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The International Comparative Legal Guide to:
Pharmaceutical Advertising 2010

A practical cross-border insight into pharmaceutical advertising

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with contributions from:

Adams & Adams
Arnold & Porter LLP
Arthur Cox
Avbreht, Zajc & Partners
Bird & Bird LLP
Borislav Boyanov & Co.
Čermák Hořejš Matějka a spol.
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Vieira de Almeida & Associados
YükselKarkınKüçük Law Firm

Bulgaria

Kina Chuturkova

Borislav Boyanov & Co.

Radoslav Alexsandrov

1 General - Medicinal Products

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

The main piece of legislation governing the advertising of medicinal products is the Medicinal Products in the Human Medicine Act (the "**MPHMA**"), (prom. SG 31/2007 as amended and supplemented from time-to-time).

Other laws, which contain provisions for the advertising of medicinal products or are applicable to such activity are the Consumer Protection Act (the "**CPA**"), the Protection of the Competition Act (the "**PCA**"), and the Radio and Television Act (the "**RTA**").

The advertising of medicinal products was regulated in details by Regulation No 13 of 14 July 2000 for the terms and conditions for approval of the advertising of medicinal products, repealed on 16 April 2007 (the "**Repealed Regulation**"). Though repealed, and since no new regulation has been adopted yet, currently the state authorities tend to follow its provisions in cases, which are not covered by the provisions of the MPHMA.

The foreign pharmaceutical companies (excluding domestic producers and traders of medicinal products) which are members of the Association of the research-based Pharmaceutical Manufacturers ("**ARPharM**"), are bound by and apply the Ethics Code, governing the advertising of medicinal products (the "**Ethics Code**"). The Ethics Code is binding only *vis-à-vis* the members of ARPharM and for the companies, which have declared their consent to be bound by its provisions.

1.2 How is "advertising" defined?

Legislative definition

According to Article 244, Para 1 of the MPHMA advertising of medicinal products shall include any form of (1) information, (2) presentation, (3) promotion or (4) proposals with the aim of encouraging the prescription, sale or use of medicinal products.

MPHMA enumerates the forms of advertising of medicinal products:

1. advertisement intended for the general public;
2. advertisement intended for medical specialists;
3. visits by medical commercial representatives to medical specialists;
4. provision of sample medicinal products; and
5. sponsorship of promotional meetings and scientific congresses attended by medical specialists, including the coverage of their travel and accommodation in the respective country in which the event takes place.

MPHMA explicitly excludes certain information as being an advertisement of medicinal products, though such enumeration is not exhaustive:

1. text appearing on the outer packaging approved during the licensing procedure for use;
2. correspondence concerning a specific issue or problems pertaining to a particular medicinal product;
3. information and instructions with regard to changes in packaging, warnings about adverse reactions as part of general measures for the safety of a medicinal product, trade catalogues and pricelists, provided they do not include data of advertisement nature with regard to the medicinal product concerned;
4. statements concerning human health or diseases when they do not, directly or indirectly, suggest a course of treatment, the prevention or diagnosis involving the use of medicinal products; and
5. campaigns conducted by the Ministry of Health for the vaccination of the population, if material associated with them contains no data about a particular medicinal product.

Ethics Code Definition

According to the Ethics Code the advertising of a medicinal product is defined as "any activity, undertaken, organized or sponsored by a pharmaceutical company, or conducted in its name and on its account, which encourages the prescription, supply, sales, application or the consumption of its medicinal products".

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?

According to Art. 245 of MPHMA, the marketing authorisation holder shall establish within its undertaking a scientific unit for distribution of information about the medicinal products for which a marketing authorisation has been issued.

