

Pursuant to Article 152, paragraph 3 of the Law on Medicines and Medical Devices ("Official Gazette of RS", No. 30/10),  
the Minister of Health and the Minister of Agriculture, Commerce, Forestry and Water Management hereby agreeably adopts

## **Rulebook on the contents and method of labelling the outer and immediate packaging of a medicine, additional labelling, and contents of the package leaflet**

*The Rulebook was published in the "Official Gazette of RS", No. 41/2011  
of 10 June 2011*

### **I. INTRODUCTORY PROVISIONS**

#### **Contents of the Rulebook**

##### **Article 1**

The Rulebook shall prescribe the contents and method of labelling the outer and immediate packaging of a medicine, additional labelling of a medicine, and the contents of the package leaflet.

##### **Article 2**

The contents and method of labelling the outer and immediate packaging of a medicine, and the contents of the package leaflet shall comply with the marketing authorization or summary of product characteristics and shall not contain elements of advertising the medicine.

All the information referring to the labelling of the outer and immediate packaging of a medicine shall be written in the Serbian language, in Cyrillic or Latin alphabet, whereas the international non-proprietary name (INN) and/or generic or chemical name of a medicine shall be written only in Latin, in conformity with the usual code of practice.

##### **Article 3**

All the information contained on the outer and immediate packaging of a medicine, as well as in the package leaflet, shall be printed with sufficient line spacing and in such a manner that it cannot be removed, in order to ensure legibility, clarity and durability of the information.

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

The outer packaging of a medicine and the package leaflet shall contain information exclusive of any abbreviations, if possible, provided that the size of the packaging allows that.

##### **Article 4**

If the outer and immediate packaging of a medicine and/or the package leaflet shall contain information in several languages, the contents of all the information shall be the same in all the languages used.

### **II. THE CONTENTS AND METHOD OF LABELLING OF THE OUTER AND IMMEDIATE PACKAGING OF A MEDICINE**

##### **Article 5**

The outer packaging shall be the packaging containing the immediate packaging of a medicine.

##### **Article 6**

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

- 1) The name of a medicine and the international non-proprietary name of the active substance (INN), if any, and/or generic or chemical name, and if there is no INN and/or generic or chemical name, the common name of the active substance should be stated;
- 2) The active substances expressed qualitatively and quantitatively per dosage unit;
- 3) The pharmaceutical form, strength (the quantity per unit of weight, per unit of volume or per dosage unit) and size of packaging;
- 4) A list of those excipients known to have a recognized action, however, if medicines are injectable, or for topical or ocular application, all excipients shall be specified;
- 5) The method of administration of a medicine;
- 6) A special warning that a medicine must be stored out of the reach of children, as well as other warnings;

- 7) The expiry date of a medicine (month and year);
- 8) Special storage precautions, if any;
- 9) Special precautions relating to the disposal and destruction of medicines;
- 10) The name and address of the marketing authorization holder;
- 11) The number and date of an authorization for placing a medicine on the market;
- 12) The manufacturer's batch number;
- 13) In the case of a non-prescription medicine, instructions for use;
- 14) The anatomic-therapeutic-chemical (ATC) classification, and for veterinary medicines ATCvet;
- 15) EAN code.

In addition to the information referred to in paragraph 1 of the Article, a veterinary medicine shall be labelled with the text in the Serbian language "For animal use".

In addition to the information referred to in paragraphs 1 and 2 of the Article, a veterinary medicine shall have a notice on the waiting period, as well as a notice on target animal species for which the medicine is intended, and for an immunological medicine for veterinary use, indications should be stated.

The outer packaging of a medicine may contain labels referring to the additional labelling of the outer packaging such as:

- 1) Reimbursement of compulsory health insurance costs;
- 2) The method of issuing a medicine (prescription or non-prescription);
- 3) Identification and authenticity of the packaging.

The outer packaging shall be labelled with the text "Read instructions before use".

The outer packaging of a medicine, if necessary, shall be labelled with other special warnings relevant for the administration of a medicine.

## **1. Name of a medicine and international non-proprietary name of every active substance**

### **Article 7**

The outer packaging of a medicine shall contain the name of a medicine which may be:

- 1) The trade name;
- 2) The international non-proprietary name (INN) and/or generic name with the trade mark or manufacturer's name, or without them;
- 3) The chemical name with the trade mark or manufacturer's name, or without them.
- 4) The generally known common name or, if there is no generally known common name, the scientific name, with the trade mark or manufacturer's name, or without them.

The trade name referred to in paragraph 1, item 1) of the Article should not cause confusion in terms of the name referred to in paragraph 1, items 2) - 4) of the Article.

The international non-proprietary name (INN) shall be the name defined by the World Health Organization.

## **Braille alphabet**

### **Article 8**

The name of a medicine for human use shall also be expressed in Braille format for blind and visually impaired persons on the outer packaging, however, it does not have to be printed on the immediate packaging.

For medicines whose immediate packaging is at the same time the outer packaging, the manufacturer shall have to put the name of the medicine in Braille format on the immediate packaging.

Points of the Braille alphabet may be printed anywhere on the outer or immediate packaging of a medicine in a way that the basic text is easily legible.

Notwithstanding paragraphs 1 and 3 of the Article, the name of a medicine which is, in accordance with a marketing authorization, amendment, addenda, and/or renewal of a marketing authorization, used exclusively in a stationary health care institution, as well as the name of a medicine used in a health care institution under control of a physician, and which is handled by trained health care workers, does not have to be written in Braille format for blind and visually impaired persons.

### **Article 9**

In addition to the name of a medicine referred to in Article 7, paragraph 1 of the Rulebook, the outer packaging of a medicine shall contain the strength of the medicine (when the medicine contains one or two active substances), and a pharmaceutical form, in accordance with the standard terminology of the European Pharmacopoeia or national pharmacopoeia.

Information on a medicine shall be listed in the following order: name, strength (when the medicine contains one or two active substances), pharmaceutical form, INN, and/or generic or chemical name, or common name of the active substance.

### **Article 10**

The outer packaging of a medicine shall, in addition to the name of the medicine referred to in Article 7, paragraph 1 of the Rulebook, contain up to three active substance in the medicine.

If the medicine referred to in paragraph 1 of the Article contains more than three active substances, the Medicines and Medical Devices Agency of Serbia (hereinafter referred to as the "Agency") shall in the process of approval of the outer packaging of a medicine also approve what active substances shall be listed on the outer packaging of the medicine.

The active substances referred to in para. 1 and 2 of the Article shall be listed after the strength and pharmaceutical form or after the trade name.

#### **Article 11**

The outer packaging of a medicine for human use shall, in addition to the name of the medicine referred to in Article 7, paragraph 1 of the Rulebook, also contain information that the medicine is intended for neonates, infants, children, or information on the age of persons whom the medicine is intended for, in conformity with the summary of product characteristics.

## **2. Active substances, expresses qualitatively and quantitatively per dosage unit**

#### **Article 12**

The qualitative and quantitative composition of a medicine shall be labelled separately in relation to the strength of the medicine.

The qualitative composition of a medicine shall be an active substance(s) in the medicine whose name shall be stated in compliance with the standard terminology of European and/or national pharmacopoeia.

The qualitative composition of a medicine shall be stated as INN, and/or generic name, and/or form of a compound of the active substance.

If there is no INN, and/or generic or chemical name, the common name of the active substance shall be stated.

### *Quantitative composition of a medicine*

#### **Article 13**

The quantitative composition of a medicine shall represent the amount of the active substance(s) in the medicine and it shall be expressed:

- a) Per number of individual doses;
- b) Per unit of volume, if in conformity with the pharmaceutical form;
- c) Per unit of weight, if in conformity with the pharmaceutical form.

#### **Article 14**

If an active substance is in the form of a compound (e.g. in the form of a salt or ester), the quantitative composition of the medicine shall be expressed in relation to the active form, with INN or generic name.

Different strengths of a medicine shall be expressed with the same units of measure, provided that the use of the comma shall be avoided (e.g. 250 mg instead of 0,25 g), 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 medicine for parenteral use, the quantity of the active substance shall be expressed either in 1 ml or as the total volume, and with regard to multiple dose medicines for parenteral use, the quantity of the active substance shall be expressed in 1 ml or 100 ml or 1000 ml, etc.

