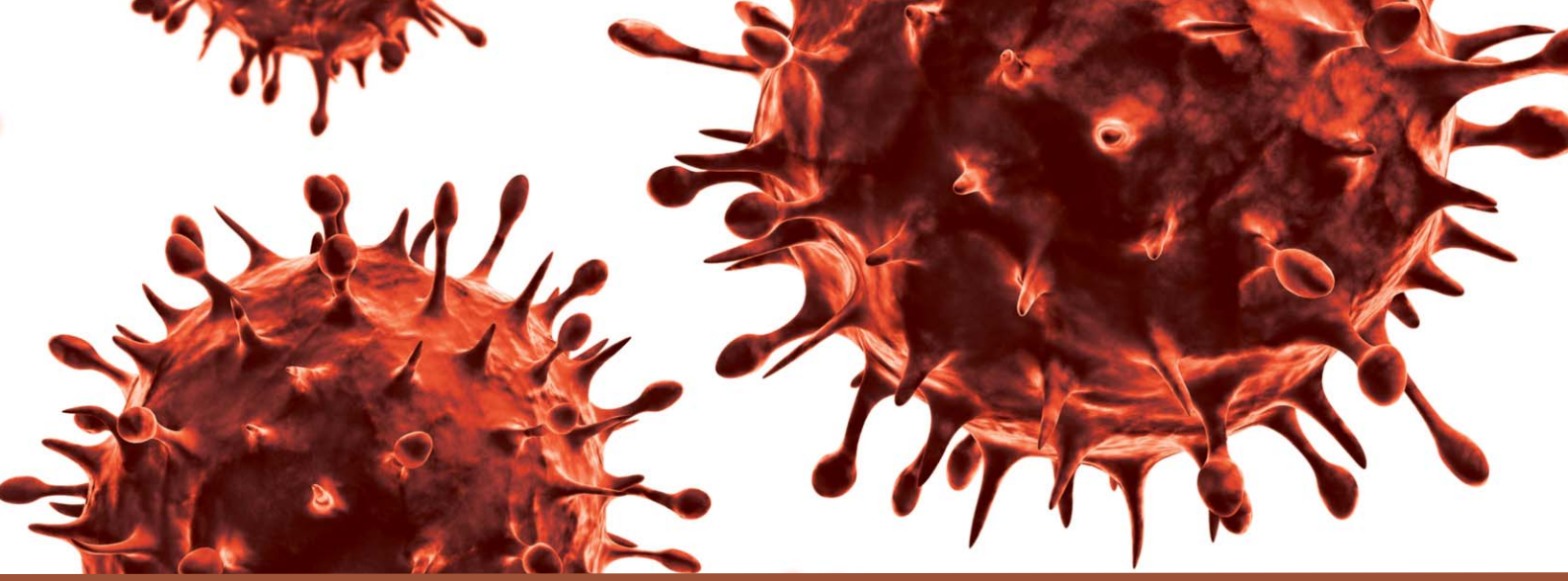

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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2014

11th Edition

A practical cross-border insight into pharmaceutical advertising

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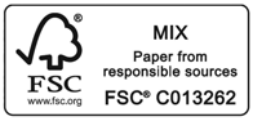

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Country Question and Answer Chapters:

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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 advertising of medicinal products in Portugal is governed by Decree-Law 176/2006, of the 30th of August 2006, as amended ("Medicines Code"), which transposed into the Portuguese legal system Directive 2001/83/EC, of the 6th of November 2001, on the Community Code relating to medicinal products for human use, as amended ("Directive").

The regime set-forth in the Medicines Code closely follows the regime provided for in the Directive, comprising a set of rules concerning, amongst others: (i) the definition of advertising; (ii) the requirements applicable to advertising to the general public; (iii) the requirements applicable to advertising to persons qualified to prescribe, dispense and administer medicinal products (healthcare professionals); (iv) the obligations of both the marketing authorisation ("MA") holder and of the company responsible for the promotion; (v) the requirements related with the activity of the medical sales representatives when advertising a medicinal product; (vi) scientific and promotional events and 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 Agency ("INFARMED").

