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Country Question and Answer Chapters:

Romania

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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?

In Romania, the advertising of medicinal products is currently regulated by the following pieces of legislation and codes of practice:

- Law no. 95/2006 regarding the reform in the healthcare field, as republished and further modified and completed, ("Law 95/2006").
- Order no. 194/2015 issued by the minister of Health regarding the approval of the Norms for the evaluation and approval of the advertising for medicinal products for human use, ("Order 194/2015").
- Order no. 263/2003 issued by the minister of Health for the approval of the Regulations regarding the marketing authorisation, supervision, advertising, labelling, and prospectus of medicinal products for human use, as further modified and completed, ("Order 263/2003").
- The Ethics Code of the Romanian Association of International Drug Manufacturers (hereinafter referred to as "ARPIM") for Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals as approved on March 31st, 2016, ("ARPIM Ethics Code"). (The Code implements the Code of the European Federation of Pharmaceutical Industries and Associations (EFPIA)).
- ARPIM Code of Ethical Practice in the Interaction with Patient Organizations, ("ARPIM Ethical Code").
- The Ethical Code of Conduct concerning the Promotion of Prescription-Only Medicines of the Romanian Generic Medicines Manufacturers Association ("APMGR Ethical Code").
- Law no. 148/2000 on advertising, as further modified and completed, ("Law 148/2000").
- Law no. 158/2008 on misleading and comparative advertising, as further modified and completed, ("Law 158/2008").
- Audiovisual Law no. 504/2002, as further modified and completed, ("Law 504/2002").
- Decision no. 220/2011 regarding the Regulation code of the audiovisual content, ("Audiovisual Code").
- Code of practice in the commercial communication of the Romanian Advertising Council ("RAC Code").

1.2 How is "advertising" defined?

According to the provisions of the Order 194/2015, advertising of medicines is defined as any type of organised activity performed with the purpose of providing information, by direct or indirect means, as well as any type of promotion intended to encourage the prescription, distribution, sale, administration, recommendation or use of one or more medicinal products for human use. Advertisements for medicinal products may be intended either for healthcare professionals or for the general public.

Order 194/2015 also mentions that advertising of medicines includes any type of information by direct contact ("door-to-door" system), as well as any type of promotion intended to stimulate the prescription, distribution, sale or consumption of medicines; advertising for medicines shall specifically include:

- advertising of medicines to the general public;
- advertising of medicines to healthcare professionals;
- visits from medical representatives to persons qualified to prescribed medicines;
- providing samples;
- stimulating prescription or distribution of medicines by offering, promising or granting certain advantages in cash or in kind, except for cases when they have a symbolic value;
- sponsorship of promotional meetings attended by persons qualified to prescribe or distribute medicines; and
- sponsorship of scientific congresses attended by persons qualified to prescribe or distribute medicines, and, specifically, payment of transport and accommodation expenses in relation thereto.

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?

Mainly, companies are required (i) to obtain prior approval for the advertising materials designed for the general public as well as for educational materials designed for the general public and for educational materials for patients from the National Medicines Agency and of Medical Devices ("ANMDM"), (ii) to declare to ANMDM any sponsorship as well as any expenses made for healthcare professionals, (iii) to obtain prior approval from ANMDM regarding the supply of medicinal products samples, (iv) the participation of marketing authorisation holders to medical events needs to be notified to ANMDM prior to the event, (v) the advertising materials need to be kept for at least three years, (vi) to offer proper training to medical representatives regarding the promotion of medicinal products, (vii) to have a responsible person that approves internally the advertising materials, (viii) to set up internally a training system regarding the manner in which the

advertising materials are used by their representatives, and (ix) to set up a scientific unit responsible for the information regarding the medicines that are put 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?

No, it is not mandatory under the laws that are currently applicable in Romania, for a company to have SOPs in place for advertising activities, but it is advisable to have them.

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?

As a general note, ANMDM is the competent authority for the evaluation and monitoring of advertising of medicinal products.

The advertising materials for the general public, the educational materials designed for the general public as well as the educational materials for patients need to be prior approved by ANMDM. In what concerns the advertising materials for healthcare professionals such can be analysed by ANMDM after being released, randomly or following a complaint.

In order to obtain approval from ANMDM for specific advertising material, companies must file an application form and pay an official fee which is made for each medicinal product that appears in the material and for each channel of communication of the respective advertising. Following confirmation of payment, ANMDM commences the analysis of the material which may result in issuing the approval or for ANMDM to request amendments to the material be performed or to be issued a refusal of approval. In general, advertising material is approved within 30 days.

