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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2009

A practical insight to cross-border Pharmaceutical Advertising work

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1 General - Medicinal Products

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

Advertising of medicinal products is mainly governed by the following laws and regulations:

- Law no. 95/2006 regarding reform in the healthcare field, implementing Directive 2001/83/EC, as further modified and completed ("Law 95/2006");
- Order no. 263/2003 for the approval of the regulations regarding the marketing authorisation, surveillance, advertising, labelling and the prospect of the medicinal products, as further modified and completed ("Order 263/2003");
- Law no. 148/2000 regarding the advertising, as further modified and completed ("Law 148/2000");
- Law no. 158/2008 regarding the misleading and comparative advertising ("Law 158/2008");
- Law no. 504/2002, the audiovisual law, as further modified and completed ("Audiovisual law"); and
- Decision issued by the National Council of Audiovisual no. 187/2006 regarding the code of regulating the audiovisual content, as further modified and completed ("Decision 187/2006").

Also, following codes of practice issued by private associations regulate the activity of their members:

- Ethics Code for the Promotion of Medicinal Products as adopted by the Directory Council and the General Assembly of the Romanian Association of the International Manufacturers of Medicinal Products ("ARPIM"), on October 25, 2007 ("Ethics Code"); and
- Code of practice in advertising as adopted by the Romanian Advertising Council ("RAC Code").

1.2 How is "advertising" defined?

As a generic term, "advertising" is defined by Law 158/2008 as any form of presentation of a commercial, industrial, artisanal or liberal activity with the purpose of promoting the sale of goods or services, including real estate goods, rights and obligations.

For medicinal products, Law 95/2006 does not provide a definition, but set forth that "advertising" includes any means of information through direct contact ("door to door system") as well as any form of promotion meant to stimulate the prescription, distribution, sale or the consumption of medicinal products.

Further, Decision 187/2006 defines advertising of medicinal products and medical treatments within the audiovisual field as any form of promotion, within the programs services, intended to stimulate the distribution, consumption or the sale of such goods and treatments.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and Codes of Practice on advertising, such as "sign off" of promotional copy requirements?

In order for the marketing authorisation holder to ensure compliance with laws and codes of practice on advertising, such have to establish within its structures a scientific department, responsible for the information regarding the medicinal products that these companies are putting on the market.

Also, the marketing authorisation holder has to:

- maintain available or communicate to the National Medicines Agency ("NMA") a sample of all the advertising materials made under its initiative together with a declaration indicating the persons to which the advertising is addressed, the method to bring to knowledge such advertising and the date when the advertising has been first brought to knowledge;
- to ensure that the advertising materials made for its medicines are compliant with the legal provisions;
- verify that its medical representatives has been properly instructed and that they comply with the legal provisions;
- supply to NMA the information and the necessary assistance for the compliance of its responsibilities; and
- to ensure that the decisions that have been taken by NMA are immediately and fully observed.

In practice, generally, pharmaceutical companies issue internal rules that regulate advertising in compliance with the applicable laws and codes of practice on advertising.

1.4 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?

The advertising for medicinal products is monitored by NMA.

For over the counter products ("OTC"), the advertising materials for general public have to be previously approved by NMA.

To this end, a request must be filed with NMA. The request must provide the duration and the modalities of releasing the advertising (TV, radio, press), accompanied by the advertising material in detail

and the video cassette or CD or audio cassette with the advertising material.

NMA approves or rejects the request for approval of the advertising material within 30 days as of the payment of the official fee. The approval granted by NMA for an advertising material is valid for a period of 6 months.

The advertising materials for persons qualified to prescribe or supply them are analysed by the NMA after dissemination, by random survey or as a result of a notification.

1.5 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 NMA observes that the advertising material infringes legal provisions in force:

- in case the advertising material was already published, it orders the cease of the misleading advertising; and
- in case the misleading advertising has not yet been published but publication is imminent, it orders the prohibition of such publication, even without proof of actual loss, damage of any kind or of intention or negligence on the part of the advertiser.

In order to eliminate the effects of the misleading advertising, whose cease was ordered by NMA, the latter may request:

- publication of the final decision in full or in part and in such form as they deem adequate; and
- publication of a corrective statement.

Even though an appeal against NMA decisions is not expressly provided by Law 95/2006, such decisions may be challenged in front of the administrative courts in accordance with the provisions of legislation regarding administrative disputes.

1.6 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?

Non-compliance with legal requirements regarding advertising of medicinal products by the manufacturer or the distributor represents a minor offence sanctioned with a fine ranging between RON 5,000 to 10,000 (EUR 1,050 to 2,100). Such sanction is applied by the inspectors of NMA.