The marketing authorisation holders have also the following obligations:

1. to ensure that the advertisement complies with the applicable legislation and the medicinal product summary (the "**MPS**");
2. to keep all data and materials from all advertising campaigns undertaken as part of its activities, including information about the groups at which advertising was targeted, about the type of the campaign and about the date on which the campaign was launched;
3. to ensure the adequate training of the medical commercial representatives; and
4. to implement with accuracy and within the set timelines the

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instructions of officials controlling advertising action.

The medical commercial representatives must report to the scientific units any information about the use of medicinal products they advertise, especially as regards information about adverse reactions notified to them by medical specialists.

The Ethics Code contains more detailed provisions regarding the internal arrangements, which the companies have to adopt in order to ensure compliance of the advertisement of medicinal products with its provision. According to it the scientific unit shall include a person with medical or pharmaceutical education, who shall be in charge of the approval of the promotional and advertising materials. Such person shall certify with his/her signature that he/she has reviewed the advertising material and according to his/her opinion the latter complies with the applicable legislation, the MPS and objectively, correctly and fully reflects the scientific facts and circumstances, relating to the medicinal product.

The Ethics Code also requires that all companies' employees or persons, engaged with the advertising are fully aware of the provisions of the Ethics Code, of the codes of EFPIA and IFPMA and the applicable Bulgarian legislation.

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?

Please refer to the provisions of the Ethics Code, reviewed in question 1.3 above, governing the standard operation provision for the internal approval of advertising activities.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

According to Art. 250 of the MPHMA the advertising of a medicinal product shall be approved in advance by the executive director of the Bulgarian Drug Agency (the "**BDA**"). For this purpose, the marketing authorisation holder shall submit a standard application with the BDA, accompanied by:

1. project for the advertisement, which shall be clear, with a text, if any that is easy to understand and allow evaluating all of its elements: text and illustrations;
2. notarised power of attorney from the holder of the marketing authorisation, when the application is filed by another person;
3. the literary sources of quotations, tables or other material used, if any; and
4. document for paid fee.

An Advertisement Expert Council at BDA, appointed by the executive director of the BDA and consisting of physicians and specialists with practical experience in the field of advertisement, reviews the project for advertisement and issues opinion to the executive director of the BDA.

If the project advertisement is found incompliant with the legislative requirements, the BDA gives one month period to the applicant to cure any defaults. The failure to remedy the found incompliance leads to termination of the procedure.

Within one month from the submission of the application for authorisation of advertisement, based on the opinion of the Advertisement Expert Council, the executive director of the BDA approves the advertisement by way of an order or issues a reasoned refusal, which is subject to both administrative (before the Minster of Health) and judicial (before the Sofia City Court) review.

The authorisation for advertisement relates to the specific medicinal product only and is valid for the term of validity of the marketing authorisation for the product.

In 2009 the BDA issued 239 authorisations for advertisement and terminated 23 procedures.

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?

According to Art.280 of the MPHMA in case an advisement is incompliant with the applicable legislation, the executive director of the BDA shall order the suspension of the advertisement. Such an order may also impose an obligation on the advertiser to publish or distribute, in coordination with the BDA, a disclaimer of the assertions contained in the advertisement through the same means, in the same format and volume. The order will enter into force within 14 days after the notification thereof is served to the advertiser, and does not have immediate effect unless the executive director of BDA rules otherwise. The order can be appealed within this term administratively (before the Minister of Health) or judicially (before the Sofia City Court).

The Ethics Commission at ARPharM, which reviews complaints for improper advertising, is entitled to issue compulsory corrective measures for surmounting the negative effect of an advertisement, which could include prohibition of its further dissemination.

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?

The MPHMA provides for different amounts of pecuniary penalties for breaches of the advertising rules, dependent on (1) the type of the breach and (2) whether the infringer is a natural person or a company.

1. A penalty between EUR 5,000 and EUR 10,000 (for natural persons) and between EUR 15,000 and EUR 30,000 (for companies and natural persons – sole entrepreneurs) is provided for the following breaches of advertising rules:
   a. Advertisement of a medicinal product, which is not authorised for use in accordance to the MPHMA.
   b. Advertisement of a product by ascribing to it and/or suggesting properties related to the prevention, diagnosis or treatment of human diseases.
   c. Advertisement in breach of any of the provisions of the MPHMA.