Regarding medicines for parenteral use which contain larger quantities of inorganic salts, or regarding x-ray contrast media, the quantity may be expressed in millimoles.

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, whereas the following labelling shall also be provided: "Dilute before use according to instructions".

If the concentrates for parenteral use referred to in paragraph 5 of the Article are diluted before use to a specific concentration according to the instructions, the outer packaging shall additionally contain the amount of the active substance expressed in mg/ml after dilution, following the instructions.

In case when, according to the instructions, more methods of dilution of the concentrate referred to in paragraph 5 of the Article are possible, and they result in various final diluted concentrations, the latter shall not be expressed with the information referred to in paragraph 6 of the Article.

Prior to be parenterally used, the powder intended for dilution or preparation of suspension shall be labelled as the total quantity of the active substance in its container labelled with: "Dilute before use according to the instructions".

If the powder referred to in paragraph 8 of the Article is before use diluted to a specific concentration pursuant to the instructions, it shall also be labelled as the quantity of the active substance contained in mg/ml after dilution, following the instructions.

In cases when according to the instructions more methods of dilution of the powder referred to in paragraph 8 of the Article are available, and they result in various final diluted concentrations, the latter shall not be expressed with the information referred to in paragraph 9 of the Article.

#### **Article 15**

Dilution agents or dilution of concentrates or powders that are part of the medicine packaging shall be clearly identified and marked.

### *Labelling transdermal patches*

#### **Article 16**

A transdermal patch shall contain the following information:

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

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

#### **Article 17**

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, if possible, per dosage unit or per unit of weight and/or in percentages.

The dosage unit referred to in paragraph 1 of the Article shall represent the measuring dose for a medicine (e.g. a tea spoon).

The weight referred to in paragraph 1 of the Article shall represent the quantity of the active substance expressed in 1 g, or 100 g of a medicine.

### *Labelling implants and intrauterine devices*

#### **Article 18**

Implants or intrauterine devices shall contain the following information:

- 1) The quantity of the active substance in every implant or intrauterine device;
- 2) A released dose per unit of time (hour, day, etc);
- 3) The total period of time (hours, days, etc) and/or time during which the whole dose is expected to be absorbed.

## **3. Pharmaceutical form and packaging**

#### **Article 19**

The pharmaceutical form of a medicine shall be the form in which the active substance shall be 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 pharmaceutical form may be:

- 1) The basic pharmaceutical form of a medicine which shall represent the form of a medicine in which the manufacturer shall place the medicine on the market (e.g. powder for suspension preparation).
- 2) The final pharmaceutical form of a medicine which shall represent the form of a medicine absorbed by a patient (e.g. suspension).

The outer packaging shall contain information on the basic pharmaceutical form of a medicine. The manufacturer may also list information about the final pharmaceutical form, in case when the two forms mutually differ.

#### **Article 20**

The pharmaceutical form shall be specified in conformity with the standard terms of the European and/or national pharmacopoeia.

### *Size of packaging*

#### **Article 21**

The size of the packaging shall be expressed in the unit of weight, unit of volume or number of units (dosages).

## **4. List of excipients**

#### **Article 22**

The outer packaging shall contain excipients known to have a recognized action.

A list of excipients known to have a recognized action is presented in Attachment 1 that is enclosed to the Rulebook and makes its integral part.

The outer packaging of a medicine for human use shall contain the qualitative composition of excipients with a recognized action.

The outer packaging of a medicine that is injectable, and for topical or ocular application, shall contain all excipients.

The outer packaging of a veterinary medicine shall state the quantity of excipients known to have a recognized action.

The names of excipients shall be listed in Serbian.

The name of the excipient shall be in the form of INN and/or, where relevant, in the form of the name of its salt or hydrate, or the name shall be in conformity with the monograph of the valid edition of European Pharmacopoeia.

If there is no name as set out in paragraph 7 of the Article, the name of the excipient shall be in the form of the common and/or 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 (E number), which may on the outer packaging be expressed without the name of the excipient, if the package leaflet shall contain the full name of the excipient and E number.

## **5. Method of administration of a medicine**

### **Article 23**

The outer packaging shall contain information about the method of administration of a medicine in accordance with the standard terms of the European and/or national pharmacopoeia.

The outer packaging shall contain space for stating the prescribed dosage.

## **6. Warning that a medicine must be stored out of the reach of children and other warnings**

### **Article 24**

The outer packaging shall contain the information that a medicine must be stored out of the reach of children.

### *Special warnings*

### **Article 25**

If a medicine intended for human use affects the ability to drive a vehicle and to use machines, the outer packaging should contain the information as a special warning, in conformity with the Rulebook.

### *Waiting period*

### **Article 26**

The outer packaging of veterinary medicines used for animal therapy, which are used in human consumption, shall contain information on the waiting period.

## **7. Expiry date (month and year)**

### **Article 27**

The outer packaging shall clearly indicate the expiry date of a medicine, i.e. month and year, without abbreviations, with a note staying "To be used before: month and year".

If the information referred to in paragraph 1 of the Article may not be expressed without abbreviations, labelling should be used in accordance with Article 33, paragraph 5 of the Rulebook.

A medicine may be used until the last day of the stated month.

The outer packaging of a medicine shall also contain information about the expiry date during the use of the medicine after dissolving or diluting it and, if necessary, after the first opening of the immediate packaging.

## **8. Special storage precautions, if any**

### **Article 28**

The outer packaging shall contain, if necessary, special storage precautions, if any (e.g. store at temperatures below 25°C; store at temperatures below 30°C, store at temperatures 2-8°C in a refrigerator, store in a freezer) in accordance with the information stated in the summary of product characteristics.

The outer packaging of a medicine shall not necessarily have to contain a storage temperature, provided that the medicine remains stable at the temperature of up to 30°C.

## *Other storage precautions*

### **Article 29**

The outer packaging shall contain other storage precautions, if necessary:

- If a medicine is sensitive to humidity: store in its original package, or store in a tightly closed container;
- If a medicine is sensitive to the light: store in its original package or store the container in its outer package in which case the correct name of the container should be stated in accordance with the standard terms;
- Do not keep in a refrigerator;
- Do not freeze.

## **9. Special precautions for disposal and destruction of medicines**

### **Article 30**

The package should contain special precautions for disposal and destruction of a medicine and/or remainder of a medicine, if necessary, or if this is the usual procedure, depending on the type of a medicine, in accordance with the regulations governing waste management.

## **10. Name and address of the marketing authorization holder**

### **Article 31**

The outer packaging shall contain the name and address of the marketing authorization holder.

## **11. Number of the authorization for placing a medicine on the market**

### **Article 32**

The outer packaging shall contain the number and date of issuing the authorization for placing a medicine on the market.

## **12. Manufacturer's batch number**

### **Article 33**

The outer packaging of a medicine shall contain either the batch or batch number. The batch number may consist of several characters.

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

The outer packaging of a medicine shall contain the following information (in the following order, if technically possible):

1. The manufacturer's batch number;
2. The expiry date (month and year).

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

If the information referred to in paragraph 3 of the Article cannot be stated without the use of abbreviations due to technical reasons, the following abbreviations shall be used:

- 1) Lot – for the batch number;
- 2) EXP – for the expiry date.

## **13. Method of administration of non-prescription medicines**

### **Article 34**

The outer packaging of a non-prescription medicine shall state the method of administration of the medicine.

The outer packaging of the medicine referred to in paragraph 1 of the Article may contain the following information:

- a) Indication(s);
- b) Recommendations for dosage, contraindications and warnings.

If all the information may not be found on the outer packaging, the following text should be included: "Read instructions before use".

## **14. ATC classification**

### **Article 35**

The outer packaging shall contain the anatomic-therapeutic-chemical (ATC) code for a medicine and/or anatomic-therapeutic-chemical veterinary (ATCvet) classification code.

## **15. EAN code**

### **Article 36**

Labelling of the outer packaging shall be conducted in the manner determined by the following standards: SRPS ISO/IEC 15420 – Information technology – Automatic identification and data capture techniques – bar

code symbology specification - EAN/UPC, in accordance with the regulations on standardization and with the Rulebook.

The outer packaging of a medicine shall contain only one EAN code which shall contain 13 symbols (EAN - 13) which shall ensure unambiguous international identification of all products, in conformity with standards of international GS1 organization competent for EAN codes.