No important examples where actions have been taken against pharmaceutical companies have been made public so far by NMA.

In what concerns competitors, such may take direct actions through the courts in order to recover damages if they can prove the existence of a prejudice, an illegal act, a determination report between prejudice and the illegal act and an intention, negligence or misconduct of the party at fault and/or they may file an action in order to determine the stop the unlawful acts if they can prove a legitimate interest.

1.7 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 control performed by NMA in relation to the advertising for medicinal products does not exclude the voluntary control by self-regulatory bodies and recourse to such bodies.

Thus, in case of infringement of the Ethics Code by one of its members brought to its attention by an ARPIM member or by a third party an "arbitration" procedure is provided which may lead to pecuniary sanctions, prompt information of the company's international central headquarters which has been found guilty about the litigation, prompt information of the other ARPIM members about the fault of another ARPIM member, prompt information of NMA about the fault of an ARPIM member, proposal to the general assembly for the suspension/cease of the membership quality of the ARPIM member found guilty.

NMA may still investigate matters drawn to its attention that may constitute a breach of the legal provisions in force regarding the advertising of medicinal products even though a self regulatory body has already assessed such or take up matters based on an adverse finding of a self regulatory body .

1.8 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?

The act and/or fact of an economic agent of communicating or of spreading in public allegations upon its enterprise or activity meant to induce in error or to create a more favourable situation that is harmful to its competitors and/or of communicating or spreading false allegations upon a competitor or upon its services/goods which may damage the good performance of the competitor's enterprise may qualify as unfair competition.

If any of the above has caused moral or economic damages, the harmed person may lodge an action with the competent courts in order to obtain the repair of the prejudice.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product?

As a general rule, advertising of medicinal products is permitted in Romania only for medicinal products that have a marketing authorisation valid on the Romanian territory.

Nevertheless, informing the health professionals about a medicinal product before that product is authorised is not expressly forbidden, as long as it is not made with advertising purpose.

No distinction is made as to whether scientific meetings are sponsored by the company responsible for the product.

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

Information on unauthorised medicines may be published as long as it is not for advertising purposes.

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

Companies may issue press releases about a medicinal product which is not authorised yet as long as such is not made with advertising purpose.

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

The fact of sending such information to health professionals by a company may be viewed as having an adverting purpose and therefore prohibited. Nevertheless, where such information is sent to health professionals as an answer to a specific question that has a scientific character, it may be viewed as not having advertising purpose, and be, therefore, allowed.

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

Communication of information to institutions in order to enable them to plan ahead their budgets for products to be authorised may be viewed as advertising and therefore prohibited.

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

Health professionals may be involved in market research exercises concerning possible launch materials for medicinal products that are not yet authorised as long as such involvement and market research are objective and not made with promotional intent. The Ethics Code contains certain specific provisions as to the deployment of the market research of medicinal products.

Still, note should be made that, according to Romanian legislation, active medical doctors may not collaborate with the manufacturers or distributors of pharmaceutical or sanitary products. Such incompatibility may be seen as preventing certain health professionals (i.e., medical doctors) from being involved in any market research exercises run by pharmaceutical companies.

3 Advertisements to Health Professionals

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

Advertising of a medicinal product directed to persons qualified to prescribe or supply such products should include:

- essential information compatible with the summary of product characteristics; and
- the classification for the supply of the medicinal product.

Any documentation relating to a medicinal product which is transmitted as part of the promotion of that product to persons qualified to prescribe or supply it shall include, as a minimum, the above information and the date on which it was drawn up or last revised.

3.2 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 are no legal requirements on data from any or a particular number of "head to head" clinical trials before comparative claims are made regarding advertising of medicinal products. However, comparative advertising must observe general principles provided by the applicable legislation.

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

The comparative advertising is regulated by Law 158/2008 and is defined as any advertising that identifies in an explicit or implicit manner a competitor or the goods or services offered by such. The comparative advertising is considered legal if such complies cumulatively with the following conditions:

- it is not misleading;
- compares goods and services that respond to the same needs or are meant for the same purposes;
- compares in an objective manner, one or more essential characteristics, relevant, which may be verified and representative of the respective goods or services, which may include the price;
- does not discredit or denigrate the trademarks, commercial denominations, other distinctive signs, goods, services, activities or situation of a competitor;
- in case of products with denomination of origin, it refers in each case, at products with the same denomination;
- it does not take advantage in disloyal manner of the reputation of a trademark, commercial denomination or of other distinctive signs of a competitor or of a denomination of origin of the products of a competitor;
- does not present goods or services as imitations or reproductions of the goods or services bearing a trademark or a protected commercial denomination; and
- does not create confusion between economic agents, between the advertiser and a competitor or between trademarks, commercial denominations, or other distinctive signs, goods or services of the advertiser and of a competitor.

