COUNTRY COMPARATIVE GUIDES 2021

The Legal 500 Country Comparative Guides

Bulgaria

PHARMACEUTICAL ADVERTISING

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Bulgaria.

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BULGARIA
PHARMACEUTICAL ADVERTISING

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In Bulgaria the advertising of medicines is regulated by the Medicinal Products in Human Medicine Act ("**MPHMA**") and Ordinance No1 of 25.01.2012 of the Ministry of Health on the Requirements for Advertising of Medicinal products (the "**Ordinance**"). The general rules of the Protection of Competition Act and the Consumer Protection Act should also be observed. The respective rules of the Radio and Television Act will also apply.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The members of the Association of Research-Based Pharmaceutical Manufacturers in Bulgaria ("**ARPharM**") adopted its own Code of Ethics for the promotion of the medicinal products to the healthcare providers ("**HCPs**") and the interactions (both traditional and digital) with the HCPs, healthcare organisations ("**HCOs**") and patients' organisations ("**POs**"). The consolidated Code of Ethics of ARPharM, effective of 1 January 2021, regulates also the disclosure of the transfers of value from pharmaceutical companies to HCPs and HCOs.

The members of ARPharM are also obliged to observe the Code of Practice of the European Federation of Pharmaceutical Industries and Associations.

The members of Bulgarian Generic Pharmaceutical Associations ("**BGPA**") follow the rules of the Code of Conduct of the European NGO "Medicines for Europe". This Code sets out a framework of principals and ethical standards that govern the industry's interactions with the HCPs, HCOs and POs.

The Ethics Code on advertising and commercial communication and the Rules for Online Behavioural Advertising adopted by the association National Council for Self-Regulation pursuant to the Radio and Television Act will also apply indirectly as they are binding for all media services providers.

b) What is the legal status of the self-regulatory codes?

The codes are binding for the ARPharM's and BGPA's members companies, respectively. The ethical rules of the codes are of self-regulatory nature and do not have legal force.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The MPHMA defines the advertising of medicines as "any information, presentation, promotion or proposals with the purpose of encouraging the prescription, sale or use of medicinal products" and includes:

- advertisement intended for the general public;

- advertisement intended for medicinal specialists;
- visits by medical sales representatives to medicinal specialists;
- the provision of samples of medicines;
- sponsorship of promotional meetings and scientific congresses attended by medical specialists, including the payment of their travel and accommodation expenses in the country where the event takes place.

Excluded from the definition are:

- text appearing on the secondary packaging and the patient leaflet approved during the procedure for the market authorisation of the medicine;
- correspondence regarding specific question related to particular medicine;
- information and instructions regarding the change in the packaging, warning regarding adverse reactions as part of the general safety measures, trade catalogues and pricelists provided they do not include data of advertising nature in respect of medicines;
- health or disease awareness statements when they do not directly or indirectly suggest a treatment, prophylactic or diagnosis with certain medicine;
- vaccination campaigns of the Ministry of Health directed at the public when they do not contain data about particular medicine.

b) Does the definition apply equally to all target audiences?

Yes, the definition applies equally to all target audiences. There are specific legal requirements governing the advertising depending on whether it targets the public or the HCPs.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

There are no specific rules on press-releases in Bulgarian law. The press releases intended for the public (i.e., in non-scientific journals), which include data of advertising nature regarding a prescription only medicine or unauthorized medicines, are not allowed. Some exclusions provided by the MPHMA include:

- the information and instructions concerning the change in the packaging;
- warning about adverse reactions as part of the general measures for the safety of the medicine, provided they do not include data of advertising nature;
- statements concerning human health and diseases, when they do not suggest, directly or indirectly, a course of treatment, prophylactic or diagnosis with a medicine.