   The above penalties may be cumulated, i.e. the authorities may impose penalties both on the company and on the natural person(s) (e.g. its executive director), liable for the breach of the advertising rules.

   A penalty between EUR 5,000 and EUR 10,000 for the above breaches is imposed also on the persons, which allowed the airing, publishing and distribution of the advertisement. Such third persons tend to be TV operators, radio stations, etc.
2. A penalty between EUR 500 and EUR 2,500 (for repeated offence between EUR 1,500 and EUR 5,000) is imposed on medical commercial representatives or persons claiming to

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be such, engaged in direct or indirect advertising of medicinal products in the printed and/or electronic media, as well as on the Internet.

The Ethics Code provide for the following penalties in case of breach of advertising rules:

1. Monetary fines from EUR 500 to EUR 2,500 (in case of repeated offense up to EUR 5,000).
2. Notification for the infringement to the parent company and the other companies, parties to the Ethics Code.
3. Notification for the infringement to the state authorities and other professional organisations (only in case of repeated offence).
4. Exclusion of the infringer from the ARPharM.

While state inspectors from the BDA and the Regional Inspectorates of Preservation and Control of Public Health ("**RIPCPH**") (the latter being a body within the Ministry of Health) are competent and responsible to establish breaches of advertisement rules, the penal decrees, sanctioning such breaches, are issued by the Minister of Health, by the Chief State Health Inspector, by the executive director of the BDA or by the director of the respective RIPCPH, depending on the hierarchical system of the official who has found out the violation.

In respect to ARPharM members, the Ethics Commission at ARPharM imposes the sanctions, but when it comes to termination of membership in ARPharM the decision shall be taken by its Management Board.

There is no public database regarding the established infringements of advertising rules, which could give basis for assessment of the vigilance of the BDA for the compliance of advertisements with the applicable legislation. The information from officials of the BDA is that in 2009 there were a dozen of checks for advertisement activities, some of which ended with issuance of penalty decrees. In May 2010 the BDA made an official statement that the broad practice in the pharmaceutical sector of distribution of leaflets, brochures, slides with promotional character constitutes advertisement activity and each individual case shall be expressly authorised for each individual case. The BDA further underlined that it is firmly decided to strengthen its control and apply all available administrative measures to prevent such practice.

Competitors are generally entitled to take action before the courts against all advertisement actions, which affect negatively their activities (e.g. loss of profit due to misleading comparative advertising) and seek for a relief. However, the common approach to such issues is that the competitors signal either the competent authorities, which supervise the advertisement practices (the BDA, the Commission for Protection of the Competition) or ARPharM (if the infringer is a member of that association).

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

The competent authorities shall always investigate any matters drawn to their attention and which may constitute a breach of the advertising rules of the MPHMA.

However, the common approach of the Ethics Commission at ARPharM is not to notify the state bodies of any breaches, which may constitute both infringement of the MPHMA and the Ethics Code. The rationale for such stance is the wish of ARPharM to resolve internally all disputable issues, without any involvement of state bodies. We are not aware of any case, in which ARPharM notified the BDA for matters, already assessed by it.

1.8 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

Any advertisement, which qualifies as unfair competition may be challenged before the Commission for Protection of the Competition (the "**CPC**").

Any competitor may bring such an action. Additionally, any party may signal the CPC about infringements of the PCA and the CPC is authorised to initiate proceedings by its own initiative.

The most common infringements, prosecuted before the CPC are those related to misleading comparative advertisement.

The claimant may request from the CPC to:

1. Establish the fact of the infringement.
2. To obligate the infringer to stop the breach and undertake any corrective measures to restore the competition.
3. To impose a monetary penalty in amount of up to 10% of the annual turnover of the infringer for the previous calendar year.

