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The International Comparative Legal Guide to:
Pharmaceutical Advertising 2010

A practical cross-border insight into pharmaceutical advertising

Published by Global Legal Group
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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 in Romania is specifically regulated under Title XVII (Pharmaceutical Products), Chapter VIII (Advertising) of Law No. 95/2006 on the health sector reform ("**Law 95/2006**", the "**Law**"), implementing Directive 2001/83/EC on the Community Code relating to medicinal products for human use. Other general enactments regarding advertising apply also the medicinal products.

Advertising of medicinal products is also regulated under the Code of Ethics issued by the Romanian Association of International Medicines Manufacturers ("**ARPIM**"). The Code of Ethics is only mandatory for ARPIM members.

1.2 How is "advertising" defined?

The Law defines the *advertising of medicinal products* as any form of door-to-door information and any advertising activity aimed at incentivising the prescription activity, distribution, sale or consumption of medicinal products including, in particular: the advertising of medicinal products to the general public or to healthcare professionals; visits by medical sales representatives to persons qualified to prescribe medicinal products; supply of samples; sponsorship of promotional meetings attended by healthcare professionals or scientific congresses, etc.

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

The marketing authorisation holder must keep available or provide the National Medicines Agency ("**NMA**") with a sample of any advertising materials prepared and a statement regarding the addressees, dissemination method and release date of the advertisement. The compliance with the advertising rules must be insured by the scientific department of the marketing authorisation holder who is in charge with the relevant public data on the pharmaceutical products released on the market.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

Neither the Law nor the Code of Ethics requires companies to have SOPs governing advertising activities.

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?

Promotional activities targeting the general public (which could only be organised for non-prescription medicines) must be approved *ex ante* by the NMA. The authorisation is granted against a fee, upon submission of a standard application form available on the NMA website.

Advertising materials addressed to the healthcare personnel are assessed by the NMA *ex post* (after dissemination) either randomly or further to a third party complaint. The pharmaceutical companies may, for legal certainty reasons, confirm with the NMA the compliance of the advertising materials, prior to release.

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 NMA may order the cessation of misleading advertising or may prohibit, provisionally or definitively, such advertising if not yet published, but publication is imminent, even without proof of actual loss or damage or of intention or negligence on the part of the advertiser. In the latter case, an accelerated procedure applies.

With a view to eliminating the effects of misleading advertising prohibited by the NMA, the advertiser could be obliged to publish the prohibition decision (in full or in part) and an additional corrective statement.

The NMA's decisions may be appealed in court subsequent to undertaking a prior administrative challenge procedure.

The Code of Ethics provide for a separate dispute resolution mechanism against ARPIM members, before the Arbitration Committee. If the resolution of the Arbitration Committee is not acceptable by one of the parties, the plaintiff party may address this issue to the NMA or further on to a civil court.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Failure to comply with the legal provisions on advertising of medicines may trigger:

- Administrative fines applied by the NMA ranging between RON 5,000 and RON 10,000 (approx. EUR 1,150 to EUR 2,500) or, in case of repeated offences, the threshold is increased and ranges from RON 10,000 to RON 30,000 (approx. EUR 2,500 to EUR 7,000) and one year suspension of the distribution license authorisation.
- Pecuniary sanctions applied by the ARPIM ranging between EUR 5,000 and EUR 15,000; the ARPIM may also inform the NMA and the media of the breach.
- Civil liability towards third parties damaged by the illegal advertising practice.

Competitors may file a complaint with the NMA aimed at obtaining a ban on the illegal advertising practice and/or may claim damages from the advertiser in civil courts based on tort liability general rules. However, actual challenges brought by competitors are rather infrequent.

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 ARPIM may inform the NMA of any advertising inconsistent with the Law, the NMA is free to take action and impose the administrative remedies provided for under questions 1.6 and 1.7 above in parallel with the measures already undertaken by the self-regulatory body.

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?

Pharmaceutical companies may also bring claims before a specialised body in the Ministry of Finance or directly in court, based on unfair competition rules, if their rivals disseminate misleading information on their business or use unfair comparative advertising methods.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to health professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product's variants not authorised)?