The EAN code referred to in paragraph 2 of the Article shall be assigned by the national GS1 organization competent for EAN standards.

If the size of a package does not allow listing of the information about EAN code referred to in paragraph 2 of the Article, the EAN code assigned by the national GS1 organization competent for EAN standards shall be composed of eight symbols (EAN - 8).

## **16. Additional labelling of the outer packaging**

### **Article 37**

The outer packaging of a medicine shall additionally be labelled with the following:

- Information to be entered in a specially designated space (blue box);
- An additional stamp.

### *Specially designated space (blue box) and control stamp*

### **Article 38**

The medicine manufacturer and/or marketing authorization holder shall paste a control stamp in the specially designed space on the outer package of a medicine (blue box) for human use in accordance with the Rulebook.

Notwithstanding paragraph 1 of the Article, the manufacturer and/or marketing authorization holder may conclude an agreement for the medicines for human use with one or several wholesale entity which conduct the activity on the territory of the Republic of Serbia, to paste control stamps on the outer package in the name and for the account of the manufacturer and/or marketing authorization holder in accordance with the Rulebook.

The marketing authorization holder shall submit to the Ministry of Health information about the wholesale entity referred to in paragraph 2 of the Article, the list of medicines for which the wholesale entity paste control stamps in the name and for the account of the manufacturer and/or marketing authorization holder, as well as any amendments to the information.

The activities referred to in para. 2 and 3 of the Article may also be conducted by the marketing authorization holder who meets the conditions for the wholesale trade in medicines and medical devices.

The control stamp referred to in paragraph 1 of the Article shall contain the following information:

- 1) Wording: "Republic of Serbia"

The Ministry of Health of the ALIMS (the abbreviation stands for the Medicines and Medical Devices Agency of Serbia);

- 2) The control stamp serial number;
- 3) The bar code containing the control stamp serial number;
- 4) A specially designed hologram with the symbols of the Ministry of Health.

### **Article 39**

The manufacturer of a medicine shall paste the control stamp in a specially designated space on the outer packaging of the veterinary medicine (blue box) in accordance with the Rulebook.

Notwithstanding paragraph 1 of the Article, only one wholesale entity on the territory of the Republic of Serbia may receive approval from a foreign manufacturer of a veterinary medicine and/or from the marketing authorization holder to paste the control stamp in accordance with the Rulebook.

The control stamp referred to in paragraph 1 of the Article shall contain the following information:

- 1) Wording: "Republic of Serbia"

MACFWM (the abbreviation stands for the Ministry of Agriculture, Commerce, Forestry and Water Management - Veterinary Administration);

- 2) The control stamp serial number;
- 3) The bar code containing the control stamp serial number;
- 4) A specially designed hologram with the symbols of the Ministry of Agriculture, Commerce, Forestry and Water Management.

### **Article 40**

Pasting of the control stamp to the outer packaging of a medicine, which is carried out under the conditions referred to in Article 38, para. 2-4 and Article 39, paragraph 2 of the Rulebook, shall not be considered to be part of the medicine manufacturing process.

## *Medicines which do not have to be labelled with the control stamp*

### **Article 41**

The control stamp shall not have to be pasted to the medicines falling into the group of medical gases, dilutions for peritoneal dialysis, dilutions for parenteral nutrition, dilutions and emulsions for infusion, medicines whose immediate packaging is at the same time their outer packaging, where the immediate packaging of a medicine is made of material that does not allow pasting of the control stamp, medicines whose outer packaging is made of material that does not allow pasting of the control stamp, and veterinary medicines whose method of storage does not allow pasting of the control stamp.

The Agency shall in the process of approval of the outer and immediate packaging determine what medicines shall fall into the group of medicines referred to in paragraph 1 of the Article that do not have to be labelled with the control stamp.

### **Article 42**

The control stamp referred to in Art. 38 and 39 of the Rulebook shall be of a rectangular form, with rounded corners, size 18 x 30 mm (height by width), white in colour, with variable data written in the black colour.

### **Article 43**

The letters on the control stamp shall be printed in the Cyrillic alphabet in the uppercase mode.

### **Article 44**

The control stamp shall be pasted on the outer packaging of a medicine in the manner that shall enable the visibility of the information stipulated by the Rulebook on labelling outer packaging of a medicine.

Notwithstanding paragraph 1 of the Article, if the size of the outer packaging of a medicine is such that pasting of the control stamp would obscure the visibility of the information prescribed by the Rulebook on labelling outer packaging of a medicine, the control stamp may be pasted on one side of the outer packaging of a medicine so that the other sides of the outer packaging preserve the visibility of the information prescribed by the Rulebook on labelling outer packaging of a medicine.

### **Article 45**

The control stamp shall be made and printed on a double-layer safety base specially manufactured and printed for the needs of the Ministry of Health and/or the needs of the Ministry of Agriculture, Commerce, Forestry and Water Management by the National Bank of Serbia – Institute for Manufacturing Banknotes and Coins Topčider (hereinafter referred to as the „Institute“).

Printing of the control stamp shall be conducted on paper in the manner which shall prevent counterfeiting of the stamps.

An agreement between the Ministry of Health and/or Ministry of Agriculture, Commerce, Forestry and Water Management and the Institute shall be regulated in the manner which shall protect against counterfeiting and other technical details, as well as other issues relevant for the issuing, taking over and delivery of the control stamp.

### **Article 46**

The Institute shall issue the control stamp to the marketing authorization holder for a human medicine, upon approval from the Agency and/or upon approval of the Ministry of Agriculture, Commerce, Forestry and Water Management – for veterinary medicines.

### **Article 47**

The marketing authorization holder shall submit an application to the Agency for issuing a control stamp – for the medicines for human use, and/or to the Ministry of Agriculture, Commerce, Forestry and Water Management – for veterinary medicines, on the ZKM Form and /or ZKMV Form – an application for issuing the control stamp (consists of four self-copying documents) that are attached to the Rulebook and make its integral part.

### **Article 48**

Once or several times a year, the marketing authorization holder shall submit an application for issuing a control stamp to the Agency and/or to the Ministry of Agriculture, Commerce, Forestry and Water Management, for the quantity of medicines which shall be labelled with the control stamp for that year.

### **Article 49**

The marketing authorization holder shall, in addition to the application for issuing a control stamp, also submit to the Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management the following:

- 1) Evidence of being the marketing authorization holder, as well as evidence of registration in the Registry of the competent authority;
- 2) Evidence of issued marketing authorization;



3) Evidence of contracted manufacturing for the process of pasting of control stamps, in case pasting of control stamps is carried out on the basis of the agreement with another manufacturer;

4) Name and address of the wholesale entity referred to in Art. 38, paragraph 2 and Art. 39, paragraph 2 of the Rulebook with evidence that the wholesale entity obtained authorization to paste control stamps in the name and for the account of the marketing authorization holder.

#### **Article 50**

An application for issuing a control stamp shall be submitted to the Agency and/or the Ministry of Agriculture, Commerce, Forestry and Water Management directly by a person employed with the marketing authorization holder and a person he authorizes to submit an application for issuing a control stamp and to take over issued control stamps.

The authorized person referred to in paragraph 1 of the Article shall, in addition to the application for issuing a control stamp, also submit to the Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management the authorization referred to in paragraph 1 of the Article signed by the person authorized to represent the marketing authorization holder, as well as a copy of his or her ID card and his or her colour photo.

The Agency and/or the Ministry of Agriculture, Commerce, Forestry and Water Management shall submit to the Institute one copy of the authorization with a photocopy of the ID card and colour photo of the person referred to in paragraph 1 of the Article who shall be authorized to take over control stamps from the Institute.

#### **Article 51**

After receiving an application for issuing a control stamp, the Agency and/or the Ministry for Agriculture, Commerce, Forestry and Water Management shall determine whether the applicant submitted prescribed documents, assign a filing number, number and date of the application and approve issuing of the control stamp for the medicine with the marketing authorization, by stamping all four copies of the ZKM Form, and/or ZKMV Form.

Agency and/or the Ministry for Agriculture, Commerce, Forestry and Water Management shall submit the first, second and third copy of the ZKM Form and/or ZKMV Form to the Institute through the authorized person of the marketing authorization holder, and keep the fourth copy for its own needs, and direct the applicant to the Institute for purpose of issuing the control stamp.