The Ethics Code also contains stipulations as to the comparative advertising of medicinal products that are mainly compliant with the provisions of Law 158/2008. According thereto, use of the trademarks of a competitor is not allowed, but only use of the international non-proprietary name.

Such stipulation is in compliance with the Romanian legislation on trademarks.

In what concerns the possibility of referring to a competitor's product that has not yet been authorised in Romania within a comparative advertising, we consider that such reference would not be in compliance with the relevant legislation.

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

There are no specific legal provisions to be observed with respect to the distribution of scientific papers and/or proceedings of congresses to doctors. Nevertheless, such distribution may qualify as advertising and therefore must comply with the legal provisions regarding the advertising directed to health professionals.

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

The concept of "teaser" advertisements is not expressly regulated by the Romanian pharmaceutical legislation. Nonetheless, if used, such form of advertising must comply with all legal and ethics requirements concerning advertising of medicinal products.

4 Gifts and Financial Incentives

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

Free samples of products may be offered, on an exceptional basis, only to persons qualified to prescribe or distribute medicinal products on the following conditions:

- the number of samples for each medicinal product each year on prescription shall be limited (the treatment of 10 patients);
- any supply of samples shall be in response to a written request, signed and dated, by the doctor;
- those supplying samples shall maintain an adequate system of control and accountability;
- each sample shall be no larger than the smallest presentation on the market;
- each sample shall be marked 'free medical sample - not for sale' or shall show some other wording having the same meaning;
- each sample shall be accompanied by a copy of the summary of product characteristics; and
- no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied.

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

Where medicinal products are being promoted to persons qualified to prescribe or supply them, it is forbidden to supply, offer or promise to such persons any gifts, pecuniary advantages or benefits in kind, unless they are inexpensive and relevant to the practice of medicine or pharmacy, e.g. texts, books or other sources of reference, anatomic models or other educational materials. According to the Ethics Code the value of the promotional objects that might be offered to health professionals should not surpass RON 120 (EUR 30), VAT included (before their personalisation). Also, according to the same stipulations objects that have a strict medical use that have a maximum value of RON 400 (EUR 95), VAT included may be offered.

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

Law 95/2006 does not expressly regulate the possibility of giving gifts or donations of money to institutions such as hospitals. However, taking into account general principles of Romanian legislation regarding sponsorship, we consider that companies may provide institutions (hospitals) with money and/or equipment, as part of a sponsorship agreement.

Such sponsorship must be meant to support a non profit activity carried out by the institution must be directly linked to the medical activity of that institution and must be unconditional.

The Ethics Code provides that, in order to support the efforts for the medical-technical and scientific development the following donations or sponsorships of the hospitals, clinics or public health institutions or NGOs are allowed for ARPIM members:

- donations or sponsorships with a specific destination (demonstrated by an official agreement) for medical or technical equipment for general usage; or
- for the hospitals/clinics restoration and adaptation.

This kind of supporting must be unconditional (without any prescriptions or other engagements) and directly linked to the medical activity of that hospital/clinic.

4.4 Is it possible to provide medical or educational goods and services to doctors that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for or an increased market share for the products of the provider of the goods or services?

The supply of medical or educational goods and services to doctors that could lead to changes in prescribing patters may be viewed as a form of advertising, or even bribery, and is prohibited.

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

The rules on advertising and inducements do not restrain the offer of a volume related discount to institutions purchasing medicinal products, provided that the public procurement and competition legal requirements are observed.

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?

Offering, providing or paying for additional medical or technical services or equipment to legal persons where this is contingent on the purchase of medicinal products could be seen as permitted as long as the applicable public procurement, competition and advertising of medicinal products legislation is complied with.

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?

Such refund schemes for a medicinal product that does not work are not forbidden under Romanian law, irrespective of the fact that the medicinal product is supplied based on a prescription or over-the-counter. However, in practice, such schemes could be difficult to implement, especially in case of products included in the public reimbursement system.

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

Pharmaceutical companies may sponsor continuing medical education provided that their implication in the sustenance of such programs is made public to participants through invitations, brochures, etc., before the events take place and also for the advertising materials published after the conference, materials that are referring to its content. The support given to the doctors or pharmacists to participate to the scientific events do no have to be conditioned of the obligation to promote or prescribe a medicinal product.

