The International Comparative Legal Guide to:

Pharmaceutical Advertising 2019

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A practical cross-border insight into pharmaceutical advertising

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Country Question and Answer Chapters:

Portugal

Cuatrecasas

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1 General – Medicinal Products

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

The advertising of medicinal products is governed by the following laws and regulations:

(i) Decree-Law 176/2006, of August 30 (Medicinal Products Act).

(ii) Decree-Law 330/90, of October 23 (Advertising Code).

(iii) Decree-Law 5/2017, of January 6, which approved the general principles on the advertising of medicinal products and medical devices and the rules on the scientific sessions to be undertaken at the hospitals of the National Health Service.

(iv) Regulation 044/CD/2008 of Infarmed (Portuguese Medicinal Products Agency).

(v) Ministerial Order 5657/2017, of June 28 (clarification on the obligations established under Decree-Law 5/2017).

(vi) APIFARMA – Code of Conduct governing the Relations Between Pharmaceutical Industry and Patients' Organizations.

(vii) APIFARMA – Code of Ethics applicable to Promotional Practices of the Pharmaceutical Industry.

1.2 How is "advertising" defined?

Advertising of medicinal products is defined in Portuguese law as any kind of information, prospective or incentive activity, purported to, or that has the effect of, promoting the prescription, supply, sale or consumption of medicinal products in any of, but not limited to, the following situations:

(i) to the public;

(ii) to wholesale distributors and healthcare professionals ("HCPs");

(iii) through visits of medical sales representatives to the persons mentioned above;

(iv) through the supply of samples or commercial bonus to wholesale distributors and HCPs;

(v) through the grant, offering or promise of any benefit, either in cash or in kind, except when its intrinsic value is insignificant (less than 60 Euros);

(vi) through the sponsorship of promotional meetings attended by wholesale distributors and HCPs;

(vii) through the sponsorship of scientific venues attended by wholesale distributors and HCPs, and in particular the payment of their travelling and accommodation expenses; and

(viii) by the reference to the name of the 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?

Companies have to provide Infarmed with the specifications of all advertising pieces used in the promotional activities of their medicinal products, within 10 days of the date of release of the relevant advertising.

Holders of marketing authorisations ("MAs") are required to have a scientific department led by a physician or pharmacist, which is responsible for the information and advertising of its medicinal products. The sign-off of all advertising initiatives is committed to this scientific body.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Apart from the obligations referred to in question 1.3 above, companies' scientific bodies responsible for the advertising of medicinal products have to implement the following SOPs:

(i) organise and keep record of all the advertising made by the company, and allow the consultation and access thereto by regulatory authorities within a period of five years;

(ii) assure that the advertising complies with all applicable legal requirements;

(iii) assure that the company's sales representatives have adequate qualifications and training; and

(iv) implement information systems aimed to assure the receipt and processing of data provided by sales representatives related to adverse events of the respective medicinal products.

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?

No, the advertising of medicinal products does not have to be approved in advance by any authority.

However, the holders of MAs or companies in charge of the promotion and advertising of medicinal products have to provide

Infarmed with the specifications of all advertising pieces used within 10 days of the date of the relevant release.

Also, the holders of MAs shall keep the documentation related to the advertising available for consultation by competent authorities for a period of five years.

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?

The Board of Directors of Infarmed have the power to compel MA holders to stop and/or correct any advertising made by them that is considered as being in breach of the applicable legal requirements. Furthermore, MA holders are bound to cooperate with the competent authorities in providing the necessary information for the purpose of performance of the relevant powers with respect to advertising.

Additionally, Infarmed may also open an investigation procedure of misdemeanour prosecution.

MA holders, or the entity responsible for the advertising at stake, are entitled to file their defence in the scope of the misdemeanour proceedings, where prevention measures or sanctions are applied by Infarmed, and also have the right to appeal therefrom. The appeal for the review of the decision has to be submitted to Infarmed. Infarmed's decision on any sanctions may also be challenged by judicial proceeding aimed at its impeachment.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

The penalties consist of a fine that may range between 2,000 Euros and 15% of the turnover, or 180,000 Euros, whichever is lower, and other ancillary sanctions. The latter may be applicable in case of serious violations of advertising rules.