#### **Article 52**

The Institute shall issue the control stamp to the domestic manufacturer of medicines through the authorized person referred to in Article 50 of the Rulebook, and for the medicines manufactured abroad, the Institute shall submit the control stamp by mail directly to the address of the foreign manufacturer of a medicine and/or to the address of the manufacturing site which the marketing authorization holder shall specify in his or her application.

At the request of the marketing authorization holder, the Institute may submit the control stamp to the foreign manufacturer of medicines through the authorized person referred to in Article 50 of the Rulebook.

If the marketing authorization contains several manufacturing sites of the foreign manufacturer of a medicine, the Institute shall submit the control stamp directly by mail or through the authorized person referred to in Article 50 of the Rulebook to the address and/or for the address of the manufacturing site which the marketing authorization holder shall specify in its application.

The Institute shall issue control stamps to the authorized person of the marketing authorization holder in accordance with Article 38, para. 2-4 and Article 39, paragraph 2 of the Rulebook.

The marketing authorization holder shall conduct activities of use, posting, handling and keeping records of the total quantities of control stamps taken over from the Institute in accordance with the Rulebook.

#### **Article 53**

Prior to issuing the control stamp, the authorized person referred to in Article 50 of the Rulebook shall submit to the Institute evidence of payment of the price for the printing and submission of the control stamp.

#### **Article 54**

At least once a year, the manufacturer and/or the marketing authorization holder shall return to the Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management damaged control stamps with visible serial number, pasted on one or more sheets of paper.

Notwithstanding paragraph 1 of the Article, when control stamps pasted on the outer packaging of a medicine are damaged in the manufacturing process, the manufacturer and/or marketing authorization holder shall submit to the Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management a report with serial numbers of damaged control stamps signed by the person responsible for issuing the batch of a medicine on the market for the manufacturing site.

In case it is not possible to record individual serial numbers on damaged control stamps, the person responsible for issuing the batch of a medicine on the market for the manufacturing site shall make a statement that it is not possible to read and/or record individual serial numbers of damaged stamps.

The manufacturer and/or marketing authorization holder may use the unused control stamps as long as there is a need for them or until they return them to the Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management.

The number (quantity) of damaged control stamps which do not have a visible label with the control stamp serial number, as well as the number of completely destroyed control stamps shall be approved by the Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management, provided that the number does not exceed 3% of the issued number of control stamps.

If the number (quantity) of damaged and/or destroyed control stamps referred to in paragraph 5 of the Article exceeds 3% of the issued number of control stamps, the manufacturer and/or marketing authorization holder shall be obliged to submit to the Ministry of Health and/or the Ministry of Agriculture, Commerce, Forestry and Water Management a report signed by the person authorized to issue the batch of a medicine on the market for the manufacturing site about the reasons that caused larger number of damaged and/or destroyed control stamps, and if control stamps are pasted by the authorized wholesale entity and/or marketing authorization holder referred to in Article 38, paragraph 4, the report shall be submitted by the responsible person in the legal entity.

The Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management shall create a separate record of returned and/or approved stamps referred to in para. 1-6 of the Article.

The Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management shall destroy control stamps referred to in para. 1 and 4 of the Article and make a record about this.

The process of destroying control stamps shall be carried out by the Committee formed by the Managing Director of the Agency and/or the Minister of Agriculture, Commerce, Forestry and Water Management.

#### **Article 55**

The Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management shall keep records of issued, used, damaged and unused control stamps for every manufacturer, and/or every marketing authorization holder.

#### **Article 56**

The records referred to in Article 55 of the Rulebook shall contain the following information:

- 1) The number (quantity) of issued control stamps;
- 2) The control stamp serial number (from – to);
- 3) The number (quantity) of used control stamps by the manufacturer and/or marketing authorization holder in the period for which information is submitted;
- 4) The number (quantity) of damaged and/or completely destroyed control stamps;
- 5) The serial number of damaged control stamps and/or the statement referred to in Article 54, paragraph 3 of the Rulebook;
- 6) The number (quantity) of unused control stamps;
- 7) The serial number (from - to) of unused control stamps;
- 8) The number and date of an application on the basis of which control stamps referred to in items 1) - 7) of the Article are issued;
- 9) The number (quantity) of medicines for which control stamps are issued.

The Agency and/or Ministry of Agriculture, Commerce, Forestry and Water Management shall also keep records about destroyed control stamps.

#### **Article 57**

The information on the manner of issuing a medicine shall be placed in a specially designated space on the outer packaging of the medicine (blue box) for human use, as follows:

- 1) "By prescription only";
- 2) "Non-prescription".

If the specially designated space on the outer packaging of a medicine (blue box) is not large enough to contain the information prescribed by the Rulebook, the information referred to in paragraph 1 of the Article may be entered to other appropriate place outside the specially designated space on the outer packaging of a medicine (blue box).

Other information relevant for medicine administration may be stated in the specially designated space (blue box) on the outer packaging of a veterinary medicine.

#### **Article 58**

The manufacturer and/or the marketing authorization holder shall keep records of the number of pasted control stamps, serial numbers of control stamps pasted on specific types of medicines (from-to control stamp serial number for every international non-proprietary name of a medicine, pharmaceutical form and/or strength of a medicine).

At least twice a year, the manufacturer and/or the marketing authorization holder shall, after pasting control stamps, submit the information referred to in paragraph 1 of the Article to the Ministry of Health and/or Ministry of Agriculture, Commerce, Forestry and Water Management.

#### **Article 59**

In the process of issuing an authorization for placing a medicine on the market, amendments, addenda and/or renewal of the marketing authorization and/or issuance of a quality certificate for every batch of an imported medicine, the manufacturer and/or marketing authorization holder shall be obliged to submit to the Agency a proposal for the wording on the outer packaging of a medicine and/or the mock-up of the outer packaging of a medicine containing a pasted control stamp.

If the wholesale entity pastes the control stamp in the name or for the account of the manufacturer and/or marketing authorization holder, and/or if the activity is conducted in conformity with Article 38, para. 2-4 and Article 44, paragraph 2 of the Rulebook, the marketing authorization holder shall be obliged to submit to the Agency information about the place on the outer packaging of a medicine which shall contain the pasted control stamp.

### *Additional sticker*

#### **Article 60**

The information contained on the original outer packaging of a medicine and printed in a foreign language shall be translated into Serbian by printing an additional sticker for the following:

- 1) A medicine with the marketing authorization for the Republic of Serbia whose consumption during a calendar year is less than 5.000 packages;
- 2) A medicine for which the authorization for marketing within the Republic of Serbia has not been issued, but is imported under the Law on Medicines and Medical Devices and is intended for the treatment of particular patients or groups of patients.

The printing of the additional sticker referred to paragraph 1 of the Article shall be provided either by the manufacturer of a medicine or by the wholesale entity, in the form of a sticker pasted on the original outer packaging of a medicine.

All the information referring to a medicine on the additional sticker shall be legible, clear and durable.

As an exception, an additional sticker may not be pasted on the outer packaging of a medicine referred to in paragraph 1, item 2) of the Article, in cases when administration of the said medicinal product, subject to the decision of the Agency, is urgent and cannot be delayed for a particular patient or a group of patients.

#### **Article 61**

An application for approval of the outer packaging of a medicine referred to in Article 60 of the Rulebook shall be submitted to the Agency for each calendar year, together with the information relating to the used quantities of the medicine during the previous year and/or in addition to the annual plan on estimated consumption of the said medicine for the relevant calendar year.

#### **Article 62**

The additional sticker shall contain the following as minimum:

- 1) The name of a medicine;
- 2) The pharmaceutical form, strength of a medicine and size of packaging;
- 3) Active substances expressed qualitatively and quantitatively per dosage unit;
- 4) The method of administration of a medicine;
- 5) The expiry date;
- 6) The name and address of the marketing authorization holder;
- 7) The number and date of issuing the authorization for placing a medicine on the market;
- 8) The method of issuing a medicine;
- 9) Manufacturer's batch number;
- 10) EAN code;
- 11) ATC classification and/or ATCvet classification for a veterinary medicine.

The information referred to in paragraph 1 of the Article shall be inserted on the additional sticker in the manner prescribed by the Rulebook on labelling outer packaging of a medicine.

