MINISTRY OF HEALTH

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Pursuant to Article 184, paragraph 2 of the Medicinal Products Act (Official Gazette 76/13 and 90/14), the minister of health hereby issues the

ORDINANCE

ON THE MANNER OF ADVERTISING MEDICINAL PRODUCTS

I. GENERAL PROVISIONS

Article 1

(1) This Ordinance lays down the manner of advertising medicinal products.

(2) This Ordinance contains provisions that are aligned with the following acts of the European Union:

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (SL L 311, 28.11.2001).

Article 2

The advertising of medicinal products implies every form of notification on the medicinal product that is intended to promote its prescription, dispensation, sale and consumption in any form, regardless of the media in which such activities are carried out.

Article 3

(1) In the sense of this Ordinance, advertising shall include:

- advertising towards the population,
- advertising towards health care workers who are authorised to recommend, prescribe or dispense medicinal products,
- advertising towards health care workers,
- distributing samples,
- organising promotional meetings attended by persons authorised to recommend, prescribe or dispense medicinal products,
- organize professional and scientific congresses intended for health care professionals, and in particularly the payment of their travel costs, registration fees and accommodation at such meetings,
- provision of support activities to professional associations and patient association, if medicinal products are promoted through such activities.

(2) Individual advertising activities from paragraph 1 of this Article may be further regulated by the minister of health by a special decision that will be published on the website www.zdravlje.hr.

(3) In this Ordinance, the term health care worker pertains to all health care workers as defined by special regulations governing health care protection.

Article 4

The following are not considered the advertising of medicinal products:

1. labelling of medicinal products, summary of product characteristics and package leaflet,
2. correspondence between health care workers, representatives of the pharmaceutical industry and relevant marketing authorisation holders in promotion, to which materials are appended that do not serve for promotional purposes, and which is in response to a specific question pertaining to a specific medicinal product,
3. informative notices on the facts and professional materials that, for example, pertain to changes in packaging, warnings of adverse reactions or other amended safety information, trade catalogues and price lists, under the condition that they contain no promotional claims on the medicinal product,
4. all unbiased, objective information about diseases, prevention or the available methods of treatment, including pharmacological measures, in which it is not permitted to single out any specific medicinal product.

Article 5

(1) All claims listed in the advertisements for the medicinal product must be aligned with the claims from the most recent approved package leaflet and summary of product characteristics of the medicinal product in the Republic of Croatia.

(2) In the case of an amendment to the approved package leaflet and/or summary of product characteristics of the medicinal product, the marketing authorisation holder is obliged to align its promotional activities with the newly approved text of the package leaflet and/or summary of product characteristics of the medicinal product within a period of 30 working days, beginning from the date when the marketing authorisation holder received the final approved and amended text of the package leaflet and/or summary of product characteristics.

(3) Advertising on the medicinal product must ensure the transfer of true and scientifically proven information on the medicinal product, with the abidance of ethical criteria, for the purpose of the proper and rational treatment of patients, without misleading health care professionals to recommend, prescribe or dispense medicinal products and medicinal product users in cases when advertising is permitted towards the population.

Article 6

(1) Marketing authorisation holders or the representative of the marketing authorisation holder in the Republic of Croatia, or in the European Union, and the advertisement client are responsible for the alignment of advertising on medicinal products with the provisions of this Ordinance.

II. ADVERTISING TOWARDS THE POPULATION

Article 7

(1) Advertising towards the population is permitted exclusively for medicinal products that are dispensed without a prescription (over-the-counter), pursuant to the marketing authorisation for the medicinal product.

(2) Advertising towards the population is prohibited for medicinal products dispensed on a prescription pursuant to the marketing authorisation, for medicinal products that are not on the list of medicinal products prescribed in the Republic of Croatia at the expense of the mandatory health insurance fund in the system of primary, secondary and tertiary health care, and for all medicinal products containing psychotropic substances and narcotic drugs, pursuant to the Joint UN Convention on narcotic drugs from 1961 and the UN Convention on psychotropic substances from 1971.

(3) The ban from paragraph 2 of this Article shall not pertain to:

- the execution of campaigns to implement vaccinations approved by the Ministry of Health;
- public health activities of the relevant institutions pertaining to the promotion of immunisation, seroprophylaxis and chemoprophylaxis, in line with the programme adopted by the minister of health pursuant to a special act that prescribed the protection of the population from infectious diseases.

