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Based on Article 71 of the Medicinal Products and Medical Devices Act of Bosnia and Herzegovina ("Official Gazette of BiH", No. 58/08), the Minister of Civil Affairs of Bosnia and Herzegovina, at the proposal of the Expert Council of the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina, adopted

ORDINANCE

ON THE CONTENT AND MANNER OF LABELLING OF OUTER AND IMMEDIATE PACKAGING OF MEDICINAL PRODUCT

PART ONE - PRELIMINARY PROVISIONS

Article 1

This Ordinance regulates the content and manner of labeling of the outer and immediate packaging of the medicinal products marketed in BiH.

Article 2

(1) Each package of the medicinal product, which is marketed in BiH, shall contain patient information leaflet that is written in one of the official languages which are in use in BiH and which complies with the summary of the main characteristics of the medicinal product, unless all the required data is already listed on outer packaging.

(2) Every package of the medicinal product, which is marketed in BiH, and the attached patient information leaflet, should not contain elements of advertising of the medicinal product.

Article 3

(1) All information stated on the label on the outer and immediate packaging of the medicinal product, as well as in the patient information leaflet, should be provided with sufficient space between the lines, and in a way so that they are easily legible, clearly comprehensible and indelible.

(2) The smallest letters in the patient information leaflet should be 7P (P - the height of the letters shall be at least 1.4 mm), with enough space between the lines, so as to ensure readability.

(3) In cases when the requirement from paragraph 2 of this Article may not be met, the Agency may allow the use of smaller font size, but not smaller than 5P.

(4) The outer packaging of the medicinal product and the patient information leaflet contain data without the use of abbreviations, if possible in relation to the size of the packaging.

(5) All information regarding the labeling of the external and internal package of a medicinal product shall be in one of the languages which are officially in use in Bosnia and Herzegovina, provided that the brand name of the medicinal product may be written in Cyrillic or Latin alphabet and may contain letters of the English alphabet, and an international nonproprietary name (INN) or generic name in Latin, or one of the languages which are officially in use in BiH, in accordance with the usual rules of the profession.

Article 4

If the outer and the immediate packaging of the medicinal product are labeled in several languages, or if the patient information leaflet is written in multiple languages, the content of all information shall be the same in every of those languages.

PART TWO - CONTENT AND MANNER OF LABELLING OF THE OUTER PACKAGING OF MEDICINAL PRODUCT

Article 5

The outer packaging is the packaging that contains the immediate packaging of the medicinal product.

Article 6

(1) The outer packaging of the medicinal product should contain the following data:

a) name of the medicinal product and the international nonproprietary name of each active substance;

b) active substances, expressed qualitatively and quantitatively per dosage unit;

c) pharmaceutical form, strength and packaging;

d) list of those excipients that have recognized effect (in accordance with annex VI of the Ordinance on the Conditions for Granting Marketing Authorization), and the outer packaging of the medicinal products in the form of injections, medicinal products for the local use and eyes preparations, should always contain a list of all excipients;

- e) method of administration and the regime of dispensing;
- f) warning that the medicinal product should be kept out of reach of children, as well as other necessary warnings;
- g) expiry date of the medicinal product (month and year);
- h) storage conditions for the medicinal product, if there are special storage conditions;
- i) special precautions for disposal and destruction of the medicinal product;
- j) name of the manufacturer, as well as the marketing authorization holder;
- k) number and date of marketing authorization for the medicinal product;
- l) batch number and EAN code.
- m) manner of administration of the medicinal products which are issued without a prescription; if the size of the packaging allows it.

(2) The outer packaging is additionally labeled with other data in accordance with this Ordinance.

TITLE I - Name of the medicinal product and international nonproprietary name of each active substance

Article 7

(1) The name of the medicinal product is stated on the outer packaging of the medicinal product, which may be:

- a) brand name;
- b) international nonproprietary name (INN), with a sign or name of the manufacturer or without them;
- c) generic name, with the symbol or name of the manufacturer or without them;
- d) exact chemical or scientific name or widely known name, with a sign or name of the manufacturer or without them.

(2) Brand name referred to in paragraph 1, item a) of this Article should not cause confusion in relation to the name or title from paragraph 1, item b) to d) of this Article.

