Pursuant to Article 121 paragraph 2 of the Law on Medicines („Official Gazette of Montenegro“ No 56/11 and 6/13), the Ministry of Health has passed

RULEBOOK ON THE CONTENTS AND MANNER OF LABELLING OUTER AND IMMEDIATE PACKAGING OF A MEDICINAL PRODUCT AND CONTENTS OF THE PACKAGE LEAFLET

(Official Gazette of Montenegro” No 021/16 from 25 March 2016)

I GENERAL PROVISIONS

Article 1

The Rulebook prescribes in more details the contents and manner of labelling outer and immediate packaging of a medicinal product and the contents of the package leaflet which shall comply with a marketing authorization and summary of product characteristics.

Article 2

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

II CONTENTS AND MANNER OF LABELLING THE OUTER PACKAGING OF A MEDICINAL PRODUCT

Article 3

The outer packaging of a medicinal product, as well as the immediate packaging which at the same time represents the outer packaging of a medicinal product, shall contain the following information:

1) name of a medicinal product;
2) pharmaceutical form, strength and size of packaging;
3) qualitative and quantitative composition of active substance(s);
4) excipients known to have a recognized action or effect, depending on the route of administration of a medicinal product;
5) route of administration and dispensing mode;
6) information on whether a medicinal product is intended for infants, children or adults;
7) warning that a medicinal product must be stored out of the reach of children, as well as other warnings;
8) expiry date of a medicinal product (month and year)
9) storage conditions;
10) special precautions relating to the disposal and destruction of medicinal products;
11) name and address of the marketing authorization holder;
12) number and date of issuance of marketing authorization;
13) batch number;
14) instructions for use of a medicinal product with a non-prescription dispensing mode, if a packaging size allows it;
15) EAN (BAR) code
16) additional labeling, where appropriate.

Article 4

The name of a medicinal product may be:

- invented name;
- international non-proprietary name (INN), i.e. generic name with a trademark or name of the manufacturer, or marketing authorization holder;
- chemical, or scientific, or generally accepted common name with a trademark or name of the manufacturer or the marketing authorization holder.

Name of the medicinal product is followed by strength of a medicinal product and pharmaceutical form in accordance with standard terminology of the European or national pharmacopoeia.
The invented name referred to in paragraph 1, indent 1 of this Article should not cause confusion in terms of the name referred to in paragraph 1, indents 2 and 3 of this Article.
Invented name of a medicinal product referred to in paragraph 1 item 1 of this Article shall not contain elements of advertising, shall not be misleading with respect to other types of products, other pharmaceutical and medical terms or medicinal product content, shall not cause confusion in prescribing, printing and pronunciation relating to names of other medicinal products.
All letters in the name of a medicinal products are typed in same font size and type.

Article 5

Up to three active substances contained in a medicinal product are listed on the outer packaging.
If a medicinal product contains more than three active substances, the Agency for Medicines and Medical Devices (hereinafter: the Agency) within the approval process of labelling the outer packaging of a medicinal product, also approves which active substances are listed on the outer packaging.
The active substances referred to in paragraphs 1 and 2 of this Article shall be stated after the strength and the pharmaceutical form or under the brand name of a medicinal product.

Article 6

Qualitative and quantitative composition of active substance is labelled separately from the strength of a medicine.
Qualitative composition of active substance is stated in accordance with standard terminology of the European, national pharmacopoeia and applicable standard expert terminology, and the INN or generic name, or generally accepted name of the active substance is also stated.
The quantitative composition of active substance shall be expressed:

- per number of individual doses;
- per unit of volume, if in conformity with the pharmaceutical form, and
- per unit of weight, if in conformity with the pharmaceutical form.