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)?

Any advertising of a medicinal product which has not obtained a marketing authorisation is prohibited.

However, if the information made available to health professionals does not qualify as advertising, but is merely an exchange of information between medicinal specialists, such communication should not trigger issues, related to breaches of advertising rules. The fact that a company sponsors the event where the information is made public should not be relevant if the above mentioned requirements regarding the content of the information were met. The approach to sharing off-label information should not be different so far as this information could not qualify as advertising.

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

Information of genuine scientific interest which is not promotional may be published.

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

The Ethics Code explicitly recognises the right of the companies to issue information about their programmes and scientific research.

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Therefore, we deem that a company should not be precluded to issue press releases to both professional and general audiences, provided that the releases concern a matter of legitimate scientific interest (e.g. results from clinical trials) and that they do not have promotional nature. The reference to a trade name shall be deemed as promotional activity.

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

Art. 244, Para 2, p.2 of the MPHMA explicitly excludes from being advertising the correspondence on a specific question, related to a medicinal product. In order to fall into the mentioned exclusion however the correspondence about an unauthorised medicinal product should be initiated by the health professional. Any unsolicited approach by the company to health professionals is likely to be perceived as having advertising nature.

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

Such activity in our view should not be deemed to be advertisement, but rather a communication with state bodies. Approaching the institutions with information about unauthorised drugs however would be highly hypothetical, since the prices of medicinal products are determined only when their marketing is authorised.

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

There are neither legal provisions nor any sort of guidelines adopted on that issue yet.

We are of the opinion that it may be possible to involve health professionals in market research exercises concerning possible launch materials for yet unauthorised medicinal products only to the extent that these activities do not qualify as disguised promotion.

3 Advertisements to Health Professionals

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

There are no explicit legislative rules in this respect. Art.246, Para1 of the MPHMA, without making distinction between advertising to health professionals and general public, sets the general requirements which an advertisement shall meet:

1. It shall correspond to the MPS and present only the approved indications.
2. It shall direct to the proper use of the medicinal product, objectively presenting its therapeutic indications, without exaggerating possibilities for treatment, prevention or diagnosis using the medicinal product concerned.
3. It must not contain misleading information.
4. It must not contain any offer/promise for a gift or another benefit.

The Repealed Regulation provided the following requirements to the content of any advertisement to health professionals: information regarding the characteristics of the medicinal product; the way the medicinal product is prescribed; the quantitative and qualitative composition of the medicinal product; the international non-patent name of the medicinal product; and the address of the manufacturer of the product or its representative. Though repealed, BDA tends to apply it to applications for authorization for advertising materials to health professionals.

In addition to the requirements of the applicable legislation, the Ethics Code requires that the advertising material shall be accompanied by the MPS or information, corresponding to the MPS.

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

There is no express legal provision on that issue. We deem that such endorsements should be avoided as expressing the private opinion of the respective healthcare professionals and undermining the objectiveness of the promotion.

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

There is no such legal requirement in place regarding comparative claims. However, any such claim must meet the general requirements of allowed comparative advertising under the PCA (Art.34) not to be misleading and compare objectively the competing products.

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

The MPHMA does not contain any specific rules on comparative advertising. Therefore, such advertising shall meet both the general requirements of the MPHMA and the specific rules of the PCA.

According to the PCA, comparative advertising shall be allowed if:

1. it is not misleading and does not constitute unfair commercial practices within the meaning of the Consumer Protection Act;
2. it compares goods or services meeting the same needs or intended for the same use;
3. it compares objectively one or more characteristic features of the goods and services which are essential, comparable and representative of such goods and services, including their prices;
4. it does not lead the audience to confuse the advertiser with its competitors, or trademarks, brand names, other distinctive features, goods or services of the advertiser with those of its competitors;
5. it does not lead to discrediting or defaming competitors' trademarks, brand names, other characteristic features, goods, services, activities or positions;
6. it compares goods having the same designation of origin;
7. it does not take unfair advantage of the popularity of competitors' trademarks, trade names or other characteristic features or of the designation of origin of competing goods; and
8. it does not present the goods or services as an imitation or copy of goods or services with a registered trademark or brand name.