(3) The international nonproprietary name (INN) is a name defined by the World Health Organization.

(4) Name of the medicinal product that is used in human medicinal product and which is issued on prescription, on the basis of a marketing authorization, may be written in Braille for blind and visually impaired persons.

Article 8

(1) In addition to the name of medicinal product from Article 7 paragraph 1 of this Ordinance, strength of medicinal product and its pharmaceutical form should be stated on the outer packaging of the medicinal product, in accordance with the standard terminology of national Pharmacopoeia and European Pharmacopoeia.

(2) Information on the medicinal product listed in the following order: name, strength, pharmaceutical form, INN or generic name.

Article 9

(1) On the outer packaging of the medicinal product, in addition to the name of the medicinal product from Article 7 paragraph 1 of this Ordinance, should be stated up to three active substances contained in the medicinal product.

(2) If the medicinal product referred to in paragraph 1 of this Article contains more than three active substances, the Agency for Medicinal Products and Medical Devices of Bosnia and Herzegovina (hereinafter: the Agency), during the approval of the outer packaging of the medicinal product, shall decide which active substances should be listed on the outer packaging of the medicinal product.

(3) The active substances referred to in paragraph 1 and 2 of this Article shall be stated after the strength and pharmaceutical form, or below a brand name of the medicinal product.

TITLE II - The active substances, expressed qualitatively and quantitatively per dosage unit

Article 10

The qualitative composition of the medicinal product according to the content of the active substance is stated in accordance with standard terminology of the International Pharmacopoeia and European Pharmacopoeia, and there is also the INN or generic name, or the active substance compound form.

Article 11

The quantitative composition of the medicinal product according to the content of the active substance or strength of the medicinal product is expressed:

- a) per dosage unit;
- b) per unit of volume, if it is in accordance with the pharmaceutical form;
- c) per unit of mass, if it is in accordance with the pharmaceutical form.

Article 12

(1) The active substance in the form of a compound (eg. In the form of a salt or ester) is expressed as the amount of the active form, with the INN or generic name.

(2) Different strengths are market with the same units of measure, provided that the use of the comma is avoided (eg, 250 mg instead of 0.25 g), and for safety reasons micrograms are indicated with the whole word, not the abbreviation.

(3) For a single dose of parenteral products, the amount of active substance is expressed in ml, or in the total volume, and in multi-dose parenteral products the amount of active substance is expressed in ml, or per 100 ml or per 1000 ml, etc.

(4) For parenteral products containing larger amounts of inorganic salts, the salt amount may be expressed in millimoles.

(5) Concentrates for parenteral use are marked as the content of the active substance in the total volume, and as the content of active substance per ml, except that the mark states: "Dilute before use according to the instructions".

(6) If the concentrates for parenteral use referred to in paragraph 5 of this Article, prior to use, according to the instructions are diluted to single concentration, they are also marked as a content of active substance in mg / ml after dilution according to the instructions.

(7) If there is a variety of possible ways to dilute the concentrate referred to in paragraph 5 of this Article according to the instructions, which provide a variety of permanent concentration of dilution, they are not marked with the data referred to in paragraph 6 of this article.

(8) Before parenteral use, powder for solution or suspension is marked as the total content of active substance in a container labeled "Dilute before use according to the instructions".

(9) If the powder referred to in paragraph 8 of this Article is diluted as directed to the single concentration prior to use, it is marked as a content of active substance in mg / ml after dilution according to the instructions.

(10) If there is a variety of possible ways to dilute the powder referred to in paragraph 8 of this Article according to the instructions, which provide different final concentrations of dilution, they are not marked with the data referred to in paragraph 9 above.

Article 13

Diluents for concentrates or powders must be clearly stated and marked.

Article 14

(1) The transdermal patch shall contain information on:

a) the content of the active substance;

b) dose absorbed by the patient per unit of time (hour, day, etc.).

(2) The information referred to in paragraph 1 of this Article shall be clearly separated.

Article 15

For multidose solid pharmaceutical forms (eg. powders, granules, etc.), the amount of active substance has to be expressed, if possible, per dosage unit or per unit of mass, or in percentages.

