionals in market research exercises concerning unauthorised medicinal products under a services agreement, and it must not be related to any supply or prescribing activities of the doctor at stake nor may such activities imply the collection and processing of data regarding prescription and supply habits.

3 Advertisements to Health Professionals

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

Advertising to health professionals must mandatorily include:

(a) the name of the medicinal product;

(b) essential information compatible with the SPC – which comprises the following information:

(i) the name of the medicinal product; (ii) the qualitative and quantitative composition; (iii) the pharmaceutical form; (iv) the therapeutic indications; (v) the posology and method of administration; and (vi) contra-indications and adverse reactions;

and, if relevant from a clinical point of view, the following information must also be included:

(i) warnings and special precautions for use; and (ii) interactions with other medicinal products and other forms of interaction;

(c) the supply classification of the medicinal product, e.g. with the indication that the medicinal product is a prescription-only medicinal product, if applicable; and

(d) the reimbursement regime.

The above information is not required when the advertisement is intended to be a reminder of the name of the medicinal product. A name reminder can only include: (i) the name of the medicinal product; (ii) the active substance; (iii) the strength; (iv) the pharmaceutical form; and (v) the identification of the MA or registry holder.

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

There are no restrictions to the inclusion of endorsements by healthcare professionals in promotional materials addressed exclusively to such professionals provided that all legal requirements are fulfilled and that such endorsements are accurate, current, verifiable and sufficiently complete. It is, however, prohibited to include any kind of endorsements by healthcare professionals in promotional materials directed to the general public.

3.3 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?

According to the Medicines Code any type of comparative advertising of medicinal products is prohibited when directed to the public in general.

The only cases of permitted comparative advertising are those directed to health professionals. In this case the regime of the Advertising Code applies.

The Advertising Code provides that comparative advertising is only allowed if (i) it is not misleading and (ii) it objectively compares one or more of the essential, relevant, verifiable and representative characteristics of the medicinal products.

Further to these requirements, the Medicines Code establishes that the information contained in documentation provided to the health professionals must be accurate, current, verifiable and sufficiently complete to enable the recipient to make a correct idea of the therapeutic value of the medicine.

Additionally, the Apifarma Code provides that (i) comparisons among different medicinal products should be based on relevant and comparative aspects of the former, (ii) should neither be misleading nor defamatory and (iii) can only be made based on the elements included in the respective summary of the medicinal products characteristics or on credible clinical data.

In conclusion, there is no specific requirement of a number of "head to head" clinical trials before comparative claims are made established in the law, however, the above mentioned regime requires that the comparative claims must be based on verifiable studies.

3.4 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 Portugal?

As mentioned in question 3.2 the rules that govern comparator advertisements are established in the Advertising Code.

According to said regime, it is possible to use another company's brand name as part of the comparison provided that it does not

create confusion in the market between the brand names and that it does not discredit/denigrate the brand name, or take unfair advantage of its reputation.

There is no specific applicable regime concerning the possibility of referring to a competitor's product which has not yet been authorised. However, the Advertising Code requires that the advertising compares products that respond to the same needs or have the same purposes, therefore, if the product is not authorised such requirement is not fulfilled. On the other hand, making reference to an unauthorised product may give rise to misleading advertising, prohibited by the Advertising Code and the Medicines Code.

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

There are no specific rules applying to the distribution of scientific papers in congresses to doctors. In any case, if these papers qualify as advertising (e.g. identification of a given product), the requirements established in the Medicines Code concerning advertising of medicinal products before health professionals, in particular the requirements mentioned in question 3.1 (article 154 of the Medicines Code), are applicable. Furthermore, article 155 of the Medicines Code requires that the documents handed over to health professionals include also the indication of the date when it was established and when it was last reviewed. The information contained therein must be accurate, current, verifiable and sufficient to allow the recipient to make a correct idea of the therapeutic value of the medicine.

If on the contrary the scientific papers do not purport to advertise any medicinal product, the provisions of the Copyrights Code (approved by Decree-Law 63/85, dated 14th March 1985, as amended and republished by Law 16/2008 dated 1st April 2008) and/or those provided in the Industrial Property Code should be taken into consideration.

3.6 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)?

There is no specific regime regarding "teaser" advertisements. However, if a teaser identifies a given medicine, it must always contain the minimum information mentioned in question 3.1.

4 Gifts and Financial Incentives

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

Free samples may only be provided to health professionals, on an exceptional basis, and under the following conditions:

(a) they do not exceed 12 units per year per health professional;

(b) any supply of samples shall be in response to a written request, signed and dated, from the recipient;

(c) they are not larger than the smallest presentation on the market;

(d) each sample shall be marked "Free sample" or "Not for sale", or similar warnings; and

(e) they are accompanied by a copy of the SPC.

Free samples of prescription-only products may only be supplied during the two years following the date of their effective commercialisation.

Samples of products containing narcotics or psychotropic substances are prohibited.

Companies are obliged to create an adequate system of control and accountability of samples, which shall be kept at the disposal of the supervisory authorities, for a period of five years.

