The International Comparative Legal Guide to:

Pharmaceutical Advertising 2019

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A practical cross-border insight into pharmaceutical advertising

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1 General – Medicinal Products

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

The advertising, and in general marketing of medical products in the Republic of North Macedonia is regulated by the Law on Medicinal Products and Medical Devices (Official Gazette of the Republic of Macedonia no. 38/2004 – as amended from time to time) and the Guidelines on the manner of advertising of medicinal products and medicinal devices (Official Gazette of the Republic of Macedonia no. 66/2008). However, the advertising of medical products shall also be in the line with the Law on Consumer Protection (Official Gazette of the Republic of Macedonia no. 106/2007 – as amended from time to time), the Law on Healthcare Protection (Official Gazette of the Republic of Macedonia no. 43/12– as amended from time to time), and the Code of professional ethical responsibilities and rights of healthcare professionals (HCPs) with a university degree in pharmacy (Official Gazette of the Republic of Macedonia no. 33/2014).

1.2 How is "advertising" defined?

The Law on Consumer Protection, as the general law that provides the general principles of advertising all kind of products that are placed on the market in North Macedonia, defines the advertising of products and services as any form of making a presentation related to a trade or business activity, craft or profession to promote the supply of products or services, including real estate, rights and obligations.

The Law on Medicinal Products and Medical Devices particularly defines the advertising of medicinal products as follows: "*Advertising of medicinal products shall mean any form of disseminating information in a written, picture, sound, oral, electronic, digital or any other form, directed to the general or professional public for the purpose of promoting prescription of medicinal products, stimulating dispense of medicinal products, their supply, sale and use*."

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

The Laws of North Macedonia do not prescribe an obligation for companies to have a special in-house unit/sector in charge of advertising. However, bearing in mind that advertising must be approved prior to publishing, all companies who are applicants for the purpose of advertising, must be in compliance with positive legislation governing the advertising of medicinal products and devices. Furthermore, if any advertisement is found to be in breach of legislation, such may be cancelled by the competent authorities, and sanctions may be applied to companies found to be in breach of positive legislation governing the advertisement of medicinal products and devices.

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

There are no specific mandatory requirements for companies to have SOPs governing advertising activities. The Guidelines on the manner of advertising of medicinal products and medicinal devices do, however, provide that advertising through the promotion of medicinal products and devices directed to the expert public shall be done by healthcare professionals who have medical, dental or pharmaceutical university degrees.

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?

In accordance with the Law on Medicinal Products and Medical Devices, marketing authorisation holders and manufacturers of medicinal products that are not subject to medical prescription, may inform the general public about the medicinal product characteristics in line with the summary of the product characteristics or patient manual, in an objective manner and upon prior approval from the Macedonian Agency for Medicines and Medical Devices. Advertising prescription-only medicine is prohibited. Advertising medical products and medical devices to the professional public is not subject to prior authorisation.

The Law and by-laws do not specifically prescribe the procedure for acquiring advertising approval.

The Macedonian Agency for Medicines and Medical Devices is the regulator that issues approvals for the advertisement of medicinal products and medicinal devices. The Macedonian Agency for Medicines and Medical Devices practice in approving advertising of medical products shows that the company shall require prior approval for each advertisement, and for each medium separately

(newspapers, TV commercials, online advertisements, etc.). To acquire approval to place an advertisement, the applicant shall submit a written request indicating all data referring to the medical product/device in question, the type of medium to be used and type of advert to be placed, as well as the proposed text of the advertisement itself. In addition to the request, the applicant shall provide the marketing authorisation for the product/device in question, and the SmPC, as well as the patient manual. The Agency has prescribed administrative fees for the purpose of acquiring approval for advertising depending on the type of advertisement and medium.

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?

Pharmaceutical inspectors, during the supervision of medicinal products and devices, are entitled to prohibit any advertising of medicinal products which are inconsistent with the Law and to order the removal or destruction of the material used to advertise the medicinal product, as well as to ban any advertising of a medical device that is against the Law and to order the removal or destruction of a material used to advertise a medical device in a manner not corresponding to this Law.