As per the Law, advertising of a medicinal product to healthcare professionals in respect to which a marketing authorisation valid for Romania has not been granted is prohibited, except for homeopathic products.

Purely informative announcements regarding pharmaceutical products which do not include promotional messages may however fail to qualify as advertising according to Article 797 (2) of the Law. As such, whether a presentation related to the unauthorised products within the context of scientific meetings is qualified as illegal advertising targeting healthcare professionals depends largely on the message and focus of such presentation and implication of the product's developer in organising the scientific event. Mere informative scientific presentations are, in principle, unlikely to be caught by the prohibition.

According to the Code of Ethics, the general promotion of off-label information is also banned. An ARPIM member may only provide off-label information, in response to an unsolicited request from a healthcare professional.

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

Information on unauthorised medicines may not be made available to the general public or to healthcare professionals if the message behind such information induces the incentive to prescribe, sell or administrate a specific product to be released. Purely informative, non-promotional data may be, however, made available. A case by case assessment is required.

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

Press releases on medicines which are not yet authorised may be considered as more obvious and effective forms of promoting products to be released, and therefore prohibited. A case by case analysis is, however, required.

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

Such information may be sent to health professionals only upon their request, as the Law does not qualify as advertising the solicited correspondence with healthcare professionals regarding a specific product.

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?

In principle, providing unsolicited information on unauthorised medicines to potential buyers such as healthcare institutions might be seen as an illegal form of advertising.

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?

No specific guidelines on market research of medicinal products have been issued. The Code of Ethics defines market research as the collection and analysis of information which must be unbiased and non-promotional. Thus, any involvement of healthcare professional in market research activities must serve statistics only and not promotional purposes. Since the market research regarding yet unreleased products is likely to involve a clear promotional component, there are good chances that contribution of doctors in such activities might be seen as illegal advertising.

3 Advertisements to Health Professionals

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

Any advertising of a medicinal product to persons qualified to prescribe or supply such products must include: (i) essential information compatible with the summary of product characteristics; (ii) the supply classification of the medicinal product; (iii) reference to the date such document was drafted or last updated. As an exception, for the case of short advertisements (reminders), the advertisement for the medicine may include only the brand name or the active ingredient (INN). All information must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form its own opinion of the therapeutic value of the respective medicinal product.

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

According to the deontological rules governing their profession, the healthcare professionals are prevented from advertising pharmaceutical products, and therefore could not endorse any promotional materials. As an application of such rule, advertisements and/or teleshopping activities presenting health practitioners or health practices which are identified or identifiable are strictly forbidden.

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

Performing a comparison between clinical trials is not a prerequisite condition for comparative advertising; however, any comparison must be based on relevant and comparable characteristics of the products.

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

Comparator advertisements are governed by Law no. 158/2008 on comparative and misleading advertising, published in the Official Gazette, Part I, No. 559 as of 24 July 2008. Comparative advertisements should, *inter alia*, not be misleading, compare products or services aimed to cover similar needs or purposes, should be objective, should not discredit competitors or competing products, if possible, refer to the same origin name, and should not create confusion for the customers. Similar rules are elaborated in the Code of Ethics.

As per the Code of Ethics, the use of a competitor's brand name is expressly banned, except for price comparisons directly quoted from the official websites of the Romanian public health authorities. Mentioning of non-proprietary (generic) names is allowed in all cases.

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

There are no specific rules on the distribution of scientific papers and/or proceedings of congress to doctors; however, if such materials are non-promotional in nature and respond to purely informative and scientific purposes, they should be, in principle, allowed.

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

As indicated by the Law and further elaborated by the Code of Ethics, any promotional announcement or material should be objective and include enough elements as to allow the accurate identification of the product and its characteristics. Consequently, "teaser" advertisements fail to comply with such requirements.

4 Gifts and Financial Incentives

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

Free samples may be provided to doctors on an exceptional basis, only in response of a written request. The samples must not exceed the size of the smallest presentation marketing form, be accompanied by a copy of the summary of product characteristics and be marked with "free medical sample – not for sale" or an equivalent wording. No samples of medicinal products containing psychotropic or narcotic substances within the meaning of United Nations Conventions of 1961 and 1971 may be supplied. A pharmaceutical company may distribute a limited number of samples each year and must ensure an adequate traceability system.