For medicines prepared immediately before use, the expiry period of the prepared medicine shall also be specified.

In addition to the information referred to in para. 1 and 3 of the Article, the Agency may also require insertion of other necessary information on the additional sticker.

For veterinary medicines, the additional sticker shall in addition to the information referred to in paragraph 1 of the Article, contain the information on the waiting period.

For an imported medicine without the marketing authorization, which is intended for the treatment of a particular patient of a group of patients, the additional sticker shall also contain information on the importer.

The additional sticker referred to in paragraph 6 of the Article shall not contain the information referred to in paragraph 1, items 6), 7), 8) and 10) of the Article.

#### **Article 63**

The outer packaging of a medicine containing an additional sticker in conformity with the Rulebook shall not be labelled with the control stamp.

### **III. CONTENTS AND METHOD OF LABELLING THE IMMEDIATE PACKAGING OF A MEDICINE**

#### **Article 64**

The immediate packaging of a medicine is the packaging of a medicine which the medicine is directly in contact with.

The immediate packaging of a medicine referred to in paragraph 1 of the Article shall at least contain the following:

- 1) The name of a medicine and international non-proprietary name (INN) of the active substance, if any, and/or generic or chemical name, and if there is no INN and/or generic or chemical name, the common name of the active substance should be stated;
- 2) The strength and pharmaceutical form of a medicine;
- 3) The name of the marketing authorization holder;
- 4) The expiry date of a medicine (month and year);
- 5) The batch number of a medicine.

#### **Article 65**

In case the immediate packaging is small (the container is 10ml in size or smaller, e.g. vial, ampoule, etc.) as well as if the immediate packaging is not able to receive all data, the immediate packaging inserted within the outer packaging of a medicinal product of a medicine shall contain the following data:

- 1) The name of a medicine and international non-proprietary name (INN) of the active substance, if any, and/or generic or chemical name, and if there is no INN and/or generic or chemical name, the common name of the active substance should be stated;
- 2) The method of administration of a medicine;
- 3) The quantity expressed in units of weight, units of volume or dosage unit;
- 4) The name of the marketing authorization holder;
- 5) The batch number of a medicine;
- 6) The expiry date of a medicine (month and year).

#### **Article 66**

If the immediate packaging of a medicine is blister, or other type of small packaging of a veterinary medicine, the immediate packaging shall contain the following data:

- 1) The name of a medicine and international non-proprietary name (INN) of the active substance, if any, and/or generic or chemical name, and if there is no INN and/or generic or chemical name, the common name of the active substance should be stated;
- 2) The strength and pharmaceutical form of a medicine;
- 3) The name of the marketing authorization holder;
- 4) The expiry date of a medicine (month and year);
- 5) The batch number of a medicine.

The wording: "For animal use" and information on the waiting period shall be added for the veterinary medicine referred to in paragraph 1 of the Article.

### **IV. PACKAGE LEAFLET**

#### **Article 67**

The package leaflet shall be in Serbian and the language shall be clear.

The package leaflet shall be enclosed to the medicine packaging and shall be in conformity with the approved summary of product characteristics.

There shall be different package leaflets for different pharmaceutical forms of the same medicine.

If the information in the package leaflet is provided in several languages, its contents shall be the same.

The package leaflet shall be written in a language clear and understandable for the patient, with short sentences.

#### **Article 68**

For the medicines referred to in Article 60, paragraph 1 of the Rulebook, the package leaflet shall be in Serbian, approved by the Agency and enclosed to the medicine packaging.

The package leaflet referred to in paragraph 1 of the Article shall be identical to the package leaflet approved in one of the countries in which the medicine obtained its marketing authorization.

For the Agency to approve the package leaflet, it needs to be supported by the translation of the package leaflet verified by a certified interpreter.

### **Article 69**

The marketing authorization holder shall be obliged to submit to the association of patients the package leaflet written in appropriate Braille format (form), at the request of the association of patients whose objective is to protect blind and visually impaired persons.

### **Article 70**

The package leaflet shall contain information listed in the following order:

- 1) Information required for the identification of a medicine with the information on therapeutic indications;
- 2) Information which must be read before use of a medicine;
- 3) Information for the proper use of a medicine;
- 4) Information about adverse reactions to a medicine;
- 5) Information about storage and expiry date;
- 6) Additional information.

### **Article 71**

For medicines that are used by health care workers in a health care institution, the summary of product characteristics shall be made available to the health care worker.

### **Article 72**

The package leaflet may also contain additional information, as well as symbols and labels for better understanding, which shall be in accordance with the summary of product characteristics, and they shall not contain elements of advertising of a medicine.

## **1. Data required for identification of a medicine with information on therapy indications**

### **Article 73**

Data required for the identification of a medicine which shall be entered in the package leaflet are as follows:

- 1) The name of a medicine referred to in Article 7 of the Rulebook, strength and pharmaceutical form of a medicine in conformity with standard terminology of the national pharmacopoeia and European Pharmacopoeia, as well as INN and/or generic or chemical name or common name if the medicine contain only one or two active substance and if it has a trade name;
- 2) The pharmacotherapeutic group or method of dosing, using the terminology that is easily understandable to the patient.

### **Article 74**

The package leaflet shall contain information about all therapy indications, using the terminology that is easily understandable to the patient, as well as information on what age group a medicine is intended for: neonates, infants, children or adults, indicating the age, in accordance with the summary of product characteristics.

## **2. Information to be read before use**

### **Article 75**

Instructions for use shall contain information which the patient shall be obliged to read before use, such as:

- 1) Contraindications;
- 2) Warnings and precaution measures when using a medicine;
- 3) Interactions with other medicines, as well as other forms of interaction (e.g. with alcohol, tobacco, food) which may affect medicine action;
- 4) Special warnings referring to the possibility of a medicine impact on psychophysical abilities to drive a vehicle and use machines, possibility of a medicine to affect special conditions of specific groups of patients (children, pregnant women, nursing mothers, the elderly, persons with a specific pathological conditions), as well as special warnings related to excipients which may affect the safe use of a medicine.

## **3. Information on the proper use of a medicine**

### **Article 76**

The package leaflet shall contain information on the proper use of a medicine relating to the following:

- 1) The dosage;
- 2) The method of administration and use;
- 3) The frequency of application, indicating, if necessary, specific times when a medicine may or shall be used;
- 4) The duration of a therapy, if it needs to be limited in time (the usual duration of a therapy);
- 5) Measures to be taken in case of overdose (symptoms of overdose, assistance measures);
- 6) Advice on how to act if one or more doses are skipped;

- 7) Indications and warnings, if necessary, about the risk of consequences which may occur after abrupt termination of use of a medicine;
- 8) The method of issuing a medicine;
- 9) Special recommendations to consult a doctor or pharmacists about the use of a medicine, if necessary.

#### **4. Information on adverse reactions to a medicine**

##### **Article 77**

The package leaflet shall contain a description of adverse reactions to a medicine which occur after use of the usual dosage of the medicine, as well as measures to be taken in case of occurrence of adverse reactions to a medicine.

The package leaflet should warn the patient that he or she should inform his or her doctor or pharmacist about any occurring adverse reactions to a medicine that are not described in the package leaflet.

#### **5. Information about storage and expiry date**

##### **Article 78**

The package leaflet shall contain information about storage and expiry date which shall also be stated on the outer packaging of a medicine:

- 1) A warning: "Keep out of reach of children";
- 2) A warning that a medicine shall not be used after the expiry date which shall be indicated on the packaging;
- 3) Conditions of storage of a medicine in accordance with Art. 28 and 29 of the Rulebook;
- 4) The shelf life after first opening of a medicine and/or after dilution and/or dissolving a medicine in conformity with Article 27, paragraph 4 of the Rulebook;
- 5) The information about conditions of storage of a medicine after first opening and/or after dilution and/or dissolving of a medicine;
- 6) A warning referring to the visible signs of medicine degradation, if necessary;
- 7) Special precautions for disposal or destruction of a medicine.

#### **6. Additional information on a medicine**

##### **Article 79**

The package leaflet shall contain additional information on a medicine as follows:

- a) The composition of a medicine:
  - Active substances;
  - All excipients;
- b) Information on the form of a medicine and contents of the packaging;
- c) The name and address of the marketing authorization holder in the Republic of Serbia;
- d) The date of the last revision of the wording of the package leaflet;
- e) The number and date of issuing the marketing authorization.

