

## **RULES**

### **OF THE MANNER AND CONDITIONS OF ADVERTISING MEDICINAL PRODUCTS AND MEDICAL DEVICES**

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#### **I BASIC PROVISIONS**

##### **Article 1**

These Rules determine the manner and conditions of advertising medicinal products and medical devices.

##### **Article 2**

Advertising medicinal products and medical devices is each form of providing information on medicinal products and medical devices to the general and professional public in order to promote the prescription of medicinal products and medical devices, their supply, sale and usage (procurement, purchase, dispensing, etc.) by marketing authorization holders, as well as by legal and physical entities conducting the marketing of medicinal products and medical devices, wholesale or retail (hereinafter referred to as: the advertiser).

Under these Rules, the general public means the citizens of the Republic of Serbia.

Under these Rules, the professional public includes: health-care and veterinary workers who prescribe, sell, i.e. dispense medicinal products and medical devices, who provide medical devices and medicinal products to the pharmacies and other health-care and veterinary institutions, i.e. for private practice or affect in any other way whatsoever the procurement and usage of medicinal products and medical devices, pharmacists with degree and other professionals from the area of production and marketing of medicinal products and medical devices, wholesale or retail, as well as individuals in the managing bodies of health-care and veterinary institutions.

Under these Rules, the professional public includes professionals employed in the Ministry of Health, organization of obligatory health insurance and the Medicines and Medical Devices Agency of Serbia (hereinafter referred to as: the Agency) who carry out activities in relation to medicinal products and medical devices, i.e. regarding the production and marketing of medicinal products and medical devices.

##### **Article 3**

Published information on medicinal products and medical devices must be true and scientifically proven and must not mislead the patients – users.

Information on medicinal products from paragraph 1 herein is provided for the purpose of correct and rational use of medicinal products and medical devices, respecting the ethical norms.

Advertising a medicinal product must be in compliance with the Summary Product Characteristics and approved Patient - user information leaflet.

Advertising a medical device must be in compliance with the approved Patient - user information leaflet.

#### Article 4

Advertising medicinal products and medical devices encompasses:

- 1) Advertising medicinal products and medical devices through the public media, Internet, advertising in public areas and other forms of advertising in public;
- 2) Promotion of medicinal products and medical devices to health-care and veterinary workers prescribing medicines, namely by providing direct information in professional magazines and other forms of promotion;
- 3) Distributing free samples to the professional public;
- 4) Sponsoring scientific and promotional meetings involving the participation of the professional public.

The promotion of medicinal products and medical devices from paragraph 1 act 2) of this Article and to the professional public from Article 2 paragraphs 3 and 4 of these Rules is carried out in the manner and under the conditions set forth herein

#### Article 5

Under these Rules, the following shall not be considered advertising the medicinal products and medical devices:

- 1) labeling medicinal products and medical devices in accordance with the regulations set forth in the area of medicinal products and medical devices;
- 2) providing objective information on medicinal products and medical devices to general and professional public, in professional magazines or health-care columns in other magazines, which do not create a misleading conclusion and aims at answering specific questions regarding particular medicinal products and medical devices, provided that the information on medicinal products and medical devices comply with the Summary Product Characteristics and approved Patient - user information leaflet, as well as that only an international non-proprietary name (INN) of the medicinal product and medical device is used, under the condition that such informing does not have elements of advertising;
- 3) information on medicinal products and medical devices regarding the change of package, adverse reactions to the medicinal products and medical devices, sales catalogue of medicinal products and medical devices with prices, provided that they do not include elements of advertising;

- 4) statements regarding the health or illness conditions, provided that the name of a medicinal product and medical device is not mentioned even indirectly.

Information regarding manner of payment of the price or its part by the organization for the obligatory, that is voluntary health insurance cannot be included in the information related to the price of a medicinal product and medical device from paragraph 1 act 3).

## II ADVERTISING MEDICINAL PRODUCTS AND MEDICAL DEVICES TO THE GENERAL PUBLIC

### Article 6

Advertising medicinal products and medical devices to the general public includes advertising medicinal products and medical devices through the public media, Internet, advertising in public areas and other forms of advertising in public (submitting advertising material by mail, visits, etc.)

### Article 7

Advertising message for medicinal products and medical devices the advertising of which is permitted, must contain clear information that the advertised product is a medicinal product or medical device and must not be misleading.