Information on specific medicines provided as press-releases to the HCPs should comply with the legal requirements.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

The marketing authorisation holder ("**MAH**") is required by law to create a scientific section within the company for the spread of information for its medicines. The medical sales representatives have to be trained through arrangements made by the MAH who has appointed them as to enable them to provide correct and complete information regarding the medicines they promote to the HCPs. The law requires also the medical sales representative to have sufficient scientific knowledge in order to provide precise and complete information about the medicines they promote. The MAHs should keep data and materials of all its advertising campaigns, including the target audience, the channels used and the launch date of the campaign.

The ARPharM's members are obliged to continuously provide training and education to their medical sales representatives in respect to the code's rules.

In practice most of the pharmaceutical companies usually adopt internal standard operating procedures to be followed by all employees regarding the advertising and promotion of the medicinal products.

6. Do companies have to have material approved by regulatory bodies prior to release?

The advertising of the medicines to the general public must be approved in advance by the Bulgarian Drug Agency ("**BDA**"). The advertisement designated to the HCPs should only be notified to the BDA. In both cases the MAH should provide a sample of the advertising material to the BDA together with the application/notification.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

With respect to the comparative advertising the general rules of the Competition Protection Act shall apply. Comparative advertising is allowed when it complies with the following conditions:

i. should not be misleading;
ii. should not constitute an unfair commercial practice (defined by the Consumer Protection Act);
iii. should compare solely similar products regarding their nature and indications;
iv. should compare objectively one or more essential characteristics of the products;
v. does not lead to confusion of the advertiser with its competitors or confusion of the advertiser's trademarks and trade names with those of its competitors;
vi. does not bring discredit on the trademarks, trade names, products, or activities of competitor and does not take unfair advantage of the popularity of the trademark, the trade name or other distinctive indicators of competitor.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

In Bulgaria the MPHMA allows the advertising only of the medicines authorised for use pursuant to the law.

The MPMHA and the Ordinance do not contain specific provisions for the exchange of information with the HCPs about unauthorised medicinal products or off-label use. The MPHMA further provides administrative pecuniary sanctions for the persons who advertise unauthorised medicines up to EUR 10'000 approximately. Therefore, as a general rule, these are not allowed under Bulgarian law. In our opinion, the provision of information during a scientific conference/congress to the HCP's containing solely the active substance name or published scientific information regarding its trials, or mentioning the trade name of medicine authorised in another country, should not be considered as advertising of unauthorised medicine.

There is a specific provision in this respect in the ARPharM's Code. An international event can be used for presenting and handing out to participants promotional information on medicines, pharmaceutical forms or therapeutic indications, which are not authorized for use in the country, where the international event takes place, or these are registered under other conditions as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the medicine, pharmaceutical form or therapeutic indication is registered and makes clear that they are not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the medicine is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

The BGPA's Code expressly prohibit the promotion of off-label use.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.

According to the MPHMA the advertising intended to the general public is allowed only for over-the-counter (OTC) medicines and vaccines and subject to an authorisation of the advertising by the BDA. Any statement or message connected with the advertising should comply with the Summary of the Product Characteristics ("**SmPC**") approved in Bulgaria and to present only the allowed with the marketing authorisation therapeutic indications. Pursuant to the Ordinance the advertising should provide, as a minimum, the following information:

- the commercial name and the international non-proprietary name (INN) of the product;
- express statement that this is a medicinal product;
- information regarding the proper use of the product;
- the age range the medicine is indicated for;
- express invitation to read the leaflet before the use;
- express statement "homeopathic medicinal product" (if applicable);
- reminder for reimmunization (if applicable);
- the registration number and date of the issued authorisation by the BDA or the registration number and date of the application to the BDA in case of tacit

approval.