The ancillary sanctions may consist of the suspension of the authorisation or licence granted to the entity that has committed the infraction ("defendant") up to a period of two years, loss in favour of the State of objects and equipment used by the defendant, and prohibition to participate in public tenders for a period of up to two years. Also, the penalties can entail the publication of the conviction in the media and suspension, for a period of up to two years, of the advertising of the medicinal product at stake.

The entity responsible for the enforcement of these rules and procedures is the Board of Directors of Infarmed and the rules are enforced in a very strict manner. It is quite common, and usually upon the complaint of a competitor, for Infarmed to open misdemeanour procedures against pharma companies based on the breach of the advertising rules.

Notwithstanding the possibility of competitors taking action by filing a complaint to Infarmed based on the illegal advertising practices, a competitor may also take direct action in court against a company that it considers to be in breach of advertising rules, to file a claim for civil liability and/or unfair competition. In any of these situations, the claim will have to be sustained on the argument that the illegal advertising is causing severe damages to the competitor.

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?

The Code of Ethics of Apifarma is a self-regulatory instrument and therefore, is only binding upon Apifarma members. However, the rules set forth in this type of instrument are consensual and followed by the majority of the pharma sector. For this reason, the competent authority, Infarmed, investigates matters that entail the breach of the Apifarma's Code provisions, and the rules set forth therein are considered as good practice standards of promotion of medicinal products.

Although Infarmed may not condemn any entity for breaching a rule laid down in the Apifarma Code that does not have a legal correspondence, the provisions set forth therein may be used as interpretative rules and as good practice standards to be considered in the analysis of a certain advertising infraction.

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?

Any competition act that is contrary to the rules and honest standards of any economic activity, namely for misleading customers and the market with respect to features of the relevant products or making false statements purported to harm competitors' reputation, is considered unfair competition.

Unfair competition practices constitute a misdemeanour according to Portuguese law. A company that is impaired due to such type of practices may take action by filing a complaint to the Economic and Food Security Authority ("ASAE").

A company impaired by unfair competition acts may also claim before a judicial court for an indemnity envisaging compensation of the damages suffered from those acts against the economic operators at stake. The law also provides for injunctions that have to be approved by court, in order to allow protection against acts of unfair competition on a preliminary/urgent basis.

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)?

These questions tackle the issue of separation between information and advertising of medicinal products, which often is not completely clear. Although it is accepted that pharmaceutical companies inform the scientific community about advances in the

field of medicinal products and therapeutics and disclose the outcome of the scientific research they are carrying out for that purpose, the advertising of unauthorised medicinal products is not allowed.

This principle is applicable in the same terms to off-label indications, where advertising is also forbidden.

The analysis of whether or not the organisation, sponsor or participation in a certain scientific meeting constitutes advertising or disclosure of scientific information shall be made on a case-by-case basis, taking into account many aspects such as the contents of the information itself, and the relationship between the speakers and the sponsor.

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

Information on unauthorised medicines and off-label indications may be published whenever it is not, directly or indirectly, purported to, or has the effect of, promoting the prescription, supply, sale or consumption of the relevant medicinal products. This situation shall also be evaluated on a case-by-case basis, taking into consideration the purpose of the dissemination of the relevant information, its contents and the relationship existent between the publisher of the information and the company responsible for the relevant product.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. main stream public media) please specify.

Apart from those referred to in question 2.2 above, it should be stated that if such press releases are considered as advertising, they would not be allowed, regardless of the audience they are addressed to.

In contrast, if the content of such press releases is effectively only informative, rather than promotional, it should be allowed.

As already commented, the situation has to be evaluated on a case-by-case basis, and for those purposes, the target audience may play an important role. In practical terms, if the target audience consists of specialised medical or scientific media, it shall be easier to justify the content of such press releases as merely informative, since it is acceptable for pharmaceutical companies to inform the scientific community about advances in the field of medicinal products.