Article 8

(1) The advertisement on the medicinal product for which advertising is permitted towards the population, must contain at least the following information:

1. name of the medicinal product, if the medicinal product contains only one active substance and the international name of the active substance,
2. necessary notification for proper use,
3. informing patients to carefully read the package leaflet or the instructions on the external packaging or container of the medicinal product.

(2) Advertising on a medicinal product that serves as a reminder, and consists exclusively of the name of the medicinal product or joint name of multiple medicinal products, is exempted from the application of the requirement from paragraph 1 of this Article, and the requirement from Article 9 of this Ordinance.

Article 9

(1) In the advertising of a medicinal product that is dispensed without a prescription, the following message must be contained within the advertisement or in the notification: “Prior to use, carefully read the instructions for use, and consult your doctor or pharmacist about the possible risks and adverse reactions”.

(2) The written warning from paragraph 1 of this Article must be prominent (e.g. in a noticeable colour or in a frame) and must take up at least one-tenth of the size of the advertisement, and must be written in a font size that can be read without difficulty.

(3) For television advertisements, the warning from paragraph 1 of this Article shall be shown independently (in its own shot) and must be read in a clearly understandable voice.

(4) For television and radio advertisements, advertisements serving as a reminder are implemented in such a way that in the promotional block, the entire advertisement of the medicinal product as stipulated in paragraphs 1, 2 and 3 of this Article is played in its entirety, and following this in the same promotional form, the advertisement may follow as a reminder.

(5) In internet advertising, the warning from paragraph 1 of this Article must be an integral part of the main page of the advertisement, and not a link.

(6)The advertisement of the medicinal product from paragraph 1 of this Article may not be misleading, and it must be clearly visible that it is an advertisement. In printed articles and articles published on the internet which advertise the medicinal product, it is necessary to state: “Sponsored advertisement of a medicinal product” in a visible part of the article, with a font size equal to or larger than the font size in the remainder of the article.

Article 10

The following is not permitted in advertising a medicinal product towards the population:

1. claims that the medicinal product has no adverse reactions, is not toxic or has no risk of addiction, or diminishing the significance and frequency of adverse reactions,
2. giving the impression that the medicinal product guarantees success in the treatment of disease,
3. suggesting that a specific medicinal product is undoubtedly better than other medicinal products,
4. claims that the medicinal product may be taken when there are no signs of disease, i.e. that it improves health,
5. claims that not taking the medicinal product may negatively impact health, except in the case from Article 7, paragraph 3 of this Ordinance,
6. suggesting that the medicinal product is safe and efficient due to its natural origin,
7. claim that the medicinal product represents a dietary, cosmetic or other mass use product,
8. suggesting that by taking the medicinal product a person may avoid a physician's exam, advise or surgical procedure, and giving diagnoses or offering advise on treatment via post or e-mail,
9. suggesting that a prescribed medicinal product be replaced by another,
10. advertisement directed exclusively or primarily towards children, showing children taking the medicinal product on their own, or that the medicinal product is within their reach without the presence of an adult,
11. including the recommendation of health care workers or scientists, or including in the advertisement persons whose popularity could stimulate the use of the medicinal product,
12. listing the notice of the inclusion of the medicinal product on the list of medicinal products prescribed in the Republic of Croatia at the expense of the mandatory health

care insurance fund in the system of primary, secondary and tertiary health care, except in the cases from Article 7, paragraph 3 of this Ordinance,

13. use of the medical history or simulation of diagnostic procedures that could lead to incorrect self-treatment or self-diagnosis,
14. use of illustrative displays of changes to the human body caused by disease, injury or effect of a medicinal product on the human body or parts of the body in an inappropriate, disturbing or misleading manner,
15. referring to evidence of cures in an inappropriate, disturbing or misleading manner.

Article 11

It is prohibited to disperse medical products to the population for promotional purposes in any form and in any way, direct or indirect.

Article 12

In advertising towards the population, it is not permitted to mention the name of a pharmacy or other retail sales location in which the retail sale of medicinal products is permitted pursuant to the valid regulations.

Article 13

In advertising towards the population, it is not permitted to collect personal data on patients, their diagnoses, therapeutic procedures they have undergone and the medicinal products they have been prescribed.