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

Finally, Resolution 044/CD/2008, of the 7th February 2008, issued by INFARMED and which came into force on the 1st of April 2008, approved the "Advertising Regulation" which specifies certain aspects related with advertising of medicinal products, such as: (i) the particulars which must be included in advertising to healthcare professionals, defining what is essential information compatible with the summary of the product's characteristics ("SPC"); (ii) the number of samples that may be distributed to physicians per year; and (iii) the submission of advertising materials to INFARMED.

At a deontological level, the APIFARMA Code of Practice for the Pharmaceutical Industry ("APIFARMA Code") and the APIFARMA Code on relationships between the Pharmaceutical Industry and Patient Organisations ("APIFARMA Code on Patient Organisations"), both 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, which implements the EFPIA Code, reinstates and, in some cases, furthers, the rules foreseen in the Medicines Code. The APIFARMA Code and the APIFARMA Code on Patient Organisations apply only to member companies of APIFARMA.

In parallel, other rules must be taken into account, particularly in what concerns competition, the protection of confidential information and unfair commercial practices. For this purpose Decree-Law 36/2003, of the 5th of March 2003 as amended ("Industrial Property Code"), Law 19/2012, of the 8th of May 2012 ("Competition Law"), and Decree-Law 57/2008, of the 26th of 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?

Advertising is defined in the Medicines Code as any form of information, canvassing or incentive which has as its object or effect the promotion of the prescription, supply, sale, purchase or consumption of medicinal products, in any of the following situations:

(a) to the general public;

(b) to wholesale distributors and healthcare professionals;

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

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

(e) through the grant, offer or promise of benefits, whether in money or in kind, except if of an intrinsic insignificant value;

(f) through the sponsorship of promotional or scientific events attended by the persons referred to in (b) above, such as, via the direct or indirect payment of accommodation costs; or

(g) 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 any document, 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;

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

(e) to measures or commercial practices in what regards margins, prices and discounts.

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?

The MA holder must create and maintain a scientific service in charge of the information about the medicinal products it places on the market.

The MA holder is further obliged to, namely through the abovementioned scientific service, amongst others: (i) keep complete and detailed records of the advertisement made by the company, in documents that mention the recipients, the means and the dates of the first disclosure; (ii) maintain these records available to INFARMED 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; (iv) ensure that medical sales representatives have the adequate qualifications and the necessary training to carry out their responsibilities in full respect of their obligations and applicable laws; and (v) cooperate with the competent public authorities, particularly by providing information and necessary assistance in what concerns the monitoring of advertising.

Furthermore, and subject to what is provided for in the Advertising Regulation, the MA holder must send INFARMED a summary description of any advertising material regarding medicinal products within 10 days counting from its first disclosure.

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?

There are no legal or deontological requirements establishing that companies must have SOPs governing their promotional activities.

Nevertheless, 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 legal 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 regulatory or industry authority.

However, the Advertising Regulation establishes that the MA holder must send INFARMED a summary description of each advertising material. Note that INFARMED may, at all times, require a copy of the material. This procedure consists of a notification to INFARMED through the submission of a form available at its website, within 10 days from the first disclosure of the advertising material at stake.

As an alternative to the above, the MA holder may submit a summary description of each advertising material included 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 is in breach of the laws regarding advertising of medicinal products, it may initiate a misdemeanour procedure – the infringement of advertisement rules being considered misdemeanours.

If, in the context of such procedure, it is found that a breach in fact occurred, INFARMED may apply a fine and order the company to stop further disclosure of the advertising materials. Ancillary sanctions may also be applied by INFARMED. INFARMED's decision is subject to appeal to the judicial courts.

If, on the contrary, what is at stake is an infringement of the APIFARMA Code, the disciplinary powers belong to APIFARMA, which may initiate a disciplinary procedure against the member company concerned. In case APIFARMA finds that a breach did take place, it may request the company to immediately stop the advertising and undertake not to repeat the violation. APIFARMA may also apply sanctions which include: (i) a warning; (ii) a pecuniary fine; or (iii) the suspension of the membership of the company from the association for a specific 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?

Infringement of the rules provided for in the Medicines Code regarding advertising constitutes a misdemeanour, which is punishable by a fine that can range from €2,000 to €3,740.98 or from €2,000 to €44,891.81 respectively, depending on whether the conduct has been undertaken by a natural or legal person. 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 punished with fines that can range from €1,000 to €35,000. Note that the advertising agency or any other entity that was involved in the advertising activity is also punished as authors or co-authors of the referred regulatory offences for the breach of the rules governing the advertising.

