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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2013

10th Edition

A practical cross-border insight into pharmaceutical advertising

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The International Comparative Legal Guide to: Pharmaceutical Advertising 2013

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Penny Smale

Group Consulting Editor
Alan Falach

Group Publisher
Richard Firth

Published by
Global Legal Group Ltd.
59 Tanner Street
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Tel: +44 20 7367 0720
Fax: +44 20 7407 5255
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Slovenia

Kirm Perpar law firm Ltd.

Andrej Kirm

1 General - Medicinal Products

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

Advertising of medicinal products is regulated in the Medicinal Product Act (Official Gazette of the Republic of Slovenia nr. 31/06 and 45/08, hereinafter: MPA). More detailed provisions are contained in the Rules on advertising of medicines (Official Gazette nr. 105/2008 and 105/2010, hereinafter: Rules). Indirectly, the Consumer Protection Act, the Consumer Protection against Unfair Commercial Practices Act, the Media Act, and the Protection of Competition Act also regulate the subject matter.

The soft law governing the advertising of medicinal products in Slovenia consists primarily of the Code of Practice for Advising, Introducing and Informing on Prescription Medicines adopted by the forum of international research and development pharmaceutical companies, EIG – hereinafter: FIRDPC, the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Associations (adopted by FIRDPC), and Slovenian Advertising Code adopted by Slovenian Advertising Chamber.

1.2 How is "advertising" defined?

Article 85 of MPA defines advertising of medicinal products as all forms of informing including "door-to-door" propaganda or encouraging which is intended for promotion, issuing, selling or use of the medicinal product.

MPA differs between:

a) advertising to the general public (Article 87 of the MPA); and

b) advertising to the professional public (Article 88 of the MPA).

Rules define "advertising" in Article 2 – this definition is virtually the same as the definition from MPA and also differs among advertising in the general public and advertising in the professional public.

The general public is defined as the groups of laypersons and individuals that do not belong to the professional public as defined in the Rules. The professional public are persons authorised for prescription and issuing of medicinal products.

Advertising to the general public is generally described as any promotional form or method of informing of individuals and laypersons, whereas advertising to the professional public is more strictly delimited as: 1) informing the persons authorised for prescription and issuing of the medicinal products, with the characteristics and effects of medicinal products; 2) funding and organisation of promotional meetings attended by professional public; 3) funding and organisation of scientific congresses, attended by professional public; 4) supplying of samples in accordance with the Rules (see further sections); and 5) stimulating prescribing or issuing by promising or offering financial or material benefits according to the Rules.

The following does, on the other hand, not constitute advertising according to the Rules: 1) package and package leaflet, approved by marketing authorisation; 2) informative publications with regard to the approved package changes, warnings of side effects and other precautionary measures to ensure safer and more efficient administration of a medicinal product; 3) sales catalogues and price lists which do not include characteristics of a medicinal product; 4) correspondence about specific questions regarding a certain medicinal product, including contained material of non-promotional nature; 5) publications and material of the institution, authorised for preparation of the programmes for prevention, control, elimination and eradication of infectious diseases about the vaccination against individual diseases, in which no specific vaccine is mentioned, and neither its effect nor other specific characteristics; and 6) information regarding health or diseases, provided that no direction is given towards a medicinal product. Information should be qualitative, objective, unambiguous, integral and balanced and should not contain direct or indirect advertising.

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?

Holder of the marketing authorisation for a medicinal product must organise and establish an expert service for preparation of information regarding the medicinal product. The responsible person of such service is liable for:

a) accessibility of certain information related to the advertising of medicinal products to the competent authority (Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia);

b) preparing of evidences on submitting samples of medicinal products;

c) assuring that provisions of legislation in force related to the advertising of medicinal products are respected;

d) supervising of capability of personnel to provide accurate and complete professional information on medicinal products and on respecting of Rules by such personnel;

e) submitting of information related to the advertising of

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medicinal products to the competent authority if so requested by competent authority; and

f) assuring that the decisions of the competent authority are respected and enforced immediately.

In addition, the recent amendment of the Rules, which were passed in December 2010 and came into force in January 2011, require from the holder of the marketing authorisation for a medicinal product:

a) to establish evidence of personnel who advertise medicinal products with direct informing of the persons authorised for prescribing or issuing of medicinal products; and

b) to inform the competent authority (i.e. Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia) of the evidence from the previous bullet point, and of the level of education of its the personnel listed in the evidence.

