SLUŽBENI GLASNIK BOSNE I HERCEGOVINE
Izdanje na hrvatskom, srpskom i bosanskom jeziku
СЛУЖБЕНИ ГЛАСНИК БОСНЕ И ХЕРЦЕГОВИНЕ
Издање на хрватском, српском и босанском језику

Year XIV Monday, 17 May / May 2010	number **40**	Year XIV Monday, May 17, 2010

ISSN 1512-7508 -English language

Based on Article 73, paragraph 2 and Article 122, paragraph 2 of the Medicinal Products and Medical Devices Act of Bosnia and Herzegovina ("Official Gazette of BiH", No. 58/08), the Minister of Civil Affairs of Bosnia and Herzegovina, at the proposal of the Expert Council of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, adopted

ORDINANCE
ON ADVERTISING OF MEDICINAL PRODUCTS AND MEDICAL DEVICES

PART ONE - GENERAL PROVISIONS

Article 1

(1) Advertising of medicinal products and medical devices includes every form of providing information on medicinal products and medical devices to the general and professional public for the purpose of the prescribing, supplying, selling and consuming of medicinal products and medical devices in written, visual, aural, oral, electronic or any other form.

(2) The general public, in terms of this Ordinance, represents the citizens of Bosnia and Herzegovina.

(3) The professional public, in terms of this Ordinance, represents health workers who prescribe, sell or dispens medicinal products and medical devices, who procure medicinal products and medical devices to pharmacies and other health care facilities or private practices, or who in any other way affect the procurement and use of medicinal products and medical devices; pharmacists and other professionals in the field of production and distribution of medicinal products and medical devices in wholesale and retail, as well as persons working in the management of health institutions.

(4) The professional public, in terms of this Ordinance, represents the professionals working in the Ministries of health, organizations of mandatory health insurance and the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (hereinafter: the Agency) who perform the tasks related to medicinal products and medical devices, or related to the production and distribution of medicinal products and medical devices.

(5) This Ordinance determines the way of advertising medicinal products and medical devices, including:
a) advertising of medicinal products and medical devices to the general public;
b) advertising of medicinal products and medical devices to the professional public;
c) advertising of medicinal products and medical devices to the professional public through professional associates of the authorization holders;
d) provision of samples;
e) encouraging health workers to prescribe and dispens medicinal products by rewarding them with money, giving them gifts or providing them any other benefit, or promising them any other privileges or rewards;
f) sponsoring of promotional meetings where the persons authorized to prescribe or dispens medicinal products / medical devices participate;
g) sponsoring of scientific congresses in which persons authorized to prescribe or dispensing medicinal products / medical devices participate, and paying for their travel expenses, registration fees and accommodation at such gatherings.

Article 2

(1) Advertising of medicinal products and medical devices must provide true and scientifically proven information about medicinal products and medical devices in compliance with ethical criteria, and in order to ensure their adequate and rational use, without misleading the users.

(2) Advertising of medicinal products must be in accordance with approved guidelines and summary of the main characteristics of the medicinal product.

(3) Advertising of medical devices must be in accordance with the approved guidelines.

Article 3

Under the advertising of medicinal products/medical devices is not considered:

a) the labeling of medicinal products and medical devices, the patient information leaflet and the summary of the main characteristics of the medicinal product that are approved in the procedure of issuing a permit for marketing authorization, and for medical device which is registered in the register of medical devices;

b) correspondence with the attached material that is not used for promotional purposes, and which gives an answer to a specific question related to specific medicinal product/ medical device;

c) informative announcements about the facts and professional materiasl that are, for example, related to changes of the packaging, side effects warnings or other altered security information, shopping catalogs and pricelists if they do not contain elements of advertising;
d) any unbiased, objective information on diseases, prevention, and available treatment methods, whereby it is not allowed to specify a particular medicinal product / medical device.

Article 4

(1) A legal entity with headquarters in Bosnia and Herzegovina, which is a marketing authorization holder in Bosnia and Herzegovina, or the holder of the certificate of registration in the register of medical devices issued by the Agency (hereinafter referred to as the authorization holder) must organize a service, or designate a person in charge of advertising and providing information on medicinal products and medical devices that are put into circulation.

(2) The authorization holder must:

a) have at its disposal, and at the request of pharmaceutical inspection, copies of all ads, together with an indication to which users they are intended, the manner of publishing and the date of first publication;

b) ensure that persons who are engaged in advertising of a medicinal product or medical device to the professional public are properly trained and that they fulfill the obligations under Article 17 of this Ordinance;

c) ensure that the advertising of a medicinal product / medical device is in accordance with the requirements of this Ordinance;

d) ensure that the decisions of pharmaceutical inspection related to the advertising of medicinal products / medical devices are fully implemented without delay;

e) provide pharmaceutical inspection with all the information necessary for the supervision of the advertising of medicinal products and medical devices.

