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Pursuant to Article 34, paragraph 10, Article 76 and Article 80, paragraph 11 of the Law on Medicinal Products (“Official Gazette of Montenegro”, No. 14/26),

the Steering Committee of the Institute for Medicines and Medical Devices, with the approval of the Ministry of Health, hereby adopts

## **RULEBOOK ON DETAILED CONDITIONS FOR GRANTING MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS**

### **I GENERAL PROVISIONS**

#### **Article 1**

This Rulebook prescribes detailed manner of submission and the content of the application and required documentation for the issuance of marketing authorisation for a medicinal product for human use (hereinafter: marketing authorisation), detailed content of the marketing authorisation, as well as the content of the summary of the product characteristics, labeling and package leaflet, content of the application for variations of the marketing authorisation and supporting documentation.

#### **Article 2**

Terms used in this Rulebook in the masculine grammatical form shall be considered as applying equally to the feminine form.

#### **Article 3**

The terms used in this Rulebook shall have the following meanings:

- 1) **Reference Member State of the European Union** means a Member State which, within a centralised, decentralised or mutual recognition procedure, prepares and issues the Assessment Report;
- 2) **Assessment Report** means a document prepared by the European Medicines Agency (EMA) or by the competent authority of a Member State of the European Union, containing the analysis and conclusions regarding the quality, safety and efficacy of the medicinal product, based on expert assessment of the submitted documentation, including regulatory recommendations and the basis for decisions on the granting, variation or renewal of a marketing authorisation;
- 3) **International Non-Proprietary Name** (hereinafter: INN) is a name recommended by the World Health Organization (WHO), or in the absence thereof, the name that is commonly used.

### **II CONDITIONS FOR GRANTING A MARKETING AUTHORISATION**

#### **Article 4**

A marketing authorisation may be granted to the applicant referred to in Article 33 of the Law on Medicinal Products (hereinafter: the Law), based on the assessment of the documentation prescribed by this Rulebook.

#### **Article 5**

The application for granting a marketing authorisation shall be submitted to the Institute for Medicines and Medical Devices (hereinafter: the Institute) in accordance with the Law and this Rulebook.

The application referred to in paragraph 1 of this Article shall contain at least the following information:

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- 1) the name and address of the applicant;
  - 2) information on the medicinal product (brand name, international non-proprietary name (INN), pharmaceutical form, strength and packaging);
  - 3) the name and address of the manufacturer of the medicinal product;
  - 4) the Anatomical Therapeutic Chemical (ATC) classification code;
  - 5) the proposed dispensing classification of the medicinal product;
  - 6) the legal basis for granting a marketing authorisation, or a type of the application for issuance of marketing authorisation (reference to the relevant Article of the Law);
  - 7) information on whether the medicinal product has been granted a marketing authorisation in the European Union, and if so, the type and number of the procedure under which the authorisation was granted;
  - 8) the date and signature of the person responsible for obtaining the marketing authorisation.

The application referred to in paragraph 2 of this Article shall be submitted for each pharmaceutical form, strength and packaging of the medicinal product, using the application form published on the official website of the Institute.

### **Article 6**

The following shall be submitted along with the application for granting a marketing authorisation:

- 1) the documentation on the medicinal product as prescribed by the Law, depending on the type of application and the legal basis for granting the marketing authorisation; and
- 2) proof that prescribed fees have been paid.

### **Article 7**

The documentation required for granting of a marketing authorisation (hereinafter: the documentation) shall be submitted in the form of the Common Technical Document (hereinafter: CTD), in accordance with the European Commission guidelines: Volume 2B, Notice to Applicants, Medicinal Products for Human Use, Presentation and Content of the Dossier.

The main parts of the CTD are as follows:

- 1) Module 1 – Administrative and regional information;
- 2) Module 2 – Summaries and expert overviews of Modules 3, 4 and 5;
- 3) Module 3 – Quality information (pharmaceutical–chemical–biological data);
- 4) Module 4 – Non-clinical (pharmacological–toxicological) study reports; and
- 5) Module 5 – Clinical study reports.

The content and structure of the documentation referred to in paragraph 1 of this Article are provided in Annex 1, which forms an integral part of this Rulebook.

### **Article 8**

The application for granting a marketing authorisation referred to in Article 5 of this Rulebook, shall be submitted using the application form published on the official website of the Institute.