Advertising message from paragraph 1 of this Article at least contains information regarding:

- 1) the name of a medicinal product and medical device, i.e. the international name of the medicinal product and medical device (INN) for the medicinal product containing only one active substance;
- 2) the way of use and data necessary for the correct use of the medicinal product and medical device;
- 3) visible, readable and clearly written, drawn of pronounced warning to the patient – user to read carefully the instruction for the use of a medicinal product and medical device and to consult the physician or a pharmacist about the possible risk or adverse reactions to the medicinal product and medical device, and the veterinarian regarding medicinal products and medical devices used only in veterinary medicine.

Advertising message from paragraph 2 act 3) of this Article contains warning reading: "Read the instructions carefully before use! Consult your physician or pharmacist about the indications, risks related to the use and adverse reactions to the medicinal product and medical device (for medicinal products and medical devices used only in veterinary medicine - consult the veterinarian)".

The warning from paragraph 3 herein shall be marked with colour more intense than the other part of the advertising message and framed, with dimensions of at least one tenth of the advertising message, with the letters of the appropriate size, making it is possible to perceive the warning easily, impossible to overlook.

## Article 8

If the advertising message from Article 7 herein is provided via the Internet, information regarding the medicinal product and medical device must be an integral part of the initial, i.e. main page of the Internet advertising message or advertisement, and not of the page given as a link, i.e. a reference for the main page.

## Article 9

When advertising medicinal products and medical devices it is not permitted to do the following regarding the general public:

- 1) lead to the impression that medicinal products and medical devices do not have the adverse reactions;
- 2) lead to the impression that it is not necessary to consult the physician prior to the use of medicinal products and medical devices;
- 3) lead to the impression that it is possible to avoid medical check up by using medicinal products and medical devices;
- 4) lead to the impression that taking medicinal products and medical devices guarantees success in the treatment of illness;
- 5) lead to the impression that particular medicinal product and medical device is better than other medicinal product and medical device;
- 6) lead to the impression that taking medicinal products and medical devices is good even when there are no signs of illness, i.e. to improve health;
- 7) suggest that the health of a person not taking medicinal products and medical devices can be endangered, except in cases of campaigns carried out by the competent ministry (epidemic and epizootic prevention), in compliance with law;
- 8) lead to the impression that medicinal products and medical devices are efficient and harmless;
- 9) lead to the impression that medicinal products and medical devices represent food, cosmetic or other product of wide consumption,
- 10) lead to the impression that medicinal products and medical devices obtained marketing authorization; i.e. that they shall obtain marketing authorization in future period;
- 11) indicate that the recommended medicinal product and medical device can be substituted with other medicinal product and medical device;

## Article 10

Advertising medicinal product and medical device to the general public is not permitted if it includes:

- 1) quotations that a medicinal product and medical device shall be added to the list of

medicinal products and medical devices the prescription and distribution of which is covered with obligatory health insurance or voluntary health insurance funds, save in case set forth in Article 9 act 7) herein;

- 2) quotations regarding the price of a medicinal product and medical device, as well as the part of price covered with obligatory health insurance or voluntary health insurance funds;
- 3) recommendations of health-care, that is veterinary or professional employees about the characteristics of the medicinal product and medical device, promoting the use thereof;
- 4) recommendations by persons which might, due to their popularity, affect the use of medicinal products and medical devices.

#### Article 11

When advertising medicinal products and medical devices to the general public, it is not permitted to use:

- 1) history of illness or illustration of diagnostic procedures which might lead to incorrect selfmedication or selfdiagnosing;
- 2) inappropriate, disturbing or misleading expressions and pictorials of changes in a human body caused by illnesses, injuries or effects a medicinal product or medical device had on the human body or its parts.

#### Article 12

When advertising medicinal products and medical devices to the general public, it is not permitted to present children who take a medicinal product and medical device, i.e. to whom a medicinal product and medical device is available without the presence of the adults.

Advertising medicinal products and medical devices to the general public shall not be exclusively and mostly focused on children.

#### Article 13

Advertising medicinal products and medical devices to the general public shall not be permitted when naming the pharmacy, specialized store and name of a legal entity engaged in wholesale marketing of medicinal products and medical devices, where medicinal products and medical devices can be purchased.

#### Article 14

When advertising medicinal products and medical devices to the general public, it is not permitted to make statements or conclusions regarding the effectiveness of medicinal products and medical devices which are subject to clinical trials in the country or abroad.

#### Article 15

When advertising medicinal products and medical devices to the general public, it is not permitted to disclose personal data on the illness of a particular person or group of persons, diagnoses, and therapeutic proceedings applied in the treatment, as well as on the medicinal

products and medical devices used in treatments of a particular person or group of persons.