Article 7

An active substance in the form of a compound or derivative (e.g. in the form of a salt or ester), shall be expressed in relation to the active form with INN or generic name.
Different strengths of a medicinal product shall be expressed with the same units of measure, provided that the use of the comma shall be avoided (e.g. 250mg instead of 0,25g), and for safety reasons, micrograms shall be expressed with the full word and not as an abbreviation.
With regard to a single dose of a medicinal product for parenteral use, the quantity of the active substance shall be expressed either per milliliter (ml) or per the total volume, and with regard to multiple dose medicinal products for parenteral use, the quantity of the active substance shall be expressed per milliliter (ml) in 100 ml or 1000 ml, etc.
Regarding medicinal products for parenteral use which contain larger quantities of inorganic salts, or regarding contrast media, the quantity may be expressed in millimoles (mmol).
Concentrates for parenteral use shall be expressed both as the quantity of the active substance contained in the total volume and as the quantity of the active substance per ml.
Concentrates for parenteral use shall be clearly labelled by:

- dilute before use (see the instructions);
- contains X mg/ml of the active substance when it is diluted according to the instruction, except in the case when more different manners of dilutions are possible and they result in various final diluted concentrations.

Prior to be parenterally used, the powder for solution or preparation of suspension shall be labelled as the total quantity of the active substance in its container labelled with:

- dilute before use (see the instructions);

- contains X mg/ml of the active substance when it is diluted according to the instruction, except in the case when more different manners of dilutions are possible and they result in various final diluted concentrations.

Article 8

Solvents for powders or concentrates referred to in Article 7 of this Rulebook, which are part of the packaging, must be clearly expressed and labelled.

Article 9

A transdermal patch shall contain the following information:

- quantity of the active substance in a single patch
- dose absorbed per unit of time (hour, day, etc.) and
- patch surface from which the active substance is released.

The information referred to in paragraph 1 of the Article shall be clearly differentiated.

Article 10

With regard to multidose solid, semi-solid or liquid pharmaceutical forms (e.g. powder, granules, ointment, syrup, etc.), the quantity of the active substance shall be expressed:

- per dosage unit (e.g. teaspoon), or
- per unit of weight (quantity of active substance, expressed in 1g or 100g) or
- in percentages.

Article 11

Implants or intrauterine devices shall contain the following information:

- quantity of the active substance in every implant or intrauterine device;
- released, i.e. absorbed by a patient, dose per unit of time (hour, day), and
- total period of time (hours, days, etc.) during which the whole dose is expected to be absorbed.

Article 12

The outer packaging shall contain information on the basic pharmaceutical form of a medicinal product and also the information about the final pharmaceutical form, in case when two forms mutually differ.

The pharmaceutical form of a medicinal product shall be the form in which the active substance is implemented using technological processes, and in this manner enable its use taking into account physiological conditions of organisms and the physical and chemical properties of the substance.

The final pharmaceutical form of a medicinal product represents the form of a medicinal product administered to a patient (e.g. suspension).

The basic pharmaceutical form of a medicine represents the form of a medicine in which the manufacturer shall place the medicinal product on the market (e.g. powder for suspension).

The pharmaceutical form is stated in accordance with standard terminology of the European Pharmacopoeia or national pharmacopoeia.

Article 13

Packaging size is expressed in units of weight, units of volume or number of units (dosages) of a medicinal product.

Article 14

The outer packaging shall contain qualitative composition of excipients known to have a recognized action or effect, in accordance with guideline of European Medicines Agency.

The outer packaging of a medicinal product for parenteral, topical or ocular use shall contain all excipients.

The name of the excipient shall be in conformity with the monograph of the valid edition of European Pharmacopoeia, or national pharmacopoeia, or where relevant, in the form of the name of its salt or hydrate.
If there is no name as set out in paragraph 3 of the Article, the name of the excipient shall be in the form of the common, generally known name of the excipient.
In addition to the name of the excipient, there shall also be stated, if any, the number of the excipient according to the directives of the European Union.

Article 15

The outer packaging shall contain information about the route of administration of a medicinal product in accordance with the standard terms of the European, national pharmacopoeia and applicable standard expert terminology.
The outer packaging shall contain space for stating the prescribed dose.

Article 16

If a medicinal product affects the ability to drive a vehicle and to use machines, the outer packaging should contain the information as a special warning.

