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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?

The main laws used to regulate advertising on medicines in Bulgaria are:

- The Medicinal Products in Human Medicine Act (MPHMA). Chapter XI of the MPHMA defines the general principles, conditions and procedures for advertising medicines in Bulgaria. The MPHMA also defines the types of advertising, the sanctions for violations and the competent authorities for control and supervision; and
- Ordinance No. 1 of 25 January 2012 on Advertising Requirements for Medicinal Products (the Ordinance). The Ordinance is issued on the basis of art 249 of the MPHMA by the Minister of Healthcare to further specify the requirements for advertising on medicines, including the necessary contents and the restrictions on the advertising aimed at both the general public and medical professionals.

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?

Yes, the Ethical Code of the Research-based Pharmaceutical Industry in Bulgaria (the ARPharM_Code) is a self-regulatory act adopted by the Association of Research-based Pharmaceutical Manufacturers in Bulgaria (ARPharM) and applies to its member companies and other companies that voluntarily adhere to it. As an EFPIA Affiliate Member Association, the *Arpharm_Code* aligns with the standards set by the European Federation of Pharmaceutical Industries and Associations (EFPIA). The *Arpharm_Code* sets ethical guidelines as well as procedural requirements for member companies for the promotion of medicinal products and interactions with the following outlined groups: healthcare organisations (HCOs), healthcare professionals (HCPs) and patient organisations (POs).

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

The ARPharM self-regulatory code applies to member companies and their employees and third parties carrying out promotion and advertising of medicinal products. Member companies are responsible for their advertising activities as well as the content of promotional and advertising materials and the conduct of their employees and third parties carrying out the advertising of medicinal product or interactions with HCPs, HCOs and POs.

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

The *Arpharm_Code* is a self-regulatory framework, relying on member companies' compliance. Companies that are not members of ARPharM can also adhere to the code voluntarily. The ARPharM Ethics Committee is a structure for receiving and processing complaints, determining sanctions and prescribing mandatory corrective action related to non-compliance with the ARPharM Code.

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?

Art 244 of the MPHMA provides a statutory definition of "advertising", in particular relating to medicinal products as any form of information, representation, promotion or offer intended to encourage the prescription, sale or use of a medicinal product.

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

The statutory definition of advertising of the MPHMA covers:

- advertising intended for the general public;
- advertising intended for medical professionals;
- visits by medical sales representatives to medical professionals;
- provision of medicinal product samples; and
- sponsorship of promotional meetings and scientific congresses attended by medical professionals,

including payment of their travel and subsistence expenses in the country where the event is held.

The statutory definition of advertising of the MPHMA explicitly excludes:

- text on the secondary packaging and in the leaflet that has been approved in the market authorisation procedure;
- correspondence addressing specific questions or issues related to a medicinal product;
- information notices and instructions concerning changes to packaging, warnings of adverse reactions as part of general safety measures for the medicinal product, sales catalogues and price lists, provided that they do not contain advertising data about the medicinal product;
- statements relating to human health or diseases that do not directly or indirectly refer to treatment, prevention or diagnosis with medicinal products; and
- public vaccination campaigns conducted by the Ministry of Healthcare, where the related materials do not reference any specific medicinal product.

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

The statutory definition of advertising set out by the MPHMA applies equally to different target audiences. However, the MPHMA has specific regulatory requirements for each type of advertising aimed at different audiences.

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)?

Press releases regarding medicines could fall withing the broad definition of advertising set out in the MPHMA and they need to comply with all the requirements and restrictions set out in the relevant legislation. Different requirements apply depending on the target audience, i.e., the general public or medical professionals. Some restrictions apply unilaterally. For example, prescription medicines cannot be advertised to the general public, nor can they be advertised to the general public through online advertising, excluding vaccination advertising campaigns. In any case, advertising must adhere to the detailed restrictions of the Ordinance, which outline the mandatory content and restrictions for medicinal product advertisement for each target group.