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?

MPA and Rules do not require standard operating procedures related to advertising activities. However such SOPs would be useful for defining obligations of service discussed under question 1.3. It would be useful to prepare such SOPs which would define obligations related to the advertising of specific medicinal products and modalities of such advertising (e.g. definition and special requirements that shall be fulfilled in case of advertising in general public, and advertising of medicinal products in professional public).

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?

Generally, advertising does not need to be approved in advance. According to the Rules, advertising of non-prescription medicinal products is possible in the general public only in case if such advertising is foreseen in marketing authorisation for the medicinal product. In this case, issuing of advertising of non-prescription medicinal product is discussed in the process of obtaining authorisation for marketing of non-prescription medicinal product.

Specific authorisation in advance is requested for advertising of vaccines. Such authorisation for advertising should be acquired from the competent authority, i.e. the Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia. Rules on administrative procedure regulate procedure for obtaining such authorisation. The competent authority must decide on the requested authorisation of advertising of medicinal products within 60 days after receipt of the complete request.

It is necessary to highlight that the advertising of medicinal products is in some cases (especially in case of prescription medicinal products) regulated specifically and partially prohibited as discussed in other parts of this chapter.

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?

Prohibition of further publication is possible according to Article 32 of the Inspection Act (Official Gazette nr. 43/2007, officially consolidated text, hereinafter: IA). Pharmaceutical supervisors are authorised for issuing such decisions. The supervisor can also impose fines according to the MPA.

According to Article 30 of IA, appeal against decision of the supervisor is possible, but does generally not suspend the enforcement of such decision.

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?

According to MPA a fine in the amount from EUR 8,000.00 to EUR 120,000.00 can be imposed to the advertiser in case of an infringement of the legislation on advertising of medicinal products. Additionally, a fine ranging from EUR 400.00 to EUR 4,000.00 can be imposed to the responsible person of the advertiser. Advertiser and responsible person of the advertiser are liable for compliance of the advertising with the legislation in force. Usually disputes among pharmaceutical companies are not resolved by the court, but in alternative dispute resolution procedures, by non-government institutions (e.g. procedures in front of the Forum of international research and development pharmaceutical companies, EIG – hereinafter: FIRDPC).

We are not aware of any important examples of the court procedures against pharmaceutical companies which would be connected to the advertising of medicinal products.

Advertising of medicinal products against legislation in force in most cases also constitutes an act of unfair competition. In such case, competitors have the option to file an action in front of the competent court according to the Protection of Competition Act. Other procedures, such as procedures related to the infringements of the intellectual property rights can be started if unlawful advertising would also infringe the said rights.

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?

Decisions of the self-regulatory body (e.g. FIRDPC) can be used as the source for investigating certain advertising of medicinal products by the competent authorities. However, decisions of the self-regulating bodies do not necessarily prejudice decisions of the competent authorities. Such decisions can be used just as the evidence on alleged infringements, but in general, it cannot be accepted as key evidence. In practice, procedures due to the unlawful advertising of medicinal products are started in other manners and not after decisions of self-regulatory bodies.

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?

As partly discussed above, acts of unfair competition can be a base for filing action according to the Protection of Competition Act.

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Generally such actions would be tort actions and would be filed by the competitor who is claiming that acts of unfair competition caused/could cause damage to him. Prohibition of certain activities can also be requested in front of the competent court.

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)?

The Medicinal Product Act states that advertising is only allowed for medicinal products which obtained marketing authorisation. Information regarding unauthorised medicinal products to health professionals can only be available when such information does not constitute advertisement (see definition of advertisement in under question 1.2). As scientific meetings are not regulated separately, the answer can only be given on a case-by-case basis, taking into regard whether a particular action or passing of information constitutes advertising.

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

Information on unauthorised medicines is not allowed to be published in all cases where such publication would constitute advertising (see definition of advertisement under question 1.2). It is important to note that the definition of advertising is quite broad.

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

Please see answers to questions 2.1 and 2.2.

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

Please see answers to questions 2.1 and 2.2.

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 Slovenia?