Article 17

The outer packaging shall clearly indicate the expiry date of a medicinal product, i.e. month and year (MM/YY), without abbreviations, with a note staying "To be used before: month and year".
If the information referred to in paragraph 1 of this Article may not be expressed without abbreviations, labelling should be used in accordance with Article 21, paragraph 5 of this Rulebook.
A medicinal product may be used until the last day of the stated month.
The outer packaging of a medicinal product shall also contain information about the expiry date during the use of the medicinal product after dissolving or diluting it and, if necessary, after the first opening of the immediate packaging.

Article 18

The outer packaging shall contain special storage precautions, if any (e.g. store at temperatures below 25°C; store at temperatures 2-8°C in a refrigerator, store in a freezer, or a warning that a medicine should not be frozen) in accordance with the information stated in the summary of product characteristics.
The outer packaging of a medicinal product shall not necessarily have to contain a storage temperature, provided that the medicinal product remains stable at the temperature of up to 30°C.
The outer packaging shall contain other storage precautions, if necessary (e.g. store in its original packaging/container, store in a tightly closed container, store the container in its outer packaging, protected from light or humidity, no special storage conditions).

Article 19

The outer package should contain special precautions for disposal and destruction of an unused or remaining medicinal product, if necessary, or that the medicinal product is disposed in accordance with the regulations governing waste management.

Article 20

The outer packaging shall contain the name and address of the marketing authorization holder, as well as date issuance and number of marketing authorization.

Article 21

The outer packaging of a medicinal product shall contain batch number. The batch number may consist of several characters.

The outer packaging of the medicinal product may also contain the date of its manufacturing, if necessary.

If technically possible, the outer packaging of a medicinal product shall contain information in the following order:

- batch number;
- expiry date (month and year).

The information referred to in the paragraph 3 of this Article shall be written free of abbreviations.

Exceptionally, if the information referred to in paragraph 3 of this Article cannot be stated without the use of abbreviations, the following abbreviations shall be used:

- Lot - for the batch number;
- EXP - for the expiry date.

Article 22

The outer packaging of a non-prescription medicinal product shall state the route of administration of the medicinal product and may contain the following information:

- indication/s
- recommendations for dosage, contraindications and warnings

If, due to outer packaging size, it is not possible to state all the information from paragraph 1 of this article, the following text should be included: "Before use, read package leaflet".

Article 23

If packaging size allows it, the information on the outer packaging shall be written free of abbreviations.

Article 24

The outer packaging of a medicinal product may contain labelling:

- price of a medicinal product;
- reimbursement of compulsory health insurance costs;
- identification and authenticity of the packaging;
- for the medicinal products produced via genetic engineering, active substances along with a label on genetically modified organisms or cell lines;
- labels important for the human health protection (e.g. limited quantity of single dispensing);
- symbols, pictures or other labels, if they facilitate understanding of information which are in accordance with approved summary of product characteristics of the medicinal product and do not contain elements of advertising.

Article 25

If the information on the outer packaging of a medicinal product is in a foreign language and whose consumption during a calendar year is less than 5000 packages, the Agency shall approve the use of additional sticker for outer packaging containing the following information in Montenegrin:

1) name of a medicinal product;
2) pharmaceutical form, strength of a medicinal product and size of packaging;
3) qualitative and quantitative composition of active substance/s;
4) route of administration and dispensing mode of a medicinal product;
5) special warning that a medicinal product must be stored out of the reach of children, as well as other warnings, if necessary;
6) expiry date (month and year);

7) time period of use, for medicinal products prepared immediately before use;
8) storage conditions, if necessary;
9) name and address of marketing authorization holder in Montenegro;
10) number and date of marketing authorization issued by the Agency;

Additional sticker contains also the following data, if they are not clearly visible on the original packaging:

1) excipients known to have recognized action, depending on route of administration of a medicinal product;
2) batch number;
3) warnings and/or labels for specific types of medicinal products, in accordance with this Rulebook, if necessary.

Article 26

For medicinal products whose outer packaging is labeled in languages officially used in Montenegro, the Agency approves additional sticker containing the following data in Montenegrin:

1) name and address of marketing authorization holder in Montenegro;
2) number and date of marketing authorisation issued by the Agency;

If technically possible, additional sticker from paragraph 1 of this Article may also contain name of a medicinal product and pharmaceutical form, strength and packaging size.