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

If information on a certain unauthorised medicine or off-label information is provided by the company responsible for such product to HCPs upon request of the latter, it may confirm that such supply of information does not envisage promotional purposes, in which case it shall not be considered advertising.

It should be noted that the law expressly qualifies information (rather than advertising) as the correspondence between companies and HCPs regarding questions on medicinal products, provided that it does not include any promotional content.

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

In fact, this case did not cause much impact, probably due to the fact that Portugal does not have a system like in German law, that allowed pharmacists to obtain, in another State, medicinal products not approved in Germany, but lawfully introduced in the market in that other State. The use of non-approved medicinal products in Portugal is only allowed in very specific situations that always require authorisation from Infarmed to the hospitals or to the holder of the MA. The regulatory requirements applicable to compassionate use purposes of medicinal products are very strict, and therefore its supply does not entail a significant flow of sales through pharmacies.

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?

In principle, healthcare institutions must submit an annual request to Infarmed on the non-authorised medicinal products they will use in the following year.

The proactive supply of this information by manufacturers to healthcare institutions may be construed as advertising.

However, this kind of information shall be evaluated on a case-by-case basis in order to assure that it is information and not advertising. Moreover, costs reduction itself does not qualify as a legitimate reason to use or to advertise non-approved medicinal products.

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

We believe that this is possible, provided that this collaboration of consultancy or advisory from HCPs is considered as inherent to the development of the company's activity, and does not fall within the concept of advertising activity of medicinal products as defined by law, or an indication not yet approved.

There are no guidelines on these matters.

3 Advertisements to Healthcare Professionals

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

Advertisements directed to HCPs must contain the following information:

(i) name of the product;

(ii) essential information compatible with the SmPC, namely:

- qualitative and quantitative composition;
- pharmaceutical form;
- therapeutic indications;
- dosage and administration;
- contraindications;
- undesirable effects; and
- special warnings and precautions for use and interactions with other medicinal products, if relevant from a clinical point of view;

(iii) the classification as a prescribed-only or non-prescription medicine; and

(iv) the reimbursement system.

Additionally, the advertisement pieces shall contain the following statement: "For more information, please contact the holder of MA."

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

Besides the general rules mentioned above, advertising to HCPs shall be accurate, current, verifiable and complete in order to allow the HCP to have a correct idea of the therapeutic value of the product.

The advertising materials may refer to studies not mentioned in the SmPC, provided that those studies, or quotes from the studies, are true, accurate, current and verifiable. This means that companies shall make these studies available to HCPs and to authorities upon their request.

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

There are no specific restrictions to the inclusion of an endorsement by HCPs regarding prescription-only medicinal products (endorsement by HCPs is not allowed for non-prescription medicinal products). However, these endorsements must comply with the rules on testimonial advertisements, which state that testimonial advertising is allowed whenever it is real and verifiable and related to the experience of the deponent.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No. The only existing rules about comparative advertisements are those described in the answer to question 3.5 below.

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

The general rule on comparative advertisements is that they are can only be viewed by HCPs, and therefore strictly forbidden to the public.

The comparative advertisement of medicines to HCPs is allowed, subject to the following rules:

(i) comparisons shall be based on relevant and comparable aspects between the medicines, and cannot be misleading or defamatory; and

(ii) comparisons between medicines can only be made based on elements disclosed in: (1) SmPC; (2) Technical Documentation; or (3) Credible Clinical Data.

Considering the above, it is possible to use another company's brand name as part of the comparison. With regards to the use of the competitor's product or an indication that has not yet been approved, this shall not be allowed once it is qualified as promotion of a product that does not hold an MA or off-label promotion of a medicinal product.

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

There are no specific rules on this matter. Therefore, and provided that the papers are in fact scientific articles, and proceedings of congresses that fully describe the content of scientific or medical presentations made in the congress, they are not qualified as advertisement materials, but as information.