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

The MPHMA requires companies to establish a scientific unit for the distribution of information on the medicinal products for which they have received a market authorisation. The Market Authorisation Holder (MAH) is obligated to ensure that the advertising of the medicinal product is presented to the public or to medical professionals in a form that complies with the requirements of the MPHMA and the Ordinance as well as the advertising authorisations granted by the Bulgarian Drugs Agency (BDA). The MAH also needs to have data on all advertising campaigns, guarantee the training of medical sales representatives and comply with instructions provided within advertising control proceedings.

The *Arpharm_Code* provides detailed requirements and restrictions on companies for the advertising of medicinal products and imposes responsibility on them for the content of the advertisements, the actions and proper conduct of their employees and of third parties involved in advertising campaigns.

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

For authorisation of advertisement targeting the general public, the MAH is required to submit a standardised application form to the BDA, accompanied by a draft or a project of the advertising materials, source materials, if applicable, and additional documents required for administrative purposes. An Expert Council on Advertising at the BDA prepares an expert opinion on the advertising materials. If non-compliance of the materials is established, the BDA provides the MAH with a term to remedy the deficiencies. Within one month of proper filing of the application, the Executive Director of the BDA issues an advertising authorisation or a motivated refusal for the advertising campaign. The refusal is subject to further control under the Administrative Procedure Code (the APC).

Advertisement targeting medical professionals is not subject to the same authorisation proceedings. Advertisement targeting medical professionals is distributed after notification to the BDA, accompanied by a draft of the advertisement materials. The content of the advertisement is still subject to the requirements set out in the MPHMA and the Ordinance.

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

The MPHMA requires that advertising of medicinal products only directs to their correct use, objectively presenting the therapeutic indications of the medicinal products without exaggerating their capabilities. Advertising for medicines must not contain any misleading information. In addition, the Ordinance provides that the advertising for medicines may not imply that the effects of the use of the medicinal product are superior or equivalent to those obtained with other treatments or the use of another medicinal product.

Beyond the guidelines set out in the MPHMA and the Ordinance, the *Arpharm_Code* further specifies what practices ARPPharM considers as comparative advertising, conflicting with the provisions of the their ethical code.

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?

Only medicinal products with a granted marketing authorisation may be advertised. Therefore, any provision of information for unauthorised medicines that falls within the definition of advertising, as set out in the MPHMA, would be prohibited (see point 3 regarding the activities within the scope of advertising of medicinal products). The same applies to advertising directed at healthcare professionals, in which unpublished research data or data with unproven clinical relevance must not be included in promotional materials. Information articles or media, information brochures and posters used at scientific congresses and other events for scientific purposes must be produced in accordance with the latest approved summary of product characteristics.

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, and include the information that must or must not be included.

According to the MPHMA, advertising prescription-only medicines to the general public is prohibited.

Advertising over-the-counter medicines (OTCs) is subject to authorisation by the BDA (see point 6).

Advertising directed at the general public must clearly state the promotional intentions and include the following information:

- the trade name of the medicinal product as well as its International Nonproprietary Name (INN);
- clear statement that it is a medicinal product;
- information necessary for the correct use of the medicinal product;
- the age limit of the patient for whom the use of the medicinal product is allowed;
- the phrase “Read the package leaflet before use";
- the phrase “homeopathic medicinal product" if advertising a homeopathic medicinal product;
- a reminder of the need for revaccinations (where applicable) if advertising a vaccine; and
- the number and date of the advertising authorisation granted by the Executive Director of the BDA or the number and date of the application for authorisation.

Advertising directed at the general public is prohibited if the advertising:

- suggests that the use of the medicinal product eliminates the need for medical consultation or surgical intervention;
- implies that the effects of the use of the medicinal product are guaranteed, accompanied by no adverse drug reactions or are superior or equivalent to those obtained with other treatments or with the use of another medicinal product;
- compels that health will be improved by the use of the medicinal product;
- suggests that non-use of the medicinal product may impair health;
- targets exclusively or mainly at children;
- refers to recommendations from scientists, medical professionals or other persons who, because of their popularity, could encourage the use of the medicinal product;
- suggests that the medicinal product is a type of food, cosmetic or other commodity;
- implies that the safety or efficacy of the medicinal product is due to its natural origin;
- includes a description or a detailed account of a medical condition's history is given that could lead to incorrect self-diagnosis;
- claims that there is a curative effect by using incorrect, threatening or misleading language;
- misrepresents, in threatening or misleading terms, changes in the human body resulting from a disease or disability and the effects of the medicinal product

on the human body;
- refers to specific diseases and symptoms;
- explicitly underlines that the medicinal product is authorised for use; or
- is for medicinal products containing narcotic substances.