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

The holder of a MA, or the company responsible for the information or promotion of a medicinal product or the wholesale distributor, may not offer or promise to offer, directly or indirectly, to health professionals gifts, bonuses or pecuniary advantages or benefits in kind, except when these are of insignificant value and relevant to the practice of medicine or pharmacy.

As there is no legal definition for "*insignificant value*", the limit of € 25 established in the Apifarma Code, and thus only binding to members of Apifarma, is usually used as a reference within the industry.

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 gifts or donations of money to institutions such as hospitals as long as these are not directed to individual health professionals and do not constitute an inducement to purchase or administer specific medicines.

The same applies to the donation of equipment and the funding of the costs of medical or technical services (such as the cost of a nurse or the cost of laboratory analyses).

According to Apifarma Code, these gifts, donations or funding should be documented in a written agreement.

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?

Gifts, donations or pecuniary advantages or benefits in kind to doctors are only possible under the terms described in question 4.2, provided that they do not lead to changes in prescribing patterns. It is possible to sponsor promotional meetings or scientific congresses attended by health professionals, including payment of travel and accommodation costs in connection therewith. Any other advantage, including medical or educational goods and services, provided to doctors, is forbidden. It is possible, however, to compensate doctors for services rendered under, and specified in, a services agreement.

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 measures or practices with regard to margins, prices and discounts are not considered advertising. Any limitations in this respect are those potentially arising from pricing and competition 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?

It is only possible to offer, provide or pay for medical or technical services or equipment for doctors in the conditions provided in question 4.2 above and to institutions as described in question 4.3 above.

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, if the product does not work, are not expressly foreseen in the Portuguese law. However, the law provides for a refunding scheme in cases where reimbursement of a given prescription-only product exceeds a previously defined threshold. Said scheme must be documented in a written agreement between Infarmed and the company.

As a general rule, over-the-counter medicines are not reimbursed.

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

Pharmaceutical companies may only sponsor continuing medical education through the sponsoring of scientific congresses (including payment of travel and accommodation costs in relation therewith). Any other initiative would fall under the prohibition of making offers or donations to health professionals (as it is not of an insignificant value) and would thus not be permitted.

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 Medicines Code and the Apifarma Code provide the following rules:

(a) the companies responsible for the sponsorship or organisation of the training, informative, promotional or scientific/professional events may only bear the hospitality costs of the respective participants and those costs are limited to the main objective of said event;

(b) hospitality costs only include those related to the signing-up, travel and accommodation of health professionals attending the abovementioned events;

(c) hospitality costs may not exceed the period between the day before the start of the congress or event and the day after its conclusion and may not include any other social program or activity which may hinder or impede a full participation in the professional or scientific events; and

(d) the choice of the location for such professional or scientific congresses or promotional events shall follow professional and logistical criteria and shall involve, particularly with regard to hospitality, financial costs appropriate to the purpose intended.

Regarding the hospitality costs in case of an event taking place in another country the Apifarma Code provides that companies cannot organise or sponsor events outside their home country, unless:

a) the majority of the participants are foreigners and taking into account the home countries of most of the guests it is more reasonable, in logistic terms, to carry out the event in another country; or

b) taking into account the location of the resources or relevant knowledge which are the object or topic of the event, it is more reasonable, in logistic terms, to carry out the event in another country.

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?

The payment of fees for the active participation of health professionals in training, promotional or scientific events is allowed, provided that said payments are not dependent on or constitute an incentive to the prescription or supply of medicines.

Expenses with travel, accommodation and enrolment fees may also be borne.

Time spent by health professionals in attending scientific events cannot be paid.

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?

Pharmaceutical companies may be held responsible by Infarmed (in a pecuniary fine that ranges from € 2,000 to € 3,740.98 or from € 2,000 to € 44,891.81) for the infringement of the applicable rules, provided in the Medicines Code, regarding scientific events and hospitality costs.

5.4 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 to provide expert services as long as the payment does not constitute an incentive for the prescription or the supply of medicines. According to Apifarma Code, said services must be ruled by a written agreement.

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

The payment of doctors for their participation in post marketing surveillance studies is allowed. Said payments may never constitute an incentive for the prescription or the supply of medicines, neither should the activities provided by the doctor imply the collection and processing of prescribing or supplying data.

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

The payment of doctors for their participation in market research involving promotional materials is allowed.

Again, said payments may never constitute an incentive for the prescription or the supply of medicines, neither should the activities provided by the doctor imply the collection and the treating of data concerning the doctor's prescribing and supplying habits.

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?

It is possible to advertise non-prescription medicines to the general public if they are not reimbursed by the NHS. In this case, advertising must be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product, and must include the following information:

(a) name of the medicinal product, as well as the common name if the medicinal product contains only one active substance, or its brand name;

(b) the information necessary for the correct use of the medicinal product, including therapeutic indications and special precautions; and

(c) invitation to the consumer to carefully read the information on the outer packaging and on the package leaflet and, in case of doubt or persistence of the symptoms, to consult a doctor or pharmacist.