Article 16

For implants or intrauterine devices the amount of active substance is expressed as:

a) the content of active substance in each implant or IUD;

- b) released dose, or dose absorbed by the patient per unit of time (hour, day, etc.);
- c) the overall duration of time (hours, days, etc.) necessary for the absorption of the entire dose.

TITLE III - The pharmaceutical form and packaging

Article 17

(1) Pharmaceutical form of medicinal product is the form in which the active substance is incorporated with the help of technological processes, and thus it allows its use, taking into account the physiological conditions of the body and the physicochemical properties of the substance, which may be:

- a) final pharmaceutical form of medicinal product which is a form of the medicinal product that the patient receives (eg. suspension);
- b) basic pharmaceutical form of medicinal product, which is a form of medicinal product is put on the market by the manufacturer (eg. a powder for suspension)

(2) The outer packaging of the medicinal product contains data about the pharmaceutical form of medicinal product, or the final or basic pharmaceutical form of the medicinal product if they differ from each other.

Article 18

The pharmaceutical form is stated according to the standard terminology of International Pharmacopoeia and European Pharmacopoeia.

Article 19

Package size is stated in units of mass, volume or number of units (doses) of the medicinal product.

TITLE IV - List of excipients and method of administration

Article 20

(1) On the outer packaging of the medicinal product there are excipients which have recognized effect from the list of excipients which must be listed on the label of the medicinal product, as well as the manner in which they have to be listed.

(2) A list of excipients, which have recognized effect, presents the integral part of the Ordinance on the Conditions for Granting Marketing Authorization (Annex VI).

(3) If the medicinal product is in the form of injection, medicinal product for parenteral, ophthalmic and external use as well as medicinal product for inhalation, which are used in human medicinal product, all the excipients are listed on the outer packaging.

(4) The names of the excipients are listed in one of the official languages which are in use in BiH, in accordance with standard terminology of International and European Pharmacopoeia.

Article 21

(1) The outer packaging of the medicinal product indicates the information on the method of

administration of the medicinal product in accordance with standard terminology of International and European Pharmacopoeia.

(2) The outer packaging of the medicinal product has to contain a space for the prescribed dose of the medicinal product.

TITLE V - Warning that the medicinal product should be kept out of reach of children, as well as other necessary warnings

Article 22

The outer packaging of the medicinal product shall provide the information that the medicinal product should be kept out of the reach of children.

Article 23

If the medicinal product affects the ability to drive and use machines, the outer packaging of the medicinal product shall contain that data as a special warning, in accordance with this Ordinance.

Section A - The expiry date of the medicinal product (month and year)

Article 24

(1) The outer packaging of the medicinal product shall contain a clearly written expiry date of the medicinal product, stating the month and the year, without the abbreviations, with the remark "valid until: month and year."

(2) The medicinal product can be used up to the last day of that month.

(3) The outer packaging of the medicinal product indicates the expiry date of the medicinal product after dissolution and dilution, and if necessary, after first opening of the container.

TITLE VI - Storage conditions for medicinal product, if special storage conditions are necessary

Article 25

(1) The outer packaging of the medicinal product may not indicate storage temperature of the medicinal product, provided that the medicinal product is stable at 30 ° C.

(2) If the medicinal product is not stable at 30 ° C, storage temperature of the medicinal product shall be specified (eg. Store below 25 ° C, store at 2-8 ° C in the refrigerator, store in freezer, and a warning that the medicinal product should not be or must be frozen).

Article 26

On the outer packaging of the medicinal product, if necessary, other storage conditions (eg. medicinal product is kept in original packaging or container, keep the container tightly closed, keep container in the outer carton, kept protected from light and moisture, no special warnings for safekeeping) are indicated.

Section B - Special precautions for disposal and destruction of medicinal products

Article 27

Special precautions for disposal and destruction of medicinal products or unused medicinal products or the rest of the medicinal product shall be specified on the packaging of the medicinal product, if it is necessary or if it is, depending on the type of medicinal product, common.