Furthermore, ancillary sanctions may be applied, such as the publication in the media, at the expense of the company, of the essential elements that determined the conviction, the suspension of the advertising activity of the product for a period of up to two years and the prohibition from participating in public tenders also 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.

INFARMED is the entity which has the responsibility for enforcing the rules applicable to the advertising of medicines.

A misdemeanour procedure with an aim to apply a fine as a result of the disregard of advertising rules is initiated and decided by INFARMED, even if on the basis of a complaint submitted to it by competitors. Therefore, competitors may not take direct action to the courts in what concerns a misdemeanour procedure. However, in general terms, a misdemeanour procedure does not exclude the potential civil liability of the company, in which case 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 powers of INFARMED and the self-regulatory processes within APIFARMA.

INFARMED is solely competent for enforcing the advertising rules provided for in the Medicines Code, whereas a breach of the rules established in the APIFARMA Code is exclusively the competence of APIFARMA.

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 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 advertisement may be based on the Unfair Commercial Practices Code. Consumers and competitors negatively affected by 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 initiated 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 healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

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 healthcare professionals regarding unauthorised medicinal products if it does not qualify as advertising and therefore does not constitute an incentive to the prescription or purchase 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 by 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 as purpose or effect the promotion of 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 to the extent they do not have as purpose or effect the promotion of prescription, supply, sale, purchase or consumption of the product – and therefore cannot in any way be considered advertising. 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 healthcare professionals by the company? If so, must the healthcare professional request the information?

The company may send such information to healthcare professionals, upon their request, and it may be accompanied by

documentation as long as it does not contain any advertising elements. This being the case, the company is addressing a specific question put forward by the healthcare professional and not acting proactively.

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

The ECJ judgment in the *Ludwigs* case regarding non-approved medicinal products has not been directly reflected in the legislation or practical guidance in Portugal.

In regard to price lists of approved medicinal products made available to pharmacists, the Medicines Code does not consider them as advertising and, consequently, the rules on advertising are not applicable to them. The Advertising Regulation clarifies what should be understood by price lists, providing that these should be identified as such and contain only the name, composition, dosage, pharmaceutical form, package size and price of the medicinal products. Price lists do not need to be notified to INFARMED.

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

Companies may only send information to institutions provided that it is necessary to answer a specific question regarding a certain medicinal product.

2.7 Is it possible for companies to involve healthcare 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 involve healthcare professionals in market research exercises concerning unauthorised medicinal products under a services agreement.

No specific guidelines have been issued in this respect.

3 Advertisements to Healthcare Professionals

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

Advertising to healthcare professionals must include:

(a) the name of the medicinal product;

(b) essential information compatible with the SmPC, which comprises the following information: (i) the name; (ii) the qualitative and quantitative composition; (iii) the pharmaceutical form; (iv) the therapeutic indications; (v) the posology and method of administration; and (vi) the contraindications and adverse reactions of the medicinal product. If relevant from a clinical point of view, the following additional 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 classification of the medicinal product for dispensing purposes; and

(d) the reimbursement regime.

The above information is not required when the advertisement consists of a name reminder of the name of the medicinal product. For a material to be considered as a name reminder, it cannot include any indications other than (i) the name, the active substance, the strength and the pharmaceutical form of the medicinal product, and (ii) the identification of the MA or registry holder.

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?

Although the ECJ judgment in Case C-249/09 was not formally implemented in Portuguese legislation or guidance, advertisements, besides not being misleading, must be in accordance with the SmPC, but do not have to reproduce it. Moreover, quotations, as well as illustrative matter taken from medical journals or other scientific works for use in the documentation, must be correctly reproduced and the respective source indicated. An advertisement may refer to studies not in the SmPC, provided that such studies are in accordance therewith.

3.3 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.

3.4 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 specific legal requirement regarding the number of "head to head" clinical trials that should exist for comparative claims to be made. In any event, the legal regime applicable to comparative advertising requires that the comparative claims be verifiable.

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

According to the Medicines Code, comparative advertising is only allowed if directed to healthcare professionals. In this case, the regime of the Advertising Code applies.