The advertising of medicinal products to the general public may not contain any material which:

(a) gives the impression that a medical consultation or a surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine, except in what respects the vaccination campaigns referred hereabove;

(e) is directed exclusively or mainly at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;

(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;

(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;

(j) refers, in improper, alarming or misleading terms, to claims of recovery; or

(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

The law prohibits any form of comparative advertising and the direct distribution of medicinal products for promotional purposes to the public.

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

Advertising to the general public of prescription-only medicines is not permitted.

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?

Companies may provide information regarding human health and diseases, provided that no reference, even indirect, is made to a medicinal product. Disease awareness campaigns are permitted under these terms. Vaccination campaigns approved by Infarmed are also permitted.

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

Press releases without promotional nature will not be considered advertising. As such, these may be published in non-scientific journals.

However, the promotional nature of a given piece of information must be assessed on a case by case basis. The inexistence of a link between the company and the journal is a factor to consider minimising the risk of the press release being considered as promotion.

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

There are no specific rules in the Medicines Code regarding this matter. However, the Apifarma Code allows the companies to disclose institutional information, such as financial data, descriptions of R&D programmes and the analysis of legislative developments which may affect the company and its products.

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 Apifarma Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations contain certain rules regarding the relationship with patient associations. Amongst such rules, there are transparency requirements as regards the recording of donations and other financing support.

7 The Internet

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

There is no specific regime regarding the advertising of medicinal products through the Internet. In case the company owner of the website and the recipient of the information are both in the Portuguese territory, the rules concerning advertising to health professionals or to the public in general provided for in the Medicines Code will apply.

The Apifarma Code further provides that advertising of medicinal products to health professionals through the Internet should be based on technical, scientific and professional principles and that companies should adopt measures to guarantee that such advertising is accessed only by them.

There is no information concerning the control of advertising 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?

Only the Apifarma Code imposes the adoption of measures to guarantee that the advertising through the Internet is accessed only by health professionals.

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?

The company owner of a website should always respect the rules applicable to the advertising of medicinal products. When the company has in its website a link to an independent website usually a warning appears stating that the user is leaving the company's website. The same happens in case of reverse linking of independent websites to the company's website. The company that has in its website a link to an independent website should not, in principle, be held responsible for the contents of the independent site in either case.

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

Companies may place on their websites information concerning non-prescription medicines (if the same are not reimbursed) provided that the requirements listed in question 6.1 are respected.

Information regarding the company's activities, research and business as well as corporate and financial aspects may also be disclosed.

8 General - Medical Devices

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

The rules applicable to the advertising of medical devices in Portugal are foreseen in Decree-Law 145/2009, dated 17th June 2009, which entered in force on the 21st March 2010 and transposed Directive 2007/47/EC, dated 5th September, as amended, consolidating in one text, amongst others, the rules applicable to the research, the manufacture, the marketing, the entry into service, the surveillance and the advertising of medical devices ("DL 145/2009").

These rules are very similar to those applicable to the advertising of medicinal products of human use.

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

The restrictions on payments or hospitality offered to doctors in connection with the promotion of a medical device are the same as those regarding medicinal products.

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?

There are no significant developments in relation to the rules relating to the advertising of medicines in the past year.

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

To the best of our knowledge no significant developments in the field of pharmaceutical advertising are expected to occur this year.

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

There are no general practice or enforcement trends that have become noticeable in Portugal over the last year or so.

9.4 Has your national code been amended in order to implement the current version of the EFPIA Code of October 2007?

The Apifarma Code was amended in order to implement the current version of the EFPIA Code of October 2007 and entered into force on the 1st July of 2008.

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With more than 30 years of existence, VdA is a major, independent Portuguese firm, with a headcount of more than 156 lawyers.

VdA evolved from the solo practice of its founder, Vasco Vieira de Almeida, who opened an office in 1976, after several years as a banker.

The firm grew steadily as the Portuguese economy developed and opened to the world. VdA is extremely proud of the loyalty of its clients, many of whom go back to the days when foreign investment – where we were very active players – was driving the Portuguese economy. As new recruits (some of whom have become partners) joined the team, VdA asserted itself as one of the biggest and most highly reputable law firms in the country.

VdA is committed to remain an independent Portuguese firm, devoted to excellence and to innovation, drawing from the experience and the cohesion of the team.

The firm's Health Practice is traditionally one of the areas of high level of expertise. With a strong reputation amongst the companies and the regulatory authorities of the health sector, the firm has a strong presence in the pharmaceutical industry and represents, on a regular and continuous basis, most of the relevant pharma companies operating in Portugal.

VdA has offices in Lisbon, Porto, Madeira and Mozambique, and also works on a platform of close collaboration with many of the most well-renowned international law firms, allowing the firm to endow each office with the same level of quality to respond to the needs of its clients.

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VdA has developed a growing number of Pro Bono projects, providing legal advice to various organisations who develop socio-cultural and educational activities for those in need.