(3) The authorization holder may authorize one or more legal entities to do the promotion and advertising of the same medicinal product.

Article 5

The authorization holder, purchaser of advertising and the public media which is advertising (radio, television, newspapers and other) are solely responsible for the compliance of advertising of medicinal products and medical devices with the provisions of this Ordinance.

PART TWO - ADVERTISING OF MEDICINAL PRODUCTS AND MEDICAL DEVICES TO THE GENERAL PUBLIC

Article 6

(1) Advertising to the general public is only allowed for the medicinal products that are issued without prescription in accordance with a permit for marketing authorization, or for medical devices for which the Agency issued a certificate of registration in the register of medical devices.
(2) Purchaser of advertising is obliged to provide the Agency with the content of the medicinal product or medical device ad (commercial) prior to the submission of advertising material to the public media.

(3) After submitting a formally complete application to the Agency, the reffered ad may be forwarded to the public media for advertising, unless the Agency decides otherwise in exceptional circumstances and prohibits the advertising of a particular medicinal product or medical device.
(4) The applimayt pays the costs of the ad content application, pays the necessary administrative fee and encloses the proof of payment to the Agency.

(5) Such proofs of payments are the requirement for the formal completeness of application.

(6) The applimayt is required to complete the Agency`s application form, submit the ad content (in written or electronic form) and payments from the previous paragraph to achieve the completeness of the application for advertising of medicinal products and medical devices.

(7) Advertising to the general public is prohibited for medicinal products issued on prescription, for the medicinal products that are on the list of medicinal products that are prescribed at the expense of the compulsory health insurance within the primary, secondary and tertiary health care, and for all medicinal products containing psychotropic substances and narcotic drugs (UN Single Convention on Narcotic Drugs, 1961, and the UN Convention on Psychotropic Substances, 1971.).

(8) The prohibition from the previous paragraph does not apply to public health actions in the interests of public health protection and for prevention of emergencies (epidemics, large scale natural disasters, state of war or other emergency cases), when advertising is allowed with the aim of informing the general the public through the public media about the use of certain medicinal products.

Article 7

(1) Advertising of a medicinal product to the general public is not allowed if the medicinal product does not have a permit for marketing authorization.
(2) Advertising of medical devices to the general public is not allowed if a medical device does not have a certificate of registration in the register of medical devices.

Article 8

The advertisement on medicinal product / medical device which has a permission to be advertised to the general public, must contain:

a) the name of the medicinal product and medical device, or the international name for a medicinal product containing only one active substance;

b) necessary information for proper use of medicinal product or medical device;

c) notification for the patients to carefully read the package leaflet or the instructions on the external packaging or container of the medicinal product/ medical device.

Article 9

(1) When advertising medicinal products or medical devices that are issued without a prescription, it is mandatory to quote the following message within the advertisement or in the notification: "Before use, carefully read the instructions for the medicinal product. For more information about the indications, warnings and adverse reactions to the medicinal product and medical device consult your doctor or pharmacist. "
(2) When it comes to the print media, warning from the preceding paragraph must be highlighted (written in a striking color or in a frame) and it must occupy at least 1/10 of the size of the advertisement, and must be written in a font size that may be read without difficulty. In television ads, warning from paragraph 1 of this Article should be visible- on screen it must occupy at least ¼ of the message and it must be clearly read.
(3) In the case of Internet advertising warning from paragraph 1 of this Article must be an integral part of the main page of the advertisement, and not a link.
(4) Advertising of a medicinal product or medical device must not be misleading, the advertising message must be clear, and it must be clearly visible that it is an advertisement for a medicinal product or medical device.

Article 10

In advertising medicinal products and medical devices to the population it is not allowed to:

a) claim that medicinal product and medical device do not have adverse effects;
b) claim that taking medicinal product and medical device guarantees success in the treatment of diseases;
c) claim that a particular medicinal product / medical device is undoubtedly better than other medicinal products and medical devices;
d) claim that medicinal product and medical device is good to use even when there are no signs of disease;
e) suggest that not taking some medicinal product or medical devices
may negatively impact health, except in the case referred to in Article 8, section c) of this Ordinance;
f) claim that medicinal product and medical device are safe and effective due to their natural origin;
g) claim that medicinal product and medical device represent dietary, cosmetic or other mass use product;
h) indicate that by taking a medicinal product one may avoid medical examination, advice or surgery, and determine a diagnosis and offer advices about the treatment by post or e-mail; i) indicate that the recommended medicinal product and medical device may be replaced by other medicinal product and medical device;
j) direct the advertising exclusively or primarily towars children, show children who use medicinal product or medical device or show children who have the access to medicinal product and medical device without the presence of adults;
k) include any recommendations from medical or scientific workers, and recommendations from people who could encourage the use of medicinal products and medical devices because of their popularity;
I) specify the notice of the inclusion of medicinal product and medical device in the list of medicinal products and medical devices that are issued at the expense of the compulsory health insurance within the primary, secondary and tertiary levels, except in the cases referred to in Article 8, section c) of this Ordinance;
m) use the disease history or display diagnostic procedures that could lead to wrong self-diagnosis or self-treatment;
n) use the inappropriate, disturbing or misleading expressions and pictorials of changes in the human body caused by disease, injury or influence of some medicinal product or medical device to the human body or parts of the body;
o) reffer to the evidence of healing in the inappropriate, disturbing or misleading manner.

Article 11

It is prohibited to directly disperse medicinal products and medical devices to the general public for the promotional purposes.

Article 12

When advertising medicinal product and medical device to the general public it is not permitted to name the pharmacy or other retail location in which the retail sale of medicinal products is permitted in accordance with the valid regulations.

Article 13

When advertising medicinal products and medical devices to the general public it is not permitted to disclose information about the disease of personal information about a specific person or group of persons, their diagnosis, therapeutic procedures applied in the treatment or medicinal products and medical devices used for the treatment of a specific person or group of persons.

PART THREE – ADVERTISING OF MEDICINAL PRODUCTS AND MEDICAL DEVICES TO THE PROFESSIONAL PUBLIC

Article 14

(1) Advertising of medicinal products or medical devices to the professional public may be done orally or in written, visual, aural, electronic or any other form with mandatory reporting of the regime of issuing a medicinal product or medical device.
(2) Advertisement and notice from paragraph 1 of this Article must enable the professional public to shape their own view on the therapeutic value of the medicinal product and medical device.

(3) Every advertisement about medicinal product or medical device intended for the professional public must contain the essential information about the medicinal product or medical device which are identical to those from the summary of the main characteristics of the product, or a patient information leaflet.

(4) Any advertising of a medicinal product to the professional public must contain at least the following information:

a) the number of approval for marketing authorization;
b) the method of publication;
c) the name and address of the marketing authorization holder;
d) the name of a medicinal product and the international name of active substance(s);
e) approved indications, contraindications, precautions and frequent adverse effects;
f) dosage and method of use and warning, and must provide health workers with the last approved summary of the main characteristics and patient information leaflet.

(5) All promotional materials must contain the date of production and the date of last modification.
(6) All information in the promotional material, that are the part of advertising of a medicinal product/ medical device, must be correct, of the new date, verifiable and sufficient to enable the professional public to shape their own view on the therapeutic value of the medicinal product / medical device.
(7) Statements, tables and other graphic material taken from medical journals or other scientific works which are part of the promotional material must be faithfully reproduced with indication of the exact sources.

Article 15

The marketing authorization holder must ensure that the access to professional information through advertising of medicinal products / medical devices to professional public in written, visual, aural, electronic or any other form, is limited solely to the professional public.

Article 16

(1) The professional public may be orally informed about about medicinal products and medical devices by the associates of the marketing authorization holder who have a university degree in health science.

(2) In addition to persons referred to in paragraph 1 of this Article, the promotion of a medical device may also be made by associates of the marketing authorization holder who have the appropriate faculty, depending on the type of a medical device. (3) Persons mentioned in paragraph 1 of this Article must be specially trained on the basic clinical-pharmacological knowledge in the field of medicinal products and on the necessary knowledge in the field of medical devices which they are promoting.

(4) The authorization holder is obliged to carry out continuous training of the professional associates who promote its medicinal product and medical device, as well as to assess their knowledge in order to provide complete, precise and accurate information about the medicinal product and medical device which they promote.

Article 17

(1) Professional associate, during each visit to a health worker, must provide the most recently approved summary of the main characteristics of a medicinal product for all the medicinal products which are presented during that visit.
(2) Associate should also convey every information on the use of the medicinal product / medical device to the service defined under Article 4 of this Ordinance, which he/she learned from a health professional who is authorized for prescribing and dispensing of medicinal products / medical devices, with special emphasis on adverse effects.

Article 18

(1) When advertising a medicinal product or medical device it is not permitted to stimulate the professional public to prescribe, dispense, procure, and recommend the use or purchase of a medicinal product and medical device, by offering and providing rewards in money and gifts or by providing any other material gain, or by promising or giving any other benefits or rewards.