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 MPHMA and the Ordinance provide the following restrictions regarding interactions between patients or patient organisations and industry:

- The direct distribution of samples of medicinal products to the population, i.e., patients and patient organisations is prohibited; and
- patient organisations may be included in the Expert Council on Advertising at the BDA and need to comply with conflict-of-interest regulations.

The *Arpharm_Code* provides more detailed guidelines on interactions between patients or patient organisations and the industry. These guidelines cover sponsorship of events, including location restrictions, hospitality restrictions, gifts prohibitions, donations requirements, consultation services agreements with patient organisations representatives, etc.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

The information contained in the advertising directed at healthcare professionals must contain accurate, up-to-date, comprehensive and verifiable information, enabling medical professionals to form their own opinion on the therapeutic value of the medicinal product.

Advertising of medicinal products directed at healthcare professionals needs to contain:

- information consistent with the data in the current summary of product characteristics;
- the dispensing route of the medicinal product;
- the qualitative and quantitative composition, the INN of the active substances and of the excipients, if necessary for the correct use of the medicinal product;
- the name and address of the MAH or an authorised representative from whom medical professionals can obtain full information on the advertised medicinal product; and
- the price and conditions for full or partial payment by the National Health Insurance Fund (NHIF) of the medicinal product.

The following restrictions to advertising directed at healthcare professionals apply:

- the inclusion of data from unpublished studies or data of unproven clinical relevance in advertising material is not permitted;
- quotations, tables, graphs and other illustrative material taken from published medical literature must be faithfully reproduced, with the source accurately cited;
- concealing of contraindications and serious adverse drug reactions is prohibited;
- informative articles and part thereof or media, informative brochures and posters used at scientific congresses and other scientific events must be produced in accordance with the latest approved summary of product characteristics; and
- advertising online may only be done in strict compliance with the MPHMA and the Ordinance and access must be restricted to healthcare professionals, ensured by the MAH.

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

Advertising may not contain an offer or promises of gifts or other material or non-material benefit. Medical professionals who prescribe medicinal products may not seek or accept any material or other benefits from manufacturers of medicinal products, MAHs, medical sales representatives and traders of medicinal products. In the case of promotional meetings, scientific congresses or other events for scientific purposes attended by medical professionals, the sponsors or organisers may cover the expenses of the medical professionals strictly for the professional and scientific purposes of the event (see point 14 regarding the sponsorship of scientific events).

The *Arpharm_Code* allows the distribution of certain informational or promotional materials without monetary value. Promotional materials must not be distributed for prescription-only medicinal products. Informational and educational materials of low value related to medicine or

pharmacy may be provided for the benefit of better healthcare services. These materials may not have compensatory purposes or promote the use of a certain medicinal product.

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

The MAH can, on exceptional occasions, provide free samples of medicinal products only to medical professionals authorised to prescribe the medicinal products. The provision of samples is subject to the following conditions:

- no more than two samples of the same dosage form of the medicinal product within a calendar year;
- each sample must be no larger than the smallest pack authorised for use and placed on the market;
- each sample must be labelled “free sample not for sale" or a similar warning; and
- the MAH must maintain a system of records and control of the samples supplied.

14. Are pharmaceutical companies permitted to sponsor 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?

Pharmaceutical companies are permitted to sponsor scientific meetings or congresses. According to the MPHMA (art 244), sponsorship of promotional meetings and scientific congresses attended by medical professionals is considered a form of advertising.

- The costs covered by sponsors must be strictly limited to the professional and scientific purposes of the event.
- Only medical professionals are eligible for sponsorship. This includes covering expenses for travel, stay and registration fees.
- Persons holding public office are excluded from receiving such sponsorship (this includes members of specific committees such as those under the MPHMA, etc.)

The applicable law does not specify additional restrictions that apply exclusively to events taking place abroad. However, the general principles and restrictions, as outlined above, would still apply regardless of the event's location.