Together with the form referred to in paragraph 1 of this Article, in addition to the information and documentation prescribed by the Law and this Rulebook, the applicant shall also submit a written authorisation issued by the marketing authorisation holder in the European Union or by the manufacturer of the medicinal product, confirming that the applicant is authorised to represent them in the procedure for granting a marketing authorisation in Montenegro.

The authorisation form referred to in paragraph 2 of this Article shall be published on the official website of the Institute.

### **Article 9**

The Institute shall, in the procedure for granting a marketing authorisation, assess the acceptability of the proposed name of the medicinal product.

The Institute may consider the proposed name of the medicinal product unacceptable, if it is not in accordance with Article 7 paragraph 1 items 45 and 100 of the Law.

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A proposed name of a medicinal product may not:

- 1) be misleading due to its similarity with the scientific/international non-proprietary name or commonly used name;
- 2) be misleading due to its similarity with the approved name of another medicinal product;
- 3) be misleading by implying therapeutic efficacy;
- 4) be misleading with regard to the composition of the medicinal product;
- 5) be misleading with regard to the safety of the medicinal product;
- 6) contain promotional wording;
- 7) be misleading with regard to the dispensing classification of the medicinal product.

#### **Article 10**

In the case of an application for a marketing authorisation based on a full dossier, in accordance with Article 34 of the Law, the documentation submitted shall include the following:

- 1) administrative information;
- 2) own data on the quality of the medicinal product;
- 3) own data from non-clinical studies; and
- 4) own data from clinical studies.

By way of derogation from items 3 and 4 of paragraph 1 of this Article, an application may contain a mixed dossier, including published literature data that complement and support the submitted data from own studies.

#### **Article 11**

In the case of an application for a marketing authorisation for a medicinal product the active substance of which has a well-established medicinal use in accordance with Article 36 of the Law, the submitted documentation shall include the following:

- 1) administrative information;
- 2) own data on the quality of the medicinal product;
- 3) scientific literature data on non-clinical studies; and
- 4) scientific literature data on clinical studies.

The bibliographic data referred to in paragraph 1 of this Article shall relate to the therapeutic indications for which the application is submitted and shall include both positive and negative published data.

In demonstrating well-established medicinal use, the applicant shall in particular take into account the following:

- 1) Criteria to be considered in establishing well-established medicinal use of the active substance:
  - 1.1 period during which the active substance has been used for medical purposes;
  - 1.2 extent to which it is used in medical practice;
  - 1.3 level of scientific interest in the active substance, as evidenced by published scientific literature; and
  - 1.4 consistency of scientific assessments;
- 2) The submitted documentation on the medicinal product shall contain all data necessary for the assessment of the safety and/or efficacy of the product, and shall include or refer to an overview of relevant literature, taking into account studies conducted before and after the product was placed on the market, as well as published scientific literature concerning experience from epidemiological studies, in particular comparative epidemiological studies. The documentation shall include all data, regardless of whether they support or challenge the safety and/or efficacy of the medicinal product;
- 3) Particular attention shall be paid to missing data, and in such cases, a justification shall be provided demonstrating an acceptable level of safety and/or efficacy, despite the unavailability of certain study data;

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4) Expert reports on non-clinical and/or clinical documentation shall contain a justification and critical review of any differences between the medicinal product referred to in the literature and the product for which the application is submitted. An assessment shall be provided on whether, despite existing differences, the product described in the literature can be considered similar to the product for which the marketing authorisation is requested;

5) Particular attention shall be paid to post-marketing experience with other medicinal products containing the same active substance as the one in the product for which the marketing authorisation is requested.

In order to establish that an active substance has a well-established medicinal use, the period of use may not be less than ten years from the date of its first systematic and documented use as a medicinal product in Montenegro or in the European Union.

### **Article 12**

In the case of an application for a marketing authorisation submitted in accordance with Article 40 of the Law, the documentation of Module 1 referred to in Article 7 paragraph 2 of this Rulebook, shall be submitted, along with a declaration by the responsible person of the marketing authorisation holder in Montenegro confirming that the use of the pharmaceutical, non-clinical and clinical documentation of the medicinal product is authorised.

The medicinal product referred to in paragraph 1 of this Article, for which the application is submitted, shall have a different brand name from the product to which the reference is made.

