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Bosnia & Herzegovina
PHARMACEUTICAL ADVERTISING

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

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BOSNIA & HERZEGOVINA
PHARMACEUTICAL ADVERTISING

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

The Law on Medication and Medical Devices of *Bosnia and Herzegovina* (Official Gazette of BH no. 58/2008) and *the Rulebook on Manner of Marketing of Medicines and Medical Devices of Bosnia and Herzegovina* (Official Gazette of BH no. 40/10) (hereinafter the "applicable legislation") regulates advertising of medicines and medical devices.

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?

The Association of Innovative Pharmaceutical Manufacturers (hereinafter: "the Association") brings together 12 innovative drug manufacturers. The Association was established as a voluntary, independent, non-governmental and non-profit organization.

It adopted the *Code of Conduct for Innovative Pharmaceutical Manufacturers* (hereinafter: the "*Code*").

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

The Code applies to the activities of advertising medicinal products towards professional public, products issued based on prescriptions only, and also to communication between the healthcare professionals and manufacturers medicinal products.

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

This Code is binding only for member companies – it is not the law and therefore does not need to be observed by non-members of the Association.

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?

Yes. The definition of advertising is very broad. It covers all product- or performance-related statements that are designed to promote the sale of the advertised medicine and medical device.

It equally applies to all target audiences: both healthcare professionals and general public.

Applicable legislation provides definition of advertising of medicines and medical devices as any form of providing information about medicines and medical devices to the general and professional public in order to encourage the prescribing of medicines and medical devices, their supply, sale and consumption in written, pictorial, audio, oral, electronic or any other form.

Therefore, information provided in patient information leaflets, catalogues, disease awareness campaigns or correspondence are suited to qualify as advertising.

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 are allowed if they comply with the general rules regarding advertising of medicines/medical devices.

The advertising of medical devices must provide true

and scientifically proven information on the medical device, respecting ethical criteria, and with aim to their proper and rational use, without misleading the consumers.

It is prohibited to directly address children in the advertising of medicines/medical devices.

Advertising to the *general public* is only permitted for over-the-counter medicine/medical devices, and under the condition that the medicine/medical device has a marketing authorization issued by the Agency for Medicines and Medical Devices of Bosnia and Herzegovina (hereinafter: "state regulatory agency"). It is prohibited to advertise medicinal products to the general public by attributing properties to the medicinal product that do not exist, exaggerate the positive effect of the medicinal product, sensationally and inappropriately describe the medicinal product or mislead the user of the medicinal product in any other way.

Advertising of medicines/medical devices to the *health care professionals* is possible verbally or in written, pictorial, sound, electronic or any other form. All information contained in the promotional materials, which are part of the advertising of the medicine/medical device, must be accurate, of a new date, verifiable and sufficient to enable the healthcare professional to form its own opinion on the therapeutic value of the medical device. Advertising of medicines/medical devices has to be in accordance with the approved instruction and summary of the main characteristics of the medicine/medical device.

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

According to the applicable legislation, Marketing Authorization Holder (hereinafter: the MAH) as legal entity with its registered seat in Bosnia and Herzegovina is required to establish a service (i.e. designate department) and designate the person in charge for advertising and providing information on medicines/medical devices that are placed on the market. MAH has to ensure that persons who advertise the medical device towards the health care professionals are properly trained.

MAH may authorize one or more legal entities to promote and advertise the medicinal products.

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

Yes. The content of the advertisement for the medicine/medical device has to be reported and approved by the state regulatory agency before submitting advertising material to the public media.

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

According to the applicable legislation, comparative advertising is not allowed.

Namely, it is strictly regulated that when advertising medicines/medical devices to the general public, it is not allowed to suggest that a particular medicine/medical device is undoubtedly better than other medicines/medical devices. It is also not allowed to indicate that the recommended medicine/medical device may be replaced by medicine/medical device.

In the process of advertising to the healthcare professionals it is not allowed to encourage the healthcare professionals that one medicine/medical device can be replaced with another from the same therapeutic group, without the existence of a clear medical indications. Furthermore, it is not allowed to diminish the therapeutic value of another medicine/ medical device that has authorization to be placed on the market or in any other way encourage doubt in the value of another medicine/medical device.