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The Ethics Code also contains specific requirements in respect to comparative advertising, specifying the conditions, which will make it prohibited:

1. if it refers to medicinal products that have different therapeutic indications in comparison with the medicinal product, subject of the advertising;
2. if it does not objectively clarify one or more of the main properties and features of the medicinal products concerned;
3. if it creates confusion in respect of the company conducting the advertising or its competitors or with respect to the medicinal products subject of the advertising, as well as the medicinal products used to serve as a comparison, or regarding the trademarks of the specified medicinal products;
4. if it contains statements defining the medicinal product used for comparison as "imitation or copy" of the medicinal product, which is subject to the advertising;
5. if it contains disparaging or disgraceful statements concerning the product, activity, personal or business standing of a company competitor or its employees; and
6. contains the trade name of the competitive medicinal product or the name of the company competitor.

As the advertising of unauthorised products is prohibited, it will not be allowed to refer to competitor's product which has not been authorised in Bulgaria yet.

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

There are no specific rules in this respect in the Bulgarian legislation.

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

The Bulgarian legislation does not provide for any specific regulation in relation to "teaser" advertisement. If the "teaser" does not make any direct or indirect reference to medicines, it shall be admissible and the general rules for advertisement shall apply.

4 Gifts and Financial Incentives

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

The Bulgarian legislation allows the possibility to provide the health professionals with samples of medicinal products, excluding products, containing narcotic substances. The MPHMA provides that the procedure and conditions for provision of samples shall be governed by a decree, which is not yet issued. In view of the lack of any detailed legislative rules, the following limitations set up in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (the "**Directive**") shall apply, subject to reasonable interpretations:

1. the number of samples for each medicinal product each year on prescription shall be limited;
2. any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;
3. those supplying samples shall maintain an adequate system of control and accountability;
4. each sample shall be identical with the smallest presentation on the market;
5. each sample shall be marked "free medical sample - not for sale" or shall show some other wording having the same meaning; and
6. each sample shall be accompanied by a copy of the MPS.

Under the Repealed Regulation, the requirements for supply of samples were:

1. the companies and wholesalers were entitled to provide up to two samples of the same medicinal product per year in the smallest existing packaging;
2. the companies and wholesalers were obligated to keep records of all individuals whom they have provided samples of medicinal products as well as records of the type, quantity and time of the delivery; and
3. all samples had to be marked "not for sale".

The Repealed Regulation provided an indication what state authorities would find to be reasonable.

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

Art 257, Para3 of the MPHMA prohibits any offering of gifts or other benefits by the medical commercial representative to healthcare professionals during the presentation of medicinal products.

Gifts may be given to medical practitioners only in case they do not constitute any inducement for the prescription or sale of a medicinal product. However, any gifts shall be in line with the requirement of Art.94, Para 1 of the Directive to be (1) inexpensive and (2) related to the practice of medicine or pharmacy.

The Ethics Code contains more specific rules and limitations for gifts. Such gifts should be allowed if they are inexpensive and relevant to the practice of medicine and are not for personal use. There are also limitations regarding the value of the gifts – up to BGN 60 (incl. VAT) or BGN 400 (incl. VAT) if the gifts are only for medical purpose. There are no limitations for the price of the gift with respect to donations of medical literature to medical practitioners.

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

The donations to healthcare institutions are explicitly recognised as source of income by Art.97 of the Medical Treatment Institutions Act and there are no legislative limitations as to the amount of the donation.