(2) The professional public must not seek or accept inducements to prescribe, issue, sell or consume medicinal products or medical devices.

(3) Promotional meetings must always be limited to the basic purpose of the meeting and include only professional public.

Article 19

(1) Professional and scientific meetings and lectures organized or funded by manufacturers, authorization holders and importers or wholesalers of medicinal products must be scientifically based and educational.

(2) The content of the above mentioned meetingss must not have exclusively promotional purpose.

(3) All the other contents of the meetings mentioned in paragraph 1 of this Article must be supporting in relation to the main purpose of the meeting.

(4) Meetings mentioned in paragraph 1 of this Article must be intended exclusively for professional public.

Article 20

(1) Professional associates who promote a medicinal product and medical device may give presents that do not have high value to the members of the professional public, or they may give presents which have symbolic value and which are related to medical or pharmaceutical practice (eg, pens, notepads, calendars and other similar things of lesser value).
(2) Professional associates may give a free sample of a medicinal product, or a free trial sample of a certain type of medical device, provided that they do not differ from the usual packaging, that it is the smallest package having marketing authorization in Bosnia and Herzegovina and that the sample is clearly labelled with the words “free sample – not for sale”.
(3) Free sample must be equipped and must include the package leaflet pursuant to the marketing authorisation.

(4) When offering a free sample of a medicinal product to a health worker, professional associate is required to attach the approved summary of the main characteristics of that medicinal product.
(5) Free sample of a medical device must be accompanied by approved instructions.
(6) Professional public may be given free sample of a medicinal product or medical device, upon written request and with the signature of receipt, only once during the course of a year, in the amount of a maximum of two of the smallest original packages, and the marketing authorisation holder is obliged to keep a record of that.
(7) The records must state the name and surname of the health worker, the name of the institution or private practice, and the date when the free sample was delivered.

Article 21

According to special regulations, it is not allowed to advertise a medicinal product to the professional public by providing them with free samples of medicinal products that contain narcotic drugs or psychotropic substances.

Article 22

(1) authorizatio holders who advertise medicinal products / medical devices are required, in addition to storing of promotional materials, to keep a record of the date and place of their publications, persons to whom the materials were delivered and the professional meetings and lectures that they organized or financially supported.
(2) Authorization holders are required to keep all the promotional materials in written, visual, aural, electronic or any other form that may be stored as well as the records referred to in paragraph 1 of this Article for the period of two years.

Article 23

In the process of advertising to the professional public it is not allowed to:

a) encourage the professional public that one medicinal product and medical device may be replaced with other medicinal product and medical device from the same therapeutic group, without clear medical indications
b) make statements or conclusions about the effectiveness of a medicinal product and medical device which are the subject of clinical trials in the country or abroad;
c) advertise medicinal products and medical devices that are undergoing a procedure of making changes to a summary of the main characteristics of the medicinal product and the patient information leaflet;
d) state the summary of the main characteristics of the medicinal product, essential information from the summary of product characteristics or the approved patient information leaflet using a font size smaller than 3 mm or other printing methods that would prevent them to be easy to read and understand;
e) publish the information intended for professional public through the mass media;

f) diminish the signifimayce of warning about precautions or adverse reactions listed in the approved summary of the main characteristics of the medicinal product;

g) diminish the therapeutic value of another medicinal product and medical device that have marketing authorization, or to in any other way encourage doubt about the value of another medicinal product and medical device;

h) use the name of the Ministry of Health, Agency, or legal entities involved in the process of investigation, and marketing authorizaton of a medicinal product or medical device;

i) use the materials protected by any form of intellectual property protection without the prior owner`s consent;

j) use the postcards or other forms of written mail whose content may be available or readable to persons other than the professional public;

k) use the telephone, fax, electronic mail or other electronic systems of the persons who belong to the professional public without their prior explicit consent for that type of advertising.

PART FOUR - FINAL PROVISIONS

Article 24

Legal entities are obliged to organize their business and organization in accordance with the provisions of this Ordinance within 60 days from the date when this Ordinance enters into force.

Article 25

The grammatical terminology of the use of male gender throughout this Ordinance implies the inclusion of both genders.

Article 26

Amendments to this Ordinance shall be conducted in a manner of and according to the procedure for its adoption.

Article 27

This Ordinance shall enter into force on the eighth date from the date of its publication in the "Official Gazette of BiH".

Minister
Mr **Средоје Новић**, s.r.
Number 08-31-3-1399-1-JD / 10
April 23rd, 2010