Unofficial Consolidated Text of the Rules on the advertising of medicinal products includes:

- Rules on the advertising of medicinal products (Official Gazette of RS, no. 105/08 dated 7. 11. 2008),
- Rules amending the Rules on the advertising of medicinal products (Official Gazette of RS, no. 105/10 dated 24. 12. 2010).

R e g u l a t i o n s
the advertising of medicinal products

(Unofficial Consolidated text no. 1)

I. GENERAL PROVISIONS

Article 1
(Scope)

This Regulation Lays Down Detailed Conditions and Manner of advertising of medicinal products for human and veterinary medicine (hereinafter: products) and accordance with 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 use and human use (OJ L no. 311 of 28. 11. 2001, p. 67), last Amended by Directive 2008/29 / EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001 / 83 / EC on the Community code relating to medicinal products for human use, as regards the Implementing Powers conferred on the Commission (OJ L 81 of 20. 3. 2008, p. 51) (hereinafter:Directive 2001/83 / EC) and Directive 2001/82 / EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use (OJ L no. 311 dated 11. 28. 2001 p. 1) last Amended by Directive 2004/28 / EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82 / EC on the Community code relating to medicinal products for veterinary use (OJ L no. 136 of 30. 4. 2004, p. 58) (hereinafter: Directive 2001/82 / EC).

Article 2
(Definition of advertising)

(1) Advertising of medicinal products are all forms of information, including information from door to door, propaganda and promotion, which is intended to promote the prescription, supply, sale and use of drugs.

(2) In view of the target groups we divide advertising on:

- Advertising to the general public and
- Advertising in expert public.

Article 3
(Definition of general and professional public)

(1) The general public are secular groups and individuals who do not belong to the professional community as defined by this policy.

(2) Professional persons authorized for prescribing and dispensing of medicines.

Article 4
(Advertising)

(1) Advertising to the general public are all promotional forms and methods of communication secular groups and individuals.

(2) Advertising in expert public is:
- Providing information to persons who are authorized to prescribe or supply medicinal products to the properties and effects of medication, including informing those persons directly;
- Sponsorship and organization of promotional meetings attended by persons authorized for prescribing and dispensing of medicines;
- Sponsorship of scientific congresses attended by persons authorized for prescribing and dispensing of medicines;
- Placing the samples in accordance with Article 22 of this Regulation.

(3) Advertising in expert public is also considered an encouragement to prescribe or dispense with the promise or give any financial or material goods, in accordance with Article 20 of this Regulation.

Article 5
(Elimination from advertising)

Advertising or advertising material does not include:
- Labeling and package leaflet approved the authorization for a medicinal product;
- Informative announcements relating to the approved package changes, warnings of side effects and other general precautionary measures with a view to safer and more effective use of medicines;
- Sales catalogs and price lists that do not include no product claims;
- Correspondence on specific issues relating to a specific product, the accompanying materials, which are not promotional in nature;
- Publications and material institutions authorized to prepare programs for the prevention, control, removal (elimination) and the eradication (eradication) of infectious diseases on the vaccination against certain diseases for which no direct mention of individual vaccines, their effect and other specific characteristics;
- Information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products. Information should be high-quality, objective, unambiguous, comprehensive, balanced, comprehensible to users and should not contain elements of direct or disguised advertising.

II. ADVERTISING CONDITIONS

6. Article
(Marketing authorization)

It is allowed to advertise only those medicines that have marketing authorization in accordance with the Medicinal Products Act (Official Gazette of RS, Nos. 31/06 and 45/08, hereinafter: the Act).

Article 7
(Compliance with the summary of product characteristics)

Each individual element of advertising and all parts of the message recipient constitute a coherent whole, they must be consistent with the approved summary of product characteristics. All properties should be presented in a balanced way.

Article 8
(Rational and safe use of drugs)

(1) Advertising of medicinal products must encourage their rational and safe use, so that it is presented objectively and without exaggerating its properties.

(2) To achieve the objective set out in the preceding paragraph, the body responsible for the product, in the process of acquisition or maintenance of the marketing authorization require special warnings that should be part of every advertising.

Article 9
(Misleading advertising)

Advertising must not be misleading as to the potential benefits or risks of using the medicinal product, taking into account the integrity of the ad impression and messages.

Article 10
(Protection of the Slovenian language)

(1) Advertising must be in the Slovenian language in the municipalities where the Italian and Hungarian national communities, but may also be in the minority language.

(2) Notwithstanding the preceding paragraph, literature enclosed with advertising material for the professional public may also be in the original language of the article. At international expert meetings in Slovenia, advertisements and advertising material may also be in the language or languages of the event participants of these events.