Article 27

Additional sticker from articles 25 and 26 of this Rulebook is provided by the manufacturer or wholesaler.

Information on additional sticker from paragraph 1 of this Article are state in the manner defined in this Rulebook for labelling the outer packaging of a medicinal product.

III CONTENTS AND MANNER OF LABELLING THE IMMEDIATE PACKAGING OF A MEDICINE

Article 28

The immediate packaging of a medicinal product shall contain at least the following information in accordance with the Article 3 of this Rulebook:

1. name of the medicinal product and INN or generic name, as stated on the outer packaging;
2. qualitative and quantitative composition of active substance/s;
3. pharmaceutical form and strength of a medicinal product;
4. route of administration;
5. name of the marketing authorization holder or the manufacturer (or its logo);
6. expiry date of a medicinal product (month and year);
7. batch number.

In case the immediate packaging is small (e.g. vial, ampoule, etc.) as well as if the immediate packaging is not able to receive data from paragraph 1 of this Article, the immediate packaging inserted within the outer packaging of a medicinal product shall contain the data from paragraph 1, points 1, 4, 5, 6 and 7 of this Article and the data on the content expressed in units of weight, units of volume or dosage unit.

The immediate packaging which is a blister, contains data from paragraph 1 points 1, 3, 5, 6 and 7 of this Article.

Article 29

All particulars contained on the outer and immediate packaging of a medicinal product shall be printed with sufficient line spacing and in such a manner that they cannot be removed, ensuring they are legible, comprehensible and indelible.

The smallest letters should be 7P (P – the height of the letter should not be smaller than 1,4mm), with sufficient line spacing to ensure legibility.

Article 30

If the outer and immediate packaging of a medicinal product shall contain information in several languages, the contents of all the information shall be the same in all the languages used.

Article 31

Name of the medicinal product shall be put in Braille format on the outer packaging as well as on the immediate packaging which is at the same time the outer packaging.

If a medicinal product has several strengths, the strength of a medicinal product is also put in Braille format in addition to the name of the medicinal product.

Notwithstanding paragraph 1 of this Article, the name of a medicinal product which is, in accordance with marketing authorization, used exclusively in healthcare institution under control of healthcare professional, as well as the name of a medicinal product which is intended for clinical trial, does not have to be written in Braille format.

IV PACKAGE LEAFLET

Article 32

Package leaflet shall contain the following:

1) data necessary for a medicinal product identification;
2) data on therapeutic indications;
3) data that should be known prior the use of a medicinal product;
4) data necessary for proper use of a medicinal product;
5) data on adverse reactions to a medicinal product;
6) data on storage conditions and expiry date of a medicinal product;
7) name and address of the marketing authorization holder and the manufacturer
8) data on additional monitoring, if applicable;
9) date of the creation/revision of the package leaflet
10) information about the appearance and packaging contents for each pharmaceutical form, strength and packaging size of the medicinal product,
11) other information at the request of the Agency.

Package leaflet from paragraph 1 of this Article shall be prepared separately for different pharmaceutical forms of the same medicinal product.

Article 33

Data necessary for a medicinal product identification are as follows:

- name, strength and pharmaceutical form of the medicinal product;
- qualitative and quantitative composition of active substances (INN or generic name) for each pharmaceutical form and strength of the medicinal product; qualitative composition of the excipients and quantitative composition of excipients referred to in Article 14 of this Rulebook;
- pharmacotherapeutic group or mechanism of action, using terminology that is easily understandable to the patient.

Article 34

Package leaflet contains information on all therapeutic indications, using terminology that is easily understandable to the patient, as well as data on age group that a medicine is intended for - infants, children or adults, specifying age, in accordance with the approved summary of product characteristics.