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

As per the Law, when medicinal products are promoted in relation to persons qualified to prescribe or supply medicines, no gifts, pecuniary advantages or benefits in-kind may be supplied, offered or promised to such persons unless they are inexpensive (according to the Code of Ethics, up to a threshold of maximum 150 RON, approx. EUR 30 - 35) and relevant to the medicine or pharmaceutical practice.

The Code further elaborates on the description of promotional items acceptable. Items for strictly medical use are allowed up to a value of RON 500 (approx. EUR 115 - 120) VAT included.

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?

Donations may be offered to hospitals. Gifts and donations to emergency units may not be provided with the purpose of obtaining preferential treatment.

As per the Code of Ethics, in order to sustain the technical-medical and scientific development, donations or sponsorships may be awarded to hospitals, clinics, public health institutions (except the private healthcare institutes) or the NGO's (affiliated to public healthcare institutes or which have healthcare professionals in their managing board) for equipping such premises with technical devices or for refurbishment purposes. This type of support must be strictly unconditioned (no drug prescriptions or other types of commitment should be required as consideration) and must be directly connected to the medical activities of the beneficiary.

For transparency purposes, all ARPIM donors must require prior approval from the ARPIM Workgroup for Ethical Environment. The sponsorships are disclosed on the ARPIM website.

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?

Any allowed incentives granted to doctors, including sponsorships or donations having as an object educational or medical goods or services, may not be conditional upon the promotion of pharmaceutical products and may not influence doctor's independent practice and prescribing decisions.

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

Commercial discounts of all types (volume discounts, natural rebates etc.) could be awarded to healthcare institutions acquiring medicinal products.

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?

Bundling sales practices are not prohibited under advertising rules, however their compliance with competition rules must be assessed.

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?

No specific provisions prohibit refunds of unsold/unused products.

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

As per the Code of Ethics, a pharmaceutical company may not sponsor medical education if it exceeds an incentive threshold reasonably accepted (for instance, in case of books and other educational materials EUR 500 per book is considered reasonable; the ARPIM Workgroup for Ethical Environment should be informed if such value is higher). For educational/training events organised by the pharmaceutical companies, please see the hospitality and related payment rules under section 5 below.

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?

As per the Law, hospitality at promotional events must be reasonable in level, remain subordinated to the main scientific objective of the meeting and may not be extended to persons other than health professionals.

The Code elaborates on the acceptable hospitality protocols.

All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events, including but not limited to visits to production sites or research laboratories, advisory board meetings, planning meetings, education (courses) or investigator meetings for clinical or non-interventional studies, organised or sponsored by an ARPIM member must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when appropriate.

Hospitality extended in connection with promotional, professional or scientific events shall be limited to travel, meals, accommodation and genuine registration fees.

Any kind of hospitality may only be extended to persons who qualify as participants in their own right, i.e. with a *bona fide* scientific professional relationship to the topics discussed at such event.

International events outside Romania can only be organised or sponsored by ARPIM members if the place abroad is more suitable given the origin of the majority of attendees or given the location of the relevant resource or expertise having occasioned the event.

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?

All forms of hospitality offered to doctors for participation to scientific meetings shall be reasonable in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what the beneficiary would normally be willing to pay for themselves.

The Code of Ethics sets maximum limits for hospitality expenses in relation to travel, accommodation, participation and speaker contribution.

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?

Please see the liability question 1.7 above.

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

As per the Code of Ethics, expert/consultancy agreements may be concluded with doctors, in consideration of reasonable compensation for those services and reimbursement for travel, lodging, and meal expenses incurred as part of providing services.

The Code provides that the following matters support the existence of a *bona fide* consulting arrangement:

- a written contract specifying the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services has been clearly identified in advance;
- the criteria for selecting the consultants are related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professional meets those criteria;
- the number of healthcare professionals retained is not greater than the number reasonable necessary to achieve the identified purpose;
- documentation of the services provided is maintained by the ARPIM member;
- the venue and circumstances of any meeting with consultants are conductive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

No consultancy fees shall be provided or offered to a healthcare professional in exchange for prescribing medicinal products or for a commitment to continue prescribing medicinal products. Consultancy fees cannot be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practice.