The *Arpharm_Code* permits the organisation or sponsorship of international events only for logistical reasons. It defines certain restrictions ensuring that the sponsorship is conducted ethically. For example, the *Arpharm_Code* recommends avoiding locations that are primarily associated with entertainment activities or are “extravagant". Hospitality that accomodates event participants in extravagant and luxurious venues primarily associated with entertainment activities is considered inappropriate.

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

Pharmaceutical companies are restricted from organising cultural, sports or other non-scientific events in relation (directly or indirectly) to scientific conferences.

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

Medical professionals who prescribe medicinal products are prohibited from soliciting or accepting any financial or other benefits from medicinal product manufacturers, marketing authorisation/registration certificate holders, medical sales representatives and medicinal product dealers.

Medical professionals may not engage in direct or indirect advertising of medicinal products in the printed and/or electronic media, as well as on the internet. Additionally, if medical professionals are participating in non-interventional post-marketing safety studies (initiated by, e.g., the MAH) they shall not receive financial or other incentives, except for compensation for the time and means spent (art 145a MPHMA).

According to the *Arpharm_Code*, pharmaceutical companies may hire medical professionals for providing expert advice and consulting services, such as speaking at or chairing meetings, participating in medical, scientific or health studies, participating in clinical exams, conducting qualification courses and trainings, participating in advisory meetings consultation and participating in market research (where such participation includes remuneration and/or hospitality). The code sets requirements for clear documentation of these relations (all agreements must be in written form and follow the terms and conditions defined by the code). For transparency, the code also sets limits for the

admissible remuneration and obliges medical professionals to declare that they are consulting a certain company in any public statement they make.

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?

Pharmaceutical companies are permitted to provide grants to healthcare institutions, provided these comply with the regulatory requirements.

Donations from MAH, manufacturers, wholesalers and retailers may only be made if agreed in advance with the Bulgarian Drug Agency (BDA). The donor must submit a sample application, and the terms of the donation must comply with the World Health Organisation's Guidelines for medicine donations(art 268a MPHMA). Both monetary and in-kind donations are subject to the same rules.

Grants and sponsorships to healthcare professionals are allowed for professional and scientific events (please see point 14 above).

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?

Pharmaceutical companies are legally required to disclose transfers of value to medical professionals and institutions. For example, all donations must be agreed in advance by the BDA (please see point 17 above). They must report, *inter alia,* the commercial/medicinal names of the products, type of the donation, the MAH, quantities, recipient and purpose, and must maintain detailed records for submission to the BDA upon request. These requirements apply to all companies, including foreign entities and those without marketed products in Bulgaria.

The *Arpharm_Code* sets out documentation and disclosure obligations regarding monetary benefits to be published on a regular annual basis.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

Advertising on social media (or the internet in general) is considered advertising to the general public. According to the law, advertising intended for the general public (including via social media) can only be conducted for medicinal products without prescription and after obtaining authorisation from the BDA.

Online advertising (including via social media) for medicinal products subject to medical prescription is prohibited. Exceptions are allowed only for vaccination campaigns approved by competent authorities.

Online advertising (of medicinal products), intended for medical professionals, must be distributed with strict access control, providing that only medical professionals can access such advertising content.

20. Is advertising on the internet 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 medicinal products online is considered advertising in the general sense of the law and is subject to all the rules applicable to the advertising of medicinal products.

All online advertisements must clearly indicate that they are advertising medicinal products.

Websites containing advertising or information intended for medical professionals must have access controls to restrict access to qualified medical professionals only (please see also point 19 above).

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

Giving or taking bribes (incl. in the pharma and healthcare industries) triggers criminal liability under the Bulgarian Criminal Code.

The MPHMA contains clear anti-bribery provisions that

regulate the interactions between pharmaceutical companies and healthcare professionals or patient organisations. These rules prohibit the solicitation or acceptance of pecuniary or other benefits, restrict the provision of samples and regulate the sponsorship of events to ensure that such interactions are conducted ethically and transparently.

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

The offering of benefits or inducements to medical professionals is highly regulated to ensure ethical conduct and prevent conflicts of interest. Statutory regulations prohibit the solicitation or acceptance of benefits, restrict the provision of samples and regulate the sponsorship of scientific events.