In addition, it is prohibited to use material protected by any form of intellectual property without prior consent of the holder.

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?

According to the applicable legislation, providing information about medicines/medical devices to the general public and health care professionals is also considered advertising.

Considering the aforesaid, it is strictly prohibited to advertise, i.e. to provide information on

medicines/medical devices that do not have a marketing authorization and to make claims or conclusions about the effectiveness of the medicines/medical devices that are the subject of ongoing clinical trials.

Professional and scientific conferences and lectures organized or financed by producers, marketing authorization holders and importers of medicines/medical devices, must be scientifically based and educational. The said gatherings must be intended exclusively for the healthcare professionals and the content may not be exclusively for promotional purposes.

Health professionals have to be able to gain further information and knowledge about the medicines/medical devices, but always in a manner that is solely intended for the purpose of gaining additional knowledge about the medicines/medical devices.

Every advertisement for a medicine/medical device intended for the health care professional must contain essential data on the medicine/medical device identical to those in the summary of main characteristics of the medicine, i.e. instructions for the patient.

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.

Advertising to the *general public* is only permitted for over-the-counter medicine/medical devices, in accordance with the marketing authorization issued by the state regulatory agency.

Advertising to the general public is prohibited for prescription only medicines/medical devices.

It is prohibited to advertise medicines/medical devices to the general public by attributing properties to the medicinal product that do not exist, exaggerate the positive effect of the medicinal product, sensationally and inappropriately describe the medicinal product or mislead the user of the medicinal product in any other way.

Advertisement for a permitted medicine/medical device to the general public has to contain:

a) the name of the medicine/medical device, i.e. the international name of the medicine/medical device it contains only one active substance;

b) information necessary for the proper use of the medicine/medical device;

c) instruction for the patient to carefully read the instructions for the medicine/medical device or the instructions on the outer packaging, that is, the packaging of the medicine/medical device

When advertising medicine/medical device that is dispensed without a prescription, it is obligatory is to state the following message in the advertisement or in the notice: "*Read the package leaflet carefully before use. For information on indications, precautions and adverse reactions to the medicine/medical device, consult a doctor or pharmacist* ".

In printed media, this warning has to be highlighted and take up at least 1/10 the size of the ad, and must be written with the appropriate font size so that it can be read without difficulty. In the case of television advertisements, this warning has to be visible on the screen for at least ¼ of the message and clearly read.

In the case of online advertising (internet, social media), the subject warning has to be an integral part the main page of the ad, not its link.

When advertising medicines/medical devices to the general public, it is not allowed to:

a) indicate the impression that the medicine/medical device does not have an adverse reaction;

b) give the impression that taking a medicine/medical device guarantees success in treatment of the disease;

c) suggest that a particular medicine/medical device is undoubtedly better than another medicine/medical device;

d) to give the impression that the medicine/medical device are good to take even when there are no signs of the disease, i.e. to improve health;

e) suggest that not taking a medicine/medical device may have a negative effect health,

f) to give the impression that the medicine/medical device are safe and effective due to their natural origin;

g) to give the impression that the medicine/medical device are food, cosmetic or another consumer product;

h) indicate that a medical examination, advice or surgery may be avoided by taking the medicine/medical device and to diagnose and provide treatment advice by mail or e-mail;

i) indicate that the recommended medicine/medical device may be replaced by another medicine/medical device

j) direct advertising exclusively or mainly at children, show children taking medicine/medical device, i.e. to which the medicine/medical device are available without the presence of adults;

k) include recommendations of health or scientific workers, and recommendations of persons who could, due to their popularity, boost the use of medicine/medical device;

l) state the notification on the inclusion of the medicine/medical device in the list of medicine/medical device issued at the expense of compulsory health insurance in the composition of primary, secondary and tertiary levels of health care,

m) use medical history or presentation of diagnostic procedures that could lead to misdiagnosis or self-diagnosis;

n) use inappropriate, disturbing or misleading expressions and pictorial representations of changes in the human body caused by disease, injury or the action of a medicine/medical device on the human body or body parts;

o)invoke inappropriate, harassing or misleading evidence of healing.

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

Applicable legislation does not contain provisions on relations with patient organisations per se.

