Pursuant to the Article 129 paragraph 5 of the Law on medical devices ("Official Gazette of Montenegro", No 24/19), Ministry of Health hereby issues

RULEBOOK

ON MORE DETAILED CONDITIONS AND MANNER OF ADVERTISING OF MEDICAL DEVICES

("Official Gazette of Montenegro", No 042/23 from 19.04.2023)

I GENERAL PROVISIONS

Subject matter

Article 1

This Rulebook determines more detailed conditions and manner of advertising of medical devices.

Use of gender sensitive language

Article 2

Terms used in this Rulebook for natural persons in masculine gender shall mean the same terms in feminine gender.

Expressions

Article 3

Terms used in this Rulebook shall have the following meaning:

1) clinical investigation of a medical device (hereinafter: clinical investigation) means any systematic investigation involving one or more human subjects, undertaken to assess safety or performance of a device;

2) intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the labeling, in the instructions for use, or in promotional materials

3) manufacturer of a medical device (hereinafter: manufacturer) means a natural or legal person with responsibility for the design, manufacture, packaging and labeling before placing it on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;

4) specialized retail store of medical devices means an outlet carrying out retail sale of medical devices (hereinafter: specialized retail store);

5) expert public means healthcare professionals who prescribe medical devices, professionals in the field of manufacturing and wholesale and retail sale of medical devices, as well as in the organization of mandatory health insurance.

II ADVERTISING OF MEDICAL DEVICES

Manner of advertising of medical devices

Article 4

Manufacturer, i.e. a legal or natural person that carry out marketing of medical devices (hereinafter: advertiser) may advertise a medical device independently or with someone else, i.e. through another legal or natural person (hereinafter: parallel promotion), in accordance with the Law and this Rulebook.

Prevention of misleading

Article 5

Wording, name, trademark, image and figurative or other signs that mislead, or may mislead general and expert public about the purpose, safety and performance of a medical device shall not be used when advertising a medical device, especially in terms of the following:

1) attributing to a medical device functions and properties that it does not have;

2) creating a wrong impression about a treatment or diagnosis;

3) failing to emphasize warning about possible risks associated with the use of a medical device, in accordance with intended purpose;

4) referring to a use that is not listed as part of the intended purpose for which the conformity assessment was carried out.

III. ADVERTISING OF A MEDICAL DEVICE TO GENERAL PUBLIC

Content of an advertising message

Article 6

Advertising of a medical device to general public is done by publishing an advertising message through public information media, or Internet, in public places and other forms of advertising, i.e. by giving a free sample in accordance with the Law.

Advertising message shall provide clear information that an advertised product is a medical device, and shall contain the following:

1) name of a medical device;

2) manner of use and data necessary for proper use of a medical device;

3) visibly, legibly and comprehensibly written, drawn or spoken warning to a patient or user to carefully read instructions for use of a medical device and to consult a medical doctor, pharmacist and/or dentist about the purpose and adverse effects of a medical device.

Warning referred to in paragraph 2 item 3 of this Article shall read as follows: "Read instructions before use! Consult a medical doctor or pharmacist about the purpose and adverse effects of the medical device", i.e. for medical devices intended for use in dentistry: "Read instructions before use! Consult a dentist or pharmacist about the purpose and adverse effects of the medical device".

Warning referred to in paragraph 3 of this Article shall be as follows:

1) written in bold in an appropriate font, easily visible, occupying at least one tenth of advertising message and framed by a straight line that cannot affect clarity and visibility of the warning, if published in print media;

2) shown independently in a separate frame, with an accompanying voice message of identical content, if published in electronic media;

3) integral part of a homepage, i.e. the main page of an internet message or advertisement, and not the page that is given as a link, i.e. a reference to the main page, if it is published via Internet.

Prohibited information in an advertising message

Article 7

Advertising message should not contain information creating a false impression that:

1) a medical device has no adverse effects;

2) it is not necessary to consult a medical doctor, pharmacist, or dentist before using a medical device;

3) medical or dental examination, advice or surgical intervention can be avoided by using a medical device;

4) use of a medical device guarantees success in the treatment of the disease;

5) a certain medical device is the best, i.e., better than other medical devices;

6) a medical device should be used even when there are no signs of illness, i.e. to improve health;

7) health of a person who does not use a medical device will be impaired, except in case of implementing a health promotion program (epidemic prevention, etc.), in accordance with the Law;

8) a medical device is food, dietary supplement, cosmetic, toy or other product on the market;

9) a medical device is, or will be registered in the following period;

10) a recommended or prescribed medical device can be replaced by an advertised medical device;

11) a medical device is harmless due to its natural origin.