Under the Advertising Code, comparative advertising (i) must not be misleading, and (ii) must objectively compare one or more of the

essential, relevant, verifiable and representative characteristics of the medicinal products. 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 does not discredit/denigrate the brand name, or take unfair advantage of its reputation.

Further to these requirements, the Medicines Code establishes that the information contained in documentation provided to the healthcare 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 comparisons between medicinal products (i) should be based on relevant and comparable aspects, (ii) should neither be misleading nor defamatory, and (iii) should only be made based on the elements included in the respective SmPC or on credible clinical data.

There is no specific 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. As such, if the product is not authorised such requirement is not fulfilled.

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

The APIFARMA Code sets out that informative or instructive material may be distributed to healthcare professionals as long as these are of low monetary value, as well as relevant to their professional activity, and directly benefit the performance of healthcare to patients.

Also, if these papers qualify as advertising (e.g. identifying a given product), the requirements established in the Medicines Code concerning advertising of medicinal products before healthcare professionals, in particular the requirements mentioned in question 3.1, apply. It should further be noted that the Medicines Code requires that the documents handed over to healthcare professionals include an indication of the date when they were established and 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.

3.7 Are "teaser" advertisements permitted that 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 if addressed to healthcare professionals.

4 Gifts and Financial Incentives

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

Free samples may only be provided to physicians, on an exceptional basis, if:

(a) they do not exceed the number of units foreseen, per year, per healthcare professional (four units, in accordance with the APIFARMA Code, and twelve units, in accordance with the Medicines Code);

(b) they are in response to a written request, signed and dated, from the prescribing agent;

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

(d) each sample is marked "Free sample" or "Not for sale", or contains a similar warning; and

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

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

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 healthcare professionals? If so, what restrictions apply?

Under the Medicines Code, 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 medical practitioners gifts, bonuses or pecuniary advantages or benefits in kind, except when these are of insignificant value and relevant to the practice of medicine.

Order 4138/2013, of the 20th of March 2013, considers of "*insignificant value*" the gifts which purchase cost does not exceed €25 – an amount which is equivalent to that provided for in the APIFARMA Code.

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

It is possible to give gifts or donations of money to institutions, such as hospitals, as long as these are not directed to individual healthcare 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). Such donations may, however, have implications under public procurement rules, should the recipient be a public entity.

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

Gifts, donations or pecuniary advantages or benefits in kind to healthcare professionals 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 healthcare 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, competition and public procurement rules.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

No. Refer to the answers to questions 4.2, 4.3 and 4.4 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 Portuguese law. However, rules on reimbursement and access of hospital products to hospitals within the National Health Service ("NHS") establish the possibility of a contract being entered into between the MA holder and INFARMED, providing that the MA holder must reimburse the NHS should the sales of the product exceed a predetermined threshold.

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 healthcare 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 healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The Medicines Code and the APIFARMA Code provide the following rules:

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

(b) hospitality costs only include those related to the enrolment, travel and accommodation of healthcare professionals attending the above-mentioned events;

(c) hospitality costs may not exceed the period between the day before the beginning of the event and the day after its conclusion and may not include any other social programme or activity which may hinder or prevent a full participation in the event; and

(d) the choice of the location of the event should follow professional and logistical criteria and involve, particularly with regard to hospitality, financial costs appropriate to the purpose intended.

Regarding hospitality costs of events taking place in other countries, the APIFARMA Code provides that these can only be organised or sponsored if:

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 is the object or topic of the event, it is more reasonable, in logistic terms, to carry out the event in another country.

Also, the threshold for the cost of meals provided to a healthcare professional is set in the APIFARMA Code at €60 for events taking place in Portugal and €90 for events abroad, unless the local regulations set different limits.

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

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

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

Time spent by healthcare 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 healthcare professionals to attend?

Pharmaceutical companies may be held responsible by INFARMED for the infringement of the rules provided for in the Medicines Code regarding scientific events and hospitality costs. Infringement of said rules by a pharmaceutical company is sanctioned with a fine that can range from €2,000 to €44,891.81.

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

It is possible to pay healthcare professionals to provide expert services as long as the payment does not constitute an incentive for the prescription or purchase of medicines. According to the APIFARMA Code, said services must be ruled by a written agreement.