### **Article 13**

In the case of an application for a marketing authorisation for a generic medicinal product in accordance with Article 7 paragraph 1 item 26 of the Law, the submitted documentation shall include:

- 1) administrative information;
- 2) own data on the quality of the medicinal product;
- 3) data from a bioequivalence study with the reference medicinal product, or a justification for not conducting such a study, in accordance with the applicable guidelines of the European Union, i.e. of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

If the active substance in the generic medicinal product is in the form of a different salt, ester, ether, isomer, mixture of isomers, complex or derivative compared to the active substance in the reference medicinal product, the evidence shall be provided demonstrating that there are no significant differences in terms of safety or efficacy compared to the reference product.

The proposed summary of product characteristics and package leaflet for Montenegro shall be aligned with the summary of product characteristics and package leaflet of the reference medicinal product authorised in Montenegro or in the European Union, as indicated in the application form for the marketing authorisation.

### **Article 14**

In the case of a hybrid application for a marketing authorisation, in accordance with Article 35 paragraph 7 of the Law, the submitted documentation shall include the following:

- 1) administrative information;
  - 2) own data on the quality of the medicinal product;
  - 3) own safety data required in relation to the differences between the reference medicinal product and the product for which the authorisation is requested; and
  - 4) own data or results of appropriate clinical studies related to the differences compared to the reference medicinal product.
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### **Article 15**

In the case of an application for a marketing authorisation for a biosimilar medicinal product, in accordance with Article 35 paragraph 8 of the Law, the submitted documentation shall include the following:

- 1) administrative information;
- 2) own data on the quality of the medicinal product;
- 3) own data or results of appropriate non-clinical studies related to the differences compared to the reference biological medicinal product; and/or
- 4) own data or results of appropriate clinical studies related to the differences compared to the reference biological medicinal product.

Due to the specific nature of biological medicinal products, the applicant shall submit data on the conducted studies in Modules 4 and 5 referred to in Article 7 paragraph 2 of this Rulebook, taking into account the specific characteristics of each biological medicinal product.

If the reference medicinal product is authorised for more than one indication, the safety and efficacy of the biosimilar medicinal product shall be justified or, where necessary, specifically demonstrated for each of the authorised indications.

### **Article 16**

In the case of an application for a marketing authorisation for a medicinal product containing a fixed combination of active substances, in accordance with Article 38 of the Law, the submitted documentation shall include the following:

- 1) administrative information;
- 2) own data on the quality of the medicinal product related to the fixed combination of active substances;
- 3) data from non-clinical studies related to the fixed combination of active substances; and
- 4) data from clinical studies related to the fixed combination of active substances.

### **Article 17**

In the case of an application for a marketing authorisation under the accelerated procedure, in accordance with Article 54 of the Law, in addition to the documentation referred to in Article 7 of this Rulebook, the following shall also be submitted:

- 1) identical documentation (consolidated file covering modules 2 - 5) approved in the centralised procedure (CP), decentralised procedure (DC) or mutual recognition procedure (MRP):
- 2) a statement by the applicant confirming that the documentation on the basis of which the medicinal product authorisation is requested in Montenegro is identical to the documentation on the basis of which the medicinal product authorisation was issued in the EU under the CP, MRP or DCP, including all variations approved by the date of submission of the application, i.e. that the submitted documentation is valid in the Member States of the European Union. The statement shall state the procedure number to which it refers and the date of the issuance of the authorisation. In case that there are differences in relation to the documentation approved within CP, DC or MRP, they shall be clearly stated and justified;
- 3) a list of variations that have been submitted and approved in the CP, DC or MRP by the date of submission of the application to CInMED, along with the information on the status of each variation in the procedure, as well as whether they have been implemented into the dossier submitted to CInMED. As for variations that have been approved and implemented, it is necessary to submit relevant approvals from the CP, MRP or DC procedure
- 4) Final Assessment Report issued by the EMA or the Reference Member State for medicinal products authorised through the Decentralised Procedure (DCP) or Mutual Recognition Procedure (MRP), including questions and answers by procedure day, i.e. the Quality, Non-

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clinical and Clinical Assessment of the response to the (outstanding) questions raised by the RMS and CMSs, and preliminary reports from all stages of the MRP or DC procedure

5) a declaration by the applicant stating that, in the event of permanent or temporary suspension or revocation of the marketing authorisation in the European Union, or in the event of any urgent safety restrictions, the Institute will be notified without delay.