The self-regulatory guidelines of the *Arpharm_Code* further emphasise ethical conduct, compliance with approved information and the need for transparency and control in promotional activities.

23. 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 regulatory authority responsible for enforcing the rules on advertising and the rule on inducement is the BDA. The Bulgarian administrative courts are competent at deciding on appeals against BDA decisions.

The public prosecutor's office is competent at investigating alleged criminal cases (e.g., corruption and bribery) and brings indictments against the accused persons.

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

The BDA plays a crucial role in regulating and overseeing the advertising of medicinal products. Companies can file complaints with the BDA if they believe a competitor's advertisement violates the requirements of the MPHMA. The BDA has the authority to:

(i) suspend the distribution of non-compliant advertisements;

(ii) order the publication or distribution of disclaimers to correct misleading information; and

(iii) impose fines (up to approx. EUR 10,000) in case of violations.

Decisions made by the BDA, including refusals to authorise advertisements or orders to suspend advertisements, can be appealed before the administrative courts under the Administrative Procedure Code.

Companies can also initiate legal proceedings for unfair competition with the Commission on Competition Protection. Appeals against decisions made by the Competition Protection Commission can be filed with the competent administrative courts under the Administrative Procedure Code.

25. 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 regulatory framework imposes stringent penalties and sanctions for violations of medicines advertising rules. These include substantial fines, suspension of advertisement distribution, disbarment from the profession for medical professionals and confiscation and destruction of non-compliant medicinal products.

For example:

1. The fines for:
    - advertising medicinal products not authorised in accordance with the MPHMA;
    - misleading claims connected with the prevention, diagnosis, or treatment of human diseases; and/or
    - advertising in violation of the legal requirements (in general) range from approx. EUR 5,000 to EUR 10,000.
2. Fines for medical professionals engaged in direct or indirect advertising of medicinal products in printed and/or electronic media as well as on the internet are up to approx. EUR 2,500.
3. The BDA may order the suspension of advertisement distribution if a violation of the advertising provisions is established.
4. The Ethical Commissions under the *Arpharm_Code*

can impose sanctions amounting up to EUR 7,000.

26. 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 procedures before self-regulatory authorities and procedures before state/governmental authorities and courts are independent procedures. However, both types of procedures are characterised by a system of checks and balances.

The self-regulatory authorities' decisions (e.g. the decisions of the Ethical Commissions under the *Arpharm_Code*) can be contested before an extended panel of the Ethical Commission. The decisions of the extended panel are final and not subject to appeal.

Competent governmental authorities like the BDA have significant regulatory and enforcement powers. Their decisions and actions are subject to judicial review and oversight by the administrative courts.

27. 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.

Recently, the Bulgarian Drug Agency (BDA) undertook several significant enforcement actions, and a few notable trends and patterns emerged from these actions:

1. Increased Focus on Digital Advertising.

Trend: There was a marked increase in enforcement actions related to digital advertising violations.

Details: The BDA targeted several pharmaceutical companies for improper use of digital platforms, including social media influencers, to promote prescription medicines. This indicates a growing concern regarding the regulation of digital marketing practices in the pharmaceutical industry.

Companies need to be more vigilant about adhering to digital advertising regulations, ensuring that all promotional content, especially on social media, complies with legal requirements.

2. Emphasis on Accurate Health Claims.

Trend: The BDA showed a strong commitment to combat misleading health claims.

Details: Enforcement actions were taken against companies making exaggerated or false claims about the benefits of their products. This underscores the BDA's dedication to protect consumers from deceptive marketing practices.

Companies must ensure that all health claims are substantiated by scientific evidence and comply with regulatory standards to avoid penalties.

3. Comprehensive Monitoring and Reporting.

Trend: The BDA's actions reflect a comprehensive approach to monitoring and reporting violations.

Details: The agency's annual reports and enforcement summaries provide detailed accounts of the violations and the actions taken, indicating a transparent and systematic approach to regulatory enforcement.

This transparency helps in building trust with the public and ensures that companies are aware of the regulatory landscape and the consequences of non-compliance.

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