TITLE VII – Name of the manufacturer and marketing authorization holder

Article 28

The outer packaging of the medicinal product shall specify the following in separate: name of the manufacturer of the medicinal product (the administrative headquarters or place of production of the medicinal product), as well as the name of the marketing authorization holder.

Section C - The number of license for marketing authorization

Article 29

The outer packaging of the medicinal product shall indicate the date and the number of license for marketing authorization which was issued by the Agency.

TITLE VIII - Batch number of medicinal product and EAN code

Article 30

(1) The outer packaging of the medicinal product shall indicate batch or batch number of the medicinal product. Batch number of the medicinal products may have more characters.

(2) The outer packaging of the medicinal product shall also indicate the date of manufacture of the medicinal product, if necessary.

(3) If it is technically possible, the following particulars shall appear on the outer packaging of the medicinal product in the following order:

- a) batch number;
- b) expiration date (month and year).

Data from this Article shall be listed without abbreviations.

(4) If the data referred to in paragraph 3 of this Article may not be listed without the use of abbreviation, the following abbreviations are used as indicated:

- a) Lot - batch number;
- b) EXP - expiration date.

Article 31

(1) The labeling of the outer packaging of medicinal product is conducted in the manner specified by the standards: ISO / IEC 15420 - Information technology - Automatic identification and data capture techniques - Bar code symbology specification - EAN / UPC.

(2) The outer packaging of the medicinal product shall indicate an EAN code that contains 13 elements (EAN-13) to ensure unambiguous international identification of all products, in

accordance with the standards of the international GS1 organization competent for EAN code.

(3) The outer packaging of the medicinal product, which is small and cannot indicate the EAN code referred to in paragraph 2 of this Article, EAN code contains eight elements (EAN - 8).

TITLE IX – Method of administration of medicinal products issued without a prescription

Article 32

The outer packaging of the medicinal product which is issued without a prescription shall indicate a method of administration of medicinal product, if the size of the outer packaging allows it.

Article 33

(1) For a medicinal product that has a marketing authorization in Bosnia and Herzegovina and which consumption during the calendar year is less than 3,000 packages, may be granted a package labeled in a foreign language, provided that the medicinal product belongs to a group of high-risk medicinal products, cytostatics, used for the treatment of rare diseases, and there is no parallel medicinal product with adapted packaging on the market.

(2) In the process of renewal, the license for the packaging that is not adapted cannot be renewed if in the meantime the medicinal product with the adapted packaging was registered in Bosnia and Herzegovina.

PART III - CONTENT AND MANNER OF LABELLING OF THE IMMEDIATE PACKAGING OF MEDICINAL PRODUCT

Article 34

(1) The immediate packaging of the medicinal product is the packaging of medicinal product which contains the pharmaceutical form or the medicinal product or which is immediately in contact with the medicinal product.

(2) Information on the medicinal product on the immediate packaging shall be easily legible, clearly comprehensible and indelible.

(3) The particulars laid down shall appear on immediate packaging of the medicinal product referred to in paragraph 1 of this Article

a) the name of the medicinal product and the international non-proprietary name of the active substance (INN);

b) qualitative and quantitative composition of the active substance;

c) strength of medicinal product and the pharmaceutical form;

d) the method of administration (eg. i.v., i.m, s.c.);

e) the name of the holder of the marketing authorization;

f) the expiration date, in accordance with Article 25 of this Ordinance, the batch number of the medicinal product and Medicinal Product information;

g) the batch number of the medicinal product and Medicinal Product information, if the size of the immediate packaging allows it.

Article 35

In the case of small immediate packaging units (vials, ampoules, etc.) on which it is not possible to list all the information indicated on the outer packaging, the following particulars at least shall appear:

- a) the name of the medicinal product and INN or generic name, as stated on the outer packaging of the medicinal product;
- b) the name of the holder of the marketing authorization (or logo);
- c) strength of medicinal product and the pharmaceutical form;
- d) the expiry date of medicinal product, in accordance with Article 25 of this Ordinance;
- e) batch or batch number of the medicinal product.