The Rules on advertising of medicines expressly enumerate acts, which do not fall within the ambit of the definition of advertising of medicines. The relevant regulation determines that sales catalogues and pricelists do not constitute advertising of medicinal products, provided that they do not include statements regarding the properties of such products.

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

Please see the answers to questions 2.1 and 2.2.

2.7 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?

This topic is not regulated by the law, and no guidelines have been issued on the topic either. In involving health professionals in market research activities, prohibition of advertising of unauthorised medicinal products needs to be taken into regard (see the answer to question 2.1).

The Code of Practice for Advising, Introducing and Informing on Prescription Medicines allows the use of health professionals as consultants and advisors for participation in market research in cases when such participation involves remuneration and/or travel. The Code provides further criteria for such engagements. Among others, the engagement of a health professional should not induce recommendation, prescription, purchase, supply, sales or administration of a particular medicinal product.

3 Advertisements to Health Professionals

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

According to Article 16 of the Rules, material used for advertising in the professional public should bear the text "For professional public only". In case of advertising with direct informing, such information provided to the professionals shall include, according to Article 18 of the Rules, the following information: name of the medicinal product; basic information from summary on main characteristics of the medicinal product (i.e. composition of a medicinal product, instruction on dosage and use, therapeutic indications, contraindications and interactions, etc.); modality and regime of prescription; and issuing of the medicinal product and date of the preparation of the information. Such information may include also information on payer for medicinal product or information on listing the medicinal product on an according list.

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

Generally, each individual element of a pharmaceutical advertisement must comply with the certified summary of product characteristics and all characteristics must be presented in a balanced manner. The information that may appear in the advertisement must be presented objectively, without exaggeration of the individual properties pertaining to the pharmaceutical product. Further, the information may not be misleading with regards to the benefits and potential risks associated with the advertised pharmaceutical product.

Article 15 of the Rules on advertising of medicines expressly outlines the following restrictions on the information that may appear in the advertisement: a) advertising shall not encourage the belief that consultation with a doctor is not necessary; b) advertising

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shall not indicate that human health can be improved only with consumption of a medicinal product; c) advertising shall not indicate that positive effects of medicinal products are certain, that there are no side-effects and that the medicine is superior to other medicines; d) advertising shall not be targeted at children; e) advertising shall not imply that the health of people or animals can deteriorate without the intake of the advertised medicine (certain exceptions to this general rule do apply); f) advertising shall not refer to the recommendation of scientists, experts from the field of human or veterinary medicine or other publicly known people, who would due to their medical influence, encourage the use of medicines; g) advertising shall not imply that the medicinal product is a food, cosmetic or other consumer product; h) shall not imply that the effectiveness and safety of a medicine is a result of its natural origins; i) the advertisement shall not include information or a description which could result in an incorrect self-diagnosis; j) use of inappropriate upsetting or misleading expressions regarding the possibility of recovering is prohibited; and k) it is prohibited to use inappropriate, misleading terms or terms that give rise to concern, images which present changes in human or animal bodies, which were caused as a result of a disease or injury, or the effects of a drug on the person's or animal's body or parts of the body.

Given the fact that each individual element of a pharmaceutical advertisement must comply with the certified summary of product characteristics, an advertisement generally may not refer to studies not in the SmPC.

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

According to Article 15 of the Rules (this Article applies only for advertising of medicinal products in the general public), advertising of non-prescription medicinal products shall not bear information which refers to the recommendations of scientists, experts from the field of human or veterinary medicine or publicly known persons which could, due to the media influence of such persons, encourage the use of medicinal products. A similar provision is also in Article 87 of MPA. Hypothetically, such endorsements could be enlisted in the promotional materials used for advertising in the professional public.

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

Such "head to head" trials are not required by the legislation in force. However, such trials may be useful in order to prove that comparative advertising is not misleading and that all requirements from the legislation in force are fulfilled.

3.5 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 Slovenia?

Comparative advertising is not regulated specifically in the case of advertising medicinal products. Article 12.c of the Consumers Protection Act (Official Gazette of the Republic of Slovenia nr. 20/1998; 25/1998; 23/1999; 110/2002; 14/2003-UPB1; 51/2004; 98/2004-UPB2; 46/2006; 126/2007 and 86/2009) which generally regulates comparator advertising must be respected in this case. It is permitted to use another company's brand name as part of the comparison. Such advertising should not be misleading, should compare true information on compared medicinal products, should be objective and should not create confusion on the market. Enlisted are basic requirements related to the comparator advertising from the said act. Since Article 6 of the Rules prohibits the advertising of medicinal products for which authorisation for marketing was not issued, it would not be possible to refer a non-authorised competitor's product.