5 Hospitality and Related Payments

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

The prohibitions provided by the law as mentioned at our answer provided to question 4.2 herein above do not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes; such hospitality shall always be strictly limited to the main scientific objective of the event; it must not be extended to persons other than health-care professionals.

Hospitality at sales promotion events shall be strictly limited to their main purpose and must not be extended to persons other than health-care professionals.

The Ethics Code differentiated the maximum limits of the offered hospitality depending on the criteria if such takes place in Romania or abroad.

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

In accordance with the provisions of Law 95/2006 hospitality may be offered to a doctor in order for such to attend a scientific meeting for purely professional and scientific purposes.

According to the Ethics Code the hospitality must be limited to the transportation, meal, accommodation expenses and real fees of participation. There are not permitted the expenses related to the participation to other events additional to the scientific meeting. As a rule, the provided hospitality should not surpass what the health professionals would normally pay for themselves.

Taking into account the limitations provided by the legislation, we consider that paying a doctor for his or her time while attending a scientific meeting is not allowed.

The Ethics Code provides for certain maximum limits to be observed by its members when providing hospitality.

By exception, doctors and the nurses in chief from the emergency units can not be sponsored and/or financed, directly or indirectly, in order to participate in conferences, congresses or other types of manifestations by the companies that commercialise pharmaceutical products and/or sanitary materials or the companies that represent their interests nor by the medical devices companies, except with the approval of the Ministry of public Health.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of and the hospitality arrangements for scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual doctors to attend?

Non-compliance by a pharmaceutical company with the legal provisions in force as to the contents and the scientific meetings, either directly sponsored by the company or independent meetings where the company provides sponsorship to individual doctors to attend may trigger its civil, administrative, penal or disciplinary liability as the case may be.

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

Under Romanian law provisions, it is possible to conclude consultancy agreements in order to obtain expert services.

Still, we reiterate the fact that, according to Romanian legislation, active medical doctors may not collaborate with the manufacturers or distributors of pharmaceutical or sanitary products. Such generic incompatibility may be seen as preventing doctors from being involved in any focus groups run by pharmaceutical companies.

According to Ethics Code the compensations paid in exchange of the supplied services should be reasonable and should take into consideration the maximum limitations provided by the code.

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

The participation of doctors in post marketing surveillance studies is allowed as long as such are not used as a form of disguised advertising. There are no specific rules that govern the participation of doctors in such studies. Still, we reiterate the fact that, according to Romanian legislation, active medical doctors may not collaborate with the manufacturers or distributors of pharmaceutical or sanitary products. Such generic incompatibility may be seen as preventing doctors from being involved in any post marketing surveillance studies run by pharmaceutical companies.

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

The participation of doctors in market research involving promotional materials may be seen as permitted as long as such is not used as a form of disguised advertising. Still, we reiterate the fact that, according to Romanian legislation, active medical doctors may not collaborate with the manufacturers or distributors of pharmaceutical or sanitary products. Such generic incompatibility may be seen as preventing doctors from being involved in any market research studies run by pharmaceutical companies.

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?

In accordance with the provisions of Law 95/2006 the advertising of non-prescription medicines to the general public is permitted as long as:

- the medicinal product has a marketing authorisation valid on the Romanian territory;
- information from the advertising material correspond to the information from the summary of the product's characteristics;
- encourages the rational use of the medicinal product through its presentation in an objective manner and without exaggerating its proprieties;
- is not misleading;
- does not contain substances defined as narcotic drugs or psychotropic substances in accordance with the United Nations conventions of 1961 and 1971 and national legislation;
- by their composition and purpose, are intended to be used without the intervention of a medical practitioner, for diagnostic purposes, prescription or monitoring of the treatment, being sufficient, if necessary the advice of pharmacists;
- they are not prescribed and supplied within the health security system;
- they are not directly distributed to the population by the manufacturers for promotional purposes;
- the advertising material should be conceived in such a manner that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product; and
- includes the following minimum information (i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance, (ii) the information necessary for correct use of the medicinal product, (iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be. This invitation can be formulate: "*This medicinal product can be delivered without medical prescription. It is recommended to read carefully the prospect or the information on the packaging. If any unpleasant manifestation appears, please address to the doctor or pharmacist.*"

The advertising of a medicinal product to the general public should not contain any material which:

- gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment at distance;
- 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;
- suggests that health of the subject can be enhanced by taking the medicine;
- suggests that health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns;
- is directed exclusively or principally for children;
- refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refers, in improper, alarming or misleading terms, to claims of recovery; and
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

Decision 187/2006 sets up specific rules for the advertising of medicinal products through audio-visual means (e.g., broadcasting of advertising and teleshopping for medicinal products or medical treatments, if the presentations contain recommendations or confirmations from the medical associations, as well as broadcasting of advertising or teleshopping for medicinal products whose costs are subject to reimbursement, is forbidden). Also, it is forbidden to mention in advertising or in teleshopping certain therapeutic indications relating to diseases as tuberculosis, sexually transmitted diseases, other infectious diseases, cancer or other tumour diseases, chronic insomnia, diabetes and other metabolic diseases.