III. ADVERTISING TOWARDS HEALTH CARE WORKERS

Article 14

(1) The marketing authorisation holder must ensure that the access to professional information through advertising the medicinal product towards health care workers in any form, including websites, is strictly and exclusively limited to health care workers.

(2) Advertising materials intended for health care workers authorised to recommend, prescribe or dispense medicinal products must bear the statement: “For health care workers only”, which is written in a visible part of the advertisement, in a font size of equal or larger size than the remaining font sizes in the remainder of the materials.

Article 15

(1) All advertising of medicinal products towards health care workers authorised to recommend, prescribe or dispense medicinal products must contain significant information on the medicinal product in accordance with the data listed in the summary of product characteristics and the approved package leaflet in the Republic of Croatia, and at least the following data: number of the marketing authorisation, manner of dispensing, name and address of marketing authorisation holder, name of medicinal product and international name of the active substances, approved indications, counter-indications, precautionary measures and frequent adverse reactions, dosage and manner of use and warnings, and must refer the

health care worker to the most recent approved summary of product characteristics and instructions for use.

(2) All promotional materials from paragraph 1 of this Article must contain the date of compilation or date of last amendment.

(3) Advertising of a medicinal product that serves as a reminder, and is comprised exclusively of the name of the medicinal product or joint name of multiple medicinal products, is exempted from the application of requirements from paragraphs 1 and 2 of this Article.

(4) All data from promotional materials from paragraph 1 of this Article, which are part of the advertising of the medicinal product, must be correct, of recent date, verifiable and credible, so as to enable health care workers to form their own position on the therapeutic value of the medicinal product.

(5) Advertising towards health care workers shall stimulate the proper and rational use of the medicinal product, presenting the medicinal product in an objective manner and without exaggeration in the description of its characteristics. It is not permitted to make claims that would suggest that the medicinal product or its active substance have special properties, qualities or effects, if such a claim cannot be corroborated by evidence.

(6) The terms from points 1, 2 and 3 of this paragraph may be used in the advertisements from paragraph 1 of this Article, only under the following conditions:

1. The word “safe” may never be used in describing a medicinal product without the necessary substantiation.

2. The word “new” may not be used in describing a specific medicinal product of a marketing authorisation holder that is available and promoted on the market of the Republic of Croatia during a period of more than one year since the date it was put on the market.

3. Labelling a medicinal product as “a medicinal product of choice, a first line medicinal product” for a medicinal product or specific indication may only be used on the basis of written guidelines (consensus or recommendation) issued by the relevant Croatian association of specialist physicians, and if there are no Croatian guidelines or such guidelines are more than two years old, on the basis of the guidelines of the European or global umbrella associations to which the Croatian professional societies are members.

(7) Advertising the therapeutic indications of a medicinal product that are not listed in the approved summary of product characteristics is not permitted.

(8) Subliminal advertising is not permitted, and instead it must be clearly visible that it is an advertisement for a medicinal product.

(9) Claims, tables or other material taken from medical journals and other scientific papers that are part of the promotional materials must be faithfully transposed with reference to the source.

Article 16

(1) Health care workers authorised to recommend, prescribe or dispense medicinal products may be verbally notified about a medicinal product by professional associates (hereinafter: professional associate) of the marketing authorisation holder, who has been educated by the employer in order to give professional and comprehensive information about the medicinal product that the health care worker will be informed of.

(2) The education from paragraph 1 of this Article includes the corresponding education on regulations pertaining to medicinal products and on the ethics in advertising on medicinal products. The marketing authorisation holder must keep detailed records of education conducted and have such records available for the entire duration of the employment of the professional associate with the employer, and two years following the termination of the labour relations.

Article 17

(1) The professional associate, in directly advertising the medicinal product, during every visit to a health care worker authorised to recommend, prescribe or dispense medicinal products, must have the most recently approved summary of product characteristics for all medicinal products represented in that visit and offered to the health care worker, and if he does not have them, to refer the health care worker to the website of the Agency for Medicinal Products and Medical Devices, or the European Medicines Agency, where all approved summary of product characteristics of medicinal products are found and are regularly updated.