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

The payment of healthcare professionals for their participation in post-marketing surveillance studies is permitted provided that it does not constitute an incentive for the prescription or the purchase of medicines. Participation of doctors in these activities should also not involve the collection and processing of prescribing data.

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

The payment of healthcare professionals for their participation in market research involving promotional materials is allowed, with the limitations provided for in question 5.5 above.

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 a medicinal product, and must include the following information:

(a) the 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) an 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 regards vaccination campaigns previously approved by INFARMED;

(e) is directed exclusively or mainly at children;

(f) refers to a recommendation by scientists, healthcare 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 by action of a medicinal product on the human body or parts thereof.

Any form of comparative advertising before the public is prohibited. Furthermore, the direct distribution of medicinal products for promotional purposes to the public, as well as the granting of any kind of benefit to the general public or to patients, are prohibited.

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.

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 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 the funding of, patient organisations?

The Medicines Code does not provide for any specific rules regarding meetings and funding of patient support groups, other than those related with transparency requirements. Should these meetings consist of advertising of medicinal products, than the rules and limitations applicable in this regard, depending on the nature of the recipient (general public or healthcare professional), must be considered.

In what transparency requirements are concerned, pharmaceutical companies have to report to INFARMED the granting of any subsidy, sponsorship, subvention or any other value, good or right which may be evaluated in money, to an association or any other entity, regardless of its nature or form, representative of a patient organisation. This same obligation exists for the recipient of the benefit.

The APIFARMA Code on Patient Organisations contains certain rules regarding the relationship with patient organisations. Amongst such rules, there are transparency requirements as regards the recording of donations and other financing support.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, what information should be disclosed, and when and how?

There is no obligation for companies to publicly disclose details of ongoing and/or completed clinical trials.

Information is however provided by companies, in the capacity of sponsors, to the competent authorities, in compliance with the regime applicable to the approval, amendment and completion of clinical trials.

7.2 Has your national code been amended in order to implement the 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and, if so, does the change go beyond the requirements of the EFPIA Disclosure Code or simply implement them without variation?

The 2013 EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations has been integrated in the revised APIFARMA Code, along with the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.

7.3 If the EFPIA Disclosure Code has not been implemented in Portugal, is there a requirement in law and/or self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what information should be disclosed, from what date and how?

Please refer to the answer to question 7.2.

The Medicines Code was amended in 2013 and a general obligation to report to the Agency all payments made by entities covered by its scope to any third parties was enacted. Such reporting obligation covers payments made above €25 to third parties, regardless of the nature of the recipient, including, amongst others, patient associations, clinical trial entities and healthcare professionals. This information is publicly available at the Agency's website.

Compliance with this legal reporting obligation has been incorporated in the revised APIFARMA Code.

8 The Internet

8.1 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 healthcare 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 healthcare 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.

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

There are no specific rules regarding website security. In any event, companies should ensure that advertising to healthcare professionals made through the Internet is only accessed by them – an obligation which is expressly provided for in the APIFARMA Code.

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

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.

8.4 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. Following the ECJ judgment in Case C-316/09,

INFARMED allows the disclosure on a website of information relating to prescription-only medicines, if such consists solely in the reproduction of administrative documents (i.e. package leaflet or the SmPC).

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

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

There are no specific rules regarding the use of social media by companies. Please refer to the answer to question 8.1 for the applicable rules.

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?

The most significant developments in relation to the rules relating to pharmaceutical advertising were the amendments made to the Medicines Code in the beginning of 2013 and which: (a) enacted transparency requirements *via* the reporting obligations mentioned in question 7.3 above; and (b) established the prohibition of any kind of benefit being granted to the general public or to patients.

Also in the beginning of 2013, the notion of "insignificant value" applicable to gifts that may be granted to healthcare professionals was specified, such being set at €25 (as was already foreseen in the APIFARMA Code).

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

No significant developments in the field of pharmaceutical advertising are expected in the next 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 2013 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals (the EFPIA HCP Code) and, if so, does the change go beyond the new requirements of the EFPIA HCP Code or simply implement it without variation?

Both the APIFARMA Code and the APIFARMA Code on Patient Organisations were amended in order to implement the current equivalent versions of the EFPIA Codes. These amendments entered into force on the 1st of January 2014 and, in general, implement the latest amendments to the EFPIA Codes.

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