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

As per the Code of Ethics, doctors may take part in post marketing surveillance studies (observational studies) and be compensated for their work, based on a written agreement, taking into account their experience level, expertise in the therapeutical area concerned and actual time and efforts spent on the study-related tasks. Overall, the amount should be reasonable, it should reflect the actual time and efforts spent in addition to the professional routine work, and not exceed what is considered to be customary as per the Code.

Under no circumstance can the study be proposed or designed with the objective of rewarding healthcare professionals for using, purchasing, recommending or prescribing the medicinal products of an ARPIM member, or to persuade them to do so by participating in such study.

Post marketing surveillance studies must not be used as disguised promotion (the organiser must not offer medicinal products used in the study or use any method to increase interest in or awareness of its medicinal products).

Observational studies are not meant to increase the number of prescriptions, but only to generate additional information on efficacy and safety in a real patient population in day-to-day practice.

Observational studies may be conducted only for a limited period of time. Successive renewals with the same healthcare professional and with the same objective are not allowed.

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

Any involvement of healthcare professionals in market research activities must serve only statistics and not promotional purposes. As per the Law, active medical doctors may not be collaborators or employees of pharmaceutical manufacturers or distributors, therefore their remunerated contribution to market research involving promotional materials might fall under the restriction.

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?

Non-prescription medicines may be advertised to the general public only based on the prior approval of NMA and subject to the following main conditions:

- advertising of medicinal products must promote rational use through an objective representation, without exaggerating on their characteristics and should not be misleading;
- information included in the advertisement corresponds to the applicable information on product characteristics;
- the advertised medicines are not part of the category of pharmaceutical products prescribed and supplied within the health insurance system (with the exception of vaccination campaigns performed by the pharmaceutical industry and approved by the Ministry of Public Health);
- the advertised medicines do not contain narcotics or psychotropic substances, as defined by the United Nations Conventions of 1961 and 1971 and/or by national enactments;
- no direct distribution of medicines to the general public for promotional purposes is allowed.

Further to the principles set above, any advertisement material destined to the general public should:

- clearly indicate its promotional nature and identify the product as a medicinal one and include the following minimum information: (i) name/brand name and applicable ICN (*international common name*) in case the product contains a single active substance; (ii) proper usage instructions; and (iii) express and legible invitation to carefully read the usage instructions included in the package leaflet or the outer package indicating: "*This medicine may be released without prescription. It is recommended to read carefully the information included in the package leaflet or on the outer package. In case of adverse reactions, please consult a doctor or pharmacist*"; as an exception, in case of remainders, it is accepted that the advertisements include only the name/brand name or ICN;
- not enclose information that: (i) gives the impression that a medical consult of surgical intervention is not necessary, especially by offering diagnosis suggestions or distance treatment (e.g. by mail); (ii) 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; (iii) suggests that the health of the subject can be enhanced by taking the medicine; (iv) suggests that the health of the subject could be affected by not taking the medicine (not applicable, however, to vaccination campaigns); (v) is directed exclusively or mainly at children; (vi) 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; (vii) suggests that the medicinal product is a food, cosmetic or other consumer product; (viii) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural; (ix) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis; (x) refers, in improper, alarming or misleading terms, to claims of recovery; (xi) 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.

Additional legal prescriptions are introduced for audiovisual advertisements according to Decision No. 187/2006 of the National Audiovisual Council, which, *inter alia*, sets a ban on advertisements or teleshopping for medicinal products, vitamins, food supplements presented or recommended by public figures, healthcare professionals, medical associations, or aimed for children (below the age of 16) or including therapeutic indications for certain diseases.

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

As per the Law, prescription-only medicines may not be advertised to the general public. As an exception, vaccination campaigns organised by pharmaceutical industry members may be promoted to the general public subject to the approval issued 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?