Article 35

Information to be read before use of medicinal product:

- contraindications;
- precautionary measures when using a medicinal product;
- interactions with other medicinal products, as well as other forms of interaction (e.g. with alcohol, tobacco, food) which may affect the action of the medicinal product;
- special warnings (e.g. referring to the possibility of a medicinal product impact on abilities to drive a vehicle and operate machinery, possibility of a medicinal product to affect special conditions of certain categories of users: children, pregnant women, nursing mothers, persons with a specific pathological conditions), as well as special warnings related to excipients which may affect the safe and effective use of a medicinal product).

Article 36

Information on the proper use of a medicinal product relating to the following:

- dosage;
- route of administration and method of administration;
- frequency of administration, indicating, if necessary, appropriate times when a medicinal product may or must be used;
- duration of a therapy, if it needs to be limited in time (the usual duration of a therapy);
- symptoms of overdose and measures to be taken in that case;
- advice on how to act if one or more doses have not been taken;
- risk consequences which may occur after abrupt termination of use of a medicinal product,
- dispensing mode
- special recommendations to consult a healthcare professional about the use of a medicinal product.

Article 37

The package leaflet shall contain a description of adverse reactions to a medicinal product, as well as measures to be taken in case of occurrence of adverse reactions to a medicinal products. The package leaflet contains standardized text which invites the patient to inform a healthcare professional about any occurring adverse reactions to a medicinal product.

Article 38

Information about storage and expiry date are the following:

- warning to keep a medicinal product out of reach of children;
- warning that a medicinal product shall not be used after the expiry date which shall be indicated on the packaging;
- storage conditions in accordance with article 18 of this Article;
- warning referring to the visible signs of medicinal product degradation or damaged medicinal product, if necessary;
- special precautions for disposal or destruction of a medicinal product;

Article 39

Package leaflet contains information on whether the medicinal product is a subject of additional monitoring in accordance with regulations on pharmacovigilance.

An inverted full black triangle is inserted in front of data referred to in paragraph 1 of this Article.

Article 40

Package leaflet may also contain symbols, pictures or other labels, if they facilitate understanding of information, in accordance with approved summary of product characteristics of the medicinal product and do not contain elements of advertising.

Article 41

Information in the package leaflet are given in the manner prescribed in articles 29 and 30 of this Rulebook and without abbreviations, if packaging size allows it.

Article 42

In the case referred to in Article 25 of this Rulebook, package leaflet shall be enclosed to each medicinal product packaging.

In the case referred to in Article 26 of this Rulebook, package leaflet shall be enclosed to each packaging of the medicinal product that is consumed less than 5000 packages per year, or without limitations for medicines having a safety features against counterfeiting in the European Union.

In the case referred to in articles 25 and 26 of this Rulebook, package leaflet shall be enclosed by the manufacturer or the wholesaler.

If data referred to in Articles from 32 to 40 of this Rulebook may be given on the outer packaging of the medicine, it is not necessary to enclose the leaflet from paragraph 1 of this Article.

Article 43

Legibility and comprehensibility of the leaflet can be verified by testing on a group of patients, comparing them with the leaflet of an already approved medicinal product or recognizing already conducted testing in other countries.

Applicant for marketing authorization, or marketing authorization holder shall submit information on the manner of testing of legibility and comprehensibility of the leaflet.

Article 44

The marketing authorization holder shall be obliged to submit to the association of patients for the protection of blind and visually impaired persons the package leaflet written in appropriate form (Braille format, big letters, electronic audio recording, e.g. tape, CD, MP3, etc.).

V SPECIAL LABELLING

Article 45

The outer packaging of a medicinal product and package leaflet of a medicinal product that contains controlled substances shall contain the following precaution measures and a warning:

- hollow triangle in the colour of the wording: relative prohibition of driving motor vehicles or using machines
- full, red colour triangle: absolute prohibition of driving motor vehicles or using machines;
- Paragraph (§), in the colour of the wording for drugs.

Article 46

The outer packaging of the medicinal product derived from blood or blood plasma contain information on the country of origin of blood or blood plasma.

Article 47

Medicinal products intended for clinical trials are labelled in accordance with regulations on clinical trials.

Article 48

Medicinal products that are not intended for sale are labelled in accordance with the regulations on advertising of medicinal products.