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

Distribution of scientific papers is regulated in Article 88 of MPA. Promotional meetings are regulated in Article 21 of the Rules. According to MPA, promotional meetings shall be strictly limited to the professional purpose which is in acquiring additional knowledge on new medicinal products. Only personnel authorised for prescription and issuing of medicinal products shall attend to such promotional meetings.

According to Article 17 of the Rules, it is possible to advertise medicinal products with authorisation for marketing in professional books, professional papers and in other professional publications. Article 18 of the Rules regulates advertising with direct informing of persons that are authorised to prescribe and issue medicinal products. Some special requirements shall be met in case of such advertising with direct informing. Direct informing of said personnel is permitted also via visits of professional personnel. The professional personnel must comply with the requirements of the Rules regarding their level and type of their education. Visits to the doctor may only be exercised in the time which is intended for the preparation for work and which is not intended for dealing with the patients. The latter limitation only applies for promotional visits in the public healthcare network.

3.7 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)?

"Teasers" are not specifically prohibited. They would be generally understood as advertising of medicinal products. Consequently, all rules on advertising of medicinal products (advertising of prescription medicinal products, permitted advertising in general public, permitted advertising in professional public, etc.) must be respected. If said criteria are not met, "teasers" shall constitute unlawful 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?

Provision of samples of products is exceptionally allowed to the persons responsible for prescribing and supplying of medicinal products, with the intention to inform the patients of the new method of administration of a medicinal product, provided the following conditions are met:

- a medicinal product is not intended for peroral use;
- a medicinal product has marketing authorisation;
- no more than two years have passed since the acquisition of the marketing authorisation or approval of the marketing authorisation;

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- the number of samples of each medicinal product for each authorised person for prescribing medicinal products is limited to up to 30 defined daily doses per year;
- the recepient has applied for free samples in writing; the application must be signed and dated;
- the recepient must keep a register of received samples;
- the recepient must not sell the received samples;
- the producers of medicinal products or representatives of producers must keep records and have estalblished control over free samples;
- samples must be in the smallest packaging available;
- each sample must be in a packaging with the leaflet instruction enclosed, approved with marketing authorisation and labelled as a free sample not intended for sale;
- to each sample an approved summary of medicinal product characterisctics must be enclosed; and
- sample must not contain narcotic or psychotropic substances.

Submitting samples which require special storage conditions (such as a cold chain) is prohibited.

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

Granting, offering or promising gifts, financial or material benefits to persons authorised for perscribing or issuing of medicinal products is generally prohibited. Granting of gifts is allowed only when they are of a small value and can be used in practicing medical, veterinary or pharmaceutical activity. The definition of small value from rules applying for public officials is used. The said rules allow gifts not exceeding the value of EUR 62.59 per individual gift and altogether not exceeding EUR 125.19 per year, when gifts are received from the same person.

The Code of Practice for Advising, Introducing and Informing on Prescription Medicines stipulates that the gifts may only include the name and logo of the company, and the name of the medicinal product or its international non-proprietary name, or the trademark. Gifts for the personal benefit of healthcare professionals (and not relating to the practice of medical, veterinary or pharmaceutical activity) are prohibited.

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 medicinal or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

Gifts or donations to institutions, in the form of money or equipment, are generally not prohibited and are not specifically regulated. Donations which would constitute unlawful medicinal product advertising are prohibited – see preceding sections regarding advertising of medicinal products.

The Slovenian commission for prevention of corruption has, in December 2009, adopted an opinion that the act of pharmaceutical company granting a donation informing the recepient of the donation that the donation is to be used for specific medical personnel (appointed by names of the personnel), fits the definition of corruption. Such forms of donations, where the company granting a donation would have the option of selecting who the end beneficiaries would be, should thus be avoided. Certain Slovenian health institutions have already incorporated the said opinion into their internal rules.

4.4 Is it possible to provide medicinal 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?

Regarding provision of goods (gifts) to medical personnel, please see question 4.1.