The advertising to the general public is not allowed to:

- suggest that the medical consultation or surgery appear unnecessary by offering a diagnosis or recommendation for a treatment by correspondence;
- suggest that the effectiveness of the product is guaranteed, free of adverse effects or it is better or equal to another treatment or medicine;
- suggest that the health might be improved by the use of the medicine;
- suggest that not taking the medicine may affect the health of the person (this is not applicable in case of vaccines' advertising);
- be directed exclusively or primarily at children;
- refer to a recommendation by scientists, medical specialists or other persons, who because of their reputation may encourage the use of the medicine;
- suggest that the medicine is food, cosmetic product or another commodity;
- suggest that the safety or the efficacy of the medicine is due to its natural origin;
- present a description or detailed representation of a decease case study that leads to incorrect self-diagnosis;
- claim a recovery by using incorrect, frightening or misleading phrases;
- present erroneously, through frightening or misleading phrases, the changes in the human body due to certain illness or injury, as well as the effect of the medicinal product on the human body;
- specify certain diseases and symptoms, such as tuberculosis, sexually transmitted diseases, other serious infectious diseases, oncology diseases, insomnia, diabetes or other metabolic or endocrine diseases;
- explicitly underline that the medicine is authorised for use.

The law prohibits the supply to the public of samples of the medicines by the medical sales representatives.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

The matter is not regulated by the MPHMA.

The codes of ARPharM and BGPA requires the members, when providing financial support, significant indirect support and/or significant non-financial support to POs, to have in place a written agreement. The agreement must state the amount of funding/ the value of non-financial support and also the purpose (e.g. unrestricted grant, sponsorship of specific event, or support of publication). In cases where direct or indirect non-financial support is provided, its nature must be described in detail in the agreement (e.g. a donation in the form of a public relations agency and the nature of its engagement). Each member should have a process in place for approving these contracts. The transfer of values under such contracts is subject to disclosure.

Companies must not influence the text of materials drawn up by POs they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies in materials. In addition, at the request of POs, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

Pursuant to the Ordinance the advertising directed at HCPs should contain:

- information corresponding to the current SmPC of the medicine;
- the supply method (i.e., prescription-only or non-prescription);
- the qualitative and the quantitative structure and the INN of the active substances when the information is necessary for the proper administration of the medicine;
- the name and address of the MAH or its authorised representative.

The advertising may include information regarding the price and the terms for reimbursement of the medicine. The Ordinance requires the information to be accurate, up-to-date, comprehensive and to be easily verified allowing the HCPs to work out their own opinion regarding the therapeutic significance of the product.

It is not allowed the advertising to include data from unpublished studies or data with unproven clinical importance. Citations, tables, graphics or other illustrative materials form peer-reviewed medicinal

journals should be precisely quoted and the accurate source should be provided. Concealing contra-indications or serious adverse reactions is forbidden. When the advertising is just a reminder for already known medicinal product, it may contain solely the trade name and the INN of the active substance(s).

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

The MPHMA prohibits the medical sales representatives when promoting medicines to the HCPS to offer gifts or other material or non-material benefits. Pursuant to the Ordinance the HCPs, who prescribes medicinal products, are not allowed to request or to accept any material or other benefits from the manufacturers, MAHs, medical sales representatives or merchants of medicinal products.

The ARPharM's Code forbids: (i) the provision of gifts for the personal benefits (such as but not limited to sporting or entertainment tickets, social courtesy gifts) or promotional-aids (a non-monetary items given for promotional purpose); or (ii) offering cash, cash equivalents or personal services to HCPs, HCOs' members and POs representatives.

The provision of informational or educational materials is permitted provided that they are unexpensive (with a value not exceeding EUR20 approximately), directly relevant to the medical practice or pharmacy and directly beneficial to the patients' care. The provision of items of medical utility, aimed at the education of the HCPs and the patients' care, are allowed if they are unexpensive (with a value not exceeding EUR 50 approximately) and do not offset the routine business practice of the HCPs that receive them.

Informational or educational materials and items of medical utility can include the company name, but must not be product branded, unless the medicinal product's name is essential for the correct use of the material or item by the patient. The transmission of such materials or items must not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer a medicine.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Pursuant to the law samples may be provided to the HCPs who prescribes medicines (i.e. the pharmacists are excluded) by the MAHs subject to the following rules:

- up to two samples of the same pharmaceutical form of one product in one calendar year;
- the sample has to be no larger than the smallest package allowed for use and placed to the market;
- the sample must contain the text "free sample, not for sale" or similar warning.