Article 49

Radiopharmaceuticals, radionuclide generators and radionuclide precursors shall on the outer packaging and protective container be labelled in conformity with the regulations about safe transport of radioactive materials adopted by the competent International Atomic Energy Agency.

Container of radiopharmaceutical from paragraph 1 of this Article is labelled in accordance with Article 3 of this Rulebook and contains the information referring to the explanation of labels and symbols indicated on a vial and a container, quantity of radioactivity per dose or per vial for the given time and date and the number of capsules or number of milliliters in a container for the liquid.

The immediate packaging of the radiopharmaceutical referred to in paragraph 1 of the Article (e.g. vial) shall contain the following information:

1. name or code of a medicinal product, including the name or chemical symbol of a radionuclide;
2. identification of the batch and expiry date;
3. international symbol for radioactivity,
4. name and address of the manufacturer
5. quantity of radioactivity as described in paragraph 2 of this Article.

The labelling of a radiopharmaceutical kit shall contain the information referred to in paragraphs 1 and 3 of the Article, except for the information about radioactivity.

Article 50

Package leaflet shall be enclosed to the outer packaging of radiopharmaceuticals from article 49 of this Rulebook.

In addition to data referred to in Articles 32 to 40 of this Rulebook, the package leaflet referred to in paragraph 1 of this Article, shall also contain all the precaution measures for the patient and user during the preparation and administration of a medicinal product, as well as special precaution measures related to the disposal of packaging and its unused contents in conformity with the regulations which regulate the manner and conditions for collecting, keeping, recording, storage, processing and disposal of radioactive waste material.

Article 51

The following particulars shall appear on the outer packaging and in the package leaflet for a homeopathic medicinal product:

1. wording: homeopathic medicinal product.
2. name of the homeopathic stock/s, degree of dilution making use of the symbols of European pharmacopoeia or national pharmacopoeia; if a homeopathic medicinal product is composed of two or more stocks, scientific name of the stocks may be replaced with the brand name;
3. name and address of the homeopathic medicinal product marketing authorization holder and of the manufacturer;
4. route of administration and method of administration;
5. expiry date (month and year);
6. pharmaceutical form and packaging;
7. composition of the medicinal product;
8. special storage precautions, if any;
9. special precaution measures, if necessary;
10. batch number;

11. number and date of issuing the marketing authorization and/or entering into the Registry;
12. warning to consult a healthcare professional if symptoms of a disease persist.

For the homeopathic medicines that are entered into the Registry of homeopathic medicines, the outer packaging and package leaflet shall, in addition to the information set out in paragraph 1 of the Article, also contain the following wording: "Homeopathic medicine without proved therapeutic indications".

Article 52

The following information shall be written on the outer packaging and package leaflet for a traditional herbal medicinal product:

1. information that the medicinal product is a traditional medicinal product for use in specified indication on the basis of the experience gained from the long- standing use;
2. information about the traditional therapeutic school from which the medicinal product originates, if such information is available.

The package leaflet from paragraph 1 of this Article shall contain warning that the patient must contact a healthcare professional if symptoms persist during the administration of a traditional medicinal product, and if adverse reactions which are/are not mentioned in the package leaflet occur.

Article 53

The medicine for which the Agency has issued the authorization for import (hereinafter: import authorisation), shall be labelled in accordance with the provisions of this Rulebook, on which the applicant for the import authorisation shall submit the appropriate statement.

Exceptionally, due to urgency and public health protection, the Agency may, issue import authorisation for a medicinal product that is not labelled in accordance with the provisions of this Rulebook, i.e. in the original packaging in a foreign language, if no other appropriate medicinal product is marketed and if the medicinal product is administered under supervision of healthcare professional.

VI TRANSITIONAL AND FINAL PROVISIONS

Article 54

Medicines manufactured and labelled before entry into force of this Rulebook may remain on the market until the expiry date of the medicine.

Article 55

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

Number: 011-88/2016
Podgorica, 21 March 2016.
Minister,
Prof. dr Budimir Šegrt