Article 11
(Responsibility)

To ensure compliance with the advertising rules rests with the holder of the marketing authorization or client advertising, but for non-compliance with the provisions on advertising of medicinal products liable any person who is involved in the improper promotion of medicines.

III. ADVERTISING IN GENERAL PUBLIC

12. Article
(Advertising in general public)

(1) The general public is permitted to advertise only medicines that are available without prescription and for which the marketing authorization for the medicinal product so decides, the authority responsible for the product.

(2) The advertising and publishing information to the general public on medicinal products containing psychotropic or narcotic substances from international conventions such as the United Nations Single Convention on Narcotic Drugs of 1961 and the United Nations Convention on Psychotropic Substances of 1971st

(3) The advertising of medicinal products for veterinary use, which can be used as growth promoters, or enhancers (eg. Hormones, beta-agonists, thyrostatic substance, bovine somatrophin).

Article 13
(In terms of advertising to the general public)

Advertising of medicinal products to the general public must be made so that the advertising nature of the message clearly identified and that the product is clearly presented as a medicine.

Article 14
(Content advertising to the general public)

(1) Advertising of any non-prescription medicines to the general public must contain at least the following information:
- Product name and the common name if the product contains only one active ingredient;
- Information that is necessary for the efficient, correct and rational use of medicines;
- Visibly and legibly written, pictorial or verbal warning about the importance of the instructions for use accompanying the product and read the medicine for human use: "Always read the manual! About the risk of adverse effects with your doctor or pharmacist. ";
- Visibly and legibly written, pictorial or verbal warning about the importance of the instructions for use accompanying the product and read the medicine for use in veterinary medicine: "Always read the manual! On the risks and adverse reactions, contact your veterinarian or pharmacist. ".

(2) a written warning from the preceding paragraph must be stated highlighted (eg .: bold, colored, box), of at least one-tenth the size of the ad and the appropriate size of the font so that it can be easily read and can not be overlooked . TV ads should be a warning on the screen independent and delivered an image (text) and oral form. Oral warning must be stated in the standard language clearly and understandably and must ensure that the severity of the message. In the case of advertisements on electronic media should be a warning shown as an integral part of the main pages interesting and not as a link to it. It must be noted (eg .: bold, colored, box) in size, which when displayed on the entire screen is less than one-fourth of the screen and the font size of not less than one-tenth of the side box warning.

Article 15
(Ban on advertising to the general public)

(1) Advertising of OTC medicines to the general public shall not contain any material which:
- Give the impression that a medical consultation or veterinary or surgical operation is unnecessary, in particular by attributing a diagnosis or by suggesting treatment by mail;

- Suggesting that the effects of taking the medicine are absolutely guaranteed that the drug has no side effects or are better than other medicines or the equivalent of another treatment or medicinal product;
- Suggests that the health of a person or animal can only be improved by taking the advertised medicinal product;
- Suggests that the health of a person or animal without taking the advertised medicinal deteriorated; this prohibition shall not apply to vaccination programs and advertising vaccines in accordance with Article 24 of this Regulation;
- Is directed exclusively or principally at children;
- Referring to a recommendation by scientists, experts in the field of human or veterinary medicine or publicly known other people who, because of their celebrity, could encourage the consumption of medicinal products;
- Indicates that the product is a food, cosmetic or other consumer product;
- Indicate that the safety and effectiveness of the result of the natural origin of the product;
- Could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- Use improper, alarming or misleading terms, to claims of recovery or
- Use inappropriate, alarming or misleading terms, pictorial representations of changes in the human or animal body caused by disease or injury, or drug action on the human or animal body or body parts.

(2) It is prohibited to direct distribution of medicinal products to end-users for promotional purposes.

IV. Advertising in expert public

16. Article
(Advertising in expert public)

(1) The holder of the marketing authorization or advertiser is obliged to ensure that any advertising in expert public designed and communicated only to persons authorized to prescribe or supply medicinal products.

(2) Information material intended for professionals, would ordinarily be labeled "For professional public.".

Article 17
(Advertising in professional publications and direct information)

(1) Holders of marketing authorization may advertise medicinal products which have obtained marketing authorization to expert public in professional books, journals and other professional publications.

(2) Holders of marketing authorization may also advertise medicines directly inform persons who are authorized to prescribe or supply medicinal products.