Educational and promotional events are allowed provided that they are strictly limited to the professional purpose of the meeting, which is in expanding knowledge regarding new medicinal products. Only persons authorised for prescribing of medicinal products may attend such events.

Educational services that would not comply with the above requirement (i.e. limitation of the event on expanding knowledge regarding new medicinal products) and which would focus or give incentive on changing the prescribing patterns, would in any case not be allowed.

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?

Rules on advertising and inducements do not govern the topic of volume-related discounts. When offering or granting volume related discounts, competition law rules should be observed specifically.

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

Provision or payment of additional medicinal or technical services or equipment, depending on the purchase of medicinal products, is not generally prohibited. Transactions which would give incentive to unlawful medicinal product advertising are prohibited – see preceding sections regarding advertising of medicinal products. Rules on public procurement should in any case be observed.

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?

This is not regulated by legislation. A refund scheme would, therefore, generally be possible.

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

Pharmaceutical companies may sponsor educational events provided that such event is strictly limited to the professional purpose of the meeting, i.e. to expand knowledge of participants regarding new medicinal products. Only persons authorised for prescribing of medicinal products may attend such events. Educational services that do not comply with the above requirement and which would focus or give incentive on changing the prescribing patterns, would in any case not be allowed. See also question 4.4.

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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 offering of hospitality to health professionals is regulated by the MPA, the Rules, and further in the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Associations and in the Code of Practice for Advising, Introducing and Informing on Prescription Medicines.

The Rules stipulate that the hospitality at promotional events and meetings should be moderate in scale and secondary to the main purpose of the meeting. It may not involve persons not authorised for prescribing medicinal products.

The Code of Practice on Relationships between the Pharmaceutical Industry and Patient Associations stipulates that any promotional, professional or scientific events, sponsored by a company, should be held in an appropriate venue that is conductive to the main purpose of the event and may offer hospitality only when appropriate. No company should organise or sponsor an event outside its home country unless most of the persons invited are from outside its home country or it makes greater logistical sense to hold the event in another country (taking into account the relevant source or expertise that is subject matter to the event).

As a general rule, the hospitality provided must not exceed what healthcare professional recipients would normally be prepared to pay for themselves. A healthcare professional must not be provided or paid for any independent entertainment and other interest or sociable activity. Moderate (simple) entertainment (when a company organises an event and provides refreshments and/or meals), e.g. lunch or dinner, background music or local performers is allowed. Nevertheless, this does not mean that a company can finance the participation of healthcare professionals in an independent concert of such same local group, since in such case the event would not be "of secondary importance" compared to refreshments and/or meals. Moderate (simple) entertainment can be understood as prohibition to invite famous and expensive performers, e.g. a T.V. celebrity or popstar, while local performers, players, actors are acceptable at meetings, which is of secondary importance compared to refreshments and/or meals. Hospitality shall not include sponsoring or organising entertainment (e.g. sporting or leisure) events. Companies should avoid using venues that are renowned for their entertainment facilities.

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?

Regarding provision of goods (gifts) to medical personnel, please see question 4.1.

The Codes of Practice state that hospitality in connection with scientific meetings or events should be limited to travel, meals, accommodation and registration fees. All forms of hospitality provided by the pharmaceutical industry to patient organisations and their members should be reasonable in level and secondary to the main purpose of the event, whether the event is organised by the patient organisation or the pharmaceutical industry.

All events sponsored or organised by or on behalf of a company must be held in an appropriate venue that is conductive to the main purpose of the event. The organiser should, according to the Code of Practice, avoid those venues that are 'renowned' for their entertainment facilities or are 'extravagant'.

Paying health professionals for their time spent on such event could constitute granting financial or material benefit to a person authorised for prescribing or issuing of medicinal products, which is prohibited, and should thus be avoided (see also question 4.2).

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?

Violation of the Rules in relation to hospitality constitutes a misdemeanour, for which the company organising or sponsoring the event would be held responsible.

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

The practice of paying doctors to provide expert services on scientific or promotional events is not regulated by MPA or the Rules, and is therefore generally possible.

