Pursuant to the Article 24 paragraph 7 and Article 132 paragraph 3 of the Law on Medicines („Official Gazette of Montenegro", No 56/11 and 6/13), the Ministry of Health hereby issues the

RULEBOOK ON THE MANNER AND CONDITIONS OF ADVERTISING OF MEDICINES

(„Official Gazette of Montenegro" No 2/14)

I GENERAL PROVISIONS

Article 1

Advertising of medicines to general public and health professionals in order to promote prescription, supply, sale and consumption, as well as informing about medicines by manufacturer and marketing authorization holder, shall be performed in the manner and under conditions laid down in this Rulebook.

Article 2

Advertising of medicines shall provide factual and scientifically proven information on a medicine, respecting ethical norms, for the purpose of its proper and rational use, without misleading general and expert public.

Advertising of medicines shall be performed under conditions determined in the authorization for placing a medicine onto the market (hereinafter: marketing authorization) and in accordance with summary of product characteristics approved by the Agency for Medicines and Medical Devices (hereinafter: Agency).

Article 3

For the purposes of this Rulebook, advertising of medicines shall not include:

1) labelling of immediate and outer packaging and the accompanying patient information leaflet;
2) correspondence, including material of a non-promotional nature, needed to answer a specific question about a particular medicine;
3) factual, informative announcements and reference material relating to packaging changes, adverse reactions to a medicine, trade catalogues and price lists, provided they include no product claim and if the content of the information is objective, relevant, reliable, non-promotional, user-friendly and completely identical to the summary of product characteristics of a medicine, patient information leaflet and packaging approved by the Agency and are an integral part of the marketing authorisation;
4) information relating to human health or diseases, provided that there is no reference, even indirect, to a medicine;
5) information during vaccination campaigns carried out by a competent authorities and health institutions;
6) providing objective information on international scientific meetings held in Montenegro about a medicine that did not obtain marketing authorization in Montegero, but it has a marketing authorisation in European Union member states or in countries that have same or similar requirements for issuance of marketing authorization as Montenegro, if providing information include no product claim.

Information on a medicine referred to in paragraph 1 item 3 of this Article may be available to general public and persons qualified to prescribe and dispense medicines.

Article 4

Marketing authorization holder and legal persons that perform manufacture and marketing of medicines are obliged to advertise medicines in accordance with the Law and this Rulebook.

The obligation referred to in paragraph 1 of this Article, shall also apply to any natural or legal person who advertises or provides information on a medicine, including its therapeutic or prophylactic properties.

Article 5

Marketing authorization holder shall advertise a medicine independently, with or via another legal person (hereinafter: co-promotion of a medicine) in accordance with the Law and this Rulebook.

II ADVERTISING OF A MEDICINE TO THE GENERAL PUBLIC

Article 6

Medicines dispensed without prescription may be advertised to the general public in accordance with the Article 2 of this Rulebook, provided they are not prescribed and dispensed at the expense of the Health Insurance Fund of Montenegro (hereinafter: Fund).

Article 7

Advertising of a medicine from Article 6 of this Rulebook shall contain clear information that an advertised product is a medicine and shall in particular contain the following data:

- name of a medicine and the international non-proprietary name, if a medicine contains only one active substance;
- method of administration and necessary information for proper use;
- visible, legible and understandably written, drawn or verbal warning to the patient or user to carefully read patient information leaflet or instructions for use on the outer packaging of a medicine and to consult a doctor, pharmacist or veterinarian on possible risks and adverse reactions. That warning reads as follows: “Carefully read the instructions before use. For information about indications, precautionary measures and adverse reactions, contact your doctor or pharmacist, or veterinarian”, if a medicine for veterinary use is in question.

Warning from paragraph 1 item 3 of this Article must be pronounced (e.g. in a noticeable colour or in a framed box) and must make up at least one-tenth of the size of the advertisement, and must be written using the appropriate font size so as to be easily legible.

In advertisements in electronic media, warning from paragraph 1 item 3 of this Article must be shown independently (in a separate frame) and must be intelligibly read.