Disease awareness campaigns may be addressed to the general public provided they are not promotional (no direct or indirect information to specific medicinal products is provided). As per the Law, general awareness campaigns must be endorsed by the Ministry of Public Health.

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

Prescription only medicines may not be released in non-scientific journals, since it would be qualified as advertising to the general public.

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

As per the Code of Ethics, websites may contain information that would be of interest to investors, including descriptions of research and development programmes and its products. Although not expressly provided, Annual Reports/corporate brochures could follow the same regime, given the same target reader.

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

The Law does not include specific provisions on such matter. However, the ARPIM issued a code of practice on the relationships between its member companies and patient organisations (implementing the applicable EPFIA pharmaceutical companies-patient organisations code). The document has equal legal value with the Code.

It includes rules considered reasonable for support or sponsorships granted by the pharmaceutical industry to patient organisations and their members in connection with the events organised by the former or by patient organisations, especially concerning hospitality issues. The set thresholds are similar to the ones provided by the Code of Ethics. Moreover, it is expressly stated that no company may require that it be the sole funder of a patient organisation or any of its major programmes.

As regards transparency, it provides that each company must make publicly available (on the ARPIM's website) a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. The list should include: the name of the organisations; a brief description of the organisations and nature of support; the period for which the support is provided; and the amount and/or percentage from the total income of the patient association, at the end of the previous financial year, represented by the support provided by the company. The information must be provided in Romanian and should be updated yearly.

7 The Internet

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

The Law does not include specific provisions on internet advertising, thus the general rules apply. However, the ARPIM Code implemented the Guidelines for Internet websites available to healthcare professionals, patients and the public in the EU (Annex B of EPFIA Code).

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 specific security standards are provided by the Law or the Code of Ethics.

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?

Links may be established to a company-sponsored website from websites sponsored by other persons, but ARPIM members should not establish links from websites designed for the general public to company-sponsored websites that are designed for healthcare professionals. In the same manner, links may be established to separate websites, including websites sponsored by the ARPIM member or by other persons. Links should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

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

The content of pharmaceutical companies' websites must comply with the advertising rules above. The Code of Ethics specifically elaborates on the allowed content.

8 General - Medical Devices

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

Medical devices in Romania are governed by Law No. 176/2000 on medical devices, as republished in 2005. However, such law does not include specific provisions on advertising. The general rules on advertising should then apply.

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.

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 2010 the new updated version of the Code of Ethics was adopted by ARPIM.

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

No major developments have been made available for public consultation.

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

Given the rather poor enforcement record, no particular practice trends may be identified.

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

The Code of Ethics implements the provisions of the EFPIA Code.

Note

This chapter is a summary of the Romanian law and regulations that are considered to be significant in relation to the above questions. It should not be construed as legal advice on specific facts. The information contained in this chapter is not, nor is it intended to be, legal advice or a legal opinion. The information disclosed under this chapter seeks to provide the reader with concise legal shorthand by way of general information. This is why it is important for anyone who is contemplating to implement an activity on the below matters in Romania to firstly get comprehensive professional local advice.

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She has an extensive expertise in competition law and has successfully assisted pharmaceutical companies before the national antitrust authority in various antitrust investigations. She has also provided customised legal training and compliance programmes to companies active in pharmaceutical field.

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ASOCIAŢII

Attorneys at law

Ţuca Zbârcea & Asociaţii is a full-service independent law firm operating in Romania and Spain. The firm is one of the largest in the local legal market, employing a cross-disciplinary, expert team comprising 100 lawyers.

Pharmaceutical law is one of the niche practice areas of Romanian law in which few Romanian attorneys have real expertise, given its complexity and close connection with other areas such as IP or even competition law. The firm's lawyers have assisted and represented companies from the pharmaceutical field in a wide range of specific regulatory matters, including in various disputes in front of the National Medicine Agency or local courts.

It was named the "Most Innovative Continental European Law Firm" in the Financial Times' Innovative Lawyers Report 2009 and the "Law Firm of the Year" for the past four consecutive years. It has recently won the "Law Firm of the Year" Award by Chambers & Partners during the 2010 Chambers Europe Awards for Excellence.