Article 18
(Data and information relating to medicinal products)

(1) All information on medicinal products intended for the professional public and the persons who are authorized for their prescribing and dispensing, shall in particular include the following information:

- The name of the product;
- For medicinal products for human use relevant information from the SPC such as the composition of medicines, therapeutic indications, dosage and method of use, a summary of adverse reactions, precautions and warnings, contraindications and interactions, name, logo and address of the marketing authorization marketing;
- Medicinal products for veterinary use relevant information from the SPC such as the composition of medicines, therapeutic indications, dosage and method of use, a summary of adverse reactions, precautions and warnings, contraindications and interactions, name, logo and address of the marketing authorization transport, the animal species to which the drug is intended, abstinence;
- The manner and mode of dispensing and prescribing medicines;
- The date of preparation of information.

(2) In addition to the data referred to in the preceding paragraph, the information shall also include information on the payer or the classification of a medicinal product on the appropriate list.

(3) All information contained in this Article shall be accurate, clear, current and verifiable to allow an assessment of the operation and the therapeutic value of the product.

(4) All quotations and tables and other illustrative matter taken from medical journals or other scientific works must be authentically summarized with exact list of resources.

Article 19
(Visits by professional staff)

(1) Direct medical information may be performed by medical staff if they meet the following conditions:
- Assistants for Medicinal Products for Human Use must have a university degree in pharmacy or medicine or a university degree in natural sciences or biomedicine, and additional knowledge in the field of medicinal products;
- Assistants for medicinal products for veterinary use must have a university degree in pharmacy or veterinary medicine or a university degree in natural sciences or biomedicine, and additional knowledge in the field of medicines;
- They must be properly trained to give accurate and complete technical information on this product.

(2) Advertising of medicinal products directly inform persons who are authorized to prescribe or supply medicinal products and practicing medicine within the public health service network, can be carried out only at the time of preparation for professional work, which is not designed to work directly with patients.

(3) Experts shall forward the information to persons who are authorized for their prescribing and dispensing, product information, in accordance with the approved summary of product characteristics. This summary must be submitted in writing or must be available.

(4) Experts are obliged to transfer the holder of the marketing authorization, any information on adverse drug reactions, as well as any other clinically relevant information in relation to the use of the product obtained by persons authorized to prescribe or supply medicinal products.

Article 20

(Give gifts)

Holders of marketing authorizations for medicinal products, manufacturers of drugs, legal or natural persons acting on behalf of producers and natural or legal persons who conduct business in medicinal and branches of foreign producers not to persons authorized to prescribe or supply medicinal products to be supplied, offered or promising any gifts, cash benefits or benefits in kind, unless they are small or symbolic value and can be used to perform medical, veterinary or pharmacy.

Article 21
(Promotional meetings)

(1) Notwithstanding the provisions of the preceding Article, holders of marketing authorizations for medicinal products, manufacturers of drugs, legal or natural persons acting on behalf of producers and natural or legal persons engaged in medicinal products and branches of foreign manufacturers allow persons authorized to prescribe or supply medicinal products to acquire additional knowledge about new findings about medicines. Acquiring additional knowledge may not exceed the technical and scientific objectives of such education be subordinated exclusively to the production of knowledge and is intended only for persons responsible for prescribing and dispensing of medicines.

(2) Hospitality at promotional meetings should be at a moderate level and secondary to the main purpose of the meeting and must not be extended to persons who are not responsible for prescribing and dispensing of medicines.

(3) The persons authorized to prescribe or supply medicinal products shall neither seek or accept any benefit that is contrary to the first and second paragraphs of this article, or to attempt to obtain.

Article 22
(Placing samples)

(1) In exceptional cases, manufacturers of medicinal products and the natural or legal person acting on behalf of producers of persons authorized to prescribe medicines forward free samples of medicines by prescription, where necessary, the patient be instructed on how to use a new drug if it is not for oral use and the following conditions are met:

- The medicinal product is authorized in accordance with the law;
- The acquisition of the marketing authorization or approval of the marketing authorization, which requires a new role, there has been more than two years;
- A person authorized to prescribe medicinal products can annually receive only one sample of each drug in the smallest package, which is authorized for marketing and for which the holder of the marketing authorization authority for medicines written notice of the actual start of the market in accordance with 44 Rule of Law;
- The recipient must apply for free samples writing. Application must be signed and dated;
- The recipient has received the samples kept;
- The recipient may not sell received samples;
- Manufacturers of medicinal products and the natural or legal person acting on behalf of producers must keep records and have a system of control and accountability over free samples;
- Each sample must be in the package, and is equipped with a package that was approved in the marketing authorization, and marked that it is a free sample, not for sale;

- In each sample it must be accompanied by an approved summary of product characteristics;
- The sample must not contain narcotic and psychotropic substances.