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

Article 154 of the Law on Medicinal Products and Medical Devices prescribes a fine in the amount of EUR 50,000, and in MKD, a counter-value shall be imposed for committing a misdemeanour on a legal entity if it:

1) offers direct or indirect financial or material benefit to the persons who prescribe or administer the medicinal products;
2) advertises prescription medicinal products to the general public through the mass media;
3) advertises a medicinal product in a manner contrary to the Law, thus misleading the user;
4) publicly advertises medicinal products through addressing children;
5) publicly distributes free samples of medicinal products; and/or
6) publicly advertises medicinal products without a marketing authorisation.

A fine in the amount of 30% of the determined fine for the legal entity shall also be imposed on the responsible person in the legal entity for the misdemeanours referred to in this Article.

A fine in the amount of EUR 5,000 to MKD 7,500 in counter-value shall be given to the employee in their legal entity for having perpetrated this misdemeanour.

Furthermore, Article 155 of the Law prescribes a fine in the amount of EUR 30,000, and in MKD a counter-value shall be imposed for committing a misdemeanour on a legal entity if it:

1) advertises medicinal products or medical devices contrary to Article 92 of the Law (rules on advertising to medical professionals);
2) provides information about the goals stipulated in Article 93 paragraph 2 in a manner contrary to Article 93 paragraph 3 of the Law (enabling persons prescribing or dispensing medicinal products to acquire additional knowledge on new medicinal products in a manner exceeding the limit of the scientific and expert objectives of such education); and/or
3) fails to advertise the medicinal products according to Article 94 of the Law (informing the general public about the medicinal product characteristics which is not in line with the summary of product characteristics for the patient manual, or is not made in an objective manner and upon prior approval from the Macedonian Agency for Medicines and Medical Devices).

A fine in the amount of 30% of the determined fine for the legal entity shall also be given to the responsible person in the legal entity for the misdemeanours referred to in this Article.

A fine in the amount of EUR 3,000 to MKD 4,500 in counter value shall be imposed on the employee in the legal entity having perpetrated this misdemeanour.

With regard to the misdemeanours determined by this Law, the competent court shall conduct a misdemeanour procedure and impose misdemeanour sanctions. With regard to the misdemeanours laid down in Articles 154, 155, 155-a and 155-b of the Law, the pharmaceutical inspector shall be obliged to issue to the perpetrator of the misdemeanour a misdemeanour payment order, in accordance with the Law on Misdemeanours.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The competent authorities shall investigate matters constituting a breach of legislation, in accordance with their competences stipulated by law, regardless of whether such is already being assessed by a self-regulatory body. Authorities should take up matters based on adverse findings of self-regulatory bodies if such matters are in the scope of such authority competences.

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?

The Law against disloyal competition (Official Gazette of the Republic of Macedonia no. 80/99) prescribes measures against unfair competition. In accordance with the Law, should one, when conducting business, and for the purposes of the competition, act contrary to good business practices or contrary to the principle of conscientiousness and honesty, such person/entity will be prohibited by the competent court from further performing those acts and actions and will be liable for the damage such acts and actions caused, under conditions determined by the Law. A proposition may be filed with a competent court and such court may reach a decision barring the entity in breach of the legislation from undertaking activities as recognised in the breach. Furthermore, the fair competition is protected by the Law on the Protection of Competition, implementation of which is supervised by the Commission for protection of competitions of North Macedonia.

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)?

Article 95 of the Law on Medicinal Products and Medical Devices prescribes that it is prohibited to publicly advertise medicinal products that have no marketing authorisation. Further, advertising medicinal products that have no marketing authorisation shall be considered a misdemeanour in accordance with the Law.

In addition, the Guidelines on the manner of advertising of medicinal products and medicinal devices, adopted by the Minister of health, based on the Law on Medicinal Products and Medical Devices, prescribe that advertising shall be done through providing information on the medicinal products to medical professionals and the public by the holder of the marketing authorisation.

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

No, information may not be published for medicinal products that have no marketing authorisation, as described above in the answer to question 2.1.

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

No, it is not possible; please see the answers to questions 2.1 and 2.2 above.

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

No, it is not possible; please see the answers to questions 2.1 and 2.2 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?

Up to this point in time, the prohibition for providing any type of information regarding products lacking a marketing authorisation has not been lifted.

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?

There is no explicit provision in Macedonian legislation with regards to this. However, considering the definition of "advertising" as well as the prohibition of advertising unauthorised medicine, it should be expected that any such disbursement of information related to unauthorised medicine would be prohibited.