#### Article 16

The advertiser must not distribute free samples of medicinal products and medical devices to the general public.

#### Article 17

The advertiser is obliged to keep records of all advertising messages given through the public media, Internet, advertising in public areas, by mail, visits, etc.

The advertiser is obliged to save all original advertising messages from paragraph 1 of this Article, in a written, visual, audio, and electronic or any other form and to provide insight into them to the inspection competent for medicinal products and medical devices.

## II ADVERTISING MEDICINAL PRODUCTS AND MEDICAL DEVICES TO THE PROFESSIONAL PUBLIC

Promoting medicinal products and medical devices to the professional public.

#### Article 18

The advertiser promotes a medicinal product and medical device by informing the professional public with the characteristics thereof, so that the public could form the attitude towards the therapeutic effects of a medicinal product and medical device.

#### Article 19

The promotion of a medicinal product and medical device is carried out in compliance with the Summary Product Characteristics thereof, which is an integral part of the marketing authorization for the medicinal product and medical device, i.e. with the approved Patient - user information leaflet.

#### Article 20

The promotion of a medicinal product and medical device shall include data on the date of obtaining marketing authorization for the medicinal product and medical device and the date of the last variation to the authorization, updated, relevant and truthfully presented data with listed literature and the accurate name of the source of information.

#### Article 21

An access to the professional information through advertising and informing the medicinal product and medical device to the professional public in written, pictorial, audio, electronic or any other form shall be limited exclusively to the professional public from Article 2, paragraphs 3 and 4 herein.

## Article 22

The promotion of a medicinal product and medical device to the professional public may be carried out by the advertiser's expert associates who graduated from the medical stomatological, pharmaceutical or faculty of the veterinary medicine.

Besides persons from paragraph 1 of this Article, the promotion of a medicinal product and medical device may be carried out by the advertiser's expert associates who graduated from the appropriate faculty, depending on the kind of the medical device.

The advertiser is obliged to carry out constant education of its expert associates who promote its medicinal product and medical device, as well as continual examination of their knowledge in order to provide complete, accurate and true information on the medicinal product and medical device they promote.

## Article 23

Expert associates who promote a medicinal product and medical device are obliged to provide the advertiser with all information regarding the treatment and adverse reactions the medicinal product and medical device, which they acquired in the course of promotion of the medicinal product and medical device.

## Article 24

Expert associates who promote a medicinal product and medical device can present the persons from the professional public only with items of minor value, that is which have symbolic value and are in connection with the medicinal or pharmaceutical, i.e. veterinary practice (for instance: pens, notebooks, calendars and other similar items which have symbolic value).

## Article 25

In the course of promotion of medicinal products and medical devices to the professional public it is not permitted to:

- 1) encourage prescribing, dispensing, procuring, recommending use or purchase of medicinal products and medical devices, by offering pecuniary rewards, presents or providing any tangible and intangible benefits, i.e. promising or giving certain benefits or rewards.
- 2) encourage the professional public to substitute a medicinal product and medical device with another medicinal product and medical device from the same therapeutic group, without the existence of clear medical indication;
- 3) make statements or conclusions regarding the effectiveness of a medicinal product and medical device which are subject to clinical trials in the country or abroad;
- 4) promote a medicinal product and medical device in the process of variation of their Summary Product Characteristics and Patient - user information leaflet;
- 5) using the Summary Product Characteristics and Patient - user information leaflet with letters smaller than 3 mm, i.e. using any other way of printing which makes easy

reading and understanding impossible;

- 6) publish information by media used for advertising in health-care institutions, i.e. private practice, i.e. veterinary institutions and specialized stores;
- 7) diminish the importance of the warning regarding precaution measures or adverse reactions to a medicinal product and medical device set forth in the Summary Product Characteristics and Patient - user information leaflet;
- 8) diminish therapeutic value of another medicinal product and medical device which obtained marketing authorization or encourage suspicion in the value of another medicinal product and medical device;
- 9) using the ministry competent for the health-care issues, ministry competent for the veterinary issues, Agency, i.e. persons involved in trials and marketing of medicinal products and medical devices;
- 10) using material protected by any kind of intellectual property rights protection without prior consent of the owner;
- 11) using postcards or other kind of written mail the content of which might be available and readable to persons other than the professional public;
- 12) using telephone, telefax, electronic mail or other electronic systems of persons belonging to the professional public without their prior explicit consent, and who advertise and inform about their work in that manner;

The promotion of medicinal products and medical devices which do not have a marketing authorization as set forth in Article 79 of the Law on Medicinal Products and Medical Devices can be carried out under the conditions provided in paragraph 1 herein.