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

Considering the requirements mentioned in question 3.1 above on the mandatory information of any advertisement of medicinal products before HCPs, it seems difficult that the accomplishment with such regulatory requirements may be compatible with a teaser. It should be noted that advertising of medicinal products has always to be identified as such.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

In case the combination of Products A and B is expressly mentioned, and consequently authorised by the competent authorities, in the Product A's SmPC, we are of the opinion that the MA holder of Product A could promote this combination of products. The fact that this combination is expressly foreseen and authorised in the SmPC, constitutes an on-label use and promotion of these products. Regarding the holder of the MA of Product B, in order to be safe, they shall firstly vary the SmPC to avoid any accusations of off-label promotion.

4 Gifts and Financial Incentives

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

Yes, it is possible, following a prior written request by HCPs. The maximum number of samples to be provided to a HCP is four per year and only within two years of the date when the medicinal product starts to be effectively marketed.

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

It is not possible to give, offer or promise to offer gifts or money to HCPs. However, giving benefits or objects up to 60 Euros that are relevant for the practice of medicine or pharmacy and/or involve a benefit for the patient, is allowed.

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

It is possible to provide support, either financially or non-financially, to healthcare organisations, with the purpose of supporting healthcare services or research activities. The granting of the support shall be preceded by a written request of the beneficiary entity and it shall not constitute an incentive to the prescription and supply of medicinal products.

However, with the entry into force of a new law, establishments, services and hospitals of the National Health Service may only receive those gifts and donations from pharmaceutical companies if authorisation is granted by Infarmed, in order to ensure that the grant of such support is not deemed to jeopardise the exemption and impartiality.

Also, for public hospitals, there is another limitation on the receiving of this type of support. In cases of direct award for the acquisition of medicinal products, the contracting authority cannot invite a company to submit a tender, from which it has received, in the last two years, gifts, supply of services carried out free of charge, or equipment, except for gifts made under the Patronage Statute.

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?

The rule is that the supply of informational or educational materials and items of medical utility may not be an incentive to the prescription, purchase, and administration or dispensing of medicinal products or a way of compensation for the latter. Considering this rule, and provided that granting medical or educational goods constitutes a benefit for the patient, if that situation leads to changes in the prescription patterns, it may be sustained that it occurred due to their benefits and not because the company was trying to encourage the prescription of its medicinal products or compensate HCPs.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

The rules on the advertisement of medicinal products are not applicable to commercial practices regarding prices and discounts.

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? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?

This type of offer and donation would most likely be considered as an incentive to the prescription, purchase, and administration or dispensing of medicinal products or a way of compensation to HCPs, and therefore they are not allowed.

However, it is possible to have commercial arrangements between pharmaceutical companies and hospitals, under which certain services related to the administration or use of the medicinal product at stake are rendered, provided that such services are also paid, even if its cost is included in the purchase price.

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?

That is not possible. The refund of medicinal products, prescription-only or not, may only occur within the specific situations and limits set forth in the Good Distributing Practice of Medicinal Products.

Nevertheless, it should be noted that this prohibition does not prevent the execution of risk-sharing agreements as foreseen in the reimbursement legal framework of medicinal products.

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

Pharmaceutical companies may sponsor medical education by granting sponsorships to events organised by third parties and may also support the hospitality costs of HCPs attending those educational events.

However, we believe that the sponsor of continuing medical education either to an entity or to a HCP may lead to the incentive of the prescription or supply of the company's products, which is not allowed.

Transparency disclosure requirements described in question 7.2 below are applicable to the sponsorship granted by pharmaceutical companies which includes the sponsorship of medical education.

4.9 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The principles and general rules for the purposes of anti-bribery are established in the Portuguese Criminal Code. Infarmed, being the competent authority for pharmaceutical advertising, is responsible for investigating any breach of the advertising rules and the anti-bribery legislation. Nonetheless, in conducting these investigations, Infarmed cooperates with a wide range of entities.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

The general rules that govern the offering of hospitality to HCPs by pharmaceutical companies, are the following:

(i) it shall be limited strictly to the main objective of the event;

(ii) it shall not be subject to the obligation of the HCP to prescribe any medicine;

(iii) it shall not be provided as a compensation for the time spent by the HCP in the participation of the event;

(iv) it shall not exceed the level that the HCP would be willing to pay, themselves, for participation in the event; and

(v) it shall not include the sponsor or the organisation of any leisure or entertainment events.