(2) Direct advertisement of medicinal products towards an individual health care worker authorised to recommend, prescribe or dispense medicinal products, and who performed health care activities within the framework of the public health network, may be made by visits, which is possible once monthly by one professional associate for a 15-minute duration, taking account of the efficacy of work with patients.

(3) The professional associate is also required to submit to the service from Article 25 of this Ordinance all information on the use of the medicinal product learned from the health care worker authorised to recommend, prescribe or dispense medicinal products, with a special emphasis on information concerning adverse reactions.

Article 18

(1) While advertising the medicinal product, it is not permitted to stimulate the health care worker authorised to recommend, prescribe or dispense medicinal products to prescribe, dispense, procure or recommend medicinal products by providing rewards in money, gifts or enabling any other material gain, or promise of benefit or reward, unless such are small and of symbolic value (to HRK 70, before VAT) and are related to the practice the health care worker performs.

(2) Health care workers may not request nor accept stimulations for the prescription, dispensing, sale or consumption of medicinal products.

(3) The provisions of this Article shall not apply to existing measures or trade practices that pertain to the determination of the price of the medicinal product, accompanying margin and discounts.

Article 19

(1) Professional and scientific meetings and lectures organised or financed by manufacturers, marketing authorisation holders and importers, or wholesale distributers of medicinal products, must be scientifically founded and educational. The content of such meetings must primarily have a professional character.

(2) All other content of the meetings from paragraph 1 of this Article must be auxiliary in relation to the main purpose and content of the meeting.

(3) The meetings from paragraph 1 of this Article must be intended exclusively for health care workers.

(4) During the organisation of meetings from paragraph 1 of this Article, it is permitted to cover the costs of the registration fee, travel, accommodation and food for health care workers that participate in the meeting, to the level of the actual value of the said costs. It is not permitted to cover the said costs of persons who are not participants of the meeting (e.g. persons accompanying the health care worker).

(5) In selecting the venue for the meeting from paragraph 1 of this Article, the manufacturers, marketing authorisation holders and importers, or wholesale distributers of medicinal products, are obliged to select an appropriate venue, with services of a primarily business and/or congress content.

Article 20

(1) The marketing authorisation holder may secure free trial samples of a medicinal product to a health care worker authorised to recommend, prescribe or dispense medicinal products, under the condition that it does not differ from the usual packaging, that it is the smallest packaging having marketing authorisation in the Republic of Croatia and which is available on the market, and that the sample is clearly labelled with the words “free sample – not for sale”.

(2) In the storage and dispatch of the free samples from paragraph 1 of this Article, it is necessary to handle them in accordance with the good practice requirements in the wholesale trade of medicinal products.

(3) Free samples must be equipped and include the package leaflet pursuant to the marketing authorisation.

(4) The health care worker from paragraph 1 of this Article may, upon written request and with the signature of receipt, receive a free sample of a medicinal product only once in the course of a year, and that in the amount of a maximum of two of the smallest original packages, and the marketing authorisation holder is obliged to keep a record thereof. The record must state the name and surname of the health care worker, the name of the institution or private practice and the date the free sample was given to the health care worker, and information on the lot number and expiry period of the sample. Records must be kept for a minimum of two years from the date the health care worker received the sample.

Article 21

It is not permitted to perform advertising towards health care workers by handing out trial samples of medicinal products containing narcotic drugs and psychotropic substances, pursuant to a special regulation governing the prohibition of drug abuse, nor medicinal products from the list of especially expensive medicines.

Article 22

In the procedure of advertising the medicinal product towards health care workers, the following is not permitted:

1. convincing the health care worker to replace one medicinal product with another from the therapeutic group, without the existence of a clear medical indication to do so,
2. making claims or conclusions on the efficacy of medicinal products in indications that are the subject of clinical trials in the country or abroad,
3. making claims that a medicinal product has no adverse reactions and that it is not toxic or that there is no risk of forming an addiction, if such claims are not corroborated by evidence,
4. indicating the summary of product characteristics of a medicinal product, significant information from the summary of product characteristics of the medicinal product or approved instructions for use, using a font size smaller than 3 mm,
5. use of postcards or other forms of postal consignments whose content may be accessible and legible to other person other than health care workers, and
6. use of the telephone, fax, electronic mail and other electronic systems without the prior consent of the health care worker as the preferred form of advertising.