Companies must have adequate systems of control and accountability for medical samples.

The codes of ARPharM and BGPA contain stricter rules. Medical samples can only be given in response to a written request from HCPs qualified to prescribe that particular medicine. Written requests must be signed and dated by those who ask for the medical samples.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

According to the Ordinance pharmaceutical companies are allowed to sponsor promotional meetings, scientific congresses, symposia or other scientific events, as well as to pay the HCPs expenses for travel, accommodation and enrolment fees in the respective country where the event will take place. The persons must not hold public office pursuant to the meaning of the Conflict of Interest Prevention Act, or to be members of certain commissions under the MPHMA or members of the Supreme Council of Pharmacy. The Ordinance requires the expenses to be strictly limited to the professional and scientific purposes of the event and to the persons who are medical specialists.

The ARPharM's Code contains more detailed regulations in this respect which differs from the law. The members may organise or sponsor an event outside Bulgaria if most of the invitees are from other countries and it make sense to hold the event abroad, or given the location of the relevant resource or expertise which is subject matter to the event, it makes greater sense to hold the event in another country. Hospitality offered to the HCPs in connection to such events may include meals fees not exceeding the EUR 50 approximately. The duration of the events organised in Bulgaria should not exceed three 24-hours periods whereas the international events should not continue more than four 24-hours periods. In both cases not less than 6 hours of

each full day of the event should be arranged for working/scientific programme. Members considering whether to participate or sponsor an event in Bulgaria or abroad or to sponsor HCPs to participate in the event, shall consult the database for a preliminary assessment of the event available on the ARPharM's website.

The BGPA Code provides similar rules. The differences are that the companies evaluate the events that will sponsor by themselves (events are relevant to the company's therapeutic areas or business interests) and there are not defined limits for the hospitality costs provided.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Pursuant to the codes of ARPharM and BGPA hospitality must not include sponsoring or organising entertainment events (sports games and other entertainment events in the free time from the scientific/work programme) for the delegates.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

In general, it is allowed to pay the HCPs as consultants or advisors for services such as speaking at and/or chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or hospitality. The consultants are entitled to adequate remuneration for the services they provide and refund for the costs incurred in relation to their contractual duties.

The BGPA's Code requires market research not to be used as a mechanism for channeling non-disclosable payments to a particular group of healthcare professionals. Experts must be selected and engaged as service providers based only on their qualifications, expertise and abilities to provide the service. All engagements must be confirmed in writing, clearly detailing the services and amount of compensation.

The ArPharM's Code set forth a number of requirements regarding the engagement of HCPs and POs' representatives as consultants (written contract, legitimate need, selection criteria to be applied, reasonable remuneration, etc). As a general rule, contracts between companies and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to Companies (not otherwise covered by the Code) are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicinal products.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Bulgarian law does not contain specific provisions regarding the donations and grants to HCOs and HCPs.

Donations and grants to HCPs are not allowed pursuant to the ARPharM's Code. Donations and grants (in cash or in kind) to HCOs and/or POs according to the ARPharM's Code are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines.

Donations in the form of repair works, technical equipment and furniture may be provided only to medical institutions for inpatient care, outpatient and diagnostic consultative centres. Donations of medicines can be provided only to medical institutions for inpatient care.

BGPA's Code allows research grants and educational sponsorship for HCPs and contributions to organisations in response to an unsolicited and independent request from the potential recipient. Unrestricted contributions to healthcare organisations, meaning donations that are not tied to a specific project or activity, are prohibited.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have

products on the market?

There is no such requirement in Bulgarian legislation. Transparency requirements about interactions between the pharmaceutical companies and the HPCs, HCOs and POs are provided in the respective codes.