The Ethics Code also treats sponsorship and donations to healthcare institutions (including hospitals), providing that no limitations to such donations shall apply if they consist of medical, technical equipment, or furniture, provision of repairing services or made for research and educational activities.

Donation and sponsorship shall be done based on a written agreement, following an explicit written request for donation. Donations and sponsorship shall not be tied with conditions for purchase, delivery, prescription or administration of medicinal products. Also, they shall be related to the medical practice of the medical treatment institution.

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

Subject to assessment of each specific case, generally such practice will not be admissible. If there is a casual link between the donation and the increasing of the market share of a medicinal product, the donation could qualify as prohibited advertising.

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

The MPHMA does not contain specific rules in this respect. Therefore, volume related discounts or other discounts, which have economic rationale (e.g. for early payments) should be considered permissible. In such cases however it should be born in mind that the sales of considerable quantities of products (including medicinal products) for a prolonged time at prices lower than the cost of their production and marketing, for the purpose of unfair soliciting of customers is forbidden by the law as constituting a violation of the PCA.

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?

As this constitutes a financial inducement for the purchase of a medicinal product, it shall qualify as advertising. According Art.246, Para 4 of the MPHMA the advertisement may not contain an offer and/or promise of a gift and/or another material or nonmaterial benefit. Therefore, such practice shall be illegal.

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

Such refund scheme is likely to be found illegal, as it is a financial inducement, which may encourage the prescription and use of the respective medicinal product.

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

There are no specific legal provisions. It is our opinion that continuing medical education shall always be considered amounting to promotional activity and not allowed.

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?

MPHMA recognises as a type of promotion the sponsorship of promotional meetings and scientific congresses, including payment of travel expenses and expenses, related to the stay of the health professional, without going in any further detail.

The Ethics Code is much more detailed and stipulates the following limitations and restrictions in respect to hospitability:

1. All sponsored events shall take place at appropriate venue. Such venue shall be in Bulgaria, unless:
   a. Most of the invitees are from other countries or due to logistics reasons the event is better to take place in another state.
   b. In view of the source of knowledge, subject of the event, it is better for logistics reasons the event to take place in another state.
2. The hospitality is limited to travel expenses (economy class), food (only breakfast), accommodation and registration fees.
3. The hospitality is offered only to healthcare professionals, who practice in the area, related with the event.
4. The hospitality shall not exceed the amount, which the healthcare professionals would be ready to pay by themselves.
5. The arrival of the healthcare specialists in the venue of the event shall be no earlier than one day before the event and not later than one day after the event.
6. The hospitality shall not include entertainment.
7. The hospitality shall not include any payment to the health professional as compensation to his participation in the event.
8. If the events take place in Bulgaria, they shall not exceed three days and if they take place abroad – four days.
9. The scientific programme shall be not less than six hours per day.

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?

The law is not so specific. It only qualifies as a promotion the sponsorship of scientific congresses, including payment of travel expenses and expenses, related to the stay of the health professional. That means that it is possible to cover the expenses of a doctor related to the attendance at a scientific meeting but subject to the permission given for the promotion by the competent authority.

If the company is a member of ARPharM, the limitations in question 5.1 above shall apply, e.g. it will not be possible to pay a doctor for his time.

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?

If by the sponsorship the individual doctor is paid to attend a meeting (not as a lecturer), than the pharmaceutical company may be held liable for infringement of the MHPMA and the Ethics Code – see question 1.6 above for the applicable sanctions.

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

There are no specific provisions in this regard in the MPHMA.

According to the Ethics Code the companies may enter into agreements with healthcare professionals for provision of consultancy services and professional expert opinions like lectures, presentations at the scientific events, participation in clinical trials, etc. Consultancy services shall be provided only if the below requirements are met:

1. There is a written consultancy agreement executed between the parties specifying the type of consultancy services provided and the ground for the remuneration.
2. There is a well grounded need for the respective consultancy services.
3. There shall exist clear criteria for selection of consultants which shall be related to the well grounded need for their services.
4. The number of the specialists must not exceed the number necessary to cover the need.
5. The documents related to the services provided are kept by the company.