Information about the composition of a medicine referred to in paragraph 1, item a) of the Article shall be stated separately for every pharmaceutical form and strength, if there are more of them.

The quantitative composition of all active substances and qualitative composition of all excipients shall be listed.

Names of medicine ingredients shall be written in Serbian in conformity with the information stated in the summary of product characteristics.

A list of excipients known to have an action, which must be stated in the package leaflet, is presented in Attachment 1 which is enclosed to the Rulebook and makes its integral part. For the excipients which are known to have an action, it shall be necessary to provide an appropriate warning in the package leaflet in the section "Important information about some medicine ingredients" in accordance with Attachment 1.

Paragraph 1, item b) of the Article, which refers to the information about the form of a medicine and contents of packaging, shall contain the pharmaceutical form, quantity per unit of individual dosage, per unit of weight or per unit of volume, short description of the form of a medicine and short description of packaging. This information shall be given separately for every pharmaceutical form, strength and size of packaging, if there are more of them.

### **V. PACKAGE LEAFLET OF A VETERINARY MEDICINE**

##### **Article 80**

The package leaflet of a veterinary medicine shall contain the following:

- 1) The name and address of the marketing authorization holder and manufacturer;
- 2) The name of a medicine (name on the outer packaging of a medicine, in accordance with Article 7 of the Rulebook. In addition to the name of a medicine, the following information should be listed, if possible: strength, pharmaceutical form, target species, INN or generic name);

- 3) The qualitative and quantitative composition of a medicine, as well as of the excipients set out in Attachment 1 of the Rulebook (quantity of the active substance(s) and a list of excipients);
- 4) Indications;
- 5) Contraindications;
- 6) Adverse effects;
- 7) Target species (species and category of animals a medicine is intended for);
- 8) The dosage and method of administration;
- 9) Instructions for proper use of a medicine (if necessary);
- 10) The waiting period;
- 11) Special warnings about the storage of a medicine (keep out of the reach of children, temperature and storage conditions, shelf life, shelf life after opening, shelf life after dilution, etc.);
- 12) Special warnings (other precautions from the summary of product characteristics related to the target animal species, pregnancy and lactation, persons administering a veterinary medicine, etc.);
- 13) Special precautions for the disposal and destruction of a medicine;
- 14) The date of approval of the wording of the package leaflet;
- 15) Other information (listing of all sizes of packaging, classification codes, limited sale, distribution or use, if any, method of issuing a medicine, number of an authorization for placing a medicine on the market, etc.).

The title in the package leaflet for the veterinary medicine referred to in paragraph 1 of the Article shall contain the name of a medicine referred to in paragraph 1, item 2) of the Article.

#### **Article 81**

The package leaflet for a veterinary medicine shall be written in Serbian.

The package leaflet for a veterinary medicine shall contain the waiting period.

The package leaflet for a veterinary medicine shall be written in a language understandable to the user, in clear and short sentences.

If information in the package leaflet for a veterinary medicine is provided in several languages, it shall have the same contents.

The package leaflet for a veterinary medicine shall be in conformity with the summary of product characteristics.

The package leaflet of a veterinary medicine shall list all target animal species which the veterinary medicine is intended for.

For the medicines referred to in Article 60, paragraph 1 of the Rulebook, the package leaflet for a veterinary medicine shall be written in Serbian and approved by the Agency.

Notwithstanding paragraph 6 of the Article, the Agency shall decide that, due to the urgent and undelayed use of a medicine by a particular patient or group of patients, the packaging of the medicines that do not have the marketing authorization in the Republic of Serbia, shall not contain the package leaflet of the veterinary medicine in Serbian.

#### **Article 82**

The package leaflet of a veterinary medicine may also contain additional information, symbols and labels for better understanding, which shall be in accordance with the summary of product characteristics of a veterinary medicine, and they shall not contain elements of advertising of a medicine.

## **VI. SPECIAL LABELLING ON THE OUTER AND IMMEDIATE PACKAGING OF A MEDICINE, AND PACKAGE LEAFLET**

### **1. Medicine that contain psychoactive controlled substances**

#### **Article 83**

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

- 1) A hollow triangle in the colour of the wording: relative prohibition of driving motor vehicles or using machines;
- 2) A full, red colour triangle: absolute prohibition of driving motor vehicles or using machines;
- 3) Paragraph (§), in the colour of the wording for psychoactive controlled substances.

### **2. Biological medicine**

#### **Article 84**

The outer packaging of a biological medicine shall contain the information referred to in Article 6 of the Rulebook.

In addition to the information referred to in paragraph 1 of the Article, the outer packaging of a biological medicine shall contain information about the strength of the biological medicine expressed in units of weight, if possible, and/or units of biological activity or international units, in an appropriate manner for the medicine.

The information referred to in paragraph 2 of the Article shall be in conformity with European Pharmacopoeia, when this is possible.

The immediate packaging of a biological medicine shall contain the information referred to in Art. 64 and 65 of the Rulebook.

### **3. Immunological medicine**

#### **Article 85**

The outer packaging of an immunological medicine shall contain the information set out in Article 6 of the Rulebook.

In addition to the information referred to in paragraph 1 of the Article, the outer packaging of a vaccine, being an immunological medicine, shall contain information about the quantity of the active substance which shall be expressed per one human dose (e.g. 0,5 ml).

If the vaccine referred to in paragraph 2 of the Article contains adjuvants, the outer packaging shall state their qualitative and quantitative composition.

The outer packaging of the vaccine referred to in paragraph 2 of the Article shall also list residues of special importance (e.g. ovalbumin in the chick embryo vaccines).

The immediate packaging of an immunological medicine shall contain the information set out in Art. 64 and 65 of the Rulebook.

### **4. Medicine derived from human blood**

#### **Article 86**

The outer packaging of a medicine derived from human blood and/or from blood components shall contain information entered in accordance with Article 6 of the Rulebook.

In addition to the information, the outer packaging of a medicine derived from blood and/or blood components shall contain the sentence: "Medicine derived from human blood. For more information see the package leaflet".

### **5. Medicine for clinical trial**

#### **Article 87**

A medicine intended for a clinical trial shall contain the following wording on the outer packaging: "For clinical trial", as well as information from the Good Manufacturing Practice – Annex XIII "Manufacturing of medicines intended for a clinical trial".

A veterinary medicine intended for a clinical trial shall contain the following wording on the outer packaging: "For clinical trial" and the information laid down in paragraph 1 of the Article.

### **6. Medicine intended for informing professional community**

#### **Article 88**

The outer packaging of a medicine intended for informing the professional community and/or intended for advertising a medicine, shall contain the wording: "Free sample, not for sale".

### **7. Radiopharmaceutical medicines**

#### **Article 89**

Radiopharmaceutical medicines, radionuclide generators and radionuclide precursors shall on the protective container contain the information set out in Article 6 of the Rulebook, as well as 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 specified date and, if necessary, hours and number of capsules or number of milliliters in a container for the liquid.

The outer packaging and container of the radiopharmaceutical medicines referred to in paragraph 1 of the Article shall be labelled in conformity with the regulations about safe transport of radioactive materials adopted by the competent International Atomic Energy Agency, and in accordance with the regulations governing the transportation of dangerous goods class 7 – radioactive substances.

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

- The name or code of a medicine, including the name or chemical symbol of a radionuclide;
- The batch number and expiry date;
- The international symbol for radioactivity;
- The name and address of the manufacturer;
- The amount of radioactivity per dosage or per vial for the specified date and hour, if required.

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

#### **Article 90**



The outer packaging of a radiopharmaceutical medicine, radionuclide generator and radionuclide precursor and radiopharmaceutical kit shall be supported by the package leaflet.

The package leaflet referred to in paragraph 1 of the Article shall be prepared in accordance with the provisions under Art. 67-79 of the Rulebook.

The package leaflet shall also have to contain all the precaution measures for the user and patient during the preparation and administration of a medicine, as well as special precaution measures related to the disposal of packaging and its unused contents in conformity with the regulations which regulate the method and conditions, as well as collecting, keeping, recording, storing, processing and disposal of radioactive waste material.

## **8. Homeopathic medicine**

### **Article 91**

The following information shall be written on the outer packaging and package leaflet for a homeopathic medicine: "Homeopathic medicine".