In order to verify the conformity, ANMDM establishes that the mandatory minimum duration for advertising materials to be kept by the marketing authorisation holder is for three years, for both printed materials as well as the ones in electronic format. This period is calculated as of the moment the material started to be used.

In addition, it should be noted that the offering of samples is also subject to prior approval by ANMDM and the participation of marketing authorisation holders to medical events needs to be notified to ANMDM prior to the event.

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?

Yes, in case ANMDM considers that an advertisement is in breach of the legal provisions, it can order further publication to be stopped if already published, or prevent (temporarily or definitively) it from being published if not yet published but its publication is imminent. In case ANMDM considers that corrective measures have to be taken, it shall inform the faulty party about it and about the term during which the measures have to be taken.

ANMDM may also order that its decision, either in whole or in part to be published or it may order the company to issue a corrective statement.

Yes, an appeal against these measures can be filed with ANMDM.

The above does not exclude the voluntary control of the advertising performed self-regulatory bodies.

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 rules regarding the advertising of medicinal products may be sanctioned with (i) fines, (ii) suspension for three months of the marketing authorisation for a certain medicinal product together with blocking of the series that are in the therapeutic circuit from that medicinal product, in case of two breaches of the regulations regarding the advertising of that medicinal products, and (iii) the withdrawal of the marketing authorisations, in case of three breaches of the regulations regarding the advertising of that medicinal products.

Healthcare associations like ARPIM or APMGR irrespective of any sanction that is applied by the competent authorities apply also sanctions to their members in case of breach of the ethical codes to which such have adhered. Mainly they apply pecuniary sanctions, but also they may go until suspension or removal of the member from the association.

ANMDM or the Ministry of Health apply the above measures. Breach of the audiovisual provisions are applied also by the National Audiovisual Council.

ANMDM is active in monitoring the market and publishes in its Informative Bulletin as well as on its website (www.anm.ro) breaches of the legal provisions and the corrective measure that have been ordered. There are several companies against which measures have been taken for breach of the legal provisions regarding advertising.

The competitors may file actions for tort liability in front of the court, but mainly they have to prove damage or unfair competition.

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?

ANMDM investigates any matter that is brought to its attention by self-regulatory bodies or associations in the advertising field and takes any decision that considers that is applicable irrespective of any other measure that was taken by a self-regulatory body or association.

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?

Yes, any person with a legitimate interest may file an action for unfair competition in front of the courts, for example, in case a competitor is denigrated or its products/services or, in general, in case of any other commercial practices that are against the fair practices and good faith that produce damage to any participants on the market.

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)?

As a general rule it is forbidden to promote a medicinal product that does not have marketing authorisation out of the approved therapeutic indications. All the promotional materials for a product have to be in compliance with the summary of product's characteristics, as approved by ANMDM.

Information regarding some indications of medicinal products that are not mentioned in the marketing authorisation ("indications outside label" = "off-label") can be supplied only as a response to a documented request from a healthcare professional. However, it is forbidden to use such information in order to promote the medicinal product for unauthorised indications or for its use in other conditions than those mentioned in the approved summary of product's characteristics. The marketing authorisation holder has to ensure that the provided material has an informative character, is non-promotional and clearly mentions that the respective information represents "indications off-label".

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

Please refer to the answer to question 2.1 herein above.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

Please refer to the answer to question 2.1 herein above.

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

Please refer to the answer to question 2.1 herein above.

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?

The legislation as currently in force in Romania does not contain any specific provisions with respect to the above-mentioned aspects.

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?

Exceptionally, the manufacturers or their representative companies on the Romanian territory may distribute relevant information in case they are the object of specific requests from authorities in the field of medical assistance.

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?

The legislation as currently in force in Romania, does not contain specific provisions with respect to the above.

However, under the ARPIM Ethics Code, healthcare professionals may be engaged in participation in market research, whether in groups or individually provided.

The arrangements that cover these services must, to the extent relevant to the particular arrangement, fulfil all the following criteria: (i) a written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services; (ii) a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants; (iii) the criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria; (iv) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need; (v) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants; (vi) the hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and (vii) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements should not be used to justify compensating healthcare professionals.

Companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/she is a consultant to the company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare his/her employment arrangement with the company whenever he/she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company.

Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of the above-mentioned provisions of the ARPIM Ethics Code, provided that the healthcare professional is not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal. Members have to provide guidance on the meaning of "minimal" in connection with any Applicable Code(s).

ARPIM member companies have to define internally reasonable maximum net amounts for such services that can be paid to any individual HCP in a fiscal year.

3 Advertisements to Healthcare Professionals

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

Any advertising material of medicinal products intended for healthcare professionals must include: (i) information compatible with the summary of product's characteristics as approved by ANMDM; (ii) the status of release of the medicinal products Rx or OTC; and (iii) information regarding the date when such have been made and their last review. These forms of advertising may contain the sale price or the estimate price of different forms of presentation and the conditions of compensation offered by the health insurance houses.

Additionally, any printed advertising materials for healthcare professionals must provide at least the following information: (i) the name of the medicinal product and the active substance (INN); (ii) the pharmaceutical form and concentration; (iii) the dosage for each manner/way of administration and for each therapeutic indication, as the case may be; (iv) the date of the first marketing authorisation or its renewal; (v) the other essential information from the summary of the product's characteristics; (vi) the last review of the text from the update of the summary of the product's characteristics; (vii) the mention "*this promotional material is intended for healthcare professionals*"; and (viii) the manner in which the medicine is to be released (Rx/OTC) and the type of the prescription. All such information must be printed using a font size of at least 10, regardless of the type of font.

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?

Making claims that a medicinal product does not have adverse effects, toxicity or dependency risks is prohibited, except where such are documented within the summary of the product's characteristics. Misleading healthcare professionals by stating or suggesting that a medicinal product is better or safer than another or risk free is also prohibited, except where such claim can be scientifically substantiated/documented within the summary of the product's characteristics.

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

Yes, such endorsements are not permitted under the legal provisions, as currently in force.

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?

The legislation as currently in force does not contain any specific provisions with respect to the above-mentioned aspects.

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?

According to the provisions of the Order 194/2015, comparative advertising of medicinal products for the general public is prohibited.

The comparative advertising for healthcare professionals is prohibited if: (i) the comparison is misleading; (ii) the trademark name of a competitor is used (only the use of INNs is allowed); (iii) the comparison involves medicines having different therapeutic indications or different pharmaceutical forms; (iv) one or more essential, relevant, verifiable and representative characteristics of a medicine, including the price, is/are not objectively compared; (v) the comparison creates confusion on the market between the advertiser and a competitor, or between different trademarks, INNs or other distinctive signs belonging to the advertiser and those belonging to a competitor; (vi) the trademark, INN, other distinctive signs, activities or other characteristics of a competitor are discredited or denigrated; and (vii) the reputation of a trademark, INN, distinctive signs or any other characteristics of a competitor is taken advantage of in an incorrect manner without having sufficient supporting evidence.

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

The same rules as in relation to advertising materials apply.

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?

No specific provisions are comprised within the legislation as currently in force regarding medicinal products as toward teaser advertisements. The same rules as for advertising materials apply.

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, samples may be offered to healthcare professionals with the observance of the legal provisions. Prior to offering the samples, an approval has to be obtained from ANMDM.

Samples are offered only as an exception to persons qualified to prescribe or distribute such products following a written, signed and dated request received from the healthcare professional. Each sample must mention that it is "*a free medical sample not intended for sale*" or a mention with the same sense, each of it must not be larger than the smallest form of presentation that is available on the market, it must be provided together with a copy of the summary of product's characteristics, the number of samples that is provided annually for each Rx being limited (for the treatment of 10 sick people). The companies that offer samples must have a strict system of control, evidence and accountancy. Provide samples of medicines that contain narcotic and psychotropic substances is prohibited within the sense of international conventions.

Samples cannot be offered for advertising purposes to the general public by the marketing authorisation holder, as well as to any entity or person that represent them or who act in their name based on a contract. It is also forbidden to offer samples for advertising purposes to the general public by companies with a commercial activity as purpose (pharmacies or third parties).

Also, samples cannot be offered directly to patients through publications sent directly or by post or by adding samples within the packaging of the publications, as well as the distribution of vouchers or tickets that allow free medicines to be obtained or at a discounted price.

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

It is forbidden to supply, offer or promise a gift, pecuniary advantage or benefit in nature to healthcare professionals in order for them to prescribe, purchase, supply, sell or administer a medicine.