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

Advertising of prescription-only medicinal products to the general public is forbidden except for the vaccination campaigns performed by the pharmaceutical industry and approved by the Ministry of Public Health.

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?

Information, education and communication campaigns, related to public health, that are to be run through mass media must be endorsed by the Ministry of Health.

Pharmaceutical companies involved in the sustenance of programs that have an educational or informative character have the obligation of making the participants aware of their sustenance of such event.

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

The issuance of press releases concerning prescription only medicinal products to non-scientific journals may be seen as permitted as long as it has not been made with promotional intent.

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

In case such presentation of medicinal products and of research initiatives has an internal information purpose no restrictions apply to such materials. Nevertheless, should such presentations be made with an advertising intent such should comply with the applicable legal provisions regarding advertising of medicinal products.

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

No specific rules apply for such kind of activities.

7 The Internet

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

Romanian legislation regulating advertising of medicinal products does not provide specific provisions with respect to advertising of such products over the Internet. Thus, all the general provisions regulating the advertising of pharmaceutical product apply.

The Ethics Code provides within its Annex A - "*Guide for the web pages accessible to the health professionals, patients and EU public*" a set of recommendations for the design of the web pages accessible to the categories mentioned within its title. Such guide contains recommendations as to the transparency of the origin of the web page, content and purpose, the content of the web pages, electronic mail enquiries, links to other web sites, web pages addresses in packaging, review of the scientific information and confidentiality.

No case law or practice is yet available with respect to enforcement of legal provisions regarding advertising to advertisements over the Internet.

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

No express requirements are imposed by Romanian legislation to ensure that members of the general public do not have access to sites intended for health professionals.

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

Romanian legislation does not specifically address this issue with respect to companies in the pharmaceutical field.

The Ethics Code provides that ARPIM members may not create links from web pages meant for the general public to web pages sponsored by the company and meant to the health professionals.

The only relevant reference Romanian legislation makes to liability related to providing links to third party websites is in Law no. 365/2002 regarding electronic commerce, as further modified and amended ("Law 365/2002"), according to which the information society service provider facilitating the access to the information supplied by other service providers or by the recipients of the services offered by other suppliers, by making available for the recipients of his service some information searching tools or links to other web sites, is not liable for the respective information, if any of the following conditions is fulfilled:

(a) the provider is not aware of the fact that the activity or information to which is grants access is illegal and, as concerning the torts, it is not aware of any facts or circumstances showing that the respective activity or information could prejudice the rights of a third party; and

(b) being aware of the fact that the respective activity or information is illegal or of facts showing that the respective activity or information might prejudice the rights of a third party, the provider acts rapidly to eliminate the access possibilities offered or to block its use.

Law 365/2002 is applicable only to service providers established in Romania and to services provided thereby, and covers only information society services which are remunerated by the beneficiaries.

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

A pharmaceutical company may place on its website any information, as long as legal provisions (including provisions regulating advertising of medicinal products) are complied with.

8 General - Medical Devices

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

No specific rules are provided by the legislation currently in force with respect to advertising of medical devices in Romania. Consequently, general legislation regarding advertising applies.

Also, no code of practice has been adopted by the only Romania association in the field of medical devices (Medical Products Suppliers Association).

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

No specific restrictions are provided by the legislation with respect to payments or hospitality offered to doctors in connection with the promotion of a medical device. However, general restrictions imposed by the Criminal Code with respect to giving bribery apply.

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?

No significant developments regarding rules relating to pharmaceutical advertising took place in the last year in Romania.

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

No information regarding any significant developments in the filed of pharmaceutical advertising to be expected in the next year in Romania has yet become public.

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

No general practice or enforcement trends have become apparent in Romania over the last year.

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

The Ethics Code, as adopted by the Directory Council and the General Assembly on October 25, 2007, reflects the requirements of the European Federation of Pharmaceutical Industries and Associations Code on promotion of prescription-only medicines to, and interactions with healthcare professionals, as adopted by EFPIA Board on October 5, 2007.

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