#### Article 26

The professional public shall neither require nor receive encouragement to prescribe, dispense, i.e. consume a medicinal product or a medical device.

#### Article 27

The advertiser is obliged to keep records of promotional material it used for the promotion of a medicinal product or a medical device to the professional public, as well as of other promotional material published in professional and other magazines, that is in other forms of promotion of medicinal products and medical devices.

The advertiser is obliged to keep records of professionals to whom promotional material from paragraph 1 herein has been submitted.

The advertiser is obliged to save all original promotional material from paragraph 1 of this Article in their written, visual, audio, electronic or any other form and to provide insight into them to the inspection competent for medicinal products and medical devices.

Providing free samples of medicinal products and medical devices to the professional public

## Article 28

An expert associate of the advertiser may provide free samples of medicinal products and medical devices to the members of the professional public provided that:

- 1) the medicinal product and medical device have a marketing authorization;
- 2) the free sample of a medicinal product and medical device has as the exclusive purpose to present the characteristics of a new medicinal product and medical device;
- 3) that the quantity of free samples is limited to 30 daily determined doses within one calendar year;  
the free sample is in the smallest package of medicinal product, i.e. in the smallest package of a particular kind of medicinal product marketed, bearing the labeling "Free Sample, Not for Sale";
- 4) the free sample of a medicinal product does not contain drugs or psychotropic substances, in accordance with law;
- 5) a copy of Summary Product Characteristics is enclosed to each free sample of a medicinal product and medical device.

The advertiser keeps records of free samples of medicinal products and medical devices provided to the members of the professional public.

The advertiser is obliged to save data from paragraph 2 herein and to provide insight into them to the inspection competent for medicinal products and medical devices.

## Article 29

Free sample of a medicinal product and medical device can be provided to the individuals in professional public on their written demand.

A written demand from paragraph 1 of this Article, contains data necessary for the identification of a medicinal product and medical device free sample of which is demanded, date and signature of the authorized person.

The advertiser keeps records of demands from paragraphs 1 and 2 herein, which contain the name of the professional who submitted the demand, the number of free samples of medicinal products and medical devices given, the name of the health-care, i.e. other institution, private practice and other legal entity, as well as the date when the free sample of a medicinal product and medical device was delivered.

The advertiser is obliged to save data from paragraph 3 of this Article and to enable insight into them to the inspection competent for medicinal products and medical devices.

## Article 30

A professional who received free samples of and medicinal products and medical devices cannot sell them.

Sponsoring scientific and promotional meetings involving the participation of the professional public

#### Article 31

The advertiser may sponsor scientific and promotional meetings, professional lectures, congresses, seminars, as well as other professional meetings which involve the participation of the professional public (hereinafter referred to as: professional meetings).

Professional meetings shall be educative and compliant to scientific achievements.

Professional meetings shall not be organized solely for the purpose of advertising medicinal products and medical devices.

#### Article 32

The contents of professional meetings shall be limited only to the main content for which a meeting is being organized, and all other contents of a professional meeting shall have accompanying character compared to the main purpose of the meeting.

Hospitality shall be limited only to the main content of the professional meeting and cannot include persons not belonging to the professional public, in accordance with these Rules.

Sponsoring professional meetings cannot include covering expenses of the accompanying manifestations such as: tourist trips, sports and other similar manifestations which do not have character of professional meetings in accordance with these Rules.

#### Article 33

The advertiser may sponsor professional meetings only to the extent of covering the essential expenses related to travel, accommodation and food, and the mandatory expenses related to the participation fee in professional meetings (conference fee).

The advertiser may sponsor expenses of participation in a professional meeting from paragraph 1 of this Article for the maximum of its duration and additional two days for arriving to and departing from the professional meeting.

The advertiser is obliged to save the data on professional meetings organized, documentation on persons whose participation it has sponsored along with the data regarding the purpose of those assets and the amount of financial assets given for the sponsorship, as well as on promotional material with the place and date of its publication.

The advertiser is obliged to save all data from paragraph 1 of this Article, in a written, visual, audio, and electronic or any other form and to provide insight into them to the inspection competent for medicinal products and medical devices.

#### IV FINAL PROVISION

These Rules become effective on the eighth day as from the publishing date in “The Official Gazette of the Republic of Serbia.”