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

There is no prohibition to engage doctors in such studies. For companies, members of ARPharM, the requirements in question 5.4 above shall be met.

There are no rules to govern such studies.

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

As far as doctors provide consulting services, such payments should be permissible. For companies, members of ARPharM, the requirements in question 5.4 above shall be met.

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?

Art.247 of the MPHMA allows such advertising. The general requirements for advertisement of medicinal products apply – see question 3.2 above.

According to the detailed provisions of the Repealed Regulation the advertisement to the general public shall include:

1. the brand name of the medicinal product and the international non-patent name;
2. specific reference that the advertising concerns a medicinal product;
3. the necessary information the correct use of the medicinal product;
4. the age of the patients who can take the medicinal product;
5. the expression: “read the instructions before use!”;
6. the expression “homeopathic medicinal product” in case of advertising homeopathic medicinal products;
7. a reminder regarding revaccinating (if applicable) in case of advertising vaccines; and
8. the number and the date of the authorisation of the advertisement by the BDA.

The Repealed Regulation further specified, that the advertisement shall not be allowed if it:

1. attempts to convince the patients that since they are using the medicinal product they do not need a medical consultation or a surgical intervention;
2. implies that the effects of the medicinal product are guaranteed and that there are no side effects or a better or equal of these, received by different treatment or another medicinal product.
3. implies that human health can be improved upon applying the medicine;
4. implies that human health may be harmed by not using the medicine;
5. if the information explicitly or mainly targets children;
6. provides information based on recommendations of scientists, medical professionals, or other persons, which due to their popularity may encourage the use of the medicinal product;
7. implies that the medicinal product is foodstuff, cosmetic or other product;
8. implies that the safety and efficacy of the product is due to its natural origin;
9. provides for a description of a disease that may lead to incorrect self-diagnosis;
10. provides that there is a healing effect by use or improper, threatening, or misleading expressions;
11. provides through pictures or through incorrect or misleading expressions the changes in the human body resulting from a certain disease or injury, as well as the effect of the medicinal product;
12. explicitly underlines that the product has a marketing authorisation;
13. specifies specific diseases as tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer and other tumorous diseases, chronic insomnia, diabetes and other metabolic illnesses;
14. the efficacy of the treatment with the medicinal product is made dependant on the duration of it use;
15. mentions the price of the medicinal product; and
16. advertises medicinal products for treatment of infants, excluding such for local treatment.

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

The advertising of prescription-only medicines to the general public is not permitted in Bulgaria.

6.3 If it is not possible to advertise prescription only medicines to the general public, are disease awareness campaigns permitted, encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Disease awareness campaigns where no direct or indirect reference to a medicine is made are permitted and do not fall under the rules which apply to advertising of medicinal products.

Vaccination campaigns organised by the Ministry of Health when the materials related to them do not contain reference to a concrete medicinal product are not restricted by the requirements applicable to advertising of medicinal products.

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

The key issue is whether such a press release will have promotional content. If not, it shall be permissible.

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

As the aim of the corporate brochures/Annual reports is not to boost sales, but rather to provide the public with information for the company through a detailed overview of its activities and products, it is in principle not to be considered as advertising. However, any promotional content in respect of a specific medicinal product (such as mentioning the trade name of the product) may raise an issue.

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?

MPHMA does not contain any specific provision in this respect. Therefore, the general rules for donations shall apply.

The Code on Relationships between scientific research industry and patient organisations in Bulgaria imposes limitations on hospitality to patient organisations similar to those in question 5.1 above. Additionally, that code requires any funding to a patient organisation to be based on a written agreement. Each company shall make public the list of patient organisations, which are financially or otherwise supported. Such information shall be renewed at least once per year.