Companies should disclose direct or indirect transfers of value to HCPs, HCOs or POs, whether it is in cash, in-kind or otherwise, made for promotional purposes or otherwise in connection with the development and sale of prescription only medicines for human use. Disclosures must be made on annual basis and cover a full calendar year. Disclosures are made on the companies' website, a link to which is published on a dedicated information website in Bulgarian http://transparencybg.org, access to which is free of restrictions and public. Disclosures must be made on an individual basis, except it is not possible for legal reasons. Research and development transfers of value are disclosed on aggregate basis.

The amount attributable to transfer of value ("ToV") should be allocated in one of the following categories according to the ARPharM's Code:

- donations and grants to HCOs;
- contributions to cost related to events, such as registration fees and travel and accommodation provided to HCOs and HCPs, and sponsorship agreement with the HCOs only or with third parties appointed by an HCO to manage an event;
- fees for service and consultancy to HCOs and HCPs, resulting from or related to contracts under which the HCOs or the HCPs provide any type of service to a company or any other type of funding not covered by the above categories.

Each company must publish a note summarising the methodologies used by it in preparing the disclosures and identifying ToVs for each category.

The disclosures of support and services provided to POs are on named basis and the information is published only on the company's website. The disclosure includes brief description of the support or the services, the monetary value of the financial support and of the invoiced costs or the amount paid for the contracted services. In case of non-financial support provided, which cannot be assigned to a meaningful monetary value, the company will disclose the non-monetary benefit for the POs.

The codes requirements affect the members of ARPharM and BGPA regardless they have products on the market or not. The ARPharM's Code can be applied voluntarily by companies that are not members of the association. Companies which are not members of ARPharM, but are members of European Federation of Pharmaceutical Industries and Associations, directly or through a subsidiary, should comply with the Code.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

The advertising of OTC medicines and vaccines designated to the public should be authorised by the BDA in advance. The MAH should submit a standard form application to the BDA together with the project being advertised, literary sources of quotations, tables or other materials used, notary certified power of attorney if the application is filed by a proxy and a document for the paid fees. The BDA will authorise or refuse to authorise the advertising within a month upon submission of the application. If in this term there is no explicit ruling on behalf of the BDA's Executive Director, the advertising is considered tacitly approved.

Advertising on the internet, including social media, is not regulated in details by Bulgarian legislation. The MPHMA prohibits the advertising of prescription only medicines in internet. The vaccination campaigns organised by the MAHs are excluded from this ban. Furthermore, a medical specialist or a person claiming to be a medical specialist may not engage in direct or indirect advertising of medicines in the printed and/or electronic media, as well as on the internet. By virtue of the recent amendments of the Ordinance, effective of 1 October 2021, the general rules governing the advertising of medicines towards the public and the HCPs shall apply as well to all advertising actions through the internet. The MAHs should ensure an access control on websites containing advertising or other information intended for HCPs in a way that this information is available only to the HCPs.

The ARPharM's Code does not specifically address the internet advertising because the digital communication (such as websites, social media, video recordings etc.) is included in the regulated by the Code methods of promotion and advertising.

The BGPA's Code requires social media messages to comply with the requirements regarding the promotional and non-promotional materials and information. Companies must ensure that the social media messages are available only to appropriate recipients and to adopt appropriate internal policy to ensure that individual employee interactions with the company's social media do not bring content to unappropriated audience.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

The MPHMA require the medical sale representatives when promoting medicines to the HCPs not to offer gifts or other material or non-material benefits. The Ordinance prohibits the medical specialists who prescribes medicines to require or accept any material or other benefits from manufacturers, MAHs, merchants or medical sale representatives. The Codes of the associations regulates more precisely the communications between the companies and the HCPs and HCOs (please refer to questions 12 to 17 above). Most of the pharmaceutical companies usually include in their written agreements with the HCOs and HCPs comprehensive anti-bribery provisions.

The bribery is a crime under Bulgarian Criminal Code also by targeting both the person who offers and the person who receives it.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

Please see answer to question 12.