In principle, the events should take place in Portugal, unless it is logistically more reasonable to hold the event in another country. In these cases, we believe the rules in force in the country where the event takes place would be followed. However, if the rules of the country of residence of the HCP are stricter, these are applicable.

There is no threshold applicable to the costs of hospitality provided to a HCP, only the rules described in question 5.2 below. Regarding the cost of meals, they may not exceed 60 Euros (in case of a national meeting), or 90 Euros (in case of an international meeting).

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 costs related to travel, accommodation and enrolment fees for the attendance of HCPs in scientific meetings are reimbursable. The costs of accommodation shall only include the period between the day prior to the beginning of the event and the day after it ends. Regarding the expenses of meals, see question 5.1.

Payment to a HCP for his/her time in attending scientific meetings is not allowed.

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?

A pharmaceutical company may be held liable for the breach of advertising regulatory requirements, either with respect to hospitality arrangements, or to the sponsor of scientific meetings, in case the relevant breach derived from an act or omission of such company even if it has acted jointly with other parties.

The mere existence of any such agreement or sponsor of a scientific meeting does not automatically trigger the company's liability. The responsibility of the pharmaceutical company in those situations shall be evaluated on a case-by-case basis. In this assessment, one should take the following into consideration: the level of engagement of the pharma company in those events; the relationship between the HCP and the pharmaceutical companies; and the context of the messages disclosed in these events, in order to verify if the company can be responsible for any illegal advertisement.

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

Yes, provided that it does not result in an incentive or compensation for such HCP to recommend, prescribe, purchase or supply certain medicinal products.

The parties shall enter into a written agreement in order to specify the nature of the contract and identify the services to be provided by the HCP.

Additionally, the pharmaceutical company shall communicate to Infarmed any amounts payable to the HCP for the provision of expert services (or any grant, sponsorship, or any other value, which may be evaluated in cash), within a timeline of 30 days after termination of the event.

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

Yes, provided that it does not constitute an incentive for HCPs to recommend or prescribe certain medicinal products.

In this case, a written contract shall be executed between the HCP and/or institutions where the study will be developed and the sponsoring company, in which the nature of the services to be provided by the HCP and the reasoning for the payment of the relevant services, shall be specified.

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

Yes, it is possible, provided that it does not result in an incentive for the HCP to recommend or prescribe certain medicinal products.

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?

Yes, it is possible to advertise non-prescription medicines to the public if such medicines are not reimbursable by the National Health System.

Advertising to the public shall not include any information that:

(i) leads to the conclusion that no medical appointment or surgical procedure is necessary and that induces a certain diagnosis, or treatment by correspondence;

(ii) suggests that the effect of the medicinal product is guaranteed, with no adverse reactions or side effects, with results greater or equivalent to those of another treatment or medicinal product;

(iii) suggests that the person's normal health condition may be improved by the use of the medicinal product;

(iv) suggests that the person's normal health condition may be impaired in case the medicinal product is not used (except for approved vaccination campaigns);

(v) is exclusively or mainly targeted at children;

(vi) refers to a recommendation from scientists, HCPs or other persons, who because of their celebrity status may encourage the consumption of medicinal products;

(vii) suggests that the medicinal product is a food, cosmetic or personal hygiene product, or any other consumption product;

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

(ix) may lead to an erroneous self-diagnosis through a detailed description or representation of patient history;

(x) refers in inadequate, alarming or misleading terms to evidence or guarantee of recovery; and

(xi) uses inadequate, alarming or misleading terms, representations of changes in the human body or parts of the human body, caused by diseases or injury or of the action of a medicinal product.

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

No, it is not possible to advertise prescription-only medicinal products to the general public.