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 Law on Medicinal Products and Medical Devices does not strictly regulate the possibility for healthcare professionals to be engaged in market research exercises concerning possible launch materials for medicinal products or indications yet unauthorised. The Law on Healthcare Protection does, however, provide for the possibility for healthcare professionals to be engaged as consultants and advisors, individually or in a group, for the purpose of providing services as speakers or meeting chairpersons, participation in medical/scientific studies, clinical trials or training services, participation in advisory meetings and participation in market research. No specific guideline has been adopted for market research focusing on medicinal products.

3 Advertisements to Healthcare Professionals

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

Advertising medicinal products intended for medical professionals shall be done by marketing authorisation holders through advertisements placed in specialised literature, specialised periodically issued magazines and other specialised publications, as well as by the direct provision of information to the healthcare professionals who prescribe or dispense medicinal products.

Advertising prescription medicinal products to medical professionals shall only be allowed in terms of providing information in line with the summary of the product characteristics or concerning marketing conditions.

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?

In accordance with the Law on Medicinal Products and Medical Devices, advertising prescription medicinal products to medical professionals shall only be allowed in terms of providing information in line with the summary of the product characteristics or concerning marketing conditions.

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, the advertisement intended for the professional public is intended for the purposes of getting acquainted with the characteristics of the medicine, i.e. a

medical device, for the expert public to acquire knowledge about their therapeutic action.

If the advertisement is done through promotion of the medicine, i.e. the medical device, the holder of the authorisation must indicate the data on the date of obtaining the marketing authorisation or the date of the last change of the authorisation, and it must be updated, relevant and faithfully transmitted data indicating the correct source and literature from where the information was taken. In addition to this data, the promotion of the medicine, i.e. the medical device, may also include the sales data price of the medicinal product or medical device.

Regarding advertisements intended for the general public, such shall not contain any information referring to studies.

In accordance with the Guidelines, when advertising through promotion there should not be any:

1) encouragement to prescribe, issue, procure, recommend the use of or purchase of the medicine or medical device through offering and giving rewards in the form of money, gifts or giving and enabling any other kind of property and inadequate benefit, that is, to promise or give some privilege or award;
2) encouragement to the professional public that one medicine, i.e. a medical device, can be replaced by another medicine or medical device from the same therapeutic group, without clear medical treatment indications;
3) made allegations or conclusions about the action of the medicine, i.e. medical device subject to clinical trials in the country or abroad;
4) promotion of a medicine or medical device that is in the process of changing the summary report on the properties of the medicinal product and of the product user manual;
5) a use of the summary of product characteristics and guidelines for patients/users, in a text of which the font size is less than 3 mm, that is, to use another method of printing that disables easy reading and understanding of the text;
6) publishing of information through the media, which is used in the procedure for advertising of healthcare institutions, i.e. specialised stores;
7) reducing the significance of the warning about the measures of caution or adverse medicine reactions, respectively the medical device, specified in the approved summary or the product characteristics report, as well as the instructions for use;
8) reducing the therapeutic value of another medicine i.e. medical device, that has a marketing authorisation or in any other way, arouse doubt in the value of another medicine or medical device;
9) use of the Ministry of Health, the Macedonian Agency for Medicines and Medical Devices, i.e. other persons participating in the examination procedure and placing the medicine or medical device on the market;
10) use of materials that are protected by any form of protection of intellectual property without prior consent of the owner of such rights;
11) use of postcards or other forms of written consignments of which the content may be available or readable to others other than the professional public; and
12) use of telephone, fax, e-mail or other electronic media of persons who belong to the ranks of the expert public without their clearly expressed prior consent, and who in such way are advertised or informed in their work.

When promoting a medicine or medical device by the holder of the authorisation, money or any other kind of benefit should not be offered to the expert public in order to encourage the prescribing, issuing, purchasing, or consumption of medicine or medical devices.

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

The Law on Medicinal Products and Medical Devices does not expressly prescribe any restrictions as to the inclusion of endorsements by healthcare professionals in promotional materials. It should, however, be noted that the Guidelines on the manner of advertising of medicinal products and medicinal devices stipulates that when advertising to the general public, recommendations made by a person who because of their popularity can affect the use of the medicine, i.e. the medical device, should not be used (the Guidelines do not specify which persons shall be considered popular in light of this).

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 Law on Medicinal Products and Medical Devices generally prohibits comparing medicinal products and devices with other medicinal products and devices when advertising.