### **III CONTENT OF THE MARKETING AUTHORISATION**

#### **Article 18**

The marketing authorisation shall contain at least the following information:

- 1) marketing authorisation number;
- 2) information (name and address) of the marketing authorisation holder;
- 3) name of the medicinal product and its INN (International Non-Proprietary Name);
- 4) pharmaceutical form of the medicinal product;
- 5) strength of the medicinal product;
- 6) qualitative and quantitative composition of the active substance(s);
- 7) type and packaging size of the medicinal product;
- 8) name and address of the manufacturer(s) responsible for batch release;
- 9) Anatomical Therapeutic Chemical (ATC) classification code of the medicinal product;
- 10) dispensing classification of the medicinal product;
- 11) method of advertising the medicinal product;
- 12) conditions and obligations in accordance with Articles 56, 57, 58 and 59 of the Law;
- 13) validity period of the marketing authorisation.

#### **Article 19**

The following approved documents are an integral part of marketing authorisation:

- 1) summary of product characteristics;
- 2) labelling and
- 3) packaging leaflet

#### **Article 20**

The summary of the product characteristics shall contain, in the order indicated below, the following information:

- 1) name of the medicinal product followed by the strength and the pharmaceutical form;
  - 2) qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used;
  - 3) Pharmaceutical form;
  - 4) Clinical particulars:
    - 4.1 therapeutic indications;
    - 4.2 posology and method of administration for adults and, where necessary, for children;
    - 4.3 contra-indications;
    - 4.4 special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such products and administering them to patients, together with any precautions to be taken by the patient;
    - 4.5 interaction with other medicinal products and other forms of interaction;
    - 4.6 use during pregnancy and lactation;
    - 4.7 effects on ability to drive and to use machines;
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- 4.8 adverse reactions;
  - 4.9 overdose (symptoms, emergency procedures, antidotes);
  - 5) Pharmacological properties:
    - 5.1 pharmacodynamic properties;
    - 5.2 pharmacokinetic properties;
    - 5.3 preclinical safety data;
  - 6) Pharmaceutical particulars:
    - 6.1 list of excipients;
    - 6.2 major incompatibilities;
    - 6.3 shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time;
    - 6.4 special precautions for storage;
    - 6.5 nature and contents of the container;
    - 6.6 special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product, if appropriate;
  - 7) Name and address of the marketing authorisation holder;
  - 8) Marketing authorisation number(s);
  - 9) Date of first authorisation or renewal of the authorisation;
  - 10) Date of revision of the text;
  - 11) For radiopharmaceuticals, full details of internal radiation dosimetry;
  - 12) For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparations and, where appropriate, the maximum storage time during which any intermediate preparation, such as the eluate or the pharmaceutical ready for use, will conform with its specifications.

As for medicinal products included in the List referred to in Article 23 of the Regulation 726/2004, the summary of product characteristics shall include the following statement: "This medicinal product is subject to additional monitoring." This statement shall be preceded by an inverted black triangle followed by the appropriate standardised explanatory sentence.

For all medicinal products, the summary of product characteristics shall include a standard text explicitly requiring healthcare professionals to report suspected adverse reactions in accordance with the spontaneous reporting system, including electronic reporting.

### **Article 21**

On the outer packaging of the medicinal product, or, if there is no outer packaging, on the immediate packaging, the following information shall be provided in Montenegrin language:

- 1) the name of the medicinal product, including strength and pharmaceutical form, and, where applicable, an indication of whether the product is intended for infants, children or adults; if the product contains up to three active substances, the INN shall be stated, or, if no INN exists, the commonly used name;
- 2) the qualitative and quantitative composition in active substances, expressed using their commonly used names, per dosage unit, or, depending on the pharmaceutical form, per unit of volume or mass;
- 3) the pharmaceutical form and content by weight, volume, or number of doses;
- 4) a list of excipients known to have a recognised effect or action; for medicinal products intended for parenteral, topical or ophthalmic use, all excipients shall be listed;
- 5) the method of administration and, where necessary, the route of administration; space shall be left for the prescribed dose to be indicated;
- 6) a special warning to keep the medicinal product out of the sight and reach of children;
- 7) a special warning for the medicinal product, if required;
- 8) the expiry date clearly stated (month/year);
- 9) special storage conditions, if any;

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- 10) special precautions for disposal of unused medicinal product or waste materials derived from such product, if applicable, and a reference to the appropriate collection system in place;
  - 11) name and address of the marketing authorisation holder, and, where applicable, the name of their authorised representative;
  - 12) marketing authorisation number;
  - 13) batch number;
  - 14) for non-prescription medicinal products, the package leaflet shall be provided;
  - 15) means of verification of whether the outer packaging has been tampered with, as well as safety features in accordance with Article 71 of the Law, except for radiopharmaceuticals, that enable wholesale distributors and persons carrying out retail sale of medicinal products to:
    - 15.1 verify the authenticity of the product, and
    - 15.2 identify individual packaging.