It is, however, possible to supply or offer promotional items to healthcare professionals only of a small value (maximum RON 150, approximately 34 Euro, VAT included, before customisation) and which are relevant to practice medicine or pharmacy. The promotional items may be imprinted only with (i) the name and logo of the company, (ii) the name/INN/trademark of the medicine, and (iii) the concentration, pharmaceutical form of the medicine, and simple declaration of the indications to designate the therapeutic category of the medicine.

The ethics codes of different associations, like APMGR, give examples of items that can be offered to healthcare professionals, e.g. books and sources of reference, anatomical models, and other educational materials, etc.

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?

Goods and services may be offered to hospitals or organisations from the medical assistance field if (i) it is in the interest of patients, (ii) not conditioned on the prescription, encouraging the prescription of or the distribution of a certain medicine, and (iii) it must not refer to a medicine.

The ARPIM Ethics Code provides that donations or sponsorships for hospitals and clinics within the public health sector are allowed if they are comprised of medical or technical equipment of general use, or for renovation and adaptation of the hospital/clinic locations. This type of support must be strictly unconditioned (no prescriptions or other types of commitment should be performed in exchange) and it must be directly connected to the medical activities, and to be directly or indirectly in benefit of the patient. The donations must be specifically based on an unsolicited request from the respective organisation.

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?

Providing medical or educational goods and services to healthcare professional cannot, under any circumstance, be conditioned by the promotion, purchase, recommendation, prescription, distribution, administration or sale of medicines.

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 advertising legislation as currently in force in Romania does not have any specific provisions in relation to the offering of volume-related discounts to institutions purchasing medicinal products. The assessment will be made in practice on a case-by-case basis.

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?

Please refer to the answer to question 4.3 herein above.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

The advertising legislation regarding medicinal products does not contain any specific provisions in this respect.

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

Programmes initiated by holders of the marketing authorisation or their representatives with the purpose to offer sponsorship for scientific research activities, study visits, etc., are allowed provided that: (i) they do not involve elements with promotional character related to a medicinal product; and (ii) they are not conditional on the prescription of a medicine or the inducement to prescribe a medicine.

ARPIM members may sponsor scientific or professional meetings, congresses, conferences, symposia, and other similar events in order to support the professional development of the healthcare professionals and to enhance their knowledge of the therapeutic areas in which they operate, provided that the following conditions are met: (i) relevant and clear medical/scientific educational/informational objectives are the principal focus of the event; (ii) sponsorship of an event and/or of a healthcare professional's attendance at an event is public information; (iii) sponsorship of the event or of the participation of healthcare professionals at an event must not be conditional to any obligation to promote, prescribe, recommend or purchase the products of the ARPIM member; (iv) the companies should follow the criteria that govern the selection and the sponsorship of healthcare professionals in order to participate at the events, as provided in the ARPIM Code or with respect to the ARPIM Code; and (v) organising any entertainment in subsidiary to an event, or sponsoring participation in entertainment during an event organised by any third party is prohibited.

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?

Hospitality to healthcare professionals is permitted in the context of scientific/professional events. The hospitality must be limited to the main purpose of the event, without being extended to other persons that are not part of the category of healthcare professionals or for which the scientific field that makes the object of the meeting does not have professional relevance. At commercial promotional events, hospitality is limited strictly to its main purpose and it is not extended to people other than healthcare professionals.

Qualified persons to prescribe or distribute such medicines must not request or accept any incentive that is contrary to legal provisions.

In relation to events outside Romania, the ARPIM code of conduct prohibits any ARPIM member from organising or sponsoring an event that takes place outside Romania, with the following exceptions: (i) if it makes greater logistical sense to hold the event in another country due to the countries of origin of most invitees; or (ii) given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

The maximum limits for hospitality expenses provided by ARPIM Ethics Code are: **Airline travel** (both domestic and abroad): economy (coach) class. Business class or above is not allowed; **Hotel accommodation** (domestic) maximum budget (incl. VAT): RON 675 per night, breakfast included, in Bucharest, (approximately 150 Euro) and **RON 520** per night, breakfast included, outside Bucharest (approximately 115 Euro); **Meals**: for domestic meals, the maximum limit is **RON 300** per day for every person (coffee-break included), when the hospitality includes lunch, dinner and coffee-breaks, (approximately 67 Euro) or **RON 150** per person, when the hospitality includes only one main meal (approximately 34 Euro). This limit does not apply for an "*official dinner*" organised as part of the international congresses (as described in the documentation of the event).