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?

In accordance with the provisions of the Law on Medicinal Products and Medical Devices, it shall be prohibited to publicly advertise a medicinal product by associating it with the characteristics it lacks, overstating its positive effects, exaggerating and describing the effects of the medicinal product in an inappropriate manner, **comparing it with other medicinal products** or misleading medicinal product users in any other way. In addition, the Law prescribes that it shall be prohibited to publicly advertise medicinal products that have no marketing authorisation.

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

There are no special rules that govern the distribution of scientific papers as of this moment. In terms of pharmaceutical advertising, such advertising directed to healthcare professionals can be done in accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices through promotion and informing health professionals who prescribe medicinal products and devices, in professional magazines and other forms of promotion as well as sponsoring scientific and promotional gatherings for the expert public. Such advertising shall be done for the purpose of getting acquainted with the characteristics of the medicinal products or devices, and for the expert public to acquire knowledge about such products'/devices' therapeutic action.

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?

Laws governing the advertisement of medicines and medical devices do not *per se* regulate "teaser" advertisements, thus "teaser"

advertisements are not explicitly prohibited. However, it should be noted that all advertisements must contain the minimum information as stipulated within the Guidelines on the manner of advertising of medicinal products and medicinal devices and should be in compliance with the general rules for advertising as provided by the Law on Medicinal Products and Medical Devices.

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

According to the Guidelines on the manner of advertising medicinal products and medicinal devices, the advertisement of medicine and medical devices shall be in accordance with the approved patient manual and summary of product characteristics.

Furthermore, Article 92 of the Law on Medicinal Products and Medical Devices prescribes that advertising medicinal products subject to medical prescription, intended for medical professionals shall only be allowed in terms of providing information in line with the summary of the product characteristics or concerning marketing conditions. Advertising contrary to the provision of Article 92 shall be considered a breach of legislation and can incur a penalty in the amount of EUR 30,000, and in MKD a counter-value shall be imposed for a misdemeanour on the legal entity in breach of this provision and a penalty in the amount of 30% of the determined fine for the legal entity shall also be imposed on the responsible person in the legal entity for the misdemeanour. The Law also prescribes a penalty in the amount of EUR 3,000 or MKD 4,500 in counter value, to be given to the employee in the legal entity having perpetrated the misdemeanour.

Bearing all of the above-mentioned in mind, the advertising of product characteristics not included in the SmPC would not be permitted.

4 Gifts and Financial Incentives

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

Advertising medicinal products to medical professionals may be accompanied by the provision of one small pack of the authorised medicinal product, labelled as a "free sample" and "not for sale", except for medicinal products containing narcotic and psychotropic substances.

Furthermore, the Guidelines on the manner of advertising of medicinal products and medicinal devices provide that during the promotion of the medicinal product, i.e. a medical device, the promoters may give free samples of the said medical product, together with a copy of the approved Summary Report on the properties of the medicinal product and the patient's manual if:

1. the medicinal product or the medical device has a marketing authorisation to be placed on the market in the Republic of North Macedonia, i.e. they are registered in the register of medical devices in the Republic of North Macedonia;
2. the free sample of the medicine, i.e. the medical device, is solely intended for getting acquainted with the properties of the new medicine, i.e. the medical device;
3. the quantity of free samples is limited to 30-day defined doses of the medicine during one calendar year;
4. the free sample is in the smallest package of medicinal products, i.e. the smallest pack of a particular kind of medical device, as it is placed on the market, with a mark on the package stating "free sample, not for sale"; and
5. if the free sample of the medicinal product does not contain narcotic drugs or psychotropic substances.

As an exemption of the above, a free sample of the medicinal product, i.e. the medical device, can be given to persons of the professional public on their written request.

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

In accordance with the Law on Medicinal Products and Medical Devices, upon advertising medicinal products, marketing authorisation holders or legal entities and natural persons acting on their behalf shall not offer gifts, direct or indirect financial or material benefit to persons who prescribe or dispense medicinal products, except such of small value and intended for performing healthcare activity.

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

The Law on Healthcare Protection provides that one of the ways of financing public healthcare institutions can be done through gifts and donations.