PART IV – SPECIAL LABELING ON THE OUTER AND IMMEDIATE PACKAGING OF THE MEDICINAL PRODUCT, AS WELL AS ON PATIENT INFORMATION LEAFLET

TITLE I – Medicinal product containing narcotic drugs or psychotropic substances

Article 36

The outer packaging of the medicinal product and patient information leaflet - for medicinal products containing narcotic drugs or psychotropic substances, shall include precautions, such as:

- a) empty triangle in color of the text: Δ Trigonik, medicinal product with possible impact on the psychophysical abilities (a warning when driving a car and using machines);
- b) full red triangle: \blacktriangle Trigonik, medicinal product with a strong influence on the psychophysical abilities (prohibition to drive and use machines);
- c) symbol of the paragraph (§), in color of the text for narcotic drugs and psychotropic substances.

TITLE II - Medicinal product derived from blood

Article 37

(1) The outer packaging of the medicinal product, which is produced from blood or from blood components, shall include information on the country of origin of the blood, or the country of origin of blood components.

(2) The immediate packaging of the medicinal product "referred to in paragraph 1 of this Article," shall contain the following data:

- a) the name and volume;
- b) the number of samples;
- c) the date and time of sampling;
- d) the name and address of the legal entity which supplied the sample;
- e) blood group ABO and Rh;
- f) the composition and volume of anticoagulant solution;
- g) basic instructions on how to store and use;
- h) information about performed tests and their results.

TITLE III - Medicinal product for clinical trial

Article 38

The medicinal product intended for the clinical trial must be labeled with an inscription on the outer packaging: "For clinical trial".

TITLE IV - Medicinal product intended for informing the professional public

Article 39

The outer packaging of the medicinal product intended for informing the professional public, and which is intended for advertising medicinal product, should be marked by an inscription: "Free sample, not for sale".

TITLE V - Radiopharmaceutical medicine

Article 40

(1) Radiopharmaceutical medicine on the outer and immediate packaging is labeled in accordance with the regulations on the safe transport of radioactive materials issued by the competent International Atomic Energy Agency, as well as in accordance with the regulations governing the field of transport of dangerous goods, class 7 - radioactive materials.

(2) Radiopharmaceutical medicine on the outer packaging must have information on the medicinal product referred to in Article 6 of this Ordinance, as well as the following information:

- a) the name of the medicine, in accordance with Article 7 paragraph 1-3 of this Ordinance, an explanation of the code, including the name or chemical symbol of the radionuclide;
- b) the international symbol for radioactivity;

- c) for the liquid and gas radiopharmaceutical medicines - information on the total radioactivity in the vial or radioactive concentration per milliliter for the specified date, and hour if necessary, and the volume of liquid in the bottle;
- d) for solid preparations (such as freeze-dried preparations) - information on the total radioactivity for the specified date, and hour if necessary;
- e) for the capsule - information on the radioactivity per capsule for the specified date, and hour if necessary, and the number of capsules per package;
- f) the name and concentration of any additional antimicrobial preservatives.

Article 41

The immediate packaging of radiopharmaceutical medicine shall contain the following data:

- a) the name of the medicine and the international non-proprietary name of the active substance INN, or for medicine, the chemical symbol of the radionuclide including the name;
- b) pharmaceutical form;
- c) the international symbol for radioactivity;
- d) for solid preparations (such as freeze-dried preparations) - information on the total radioactivity for the specified date, and hour if necessary;
- e) for the capsule - data on the radioactivity per capsule for the specified date, and hour if necessary, and the number of capsules per package;
- f) for the liquid and gas radiopharmaceutical medicines - data on the total radioactivity in a bottle or radioactive concentration per milliliter for the specified date, and hour if necessary and the volume of liquid in the bottle;
- g) the name of the manufacturer of the medicinal product;
- h) the batch number;
- i) the expiry date of medicinal product, in accordance with Article 24 of this Ordinance

Article 42

(1) In addition to the outer packaging of radiopharmaceutical medicinal product, special instructions for handling radiopharmaceutical medicine shall be enclosed.