Advertising message should not bring out the following:

1) price of a medical device;

2) recommendations of healthcare professionals, or scientific workers about the performance, that is, the features of a medical device that encourage its use;

3) recommendations, as well as the image of a person who, due to his/her popularity, could influence the use of a medical device.

Limitations in a medical device advertising

Article 8

When advertising a medical device, the following should not be used:

1) medical history or display of diagnostic procedures that may lead to self-medication or self-diagnosis;

2) inappropriate, disturbing or misleading expressions and pictorial presentations of changes in human body caused by disease, injury or the action of a medical device on the human body or parts of the body;

3) name of a health institution, a legal entity that performs wholesale of medical devices or a specialized retail store performing retail sale of medical devices;

4) personal data, data on the disease or condition of a specific person or group of persons, diagnosis, therapeutic procedures used in the treatment process, as well as a medical device used in the treatment of a specific person or group of persons.

IV. ADVERTISING OF A MEDICAL DEVICE TO EXPERT PUBLIC

Manner of advertising of a medical device to expert public

Article 9

Advertising of a medical device to expert public is done by the following: delivering promotional material, providing information at scientific and promotional events (hereinafter: expert meeting), in expert journals and other forms of promotion, giving a free sample, as well as sponsoring expert meetings in which expert public participates, in accordance with the Law.

Providing information referred to in paragraph 1 of this Article can be made with use of promotional material in written, pictorial, audio, electronic or other form, which can only be given to persons belonging to expert public.

Content of promotional material

Article 10

Promotional material shall contain the following:

1) note: "For expert public only!";

2) general information about a medical device, which must be relevant, accurate, updated, verifiable and sufficient for expert public to form an expert opinion based on them;

3) date of registration of a medical device;

4) statements, tables or other data taken from expert journals or scientific papers, which are current, relevant and faithfully conveyed, with reference to literature and exact source of information;

5) date of creation and last revision of the promotional material.

Promotional material should not contain the term "safe", unless it refers to a description of a medical device that contains appropriate explanations in accordance with essential requirements.

Expert associates of advertisers

Article 11

Advertising of a medical device to expert public can be carried out by persons employed or otherwise engaged by the advertiser, with VII1 level of education at a faculty of medicine, dentistry, pharmacy, technology, electrical engineering, mechanical engineering, chemistry or other appropriate faculty, depending on type of a medical device and who have appropriate knowledge and additional training in essential requirements for safety and performance of advertised medical device (hereinafter: expert associates). Advertiser shall provide continuous training to expert associates and also test their knowledge in order to provide complete, precise and accurate information about a medical device being advertised.

Visitations of expert associates

Article 12

Promotion of a medical device shall be organized exclusively at a time and place determined by a responsible or authorized person of the employer, in a manner that does not interfere with the work of employees.

Manner of advertising of a medical device to expert public

Article 13

When advertising a medical device to expert public:

1) the following should not be done:

- encouraging that one medical device can be replaced by another without a clear medical indication,

- making claims or conclusions about the effectiveness of a medical device that is the subject of clinical investigations in the country or abroad, except in case of a post-marketing non-interventional clinical investigation,

- minimising the importance of warnings about the purpose or adverse effects of a medical device,

- diminishing the value of another registered medical device or raising doubts about its value in any other manner;

2) the following should not be used:

- name of the state administration authority responsible for health affairs, the Institute for Medicines and Medical Devices or the name of a person participating in the procedure of a clinical investigation, conformity assessment or entering a medical device into the register,

- postcards or other forms of written mail, the content of which may be available or readable to other persons as well,

- telephone, telefax, email address or other address for electronic communication of a person belonging to expert public, without his/her prior consent,

- material protected by any form of intellectual property protection, without prior consent of the owner,

- information used in advertising of health institutions, i.e. specialized retail stores in the media.

Providing free samples to expert public

Article 14

Upon written request, an expert associate can provide a healthcare professional who prescribes or uses a medical device with a free sample of the following medical device:

1) that contains a note: "Free sample, not for sale" on the packaging

2) that is registered in accordance with the Law;

3) which is exclusively intended for getting acquainted with features of a medical device;

4) to which a copy of the instructions for use is attached, and the instructions are not provided in the packaging of a medical device.

A maximum of 15 free samples of a single-use medical device or one free sample of a reusable medical device can be given within 12 months.