7 The Internet

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

The advertising of prescription-only medicinal products is prohibited by Art.248a of the MPHMA. This prohibition does not apply to advertisement campaigns for vaccination, conducted by the marketing authorisation holder and approved by the BDA. There is no public data regarding the control of such prohibition.

The advertisement of over-the-counter drugs in the Internet is permitted.

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?

There are no specific rules in Bulgarian legislation and no specific guidelines on website security required to ensure that members of the general public do not have access to sites intended for health professionals. Usually the sites for healthcare professionals make explicit reference that they are not intended for the general public and require registration and explicit confirmation that the registrant is a healthcare professional.

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?

There are no specific provisions in Bulgarian legislation on this matter.

We are of the opinion that the company should not be held liable for the content of independent website, as it does not determine the content of the latter.

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

Any information which is not directly or indirectly related to a medicinal product, such as corporate, investor or contact information, may be placed on the pharmaceutical company website without restrictions.

Information with regard to medicinal products may likely be considered advertising as a result of the broad construction of this notion and should therefore comply with the applicable advertising rules discussed above.

8 General - Medical Devices

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

The Medical Devices Act does not contain special provisions regarding advertising of medical devices. Therefore, the general rules of the PCA shall apply.

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

There are no specific rules regarding payments or hospitality offered to doctors in respect of promotion of medical devices. Therefore, the general rules of the PCA shall apply.

9 Developments in Pharmaceutical Advertising

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

No changes in respect of adverting of medicinal products were introduced in 2009.

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

According to officials from the BDA, the MPHMA is likely to be amended in order to reflect the recent changes in EU law in advertising medicinal products. However, there are no specific comments regarding the contemplated changes.

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

The public information for the BDA shows a significant increase in the number of penalty decrees issued in 2009 as compared to 2008. However, as there is no public information specifically in respect to pharmaceutical advertising, it is difficult to outline any enforcement trends in that specific field.

The Ethics Commission of ARPharM is generally active in the field of observing pharmaceutical advertising, but no substantial changes in its policy can be identified.

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

Yes, the Ethics Code has been amended in June 2008, incorporating 2007 changes of EFPIA Code.

Kina Chuturkova

Borislav Boyanov & Co.
82 Patriarch Evtimii Blvd
Sofia-1463
Bulgaria

Tel: +35 92805 5055
Fax: +35 92805 5000
Email: k.chuturkova@boyanov.com
URL: www.boyanov.com

Kina is a partner and co-head of Litigation Department of the law firm. She has joined the law firm in 2002 after more than 20 years of practice in the bench, starting from being a junior judge in Sofia City Court, judge with the Sofia Region Court, judge with the Sofia City Court, and after that - elected a judge in the Supreme Court of the Republic nowadays the Supreme Court of Cassation, where she ended up as Chief of Commercial Department of that court. She is dealing with civil and commercial litigation, IP litigation, judicial review of administrative acts, including cases in front of the Commission for Protection of Competition. She has been working in the field of pharmaceutical law and practice for a number of foreign and domestic pharmaceutical companies, including defending their rights and interests in front of the Bulgarian courts and in international arbitration proceedings.

Radoslav Rumenov Alexsandrov

Borislav Boyanov & Co.
82 Patriarch Evtimii Blvd
Sofia-1463
Bulgaria

Tel: +35 92805 5055
Fax: +35 92805 5000
Email: r.alexandrov@boyanov.com
URL: www.boyanov.com

Radoslav is an associate at the Litigation Practice Group in Borislav Boyanov & Co. He joined Borislav Boyanov & Co. in 2006, after several yeas as legal adviser of a utility company. His practice is focused on litigation and ADR, corporate, commercial and employment law. Radoslav advises pharmaceutical companies on various matters, including commercial, corporate, and regulatory and employment issues. He has also represented pharmaceutical companies before the courts and the Ethics Commission at ARPharM.

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