The members of the ARPharM are bound not to perform or encourage activities directed towards inducement of HCPs to prescribe particular medicines for material benefits (items, money or services). Items, subsidies, financial support, scholarships, grants, invitations to participate in conferences, cannot be offered or provided to HCPs against prescription or undertaking of engagement to prescribe certain medicines. Medical sales representatives must not pay a fee, provide any material benefit, inducement or subterfuge to get an appointment at an HCP or HCO.

The BGPA members may provide occasionally educational materials, unexpensive medical utility items or unexpensive promotional items to HCPs but not for a personal benefit of the HCPs or for influencing them improperly. Companies must not give cash, items that could be easily resold or personal gifts to the HCPs.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

The Executive Director of the BDA is the competent authority which may ascertain the infringement of the legal rules regarding the advertising of medicines and to issue an order for suspension of the advertising's dissemination. The regulator is entitled with the same order to lay an obligation to the advertiser to publish a refutation of the statements in the advertising using the same channels. The content of the refutation should be agreed in advance with the regulator. The Executive Director of the BDA is competent also to enforce the inducement rules. The order of the Executive Director of the BDA is subject to appeal before the administrative court.

Complaints for violation of the ARPharM's Code from inside and outside the industry will be heard by the Ethics Committee of the association. The Ethics Committee may at its own initiative to start a procedure against a member company for violation of the Code as well. In case of establishing and infringement, the Ethics Committee is entitled to impose a fine from EUR 1'000 up to EUR 3'500 approximately and in case of relapse (two or more offences within 1 year), the penalty is twice the maximum amount. The decision may be announced to the other members and the parent company to be notified as well. The Ethics Committee may prescribe mandatory corrective actions and to monitor their implementation. When consider necessary the Committee may propose to the Managing Board to expel the respective company.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

The competitors may lodge a complaint before the Competition Protection Commission ("**CPC**") for misleading or prohibited comparative advertising as well as for other violations of the rules the Protection of Competition Act governing the unfair competition. The CPC is entitled to impose a pecuniary sanction up to 10% of the total turnover of the company for the preceding financial year. The decision of the CPC is subject to

appeal before the Sofia District Administrative court and its ruling is appealed before the Supreme Administrative Court.

Affected competitors may bring damages claims before the regular civil courts in case they have suffered damages in result of such breach.

Complaints for advertising infringement may be submitted to Ethics Committee of the ARPharM or to the National Council for Self-Regulation. There is a procedure for hearing of complaints under the BGPA's code as well.

Consumers may file a complaint to the Consumers Protection Commission.

24. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

The violation of the MPHMA rules for the advertising of medicines are subject to an administrative fine from EUR 5'000 up to EUR 10'000 approximately. A medical specialist which advertises directly or indirectly medicines in the print media and the electronic media, including in internet, is subject to an administrative fine from EUR 500 up to EUR 2'500 and in case of repeated misconduct the fine is from EUR 1'500 up to EUR 5'000.

The MPHMA provides for pecuniary sanction for the medical sales representatives who offer and for the HCPs who accepts any material or other benefits from EUR 500 to EUR 1'500 and in case of repeated violation – from EUR 1'500 to EUR 2'500.

The sanctions imposed by the CPC in cases of a breach of the CPA provisions can be up to 10% of the aggregate annual turnover of the infringer for the previous financial year.

The Ethic Committee of ARPharM may impose sanctions from EUR 1'000 up to EUR 3'500. In cases of relapse (two or more offences within 12 months), the committee imposes a penalty of twice the maximum penalty.

25. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The courts/government competent authorities are not bound by the findings and decisions of the self-regulatory authority. Matters constituting a violation of the codes will be subject to investigation by the courts/government authorities to the extent they constitute a violation of the law.

26. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

There are no significant enforcement trends or actions in relation to the pharmaceutical advertising in Bulgaria in the last two years. The insufficient capacity of the BDA to adequately regulate the industry promotional activities results in more active and important role of the self-regulatory bodies.

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