Excluded from paragraph 1 item 4 and paragraph 2 of this Article, it is not necessary to attach a copy of the instructions for use, i.e. there is no limit to the amount of free samples of a medical device that can be sold at other closed retail sites, in accordance with regulations governing marketing and the decision on the registration of a medical device or a medical device in question is used during the implementation of preventive programs, i.e. health promotion campaigns (epidemic prevention, etc.).

Request referred to in paragraph 1 of this Article shall contain data on the identification of a medical device, as well as the date and signature of a healthcare professional.

Packaging of a free sample of a medical device may be smaller than the registered packaging of a medical device in question.

Requirements for expert meetings sponsorship

Article 15

Expert meeting (expert lecture, congress, seminar, etc.) in which the expert public participates can be sponsored by the advertiser, if:

1) it is not organized solely for the purpose of a medical device advertising;

2) it does not affect impartial performance of the work of expert public;

3) it is educational and in accordance with scientific achievements.

Advertiser should not influence the content of the expert meeting organized by expert public, nor organize an ancillary expert meeting at the same time, in the same room, but may provide information about a medical device in designated places outside the venue of the main event.

Costs of expert meetings sponsorship

Article 16

Expert meeting sponsorship is carried out by the advertiser by paying travel expenses, accommodation costs, food, as well as costs of mandatory participation in expert meetings for the course of expert meeting, and at most two more days for arrival to the meeting and departure from it.

Costs referred to in paragraph 1 of this Article shall be paid by the advertiser up to the amount of funds actually spent during the course of expert meeting.

Notifications about sponsors

Article 17

In the announcement of the organization sponsoring the expert meeting, i.e. at the beginning of the expert meeting, the advertiser shall inform the participants about the name of the sponsor.

At the expert meeting organized, or participated by expert public, regardless of whether the meeting is sponsored by an advertiser or not, the author, i.e. the person giving presentation, must, before the start of the presentation, on the first slide or in another appropriate clear and unambiguous manner, note that his/her presentation is sponsored by an advertiser.

Person belonging to expert public shall point out the note referred to in paragraph 2 of this Article also in case of publication of works in expert and scientific journals, i.e. publications or in public media.

Person belonging to expert public shall provide the note referred to in paragraph 2 of this Article to his/her employer, i.e. the entity where he/she performs certain tasks related to medical devices.

Content of an expert meeting

Article 18

Regarding expert meetings organised by the advertiser, the advertiser shall engage persons belonging to expert public as lecturers, participants in a round table/workshop or other form of participation or as participants in the training, in order to acquire expert knowledge.

Content of an expert meeting is limited only to main content for which it is organized, and all other contents have an ancillary character in relation to the main purpose of the meeting.

Content of an expert meeting shall be determined by the organizer of the meeting in question.

V. RECORDS AND REPORTS

Records

Article 19

Advertiser shall keep record on the following:

1) parallel promotions, containing the following: name, main office and activity of a legal entity that carries out parallel promotion, first and last name, residence, employment and occupation of an expert associate;

2) advertising messages, containing the following: name of a medical device, means of public information, i.e. website on which the advertising message was published and the advertising period;

3) promotional material, containing the following: name and purpose of promoted medical device, type and amount of promotional material, number and date of issuance of promotional material;

4) expert public to whom the promotional material was delivered, containing the following: name and surname of a healthcare professional to whom the promotional material was delivered, name of the employer, name and purpose of promoted medical device, type and quantity of promotional material, date of delivery of promotional material;

5) requests of expert public for the provision of free samples of a medical device, containing the following: name and surname of a healthcare professional who prescribes or uses a medical device, name of an employer, amount of free samples of a medical device provided, date of delivery of a free sample of a medical device;

6) sponsored expert meetings, containing the following: name of an expert meeting, time and place of holding, information on persons from expert public, total amount of funds spent, amount of funds spent by items (travel expenses, accommodation, meals, costs of participation in the meeting), total amount of funds spent on an annual basis.

Reports

Article 20

Based on the data from the records referred to in Article 19 of this Rulebook, the advertiser shall prepare an annual report on the advertising of medical devices, which shall be published on its website and submitted to the state administration body responsible for health affairs.

Keeping the documents

Article 21

Advertiser shall keep the original of advertising messages, promotional materials and published expert works for a period of five years.

VI. FINAL PROVISION

Entry into force

Article 22

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

Number: 5-040/23-618/3
Podgorica, 10 April 2023
Minister,
Dragoslav Šćekić, m.p.