However, it is regulated that when advertising a medicine/medical device to the general public, it is not allowed to present personal information data on the disease of a particular person or group of persons, their diagnoses, therapeutic procedures which are applied in the treatment process, as well as the medicine/medical device that are used in the treatment of a particular person or group of persons.

It is worth mentioning that it is also prohibited to include recommendations from health care or scientific professionals in advertising materials, and recommendations from people who could, due to their popularity, boost the use of drugs and medical devices.

Professional and scientific conferences and lectures organized or funded by manufacturers, marketing authorization holders and importers, or wholesalers of medicine/medical device must be scientifically based and educational and must be intended exclusively for the healthcare professionals. The contents of the mentioned meetings must not be for promotional purposes only.

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?

It is strictly prohibited to advertise, i.e. to provide information of medicines/medical devices that do not have a marketing authorization and to make claims or conclusions about the effectiveness of the medicines/medical devices that are subject of ongoing clinical trials.

When marketing the medicines/medical devices, the marketing authorization holders are not allowed to encourage healthcare professionals to prescribe, issue, procure, recommend or purchase medicines/medical devices by offering or providing cash remuneration, gifts or material benefits, or other benefits or rewards. Healthcare professionals are also prohibited from receiving such encouragement. It is prohibited to encourage the healthcare professionals to prescribe, dispense, obtain, recommend the use or purchase of medical device, by offering and giving a prize in cash, by giving gifts or by giving and enabling any other material gain, making promise or making any privileges or rewards.

The advertising of medicines/medical devices must provide true and scientifically proven information on the medical device, respecting ethical criteria, and with aim to their proper and rational use, without misleading the consumers.

Advertising of medicines/medical devices has to be in accordance with the approved instruction and summary of the main characteristics of the medicines/medical devices.

All information contained in the promotional materials, which is part of the advertising of the medicines/medical devices, must be accurate, of a new date, verifiable and sufficient to enable the healthcare professional to form

its own opinion on the therapeutic value of the medicines/medical devices.

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

When marketing the medicines/medical devices, the representatives of the producers/marketing authorization holders are not allowed to encourage healthcare professionals to prescribe, issue, procure, recommend or purchase medicines or medical devices by offering or providing cash remuneration, gifts or material benefits, or other benefits or rewards. Health care professionals are also prohibited from receiving such encouragement.

The only gifts which may be given to health care professionals are gifts of symbolical value and strictly related to the medical/pharmaceutical practice – e.g. pens, notepads, calendars and other similar items of small value.

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

Healthcare professionals may be given free samples of medicine/medical device by the expert associates, but only upon written request and with the signature of the receipt and under the condition that such sample represents the smallest available packaging, with clear indication that it is a free sample (not for sale). The free sample of a medicine/medical device must be accompanied by an approved instruction. A free sample of the medicine/medical device may be given to the healthcare professional only once per year, up to two the smallest original packaging. Marketing Authorization Holder is required to keep records on this accordingly, i.e. to keep a registry of samples given out to healthcare professionals, with indication of name of the person, name of the institution and the date when the sample was given.

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?

Promotional gatherings must always be limited to the basic purpose of the meeting and involve only the professional public. Professional and scientific conferences and lectures organized or funded by manufacturers, marketing authorization holders and importers, or wholesalers of medicine/medical device must be scientifically based and educational. The contents of the mentioned meetings must not be for promotional purposes only.

Marketing authorization holders who market the medicines/medical devices are obliged to, in addition to storing the marketing materials, keep a registry in which they will inscribe the day and place of the marketing, persons to who the materials were delivered, professional meetings and conferences organized or financially supported.

No additional restrictions apply to events taking place abroad.

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

As noted above, the applicable regulations allow for the offering of hospitality within a scientific event provided that (i) the hospitality is based on scientific and educational objective and not for promotional purposes only and (ii) that the person to whom it is provided or offered is a health care professional.

Therefore, if the cultural, sports or other non-scientific events is included within a scientific conference, the hospitality could be regarded as prohibited which precludes hospitality that is not based on scientific and educational objective but for promotional purposes only.

All other activities which are taking place during such meetings/conferences must be supporting when compared to the main purpose of the conference.

Events that are for the general entertainment of the attendees and that go beyond these purposes are most likely to be regarded as inacceptable forms of hospitality.