For Internet advertisements, warning from paragraph 1 item 3 of this Article must be an integral part on the main page of the advertisement, and not a separate link.

Article 8

Advertisement to the general public, shall not create the impression:

- that a medicine has no adverse reactions;

- that consultation with a doctor before taking a medicine is unnecessary, i.e. suggesting that taking a medicine may serve to avoid a medical examination, consultation or surgery or to establish a diagnosis or offering treatment advice via regular or electronic mail, or via other means of informing the public;

- that a medicine guarantees successful treatment of a disease;

- that a medicine is equivalently efficient as some other medicine, or even better;

- that it is advisable to take a medicine even if there are no signs of a disease or that it improves health;

- that health of the subject could be affected by not taking a medicine; except in cases referred to in Article 3, paragraph 1 item 5 of this Rulebook;

- that a medicine is safe and efficient due to its natural origin;

- that a medicine is a foodstuff, cosmetic product or other consumer product;

- that a product which is not considered to be a medicine has medicinal properties

- that a prescribed medicine may be replaced by another.

Advertisement from paragraph 1 of this Article shall not:

- be directed exclusively or principally at children, showing children taking the medicinal product or that the medicinal product is in their reach without the presence of an adult;

- include recommendations of health professionals or scientists or persons who, due to their popularity, could influence the use of a medicine;

- use case histories or simulations of diagnostic procedures that could lead to erroneous self-treatment or self-diagnosis;

- call upon proof of healing in an inappropriate, alarming or misleading manner;

- use improper, alarming or misleading terms and pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicine on the human body or parts thereof.

- provide information about the inclusion of a medicine on the list of medicines prescribed and dispensed at the expense of the Fund with the exception of cases from Article 3, paragraph 1 item 5 of this Rulebook;

- provide prices of a medicine, i.e. prices reimbursed by the Fund.

Article 9

In advertising to the general public, it shall not be permitted to collect and present personal data on patients, their diagnoses, therapeutic procedures that patients have undergone, or the medicines prescribed to them.

Article 10

In advertising to the general public, it shall not be permitted to make reference to a pharmacy, veterinary institution and legal person performing wholesale of medicines.

Article 11

In accordance with the Law, when assessed that it is of public interest (in the case of epidemic, epizootic, natural disasters or emergencies), state authority responsible for health matters, or state authority responsible for veterinary care may inform citizens about the use of medicines that are dispensed with a prescription through the media or other appropriate means of informing the public.

III ADVERTISING TO EXPERT PUBLIC

Article 12

Advertising of a medicine dispensed on a prescription aimed at health professionals contains information provided in accordance with Article 2 of this Rulebook.

Information on a medicine from paragraph 1 of this Article must be accurate, up-to-date, relevant and verifiable with reference to the source of information, sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicine and must contain date of their preparation or the date of the most recent revision.

Quotations as well as tables and other information taken from medical journals or other scientific works that are part of the promotional materials must be accurately reproduced with a precise citation of the source.

In addition to information from paragraph 1 of this Article, promoting of a medicine may contain data on the selling price of the medicine, i.e. on the reimbursed by the Fund.

Article 13

Access to materials used in advertising of a medicine to expert public in any form is restricted to expert public only.

Organising promotional meetings shall always be limited to the basic purpose for holding the meeting and may include expert public only.

Article 14

Advertising of a medicine to expert public is performed by representatives of marketing authorization holder who possess adequate knowledge about a medicine and additional training required to provide all necessary expert information to health professionals in accordance with Article 2 of this Rulebook.

Marketing authorisation holder shall provide an ongoing training of its representatives that advertise medicines, as well as check of their knowledge, with the aim of providing complete, precise, and accurate information about medicine that they are advertising and keep record on it.

Article 15

Representatives from Article 14 paragraph 1 of this Rulebook shall during each visit to the persons qualified to prescribe or dispense medicines provide the most recent approved summary of product characteristics for all medicines represented in the visit.

Persons from paragraph 1 of this Article shall pass to the marketing authorization holder all the information obtained through advertising of a medicine, with an emphasis on adverse reactions.