In addition, the Law on Medicinal Products and Medical Devices provides that medicine can be donated with prior consent issued by the Minister of Health. Such donated medicine can be imported and used in accordance with its need, without the need for a marketing authorisation. Donated medicine must be labelled as donated as well as labelled free of charge, clearly and permanently. Authorisation for the import of donated medicine shall be issued by the Macedonian Agency for Medicines and Medical Devices.

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?

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, advertising medicinal products and devices intended for health professionals shall not be done in a manner, which encourages prescribing, issuing, procurement, recommending use or purchase of the medicine or medical device through offering and giving a reward in the form of money, giving gifts or giving and enabling any other kind of property and inadequate benefit, that is, promise of giving some privilege or award.

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?

Prices of medicinal products are formed freely, except for the prescription-only medicinal products and the medicinal products that are on the list of essential medicinal products.

With regards to the formulation of prices, the Law on Medicinal Products and Medical Devices further prescribes that the pricing of medicinal products shall be performed in a manner, which is not discriminatory and does not allow dumping. The wholesale price of the medicinal products shall be calculated as the sum of the production price and wholesale margin.

If a manufacturer supplies healthcare institutions with medicinal products from its own production programme directly, or through their own wholesaler, the price of the medicinal product shall be identical with the production price of such product.

If a wholesaler supplies healthcare institutions with medicinal products, the price of such product cannot exceed the formed price for the product in wholesale, established by the methodology prescribed by the Government.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable?

Unless offerings of insignificant value are provided (in accordance with the provisions regulating advertisements for healthcare professionals), offering such a package deal may be considered a breach of the Guidelines on the manner of advertising of medicinal products and medicinal devices, which provides that promoting products shall not be done in a manner that encourages the prescription or promotion of products as well as in breach of the ban for disloyal competition.

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?

There are no specific provisions regulating this, however, if advertisements contain information on how to collect an offered refund, it may be considered as misleading, especially bearing in mind the fact that advertisements may not contain information regarding the efficiency of the product.

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

Marketing authorisation holders may enable persons prescribing or dispensing medicinal products to acquire additional knowledge on new medicinal products and already marketed medicinal products, through organising and holding promotional seminars. Marketing authorisation holders are obliged to provide the information for the purposes referred to above, in a manner not exceeding the limit of the scientific and expert objectives of such education, being organised exclusively for acquiring new knowledge for the medicinal product and being directed solely at the persons prescribing or dispensing medicinal products.

Additionally, the Law on Healthcare Protection provides that healthcare workers and healthcare co-workers have the right and duty to train and improve in accordance with the needs of the healthcare institution in which they are employed. The healthcare professional may receive a donation and sponsorship from natural persons or entities, for participation in professional meetings, seminars, workshops, etc. for the purpose of further training and improvement. For the donation and sponsorship, previous approval shall be provided by the Ministry of Health. Donations and sponsorships shall be evidenced in the register of sponsors and donations *ex officio* by the Ministry of Health.

The Law on Donations and Sponsorships in public activities prescribes that a donation is a voluntary and impeccable aid of money, goods and/or services that does not directly benefit the lender and does not oblige the recipient to return the donation, which can be given for the purposes of public interest or to support the activities of the recipient.

The subject of donation and sponsorship in accordance with this Law can be:

- financial assets;
- any kind of goods and services, including material goods, own manufactured or procured; and
- legacies and other rights in traffic.

Donations and sponsorships must be in accordance with the activity of the recipient of the donation and sponsorship, and cannot be goods and services of which the traffic is prohibited by law.

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

General anti-bribery rules are regulated by the Criminal code (Official Gazette of the Republic of Macedonia no. 37/9 – as amended). Such rules apply to any and all individuals and entities both in the private as well as the public sector. There are no special rules regulating the relationship between competent authorities for pharmaceutical advertising and anti-bribery/anti-corruption authorities. However, under the Law on Medicinal Products and Medical Devices, pharmaceutical inspectors are authorised to investigate and prosecute offerings and/or givings of gain in breach of the Law provisions, which may also be considered as a breach of anti-bribery/anti-corruption legislation. As administration officials, the inspectors shall be entitled to initiate criminal proceedings before competent authorities.

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?

Offering hospitality to healthcare professionals is in general regulated by the Law on Medicinal Products and Medical Devices and the Guidelines on the manner of advertising of medicinal products and medicinal devices. Covering the essential costs for transport, accommodation and the attendance fee is considered a sponsorship to healthcare professionals in light of the Law and the Guidelines. There is no specific threshold prescribed therein and there are no specific rules regarding choosing the location of the event. It should, however, be taken into consideration that all costs should strictly be connected to the purpose of the scientific event in question.