IV. ADVERTISEMENTS ON MEDICINAL PRODUCTS VIA THE INTERNET

Article 23

(1) It is permitted to advertise medicinal products on the internet pursuant to the provisions of this Ordinance. The content of websites should be separated, according to the user category, into a section intended for the population and a section intended for health care workers. Sites intended exclusively for health care workers must be protected with a user name and password.

(2) The website of the marketing authorisation holder that is accessible to the population may contain the list of medicinal products of the authorisation holder that are dispensed by prescription, under the condition that they are listed in the following manner: name of medicinal product and/or common name (INN) and a faithful reproduction of the approved instructions for use. Any texts pertaining to information about diseases, prevention and available treatment methods may not contain links to medicinal products from such lists of products of the marketing authorisation holder.

(3) The content of the website must be regularly updated and must unambiguously show the date of the most recent update of content for each page and/or topic covered.

(4) On websites, it is permitted to enable the asking of questions via e-mail in order to request additional information about a medicinal product. The marketing authorisation holder may respond to such a question in the same manner that it would respond to a question received via post, telephone or other media. In communication with the population, any discussion of the personal health condition must be avoided, and instead patients should be referred to consult their doctor.

(5) The marketing authorisation holder should disable the linking of website content intended for the population to pages intended exclusively for health care workers.

(6) All scientific and medical information published on the website, if they serve to advertise a medicinal product, must be true and aligned with this Ordinance and the Medicinal Products Act.

(7) The website must satisfy all the special regulations that govern the protection of confidentiality of information and the protection of personal data.

(8) In internet advertising of a medicinal product, every website must contain clear information on:

- identity of the client ordering the creation of the website and their contact data (physical and electronic),
- sources of information contained on the site, date of their release and information on copyrights, or sources of data published.

V. ARCHIVING OF MATERIALS, LOGBOOKS, SERVICE/PERSON RESPONSIBLE FOR ADVERTISING AND PROVIDING INFORMATION ON MEDICINAL PRODUCTS

Article 24

(1) Marketing authorisation holders advertising a medicinal product are obliged, with the archiving of promotional materials, to keep a logbook of the date and place of their publication, persons to whom the materials were delivered, and on professional meetings and lectures that they organised or financially supported.

(2) Marketing authorisation holders are obliged to keep promotional materials in written, visual, audio, electronic or any other form that can be archived, with the logbooks from paragraph 1 of this Article for two years.

Article 25

(1) The legal person named in the marketing authorisation must organise a service, or appoint a person, that is responsible for advertising and the provision of information about medicinal products that are placed on the market.

(2) The marketing authorisation holder must:

- have at their disposal and, at the request of the pharmaceutical inspection, deliver copies of all advertisements, together with notes as to which users they were intended for, the manner of publication and date of first publication,
- ensure that professional associated publishing advertisements on medicinal products towards health care workers are properly trained, and that they meet the obligations prescribed in Article 16 of this Ordinance,
- ensure that advertising on a medicinal product is in accordance with the requirements of this Ordinance,
- ensure that the decision of the pharmaceutical inspection with regard to advertising the medicinal product is fully implemented without delay,
- deliver to the pharmaceutical inspection all data necessary to perform supervision over the advertisement of medicinal products.

(3) The marketing authorisation holder may authorise one or more legal persons for the tasks of promotion and advertisement of the same medicinal product.

(4) Individual requests by citizens for advice pertaining to the personal health care problems should be avoided, and instead the person making the request should be referred to consult with their doctor.

VI. HOMEOPATHIC MEDICINAL PRODUCTS

Article 26

The provisions of this Ordinance shall apply appropriately to homeopathic medicinal products, pursuant to Article 71, paragraphs 3 and 4 of the Medicinal Products Act.

VII. TRANSITIONAL AND FINAL PROVISIONS

Article 27

(1) With the entry of this Ordinance into force, the Ordinance on the manner of advertising medicinal products and homeopathic products (Official Gazette 118/09 and 140/09) shall cease to have effect.

(2) Advertisement that are prepared pursuant to the Ordinance on the manner of advertising medicinal products and homeopathic products (Official Gazette 118/09 and 140/09) must be aligned with this Ordinance within a period of 12 months following the entry of this Ordinance into force.

Article 28

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

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Zagreb, 9 April 2015

Minister
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