In countries – "host countries" – where local provisions do not set a limit for meals the maximum limit is **150 Euro** per day (or the relevant equivalent) for lunch plus dinner.

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?

Speakers' services agreements may be concluded with healthcare professionals. The ARPIM Ethics Code provides a total value for fees for lecturing services of maximum 500 Euro per activities and event-day, depending on the lecturer's expertise and educational degree. The fee should be reasonable as per the usual market value. Pursuant to the ARPIM Code of Ethics, as well as APMGR Code of Ethics, it is possible to pay hospitality expenses for airline travel (both domestic and abroad, only economy class), hotel accommodation (domestic, up to four stars), and meals to a healthcare professional in relation to its attendance of a scientific meeting.

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?

This is assessed on a case-by-case basis. If in breach of the legal provisions, it is possible for the company to be sanctioned.

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, it is possible to pay reasonable compensations to healthcare professionals for such services, including travel expenses, meals and accommodation, with the observance of the legal provisions, as in force.

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

Yes, healthcare professionals may be paid in order to take part in observational studies, provided that the remuneration is reasonable and reflects the fair market value of the performed work.

A written study plan (protocol) and a written contract must exist between the healthcare professionals and/or the institutes where the study takes place and the company sponsoring the study. The study protocol must be approved by the company's scientific unit, which will supervise the study.

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

Please refer to the answer to question 2.7 herein above.

6 Advertising to the General Public

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

Yes, OTC products may be advertised to the general public, provided that a marketing authorisation for that medicine exists. All the advertising and educational materials for the general public are subject to approval from ANMDM and the visa granted by ANMDM in this sense must be placed on their product as well as the date when such was granted.

Advertising the following are prohibited to the general public: (i) Rx products; (ii) medicinal products that do not have a valid marketing authorisation; (iii) those that contain narcotic and psychotropic substances within the sense of international conventions; and (iv) are prescribed and released within the healthcare system, except for the vaccination campaigns performed by the pharma industry and approved by the Ministry of Health.

Medicines cannot be distributed directly to the general public by manufacturers for advertising purposes.

Also, advertising to the general public through social media and mobile applications is forbidden.

Any form of advertising to the general public must be conceived in order to reveal in an obvious manner its promotional character and the product has to be clearly identified as a medicinal product and it has to include at least the following information: (i) name of the medicine, as well as the INN, where the medicine has only one active substance; (ii) the necessary information for the correct use of the medicine (therapeutic indication(s)/daily recommended dosage in accordance with the therapeutic indication(s) to which reference is made); (iii) an explicit and legible invitation to read carefully the instructions from the prospectus or from the exterior package drafted in accordance with the legal provisions; and (iv) reminder materials must include the name of the medicine and the invitation to read the instructions from the prospectus or the exterior package, as the case may be.

It is forbidden to advertise to the general public therapeutic indications for tuberculosis, STIs, severe infectious diseases, cancer and other tumour diseases, chronic insomnia, diabetes and metabolic diseases.

Also, advertising medicines to the general public whose cost is reimbursed or compensated is forbidden.

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

No, it is not.

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?

Campaigns intended to raise awareness on certain diseases are encouraged, as long as the campaign materials do not contain, directly or indirectly, any promotional messages for a medicine, and it does not encourage excessive consumption or abusive use of medicines. It is prohibited to promote messages that reduce the therapeutic range of the said disease and it should be made clear that the therapeutic decision belongs to the doctor. Such campaigns have to be approved by ANMDM.

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

No, it is not possible.

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

No specific rules are provided in this sense by the advertising legislation as currently in force in Romania. General rules apply.

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

The general rules regarding advertising apply. The meeting cannot make reference to a specific medicine. Any costs incurred for patient organisations need to be declared to ANMDM according to the transparency rules, as currently in force.

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?

Yes, but all promotional items offered to the general public must be associated only with OTCs, promoting health and must be inexpensive.

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?

According to the legislation as currently in force, clinical trials have to be prior authorised by ANMDM, while the non-interventional ones need to be notified with ANMDM. When submitting the application for approval, a detailed presentation and documentation of the clinical trial have to be provided. When the study is completed, it must be notified to ANMDM together with the results.

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, what information should be disclosed, from what date and how?