The excipients referred to in item 4 of paragraph 1 of this Article shall be listed in accordance with the applicable European Commission guideline.

### **Article 22**

No more than three active substances shall be listed on the outer packaging of a medicinal product.

If the medicinal product contains more than three active substances, the Institute shall, during the approval procedure for the labelling of the outer packaging, determine which active substances shall be listed.

The active substances referred to in paragraphs 1 and 2 of this Article shall be indicated either after the strength and pharmaceutical form or below the brand name of the medicinal product.

### **Article 23**

On the outer packaging of the medicinal product, if required, additional information may be included, such as:

- 1) price of the medicinal product;
- 2) information on reimbursement of the medicinal product from mandatory health insurance funds;
- 3) classification of medicinal products;
- 4) markings for identification and verification of the authenticity of the medicinal product packaging;
- 5) symbols, images or other markings, provided they facilitate understanding of the information, are consistent with the approved summary of product characteristics and do not contain promotional elements.

### **Article 24**

The inner packaging of the medicinal product shall contain the information referred to in Article 21 of this Rulebook.

The inner packaging, presented in a blister pack and contained in the outer packaging, shall contain at least the following information:

- 1) the name of the medicinal product with the strength and pharmaceutical form and, if applicable, whether the medicinal product is intended for infants, children or adults; if the medicinal product contains
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up to three active substances, the INN shall be stated or, if it does not exist, the common name shall be provided;

- 2) name of the marketing authorisation holder for the medicinal product;
- 3) expiry date of the medicinal product;
- 4) batch number of the medicinal product.

If the inner packaging is small and in the case of an inner packaging where it is not possible to state the information referred to in paragraph 1 of this Article, the inner packaging shall contain at least the following information:

1) the name of the medicinal product with the strength and pharmaceutical form and, if applicable, whether the medicinal product is intended for infants, children or adults; if the medicinal product contains up to three active substances, the INN shall be provided or, if it does not exist, the common name shall be provided; if necessary, the route of administration shall be provided;

- 2) method of administration;
- 3) the date of expiry of the period of use of the medicinal product;
- 4) batch number of the medicinal product, and
- 5) information on the content expressed in units of mass, volume or per dosage unit.

### **Article 25**

By way of derogation from Article 21 paragraph 1 of this Rulebook, the Institute may, in the marketing authorisation procedure and upon a duly justified request by the applicant, approve the use of outer packaging labelled in a foreign language, provided that such packaging has been approved in the country of origin, that the Institute has been provided with documentation identical to the one approved in the country of origin, and that the annual consumption of the medicinal product in Montenegro does not exceed 5,000 packs.

In the case referred to in paragraph 1 of this Article, the outer packaging shall bear an additional label in Montenegrin, the content of which is approved by the Institute, and shall contain at least the following information:

- 1) name of the medicinal product;
- 2) pharmaceutical form, strength, and packaging size;
- 3) qualitative and quantitative composition of the active substance(s);
- 4) method of administration and classification for dispensing;
- 5) a warning to keep the medicinal product out of the reach of children and other warnings, if necessary;
- 6) the expiry date (month and year);
- 7) the in-use shelf life, for medicinal products prepared immediately prior to administration;
- 8) storage conditions, if applicable;
- 9) name and address of the marketing authorisation holder in Montenegro;
- 10) number of the marketing authorisation granted in Montenegro.

The following information shall also be included on the additional label if they not clearly visible on the original packaging:

1. excipients with known effect, depending on the method of administration;
2. batch number of the medicinal product

### **Article 26**

By way of derogation from Article 21 of this Rulebook, the Institute may, during the marketing authorisation procedure and upon a duly justified request by the applicant, approve the use of outer

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packaging labelled in a language that is in official use in Montenegro, provided that such packaging has been approved in the country of origin and that the Institute has been provided with documentation identical to the one approved in the country of origin of the packaging.

In the case referred to in paragraph 1 of this Article, the outer packaging shall bear an additional label in Montenegrin the content of which is approved by the Institute and shall contain at least the following information:

- 1) name and address of the marketing authorisation holder in Montenegro;
- 2) marketing authorisation number granted in Montenegro.

The additional label referred to in paragraph 2 of this Article may also include the name of the medicinal product, pharmaceutical form, strength, and pack size, if technically feasible.