Instructions from paragraph 1 of this Article shall contain:

- a) the name of the medicinal product, in accordance with Article 7 paragraph 1-3 of this Ordinance, an explanation of the code, including the name or chemical symbol of the radionuclide;

- b) the international symbol for radioactivity;
 - c) for the liquid and gas radiopharmaceutical medicines - information on the total radioactivity in the bottle or radioactive concentration per milliliter for the specified date, and hour if necessary, and the volume of liquid in the bottle;
 - d) for solid preparations (such as freeze-dried preparations) - information on the total radioactivity for the specified date, and hour if necessary;
 - e) for the capsule, information on the radioactivity per capsule for the specified date, and hour if necessary, and the number of capsules per package;
 - f) the name and concentration of any additional antimicrobial preservatives;
 - g) the name and address of the holder of the marketing authorization, as well as manufacturer of the medicinal product;
 - h) indications;
 - i) dosing;
 - j) the method of administration;
 - k) contraindications;
 - l) side effects;
 - m) the date of approval of the patient information leaflet;
 - n) other information (referred to all sizes of packaging, etc.);
 - o) the necessary and usual instructions for proper use of the medicinal product;
 - p) information on the expiration date of the medicinal product;
 - q) a list of the names under which the medicinal product has been given permission for marketing in the European Union
 - r) precautions to be taken by the patient and the person who handles the radiopharmaceutical medicine during the preparation and of the medicinal product;
 - s) data on handling the waste or unused remnants of radiopharmaceutical medicinal product, and on handling the radiopharmaceutical medicine after the expiry date in accordance with the regulations governing the manner and conditions, as well as collecting, storing, recording, storage, treatment and disposal of radioactive waste material.
- (2) Instructions for the administration of a radiopharmaceutical medicinal product for single (one-time) use also contains the maximum storage time in which the effluent and radiopharmaceutical medicine prepared for single (one-time) use comply with the requirements prescribed by the specification.

(3) Instructions for the patient may also contain additional information, symbols and codes for

better understanding, and which shall be in accordance with the summary of the main characteristics of the medicinal product and shall not include elements of advertising of medicinal product.

TITLE VI - Homeopathic medicine

Article 43

(1) The outer packaging of the medicinal product and the patient information leaflet for the homeopathic medicine shall contain the inscription: "homeopathic medicine which safety and efficacy have not been proven according to scientific principles."

(2) The outer packaging and patient information leaflet referred to in paragraph 1 of this Article shall contain the following information:

a) the name of the starting homeopathic raw materials (stock), the degree of dilution with markings of the European Pharmacopoeia and the National Pharmacopoeia (if homeopathic medicine contains two or more stocks, the scientific name of the stock can be replaced by the brand name);

b) the name and address of the Marketing Authorization holder of homeopathic medicinal product, as well as the manufacturer;

c) the method of administration;

d) The expiry date of the medicinal product (month and year);

e) pharmaceutical form;

f) appearance of package meant for sale;

g) composition of the medicinal product;

h) special warnings for storing of the medicinal product, if any;

i) special precautions, if needed for the given medicinal product;

j) a batch or batch number of production;

k) number and date of marketing authorization for the medicinal product;

l) Warning: "If symptoms of the disease persist even after a prolonged taking of this medicinal product, inform your doctor."

TITLE VII -Traditional medicine

Article 44

(1) The outer packaging of the traditional medicinal product and patient information leaflet shall indicate the information that it is a traditional medicine and that is used to treat certain

indications on the basis of previous experience.

(2) The outer packaging of traditional medicinal product and patient information leaflet should indicate the information about traditional therapeutic school from which the medicine has originated, if that information exists.

(3) Patient information leaflet for a traditional medicine shall contain a warning that the patient should contact a doctor if symptoms last during the administration of traditional medicine, as well as if there is an adverse reaction to a medicine that is, or is not, included in the leaflet.

PART FIVE - FINAL PROVISIONS

Article 45

Holder of the marketing authorization, to the effective date of this Ordinance, shall coordinate outer and immediate packaging of the medicinal product, as well as the patient information leaflet with the provisions of this Ordinance by the time of the next renewal, or if the medicinal product has just been registered, within a year from the date of issuance of the decision.

Article 46

This Ordinance shall enter into force eight days after publication in the "Official Gazette of BiH".

Number 08-31-3-1292-1-JD / 10

On April 22nd, 2010

The Minister

Mr Sredoje Novic, s. r.