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?

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, sponsoring, in the sense of the guidelines, consists of covering the necessary travel expenses, accommodation and payment of the mandatory costs for participation in the professional event (registration fee) for the duration of the expert event. The Guidelines prescribe that advertising a medicine or medical device can be performed by the applicant of the advertisement by sponsoring scientific and promotional gatherings, professional lectures, congresses, seminars, as well other expert events attended by the expert public that are educational and consistent with scientific achievements.

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?

Sponsoring healthcare professionals to attend scientific meetings shall be considered covering of essential expenses for transport, accommodation and attendance fees, whereas covering expenses for concomitant events such as tourist travels, sport and other similar events, which are not considered expert meetings/events, shall not be considered sponsorship. Any additional offerings may be considered as direct or indirect financial or material gain and is thus prohibited. In accordance with the penalty provisions of the Law on Medicinal Products and Medical Devices, a fine in the amount of EUR 50,000 in MKD counter-value shall be imposed for a misdemeanour on a legal entity if it offers direct or indirect financial or material benefit to the persons who prescribe or administer medicinal products. With regard to all misdemeanour sanctions prescribed, the proceedings shall be conducted by a competent court and such court shall impose misdemeanour sanctions.

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

Healthcare workers and healthcare associates may be consultants and advisors, individually or within a group, for the purpose being to provide services as speakers or chairpersons on scientific meetings, and to participate in medical/scientific studies, clinical trials or training services, in advisory meetings and in market research, where such participation includes a fee and/or travel.

The relationship between the healthcare professionals and the contracting entities for the purpose described above shall be set out in advance, by a written agreement, stating in particular:

- a description of the services and the basis for payment thereof;
- the clear identification of the justified need for such services by consultants and/or advisers;
- clearly defined criteria on the basis of which the consultants or councillors were selected and their direct connection with the identified need and the persons responsible for the selection of consultants and/or advisers;
- an explanation for the necessity of engaging the number of consultants or advisors according to the goal to be achieved;
- a provision that the engagement of healthcare professionals is not intended to recommend, prescribe, buy, procure, sell or administer a particular remedy;
- the amount of the fee for the service that is appropriate to the market value of the provided service;
- an obligation for the contractor to record the services provided by the healthcare professionals; and
- the obligation of the healthcare professionals to inform when they are acting in public or when writing about an issue that is the subject of the contract or any other matter regarding the contractor and/or adviser of the service provider.

The offering and provision of consulting services to patients by healthcare professionals employed in a public healthcare institution, outside the healthcare institution in which they are employed, is prohibited.

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

Yes, please see the answer to question 5.4 above.

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

Yes, please see the answer to question 5.4 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?

Marketing authorisation holders and manufacturers of medicinal products that are not subject to a medical prescription may inform the general public about the medicinal product characteristics in line

with the summary of product characteristics or patient manual, in an objective manner and upon prior approval from the Macedonian Agency for Medicines and Medical Devices.

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, the advertising of medicine, i.e. a medical device intended for the general public, should be carried out through messages that contain clear information that the product being advertised is a medicine, that it is a medical device, and they should not provide a misconception to the patient.

When advertising, the message should contain at least:

1) the name of the medicinal product i.e. the medical device, i.e. International Non-proprietary Name (INN) for a medicinal product containing only one active substance;
2) the manner of use and the data necessary for the correct use of the medicine i.e. the medical device; or
3) a visible, legible and understandable written, drawn or spoken warning for the patient/user, that instructions for use of the medicinal product or medical device should be carefully read and a doctor or pharmacist should be consulted regarding the possible dose risk, and adverse reactions to the medicine or medical device.

In the message the warning should read: "Read the manual carefully before use! For indications, risk of use, and adverse reactions to the medicine or medical device, consult your doctor or pharmacist" and should be marked with a stronger colour in relation to the other part of the message, in a frame of at least one tenth of the size of the message, written in a letter size that allows it to be normally visible and not overlooked.

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

The Law on Medicinal Products and Medical Devices prohibits the advertising of prescription-only medicines to the general public through the media.

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?