Article 16

Health professionals receive from the representatives referred to in Article 14 paragraph 1 of this Rulebook, only items that are inexpensive and that are related to medical, dental, pharmaceutical or veterinary practice or business of the employer of health professionals.

Health professionals must not receive any kind of incentives for prescribing, dispensing, selling or consumption of medicines with the exception of items referred to in paragraph 1 of this Article.

Article 17

In the procedure of advertising of a medicine to expert public, the following shall not be permitted:

- persuading health professionals and veterinarians to substitute a medicine with another from the same therapeutic group, with no clear medical indication;
- making statements or conclusions concerning the efficacy of medicines that are subject to clinical trials in the country or abroad, with the exception of post-marketing non-interventional trial of a medicine;
- indicating the summary of product characteristics, patient information leaflet by using a font size of less than 3 mm or other method of printing which prevents legibility and comprehension;
- using the media to release information intended for health professionals and veterinarians;
- underestimating the significance of warnings and precautions or adverse reactions indicated in the approved summary of product characteristics and patient information leaflet;
- underestimating therapeutic values of other medicine having marketing authorisation or to raise suspicions as to the value of another product in any other way;
- using materials protected by any form of intellectual property protection without prior approval of the owner;
- using postcards or other forms of letter parcels, the contents of which may be available and be read by others apart from expert public;
- using telephone, fax, e-mail or other electronic systems without prior consent of persons from expert public on such a manner of advertising or informing on their work.

Article 18

Professional and scientific meetings and lectures organised or financed by manufacturers, marketing authorisation holders or wholesalers of medicines shall be scientifically based and educational and shall not be exclusively promotional.

All other purposes of the gatherings referred to in paragraph 1 of this Article shall be ancillary in relation to the main purpose of the gathering.

Article 19

Representatives referred to in Article 14 paragraph 1 of this Rulebook may, upon written request, provide to health professionals and veterinarians who prescribe or dispense medicines, free sample of a medicine, under the following conditions:

- that a medicine has been granted a marketing authorisation;
- that a sample is no larger than the smallest presentation on the market and shall be marked by wording “Free sample – not for sale”;
- that a sample is solely intended for learning about the characteristics of a new medicine that is to be place onto the market for the first time;
- that a quantity of free samples is limited to one smallest packaging of a new medicine in the course of one year;
- that a free sample of a medicine does not contain narcotic drugs or psychotropic substances;
- that each free sample of a medicine is accompanied by summary of product characteristics.

Article 20

Marketing authorization holder is obliged to keep records on each free sample provided to health professionals and veterinarians together with their requests.

The records must list name and surname of health professional or veterinarian, name of health or veterinary institution and the date when free samples were supplied to them.

Article 21

Marketing authorisation holder shall be required to keep records and store samples of all promotional materials and advertisements used for advertising of medicines, with reference to who they were intended for, date and place of their publication, and persons to whom the materials were delivered.

Article 22

Organizers of gatherings and lectures from Article 18 of this Rulebook, shall be required to keep records and store data on events that they organized or financially supported.

Article 23

Provisions from this Rulebook are applied to advertising of traditional herbal medicine entered into the Register of the Agency, including the following statement: "Traditional herbal medicine for use in indications that are solely the result of its long-term use and experience"

Article 24

Provisions from this Rulebook are applied to advertising of homeopathic medicine entered into the Register of the Agency, including the following statement: "Homeopathic medicine without approved therapeutic indication. Consult a doctor if symptoms persist".

In advertising of homeopathic medicine that is entered into the Register of the Agency, only information approved for labeling of homeopathic medicine may be used.

Article 25

If advertising of a medicine is performed contrary to the provisions of this Rulebook, the Agency shall report it to the competent inspection and notify general public and expert public, if necessary.

IV FINAL PROVISION

Article 26

This Rulebook shall enter into force eight days from the day of its publication in "Official Gazette of Montenegro".

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Podgorica, 27 December 2013

Minister,
Miodrag Radunović, MD, PhD.