The Code of Practice for Advising, Introducing and Informing on Prescription Medicines specifically permits the use of healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or travel. The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all of the following criteria: (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, subject to clause (g) below, the basis for payment of those services; (b) legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants; (c) 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; (d) the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need; (e) the contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants; (f) the hiring of the healthcare professional to provide the relevant service may not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and (g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, fictitious consultancy arrangements should not be used to justify compensating healthcare professionals.

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

The practice of paying doctors to take part in post marketing surveillance would fall under the category of participation in market

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research, which is generally permitted by the Code of Practice for Advising, Introducing and Informing on Prescription Medicines. Criteria set forth in the Code of Practice should be fully observed (see question 5.4).

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

Such practice is generally possible. See also question 5.5.

5.7 Is there a requirement in law and/or self-regulatory code for companies to make publicly available information about donations, grants, benefits in kind or any other support provided by them to health professionals, patient groups or other institutions? If so, what information should be disclosed, from what date and how?

Regulations generally do not require that a privately owned company reports a donation, grant or benefit in kind made to health professionals, patient groups or other institutions. The obligation of reporting is generally imposed upon the recipient of support. The company is however obligated to submit all information connected to such support, upon the request of the Commission for the Prevention of Corruption within 15 days upon receipt of such a request.

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?

According to Article 87 of MPA, only advertising of non-prescription medicines is permitted to the general public.

Such advertising must be conducted in a way that it is clear that the message has an advertising nature and that the medicinal product is clearly identified as such. Required content of such advertising is specified in detail in Article 14 of the Rules (e.g. name of the medicinal product shall be enlisted, information necessary for efficient, correct and rational use of advertised medicinal product). Article 15 of the Rules expressly defines restrictions related to such kind of advertising. The most relevant restrictions from the said Article are: a) advertising shall not encourage the belief that consultation with a doctor is not necessary; b) advertising shall not indicate that human health can be improved only with consumption of a medicinal product; c) advertising shall not indicate that positive effects of medicinal products are certain; and d) advertising shall not be targeted at children. Only the most important restrictions are described above.

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

Such advertising is possible only in special cases provided certain conditions are met. According to Article 89 of MPA, competent ministry can exceptionally permit advertising in the media if such advertising is necessary for the public interest. Such advertising is generally possible in cases of an epidemic.

The competent authority can permit advertising of medicinal products which are used in vaccine programmes for the general public. If such advertising is permitted, all other restrictions, which are discussed in detail in other parts of this chapter, shall be respected.

Advertising of the vaccines (which is, as mentioned, permitted only under special conditions) is regulated in Articles 24 and 25 of the Rules. The competent authority can permit advertising of medicinal products which are used in vaccination programmes for the general public. Such advertisement must be equipped with the text "Before vaccination discussion on risks and undesirable effect shall be made with the doctor". In application for permission of such advertising, the advertiser shall present to the competent authority an accompanying letter, proposal of advertising materials with detailed explanation together with target groups, modality and the timeframe of advertising. A certificate on payment of administration fees must also be enclosed.

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 medicinal condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Please refer to question 6.2.

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

According to the MPA and the Rules, such press releases would be advertising and as such are generally prohibited unless special criteria, discussed in other sections of this chapter, are met. Content of such press releases shall be closely examined in each case. For example, if it could be proven that a press release does not promote prescription, issuing, selling and use of the medicinal products such as a press release would not fit the definition of advertising contained in the Rules and MPA. For example, it could be concluded with a high degree of probability that in case if some accusation related to the poor quality of medicinal product would be published in the media, a press release as a reaction to such publication would not be understood as advertising and would therefore be permitted.

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

If such description can be understood as the advertising of a medicinal product (refer to question 1.2 of this chapter), all requirements related to the advertising of medicinal product should be respected. Discussed question is not expressly regulated in the legislation in force.

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?

Legislation in force does not regulate this question. The code of conduct in relations between the pharmaceutical industry and patient organisations (hereinafter: Code) accepted by FIRDPC as act of self-regulation govern this field. As mentioned, this is a self-regulatory or a "soft law" act. According to the Code of FIRDPC, such relationships should be transparently regulated with written contract. Such donations should also be fully disclosed and presented in corporate reports.

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7 The Internet

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

Internet advertising is subject to the general rules of advertising of medicinal products, described in this chapter. Internet advertising shall be generally considered as advertising to the general public. In cases where mechanisms are used to allow only Internet access of health professionals, such advertising would fall under the category of advertising to the professional public.