The outer packaging of a medicine and package leaflet referred to in paragraph 1 of the Article shall contain the following information:

1) The name of the original homeopathic stock, degree of dilution making use of the symbols of European pharmacopoeia and national pharmacopoeia (if a homeopathic medicine is composed of two or more stocks, the scientific name of the stocks may be replaced with the trade name);

2) The name and address of the homeopathic medicine marketing authorization holder and of the manufacturer;

3) The method of administration;

4) The expiry date, in accordance with Article 27 of the Rulebook;

5) The pharmaceutical form;

6) A list of those excipients known to have a recognized action, and if medicines are injectable, or for local or eye application, all excipients shall be specified;

7) Special storage precautions;

8) Special precaution measures;

9) Manufacturer's batch number;

10) The number and date of issuing the marketing authorization and/or registration in the Registry;

11) A warning: "If symptoms of a disease persist, consult a doctor".

For the homeopathic medicines that are registered in the Registry of homeopathic medicines, the medicine packaging and package leaflet for a homeopathic medicine shall, in addition to the information set out in paragraph 2 of the Article, also contain the following wording: "Homeopathic medicine without proved therapeutic indications".

## **9. Traditional medicine and traditional herbal medicine**

### **Article 92**

In addition to the requests for general labelling of a medicine, the outer packaging of a traditional medicine and traditional herbal medicine, as well as the package leaflet shall contain information that the medicine is a traditional medicine and/or traditional herbal medicine, and that it is administered in case of a particular indication on the basis of the experience gained from the use of the medicine for a longer period of time.

The outer packaging of a traditional and traditional herbal medicine shall not contain information referring to the ATC classification.

The outer packaging of a traditional medicine and package leaflet shall show information about the traditional therapeutic school from which the medicine originates, if such information is available.

The package leaflet for a traditional medicine shall contain warnings that the patient must contact a doctor if symptoms persist during the administration of a traditional medicine, and if there are adverse reactions to the medicine which are and/or are not specified on the package leaflet.

## **10. Galenic medicine**

### **Article 93**

A galenic medicine prepared in a pharmacy galenic laboratory shall on its outer packaging and package leaflet contain the information referred to in Article 6, paragraph 1, items 1) - 9), 12) and 13).

In addition to the information referred to in paragraph 1 of the Article, the outer packaging of a galenic medicine shall contain the name and address of the pharmacy galenic laboratory.

## **VII. TRANSITIONAL AND FINAL PROVISIONS**

#### **Article 94**

The marketing authorization holder shall be obliged to comply the labelling of the outer packaging of a medicine with the provisions under the Art. 38 and 39 of the Rulebook, the latest by 1 January 2012.

The batches of medicines manufactured before the date referred to in paragraph 1 of the Article, and which are on the market, shall not have to be labelled with the control stamp.

#### **Article 95**

The Rulebook on the Contents and Method of Labelling of the Outer and Immediate Packaging of a Medicine and on the Contents of the Package Leaflet for the Patient-User ("Official Gazette of RS", Nos. 27/08, 31/08 and 104/09), shall cease to be effective on the day of entry into force of the Rulebook.

### *Entry into force*

#### **Article 96**

The Rulebook shall enter into force one day after the date of its publication in the "Official Gazette of the Republic of Serbia".

No. 110-00-224/2010-03

Belgrade, 27 April 2011

Minister of Health,

Proff. Dr. **Zoran Stanković**, sgd.

Minister of Agriculture, Commerce,  
Forestry and Water Management,  
**Dušan Petrović**, sgd.

**LIST OF EXCIPIENTS KNOWN TO HAVE A RECOGNIZED ACTION WHICH SHALL BE LISTED ON THE OUTER PACKAGING OF A MEDICINE AND PACKAGE LEAFLET**

Name	Method of administration	Threshold	Information for the package leaflet	Comments
Azo colouring agents: For example: E102, tartrazine E110, sunset yellow FCF E122, azorubine, carmoisine E123, amaranth E124, ponceau 4R red, cochineal red A E151, brilliant black BN, black BN	Oral	Zero	May cause allergic reactions.	
Aprotinin	Topical	Zero	May cause hypersensitivity or severe allergic reactions.	The topical method of administration in this case means sites that may have access to the circulation (e.g. wounds, body cavities, etc.).
Aspartame (E 951)	Oral	Zero	Contains a source of phenylalanine. May be harmful for persons with phenylketonuria.	
Benzalkonium chloride	Ocular	Zero	May cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Known to discolour soft contact lenses.	
	Topical		Irritant, may cause skin reaction.	
	Respiratory	10 micrograms/ delivered dose	May cause bronchospasm.	
Benzyl alcohol	Parenteral	Exposure less than 90 mg/kg/day	Must not be given to premature babies or neonates.  May cause toxic reactions or allergic reactions in children up to 3 years old.	SmPC <sup>1</sup> : "allergic" should be expressed as "anaphylactoid".  The amount of benzyl alcohol in  mg per volume should be  stated in the package leaflet

				and SmPC <sup>1</sup> .
		90 mg/kg/day	<p>Must not be given to premature babies or neonates.</p> <p>Due to the risk of fatal toxic reactions in case of exposure to benzyl alcohol in excess of 90 mg/kg/day, the product should not be used in infants and children up to 3 years old.</p>	The amount of benzyl alcohol per volume should be stated in the package leaflet and SmPC <sup>1</sup> .
Benzoic acid and benzoates For example: E210 benzoic acid E211 potassium benzoate E212 sodium benzoate	Local	Zero	Mildly irritant to the skin, eyes and mucous membranes.	
	Parenteral	Zero	May increase the risk of jaundice in newborns.	
Bronopol	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis).	
Butylated hydroxyanisole (E320)	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.	
Butylated hydroxytoluene (E321)	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.	
Galactose	Parenteral	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of galactose intolerance e.g. galactosaemia should not take this medicine.
	Oral	Zero	If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> recommendation: Patients with a rare hereditary disease of galactose intolerance, e.g. galactosemia or glucose-galactose malabsorption, should not use this medicine.
	Oral Parenteral	5 g	Contains x g of galactose per dose. This should be taken into account in patients with diabetes mellitus.	
Glycerol	Oral	10 g/dose	May cause headache, upset stomach and diarrhea.	
	Rectal	1 g	May have a mild laxative effect.	
Glucose	Oral	Zero	If you have been told by your doctor that you have an intolerance to some sugars,	SmPC <sup>1</sup> proposal: Patients with rare glucose-galactose

			contact your doctor before taking this medicinal product.	malabsorption should not take this medicine.
	Oral and parenteral	5 g	Contains x g of galactose per dose. This should be taken into account in patients with diabetes mellitus.	
	Oral liquid, lozenges and chewable tablets	None	May be harmful to the teeth.	Information to be included only when the medicinal product may be intended for chronic use, e.g. for two weeks or more.
Dimethyl sulphoxide	Topical	Zero	May cause skin irritation.	
Ethanol	Oral and parenteral	Less than 100 mg per dose	This medicinal product contains small amounts of ethanol (alcohol), less than 100mg per dose.	This statement is to provide reassurance to parents and children concerning the low levels of alcohol in the product.
		100 mg-3 g/dose	This medicinal product contains ... vol % ethanol (alcohol), i.e. up to ... mg per dose, equivalent to ... ml beer, ... ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.	
	Oral and parenteral	3 g/dose	This medicinal product contains ... vol % ethanol (alcohol), i.e. up to ... mg per dose, equivalent to ... ml beer, ... ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease or epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines. The amount of alcohol in this medicinal product may impair your ability to drive or use	

			machines.	
Invert sugars	Oral	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of fructose intolerance or glucose-galactose malabsorption should not take this medicine.
		5 g	Contains x g of galactose in one dose. This should be taken into account in patients with diabetes mellitus.	
	Oral solutions, lozenges and chewable tablets	Zero	May be harmful to the teeth.	Information to be included only when the medicinal product may be intended for chronic use, e.g. for two weeks or more.
Potassium	Parenteral	Less than 1 mmol/dose	This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially “potassium- free”.	Information relates to a threshold based on the total amount of potassium in the medicinal product. This information is especially important for the doses administered to the pediatric population.
	Parenteral Oral	1 mmol/dose	This medicine contains x mmol (or in mg) potassium per dose. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.	
	Parenteral - intravenous	30 mmol/l	May cause pain at the site of injection.	
Peanut oil	All	Zero	This product contains peanut oil. If you are allergic to the peanut or soya, do not use this product	Refined peanut oil may contain peanut protein. European Pharmacopoeia monograph does not contain a test for residual