(2) Share of samples that require special storage conditions, such as cold chain, is prohibited.

V. PROFESSIONAL SERVICE

23 Article
(Professional service)

(1) Holders of marketing authorization must establish service, which is responsible for the preparation of information on medicinal products which are placed on the market.

(2) The responsible person is the holder of the marketing authorization must:
- Ensure that the body responsible for the supervision of advertising of medicines and other supervisory bodies in the samples of all promotional materials, together with an indication of the target groups to which they were intended, method of dispatching and date of the first shipment;
- Ensure the maintenance of records given free samples of medicinal products must contain a written request of persons authorized to prescribe drugs in accordance with the fourth indent of the first paragraph of the preceding article. Records must be kept for at least three years;
- Ensure that medicines are advertised in accordance with these Rules;
- Verify that medical sales representatives are properly trained to give accurate and complete technical product information and perform tasks in accordance with these Rules;
- Keep a list of assistants who advertise medicines directly inform persons who are authorized to prescribe or supply medicinal products, the particulars of their qualifications;
- The list referred to in the previous indent to the authority competent for medicinal products for the purpose of carrying out professional supervision is carried out under pharmaceutical supervision in accordance with the law;
- Provide to the body responsible for monitoring advertising of medicinal products and other supervisory bodies, all the information they require in connection with advertising;
- Ensure that the decisions of the authorities responsible for the control immediately and fully complied with.

(3) Changes in the data of the fifth indent of the preceding paragraph, the person responsible for the holder of the marketing authorization communicated to the authority competent for medicinal products within 15 days of their changes.

VI. Climbing VACCINE

24. Article
(Advertising vaccines)

(1) Advertising of medicinal products which are used in vaccination programs, the general public may authorize the authority responsible for the product.

(2) Any advertising is permitted under the preceding paragraph must include the warning: "Vaccination is the risk of adverse effects with your doctor.", Which shall meet the requirements as defined in Article 14 of this Regulation.

(3) Medications used in vaccination programs may be advertised to the general public only with the international non-proprietary names. Advertising must be in accordance with Article 15 of this Regulation and should not contain elements which would reduce the objectivity of information on medicinal products used in vaccination and vaccination.

(4) Advertising of medicinal products which are used in immunization programs must contain information about all the medicines with the same indication, which are present on the market in the Republic of Slovenia.

Article 25
(Approval of advertising vaccines)

(1) For pre-approval of advertising in the preceding article, the holder of the marketing authorization by a competent authority for medicines, filed an application containing:
- Covering letter,
- Proposal grounded advertising materials together with an indication of target groups, method and timing of advertising and
- Proof of payment of the costs and administrative fees.

(2) The competent authority for medicinal decision on the application within 60 days of receipt of the complete application.

VII. Climbing Other special MEDICINES

Article 26
(Advertising traditional and homeopathic medicines)

(1) Traditional herbal medicinal products may be advertised in accordance with these rules and regulations governing traditional herbal medicinal products.

(2) Homeopathic medicinal products may be advertised in accordance with the rules and the rules governing homeopathic medicines.

VIII. ADVERTISING MONITORING

27 Article
(Monitoring of advertising)

(1) The competent authority for medicinal products may establish a permanent commission of expert in the field of advertising or representatives of interested public to monitor compliance of advertising with these rules.

(2) Based on data from the list of assistants in the fifth indent of the second paragraph of Article 23 of this Regulation, the authority responsible for the product within the professional supervision of an overall verification of the fulfillment of conditions for professional staff who work with the holders of marketing authorization.

Rules on the advertising of medicinal products (Official Gazette of RS, no. 105/08 **) contains the following transitional and final provisions:**

"IX. TRANSITIONAL AND FINAL PROVISIONS

28 Article
(Termination)

The effective date of these Rules, the Rules on the advertising of medicinal products and medical devices (Official Gazette of RS, no. 76/01) in so far as it relates to drugs, and the Rules on advertising of medicinal products for veterinary use (Official Gazette of RS, No. . 70/03).

Article 29
(Enforcement Regulations)

This Regulation shall enter into force on the fifteenth day following its publication in the Official Gazette of the Republic of Slovenia. ".

Rules amending the Rules on the advertising of medicinal products (Official Gazette of RS, no. 105/10 **) contains the following transitional and final provisions:**

»8th Article

Holders of marketing authorization communicated to the authority competent for medicinal products, the list of assistants in the fifth indent of the second paragraph of Article 23 of this Regulation no later than one month from the entry into force of this Regulation.

Article 9

This Regulation shall enter into force on the fifteenth day following its publication in the Official Gazette of the Republic of Slovenia. ".