Prescription-only medicinal products can only be advertised to HCPs under certain conditions.

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?

Disease awareness campaigns are permitted if no reference, even if indirect, is made to any medicinal product.

These initiatives are permitted based on the grounds that the information is disclosed to the public in order to raise awareness for a particular medical condition, and to provide information that is valuable for the relevant patients. It does not constitute advertising of any product.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

It would be likely that such press releases would be considered advertising, which is not allowed for prescription-only medicines when addressed to the public and non-scientific journals being targeted at the general public.

Notwithstanding, press releases on developments in relation to unauthorised medicines or unauthorised indications are, in general, not allowed.

In both cases, if the contents of such press releases are effectively only informative, rather than promotional, it should be allowed.

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

Companies' institutional advertising, such as financial data, description of research and development programmes, corporate brochures and annual reports, does not qualify as the advertising of medicinal products.

However, if such institutional information includes contents related to specific medicinal products that are subject to medical prescription, it may be considered advertising to the general public, which is not allowed for prescription-only medicinal products.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

There is a code of practice applicable to Apifarma members: the Apifarma Code of Conduct Governing the Relations between the Pharmaceutical Industry and Patients' Organisations.

Pharmaceutical companies are allowed to support patients' organisations and to sponsor meetings organised by said institutions provided that it is not an incentive for the recommendation of a particular medicinal product.

Transparency disclosure requirements set forth in the Medicinal Products Act are also applicable to any funding granted by pharmaceutical companies to patients' organisations.

6.7 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

The rule is that companies cannot provide patients with any items (such as prizes, offers, bonuses or cash benefits or in kind).

However, objects of insignificant value, defined as objects with a purchase cost for the pharma company that does not exceed 60 Euros, and that are relevant for medicine or pharmacy practice, may be supplied to patients through their HCP.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

The clinical trials regulatory framework establishes certain information obligations for the sponsors, notably the registration of trials in the National Registry of Clinical Trials and report of the results to Infarmed.

Besides that, pharmaceutical companies may release information relating to clinical trials, subject to certain limitations.

If the company chooses to release information on clinical trials, such disclosure has to comply with the following requirements:

(i) its contents shall be in accordance with the observations and the results of the relevant study;

(ii) allow the verification of the observations made in the study, through the disclosure of the relevant scientific grounds;

(iii) indicate the members responsible for the study, notably the main investigator, the main sponsor and the centre of the study;

(iv) indicate any existing conflict of interests between the investigator, the sponsor and the centre of the study, if any; and

(v) indicate the funding sources of the study.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Yes. The holders of MAs and distributors of medicinal products shall inform Infarmed of the grant of any subsidies, gifts, supports, sponsorships or any other sum, asset or right with cash value, from 60 Euros, to any person or entity, namely to HCPs, patients' associations, healthcare service providers or medical and scientific societies.

Such obligation is accomplished by the upload of the relevant information on the transparency platform available on Infarmed's website within a 30-day period.

These reporting obligations only apply to entities that are subject to the Medicinal Products Act, namely holder of MAs, local representatives of marketing authorisation holders, manufacturers and wholesale distributors of medicinal products and/or entities responsible for information provision and advertising of medicinal products. Therefore, a company that acts in any of the mentioned capacities, even if it has not yet been granted a marketing authorisation, must comply with the reporting obligations.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

According to the Apifarma Code of Conduct Governing the Relations between the Pharmaceutical Industry and Patients' Organisations, the holders of marketing authorisations must publish on their institutional website their sponsorship of patients' organisations until May 31 each year.

Regarding companies that have not yet been granted a marketing authorisation, see question 7.2 above.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

An individual HCP, who has received transfers of value from a pharmaceutical company, is also bound to validate, even if tacitly, that fact to Infarmed. Thus, if such person refuses to make such validation/disclosure, the company shall comply with its obligation to report the relevant act on the transparency platform, and request the HCP to comply with its obligation too.