				protein.
Xylitol	Oral	10 g	May have a laxative effect. Caloric value 2,4 kcal/g xylitol	
Lactitol (E966)	Oral	Zero	If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of fructose intolerance, galactose intolerance, galactosaemia or glucose-galactose malabsorption should not take this medicine.
		10 g	May have a slight laxative effect. Caloric value 2,1 kcal/g lactitol	
Lactose	Oral	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
		5 g	Contains x g of lactose (x/2 g of glucose and x/2 g galactose) in one dose. This should be taken into account in patients with diabetes.	
Lanolin	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis).	
Latex Natural rubber	All	Zero	The container of this medicinal product contains latex rubber. May cause severe allergic reactions..	Not a typical excipient, but a warning is considered necessary.
Maltitol E965 and isomaltitol E953, maltitol liquid (see hydrogenated glucose syrup)	Topical	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of fructose intolerance should not take this medicine.
		10 g	May have a mild laxative effect. Caloric value 2,3 kcal/g of maltitol (or isomaltitol).	

Mannitol, E421	Oral	10 g	May have a mild laxative effect.	
Sodium	Parenteral	Less than 1 mmol/dose	This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially "sodium- free".	Information relates to a threshold based on the total amount of sodium in the medicinal product. This information is especially important for the doses administered to the pediatric population.
	Oral Parenteral	1 mmol/dose	This medicinal product contains x mmol (or y mg) sodium per dose. To be taken into consideration by patients on a controlled sodium diet.	
Organic mercury compounds For example Thiomersal, Phenylmercury (II) nitrate, Phenylmercury (II) acetate, Phenylmercury (II) borate.	Ocular	Zero	May cause allergic reactions.	See: EMEA Public Statement 8 July 1999, EMEA/20962/99
	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis) and depigmentation.	
	Parenteral	Zero	This medicinal product contains (thiomersal) as a preservative and it is possible that you/your child may experience an allergic reaction. Tell your doctor if you/your child have/has any known allergies.	See: EMEA Public Statement 8 July 1999, EMEA/20962/99
			Tell your doctor if you/your child have/has experienced any health problems after previous administration of a vaccine	Additional statement to be mentioned for vaccines
Parahydroxybenzoates and their esters For example E214 Ethyl parahydroxybenzoate E216 Propylparahydroxybenzoate E217 Sodium-propylparahydroxybenzoate E218 Methylparahydroxybenzoate E219 Sodium-methylparahydroxybenzoate	Oral, Ocular Local	Zero	May cause allergic reactions (possibly delayed)	
	Parenteral Respiratory	Zero	May cause allergic reactions (possibly delayed), and exceptionally, bronchospasm	
Balsam of Peru	Topical	Zero	May cause skin reactions.	
Polioxyl castor oil and polioxyl hydrogenated castor oil	Parenteral	Zero	May cause severe allergic reactions.	
	Oral			



	Topical	Zero  Zero	May cause upset stomach and diarrhea.  May cause skin reaction.	
Propylene glycol and propylene glycol esters	Topical Oral Parenteral	Zero Adults 400 mg/kg Children 200 mg/kg	May cause skin irritation. May cause alcohol-like symptoms.	
Wheat starch	Oral	Zero	Suitable for people with coeliac disease. Patients with wheat allergy (different from coeliac disease) should not take this medicine.	Wheat Starch may contain gluten, but only in trace amounts, and is therefore page 17 considered safe for people with coeliac disease. (Gluten in wheat starch is limited by the test for total protein described in the PhEur monograph)
Sucrose	Oral	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
		5 g	Contains x g of sucrose per dose. This should be taken into account in patients with diabetes.	
	Oral liquids, lozenges and chewable tablets	Zero	May be harmful to the teeth.	Information to be included only when the medicinal product may be intended for chronic use, e.g. for two weeks or more.
Sorbic acid and sorbic acid salts	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis).	
Sorbitol E420	Oral Parenteral	Zero	If you have been told by your doctor that you have an	SmPC <sup>1</sup> proposal: Patients with rare

			intolerance to some sugars, contact your doctor before taking this medicinal product.	hereditary problems of fructose intolerance should not take this medicine.
	Oral	10 g	May have a mild laxative effect. Caloric value 2,6 kcal/g sorbitol.	
Suphites including metabisulphites For example: E220 sulphur-dioxide E221 sodium-sulphite E222 sodium-bisulphite E223 sodium-metabisulphite E224 potassium-metabisulphite E228 potassium-bisulphite	Oral Parenteral Respiratory	Zero	May rarely cause severe hypersensitivity reactions and bronchospasm.	
Sesame oil	All	Zero	May rarely cause severe allergic reactions.	
Stearyl alcohol	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis)	
Soybean oil (and hydrogenated soybean oil)	All	Zero	(Medicinal product) contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.	Align with the peanut oil comments. SmPC <sup>1</sup> : contraindications.
Bergamot oil Bergapten	Topical	Zero	May increase sensitivity to UV radiation (natural and artificial)	Do not use if it was proved that there is no bergapten in the oil
Phenylalanine	All	Zero	This medicine contains phenylalanine. May be harmful for people with phenylketonuria.	
Formaldehyde	Topical	Zero	May cause local skin reactions (e.g. contact dermatitis).	
	Oral	Zero	May cause stomach cramps and diarrhea.	
Fructose	Oral Parenteral	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of fructose intolerance should not take this medicine.
		5 g	Contains x g of fructose per dose. This should be taken into account in patients with diabetes mellitus.	
	Oral liquids and lozenges and chewing tablets	Zero	May be harmful to the teeth.	Information to be included only when the

				medicinal product may be intended for chronic use, e.g. for two weeks or more
Heparin (as an excipient)	Parenteral	Zero	May cause allergic reactions and reduced blood cell counts which may affect the blood clotting system. Patients with a history of heparin-induced allergic reactions should avoid the use of heparin-containing medicines.	
Hydrogenated glucose syrup (see maltitol liquid)	Local	Zero	If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product	SmPC <sup>1</sup> proposal: Patients with rare hereditary problems of fructose intolerance should not take this medicine.
Chlorocresol	Topical Parenterally	None	May cause allergic reaction.	
Cetostearyl alcohol including cetyl alcohol	Local	Zero	May cause local skin reactions (e.g. contact dermatitis).	

<sup>1</sup>Summary of product characteristics - SmPC.

Medicines and Medical Devices Agency of Serbia	Document 1 Kept by the marketing authorization holder
Record number _____ Date _____	Stamp place

<b>APPLICATION FOR ISSUING THE CONTROL STAMP</b>	No:	Date:
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**I Information on the applicant – populated by the marketing authorization holder (domestic manufacturer, representative or agent)**

Company	Place and address	
Current account number	Activity code	Registration number

**II Information on the foreign manufacturer of the medicine – populated by the marketing authorization holder**

Company of the foreign manufacturer of the medicine	Place and address	Address where to send the control stamp
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III Information on the required control stamps – populated by the marketing authorization holder		IV Information on issued control stamps – populated by the Institute	
Required quantities of control stamps	Issued control stamps		
	From the serial number of the control stamp	To the serial number of the control stamp	
Signature and stamp	Date of issue	Signature and stamp	
	Tracking number		
	Received by	Signature of recipient	
	Personal identification number		

**Note: The medicine importer shall submit a copy of the document to the competent customs authority for clearance.**

Medicines and Medical Devices Agency of Serbia	Document 2 The Institute submits to the Agency
Record number _____ Date _____ Stamp place _____	

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Ministry of Agriculture, Commerce, Forestry and Water Management, Veterinary Administration	Document 1 Kept by the marketing authorization holder
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Ministry of Agriculture, Commerce, Forestry and Water Management, Veterinary Administration	Document 2 The Institute submits to the Veterinary Administration
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Ministry of Agriculture, Commerce, Forestry and Water Management, Veterinary Administration	Document 3 Kept by the Institute
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