As an exemption to the prohibition described in question 6.2, and for the purpose of protecting the public health or preventing extraordinary situations (epidemic, larger-scale natural disasters, etc.), the director of the Macedonian Agency for Medicines and Medical Devices, upon a proposal of the Committee for Medicinal Products, may allow advertising in the media aimed at providing information to a wider public regarding the use of certain medicinal products.

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

The prohibition as described in the answer to question 6.2 above shall apply to all types of media directed at the general public.

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

Bearing in mind that pharmaceutical advertising must be approved prior to publishing, and as corporate brochures/annual reports may be publicly available (to the general public), depending on the legal form of the company, including information on products shall be acceptable if such information is not intended to advertise such pharmaceuticals. Providing information with regards to the quantity of production or sales should not be considered advertising.

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

There are no specific rules, which apply to meeting with and funding patient organisations.

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

There is no general prohibition as to such activity. However, it must be noted that dispensing medicine samples to the general public is prohibited.

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?

In accordance with the Law on Medicinal Products and Medical Devices, the applicant for a clinical trial is responsible for the implementation of the trial and for the course of the clinical trial, and is obligated to submit a report to the Macedonian Agency for Medicines and Medical Devices, every three months as well as to submit a final report for the results of the clinical trial of the medicinal product, within one year as of the day of concluding the clinical trial of the medicinal product.

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

In accordance with the Law on Medical Products and Medical Devices, upon advertising medicinal products, marketing authorisation holders or legal entities and natural persons acting on their behalf shall not offer gifts, direct or indirect financial or material benefit to persons who prescribe or dispense medicinal products, except those of small value and intended for performing healthcare activities.

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

Please see the answer to question 7.2 above.

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

Please see the answer to question 7.2 above.

8 The Internet

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

In accordance with the Guidelines on the manner of advertising of medicinal products and medicinal devices, the advertising of a medicine or medical device can be performed through advertising in the public media, via the Internet, advertising on public places and other types of advertising intended for the general public.

The prohibition on advertising prescription medicines also applies to advertising via the Internet.

If the advertising of the medicine or the medical device is carried out via the Internet, the message which must be included in all types of medical advertisements ("Read the manual carefully before use! For indications, risk of use, and adverse reactions to the medicine or the medical device, consult your doctor or pharmacist") should be an integral part of the initial, i.e. the main page of the Internet message from the advertisement, and not the page which is given as a link, i.e. the reference to the main page.

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?

If the advertisement is intended for the expert public, the holder of the authorisation shall limit the access to information only to the persons referred to as the "expert public" in the Guidelines on the manner of advertising of medicinal products and medicinal devices ("*expert public, means all health workers who prescribe, sell, or issue medicine or medical devices, which purchase the medicine i.e. medical device for pharmacies, that is, for the specialised stores for other healthcare institutions, or in any other way affect the procurement and use of the medicinal products i.e. medical devices, graduated pharmacists and others professionals involved in the production and marketing of medicinal products i.e. medical devices wholesalers and retailers, as well as professional employees of the Ministry of Health and the Macedonian Agency for medicines and Medical Devices*").

However, there are no special provisions as to the level of security required in order to insure that the general public does not have access to websites or data on websites intended for the expert public. With this in mind, at this time, unfortunately, the restriction application is left to the conscientiousness of the companies.

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?

If any such content published on company-related/sponsored sites is considered in breach of legislation, competent authorities may order such content to be removed. The company may be held responsible for any advertising in breach of positive legislation governing the advertisement of medicinal products as well as advertising in general.

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

A company may provide general data relating to a company's name, address, legal form, etc. Any information published should be truthful and correct and not in breach with positive legislation. In connection to pharmaceutical advertisement, the general rules apply.

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

There are no specific rules, laws or guidance controlling the use of social media as of this moment. However, it should be noted that the general rules for advertising apply to advertising on social media as well.

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?

There have not been any legislation changes regarding the advertising of medicinal products and devices in the past year.

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

New laws governing medicinal products, medicinal devices and pharmacies should be adopted by the end of 2019, mainly for the purposes of aligning with the European Union regulative and following modern trends in regulation with the pharmaceutical industry.

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

There have not been any general practice or enforcement trends that have become apparent over the last year.

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Accepting the premise that no one can be equally versed in all fields of law, Debarliev, Dameski & Kelesoska Attorneys at Law (DDK) has been created as a company committed to be the leading business law firm in the Republic of North Macedonia.

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