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

If there is element of promotion, the only gifts which may be given to health care professionals are gifts of symbolical value and strictly related to the

medical/pharmaceutical practice – e.g. pens, notepads, calendars and other similar items of small value.

If there is no element of promotion, it is possible to pay healthcare professionals to provide consultancy or other services such as speaking meetings, involvement in scientific studies, clinical trials or training services.

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?

According to the applicable legislation, the following persons are deemed to be health care professionals:

- healthcare workers who prescribe, sell or issue medicines and medical devices,
- persons who procure medicines and medical devices for pharmacies and other health institutions, or private practices,
- persons who in any other way impact the procurement or usage of medicines and medical devices,
- pharmacists and other professions in the areas of production or trading of medicines and medical devices,
- persons appointed in the management bodies of the health care institutions,
- professionals employed in health ministries, organizations of health insurance, Agency for Medication and Medicinal devices of Bosnia and Herzegovina who perform activities in relation to (production and trading of) medicines and medical devices.

Therefore, as noted above, producer of medicine/medical devices and/or legal and physical entities acting on their behalf are not allowed to offer direct or indirect material benefit to persons prescribing/issuing medicine/medical devices. The only gifts which may be given to medical professionals are gifts of symbolical value and strictly related to the medical/pharmaceutical practice – e.g. pens, notepads, calendars and other similar items of small value. Additionally, medical professionals may be given free samples of medicine/medical device, but only under the condition that such sample represents the smallest available packaging, with clear indication that it is a free sample (not for sale). Such samples may be given once a year in the amount of maximum two smallest packages.

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?

Marketing authorization holders who market the medicines/medical devices are obliged to, in addition to storing the marketing materials, keep a registry in which they will inscribe the day and place of the marketing, persons to who the materials were delivered, professional meetings and conferences organized or financially supported. They must also keep a registry of samples given out to medical professionals, with indication of name of the person, name of the institution and the date when the sample was given. Although these registries are not publicly available, they must be presented to the state regulatory authority upon request.

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?

It is strictly prohibited to advertise medicines/medical devices that do not have a marketing authorization. The content of the advertisement for the medicine/medical device has to be reported and approved by the state regulatory agency before submitting advertising material to the public media.

General advertising rules would apply (please see under 9.) for advertising on internet including social media for medicines/medical devices. Advertising to the general public is only permitted for over-the-counter medicine/medical devices prescription, in accordance with the marketing authorization issued by the state regulatory agency.

Marketing authorization holders should include access restrictions on websites containing advertising or other information intended for healthcare professionals.

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

Please see under 12.

In the context of the promotion of medicines/medical devices, it is prohibited to offering or providing cash remuneration, gifts or material benefits, or other benefits or rewards. Health care professionals are also prohibited from receiving such encouragement, except where such advantage is of negligible value and relevant to medical or pharmaceutical practice – e.g. pens, notepads, calendars and other similar items of small value.

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

The rules which govern the offering of benefits or inducements to healthcare professionals are regulated under the applicable legislation. Please see under 12.

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.

Pharmaceutical inspection of state regulatory agency is competent authority to enforce the rules of advertising and inducement.

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

On the basis of applicable legislation, proceedings against competitors for advertising infringements can be initiated before the state regulatory agency.

Civil claims (e.g. damages) are asserted before civil courts.

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?

In case of non-compliance fines may be imposed in the range between BAM 20,000 (approx. EUR 10,000) and BAM 50,000 (approx. EUR 25,000) for the legal entity committing the misdemeanour, and BAM 3,000 (approx. EUR 1,500) to BAM 10,000 (approx. EUR 5,000) for its authorized representative.

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?

Only measures taken by courts and competent state regulatory agency are binding.

Self-regulatory measures would be binding for members that voluntarily comply with the rules of the Code.

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.

According to the publicly known enforcement actions in relation to the pharmaceutical advertising in Bosnia and Herzegovina, i.e. as per the Decision no. 07-07.7-10-4194-1/20 dated August 26, 2020, “ADA Pharmaceuticals“ d.o.o. Lukavac was prohibited from advertising the medicine MALCOVIR®, due to non-compliance with the applicable legislation.

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