Yes, the manufacturers, the holders of the marketing authorisation or their representatives in Romania as well as the wholesale and retail distributors of medicines have to declare to ANMDM, before March 31st of each year, all the sponsorship activities, as well as any expenses incurred in the year prior to the declaration, for healthcare professionals, professionals organisations, patients' organisations and any other type of organisation that carries out activities regarding human health, medical or pharmaceutical assistance. The same obligation exists for the beneficiaries. Order 194/2015 contains the standard forms for this declaration which are published on ANMDM's website.

Also, companies involved in educational or informative programmes have to make their involvement public.

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, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Companies that are members of associations like ARPIM and APMGR have to make information public about transfers of value, e.g. sponsorships, donations, grants, to healthcare professionals, hospitals, patients' organisations, etc.

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?

This is a legal obligation for the company, irrespective of what the healthcare professional agrees or not. Otherwise the company will be sanctioned. The same obligation exists for the healthcare professionals.

8 The Internet

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

Advertising on the internet must be submitted to ANMDM for approval. ANMDM is an active authority in the field of supervision and monitoring of advertising of medicines.

Any website page must contain at least the following information: (i) the identity and physical and electronic address of the website's sponsor(s); (ii) complete references for the source(s) of all medical information included in the website page; (iii) target audience; (iv) the number and date of issuing for the approval visa from ANMDM; (v) aspects that may be of interest for investors, media channels, and for the general public, including financial data, description of research and development programs, the company's products, discussions regarding the regulations that affect the company and its products, information for future employees; (vi) non-promotional information on health education, characteristics of the disease, prevention methods, screening and treatment, as well as any other information with the intention to promote public health. These may refer to existent medical therapeutic options, under the condition to be balanced and exact; (vii) relevant matters on therapeutic alternatives which do not require medicines, including, if the case, surgery, diet, behaviour change; (viii) the latest approved information, prospectus and summary of the product's characteristics of the advertised medicines; (ix) non-promotional aspects for patients and the general public regarding the OTC from the company's portfolio; (x) links to a public evaluation report issued by the Committee for Medicinal Products for Human Use of the European Medicines Agency or by a relevant national authority; and (xi) recommendation for visitors to seek the advice of a healthcare professional for additional information.

This information needs to be updated each time there are significant changes to the marketing authorisation and/or medical practice and are subject to approval by ANMDM. It has to be displayed in a clear manner on each page and/or subject, as applicable, the most recent date when the information was updated.

Advertising medicines to the general public on social media, through e-mail or mobile phones (SMS) is strictly prohibited.

The websites need to comply with the privacy legal provisions.

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 websites for healthcare professionals where Rx products are presented needs to be restricted by means of a valid and verifiable password-based system.

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

The ARPIM Ethics Code provides that links may be established with 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. The 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.

Member companies of APMGR should not develop links from websites accessible to the general public to company-sponsored websites that are designed for healthcare professionals. If the websites include links designed for users from other countries, the Romanian users must be specifically informed in this respect.

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

The information placed by a company on its website intended for the general public must not promote Rx products.

Please refer to answer to question 8.1 herein above.

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

Companies are prohibited from using social media to advertise medicines to the general public.

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?

By the end of 2015, despite the opposition from both the media and pharma industry as well as of the Government, the Parliament has adopted a new law that modifies that Audiovisual as well as the Advertising Law, which more or less prohibits the advertising of medicinal products on TV and on the radio as well as imposing very restrictive advertising of pharmacies. The law is not yet in force as the President has sent it back to the Parliament for further review.

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

Please refer to the answer to question 9.1 herein above.

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

Yes, the authorities that investigate anticorruption crimes have made several investigations in relation to different companies from the pharma sector in the last year or so, especially in relation to granting sponsorships to healthcare professionals.

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A licensed European trademark and design attorney, Delia is a member of the Romanian National Chamber of Industrial Property Attorneys and of the Bucharest Bar. Her professional affiliations include, among others, The Global Advertising Lawyers Alliance and The European Communities Trade Mark Association (ECTA) where she is the vice-chair of the Internet Committee.

WTR 1000 ranked Delia in its 2015 and 2016 editions as a Leading Trademark Professional (Silver Band). She is also recommended by Managing Intellectual Property as an IP Star both in the 2014 and 2015 edition.

Delia provides assistance in the Pharmaceutical and Health Care, with a wide experience in various legal and regulatory matters such as biotechnology, donation of medicinal products for compassionate use, clinical trials, claw back, pricing, reimbursement, anticorruption, contracts, drafting and revising marketing and advertising policies.

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