8 The Internet

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

There are no specific legal rules on advertising on the Internet, therefore, it is subject to the general legal framework applicable to the advertising of medicinal products.

The Apifarma Code foresees the obligation for companies to adopt specific measures in order to ensure that the advertisement of prescription-only medicinal products is only accessible through the Internet by HCPs. However, those measures are not specified.

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?

The Apifarma Code does not specify the level of website security required to ensure that the public does not have access to sites intended only for HCPs.

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?

There are no specific rules on these matters. Therefore, a company must ensure, or at least must not contribute to, access by the public to advertising of prescription-only medicinal products.

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

Pharmaceutical companies are allowed to make institutional advertising which may be published on their websites.

Moreover, pharma companies may place on their websites the respective medicines, as well as information on the characteristics of such products (namely official and approved documents, such as the SmPC or the Patient Information Leaflet). Any type of information regarding those products that may be deemed as promotional must observe the general rules applicable to the advertisement of medicines.

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

No, there are not.

The legal concept of advertising of medicinal products includes communication released through any media, which includes social media.

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?

In January 2017, a new law was published, Decree Law 5/2017, approving the general principles of medicinal products and medical devices advertising, which had a great impact on the relationship between pharma companies and hospitals and other entities from the National Health Service.

The new law adopted the following measures:

(i) Prohibition on hospitals and services of the National Health System on receiving financial benefits or benefits in kind from pharmaceutical and medical devices companies, except if those actions do not undermine the services exemption and impartiality and are authorised by the Health Minister. The authorisation procedure has not yet been defined, nor has the criteria to evaluate exemption and impartiality.

(ii) Prohibition on hospitals and services of the National Health System on carrying out promotional and scientific actions sponsored by pharmaceutical and medical devices companies. Contrary to the prohibition referred to in (i), in this case there are no exceptions foreseen. This will lead to a discussion of what is considered to be the promotion of medicinal products and what is simply information.

(iii) Facilitation of the communication procedure to Infarmed by HCPs who receive benefits from the pharmaceutical industry, now only requested to validate the information submitted by the pharmaceutical industry to Infarmed on that matter.

Following the impact caused by these measures, especially that which prevented public hospitals from carrying out scientific meetings and events at its premises, the Government has made a U-turn, and it is now possible to organise scientific events at hospitals, provided that authorisation is granted by Infarmed.

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

There are fields that need to be further developed, namely off-label promotion, access to information of prescription-only medicinal products by the public, and advertisement on the Internet.

Once the medicinal products regulatory framework is harmonised through European legislation, we believe that the national legislator will only approve any further statutes on this matter upon the implementation of EU directives.

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

Our national agency, Infarmed, has a very conservative interpretation of the definition of advertisement of medicinal products. Therefore, often this agency qualifies as advertising most information released by pharmaceutical companies to the public and also most interactions with HCPs.

It should also be noted that, recently, promotional activities for food supplements have been relevant for many reasons, notably for advertising products that are often confused with medicinal products. This trend led to the approval of guidelines related to borderline products by administrative entities with authority on medicinal products and food safety ("ASAE" and "DGAV"). It is expected that better coordination between such entities will provide more effective law enforcement against abusive promotional practices in this field.

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Joana provides regular legal assistance to pharmaceutical companies, cell and tissue banks, especially in regulatory areas and in what regards the marketing of health and pharmaceutical products. She also provides legal assistance in biotechnology projects and to start-up companies, as well as to medical devices distributors.

She gives advice on clinical trials and issues related to the protection of personal data and due diligence exercise, restructuring transactions and merger and acquisitions operations in the healthcare sector.

She was admitted to the Portuguese Bar Association in 2005.

She holds a law degree from the School of Law of the Portuguese Catholic University of Lisbon, 2005, has a postgraduate qualification in Business Law from the School of Law of Nova University of Lisbon, 2007, attended a training course in Health Law, Biolaw and Bioethics, in the context of *Programa de Formação Avançada Justiça XXI*, 2009, and has a Master's in Law and Management, from the School of Law of the Nova Lisbon University, 2016.

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