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?

The question of website security is not regulated in our legislation. It is the responsibility of the website owner and/or advertiser to ensure the level of website security which only enables access of the professional public to its content.

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?

Any website provider is generally liable only for the content of the website he is providing. We see no legal basis or grounds for liability of a company for website content which is not under its direct or indirect control.

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

Rules on advertising for the general public fully apply. Please refer to the preceding sections of this chapter.

8 Developments in Pharmaceutical Advertising

8.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

The latest amendments of the Rules on advertising of medicines came into force in January 2011.

The major changes which were brought by the latest amendments are with regards to the advertising of medicinal products with direct information to the persons who are responsible for prescribing and dispensing medicines within the public health service network. Visits to the said persons (i.e. doctors) are now only allowed during the time of professional preparation for work which is not intended for work directly with patients. The holder of marketing authorisation must provide a list of personnel who will be carrying out the visits to the competent authority (Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia).

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

The Ministry of Health of the Republic of Slovenia prepared a draft of the new Medicinal Products Act, which is now in inter-ministerial coordination.

The Act will implement into the Slovenian law the provisions of:

- Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010, amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community Code relating to medicinal products for human use.
- Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.
- Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance.

The chapter about Pharmaceutical Advertising determines the rules regarding the advertising of medicinal products to the general public and to the professional public, the advertising in a state of emergency and the cases of exclusion from the extent of advertising. The Act initiates the Register of professional personnel for the Pharmaceutical Advertising to the professional public.

The main novelty of the Act is the newly established Register of professional personnel. The holders of the marketing authorisation shall be obligated to report to the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (hereinafter: JAZMP) the names of professional personnel who will be performing advertising of medicinal products. The Act also determines fines for the violation of this provision.

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

In the previous year, administrative inspectors have been largely relying on anonymous reports of infringements of advertising regulations pertaining to medicines. Enforcement trends have given rise to stricter enforcement via official reminders regarding infringements and penalties.

8.4 Has your national code been amended in order to implement the 2011 version of the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals and the 2011 EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011 and, if so, does the change go beyond the requirements of the EFPIA Codes or simply implement them without variation?

The Rules on advertising of medicines already largely incorporate Article 16 of the amended EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals. The Rules include stricter regulations as opposed to those included in the relevant Code. The Rules specifically limit the allocation of medical samples for the purpose of teaching the patient how to use the medicine. Pursuant to the Rules, a medical practitioner can receive only one sample per year, as opposed to four, stipulated in the Code. Further, the Code allows the receipt of samples for a period of two years after the practitioner first requested the sample, whereas the Rules provide for the same

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period, the duration of which runs from which marketing authorisation of the drug was issued. Other conditions, such as requesting samples in written format, establishing systems of accountability and labelling samples as such are included in the Rules.

Slovene regulations have not as yet implemented stricter regulations binding pharmaceutical companies with regards to the publication or availability of information regarding financial support rendered to patient organisations (Article 5 of the EFPIA Code on relationships between the pharmaceutical industry and patient organisations 2011), nor has it expressly implemented provisions of Articles 6 and 8 of the Code. The Rules do incorporate Article 8 of the Code, however purely with regards to educating individuals who are authorised to issue prescription medicine.

Andrej Kirm

Kirm Perpar law firm Ltd.
Poljanski nasip 6
Ljubljana
Slovenia

Tel: *+386 8 205 9221*
Fax: *+386 8 205 9220*
Email: *andrej.kirm@k-p.si*
URL: *www.k-p.si*

Andrej Kirm is a partner and attorney-at-law in Kirm Perpar law firm Ltd.
Andrej regularly advises clients in the pharmaceutical sector. Consulting often focuses on compliance and risk assessment of particular actions with Slovenian legislation, including regulations regarding advertising of medicinal products and medicinal devices. He has provided full legal support in several legal transactions in the pharmaceutical sector.
He appears as a lecturer on expert seminars and events and has authored several legal publications.

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GLG
Global Legal Group

59 Tanner Street, London SE1 3PL, United Kingdom
Tel: +44 20 7367 0720 / Fax: +44 20 7407 5255
Email: sales@glgroup.co.uk

www.iclg.co.uk