Alternatively, the information required on the additional label referred to in paragraph 2 of this Article may be printed directly on the outer carton, provided that prior approval for such printing has been obtained from the competent authority in the country of origin of the packaging.

### **Article 27**

The additional label referred to in Articles 25 and 26 of this Rulebook shall be provided by the manufacturer or the holder of the wholesale distribution authorization for medicinal products.

### **Article 28**

A package leaflet shall be enclosed with the medicinal product packaging, unless all the information referred to in paragraph 2 of this Article and Article 29 paragraph 1 of this Rulebook is provided on the outer or immediate packaging of the medicinal product.

The package leaflet shall be consistent with the summary of product characteristics and shall contain the following information in the order given below:

- 1) data necessary to identify of the medicinal product:
    - 1.1 the name of the medicinal product followed by the strength and pharmaceutical form, and, if applicable, whether it is intended for infants, children, or adults. The common name shall be stated if the product contains only one active substance and the name of the medicinal product is an invented name;
    - 1.2 the pharmacotherapeutic group or type of activity in terms understandable to the patient;
  - 2) therapeutic indications;
  - 3) information necessary before the medicinal product is taken:
    - 3.1 contra-indications;
    - 3.2 appropriate precautions for use;
    - 3.3 interactions with other medicinal products and other forms of interactions (e.g., with alcohol, tobacco, food) that may affect the efficacy of the product;
    - 3.4 special warnings;
  - 4) instructions for proper use, in particular:
    - 4.1 dosage;
    - 4.2 method and, if necessary, route of administration;
    - 4.3 frequency of administration, specifying, if needed, the appropriate time when the product can or should be administered;and, if necessary, depending on the nature of the medicinal product:
    - 4.4 duration of treatment, if treatment should be limited;
    - 4.5 actions to be taken in case of overdose (such as symptoms and emergency measures);
    - 4.6 actions to be taken in case of missed doses;
    - 4.7 a warning, if necessary, regarding the risk of withdrawal effects;
    - 4.8 a specific recommendation to consult a doctor or pharmacist for clarification regarding use.
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- 5) description of possible adverse reactions during normal use, and, if necessary, actions to be taken;
  - 6) reference to the expiry date indicated on the packaging, including:
    - 6.1 a warning to not use the medicinal product after the expiry date;
    - 6.2 any special storage conditions;
    - 6.3 a warning regarding visible signs of quality defects, if applicable;
    - 6.4 the full qualitative (active and excipient) composition and quantitative composition of active substances using their common names for each packaging size;
    - 6.5 the pharmaceutical form and contents in terms of mass, volume, or dosage units for each packaging size;
    - 6.6 the name and address of the marketing authorisation holder and, where applicable, its local representative in Montenegro or EU Member States;
    - 6.7 the name and address of the manufacturer;
  - 7) as for medicinal products authorised through decentralised or mutual recognition procedure under different names in EU Member States, the name of the product in each Member State shall be provided;
  - 8) date of the last revision of the package leaflet.

For medicinal products under additional monitoring, the package leaflet shall include the following statement: “This medicinal product is subject to additional monitoring.” This statement shall be preceded by an inverted black triangle and followed by the corresponding standardised explanation.

For all medicinal products, the leaflet shall include a standardised statement encouraging patients to report suspected adverse reactions to their doctor, pharmacist, healthcare professional, or the Institute, including details of available reporting options (e.g., electronic reporting, postal address or other available methods).

The list of information referred to in paragraph 2, item 3, shall:

- 1) take into account special conditions of certain patient groups (e.g., children, pregnant or breastfeeding women, elderly persons, patients with specific pathological conditions);
- 2) indicate, if applicable, the potential effect on the ability to drive or use machines;
- 3) indicate those excipients which may affect the safety and efficacy of the product, as covered by the detailed guidance of the European Commission.

The package leaflet shall reflect the results of consultations with target patient groups to ensure it is legible, clear and user-friendly.

The applicant for marketing authorisation or the marketing authorisation holder shall submit data on the readability and comprehension testing of the package leaflet.

Readability and comprehension may also be confirmed by reference to the leaflet of a comparable authorised medicinal product or by recognising existing testing conducted in other countries.

## **Article 29**

The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information required by this Rulebook, as well as other information consistent with the summary of product characteristics that is useful to the user, provided that such elements are not of a promotional nature.

The information referred to in Articles 21 and 28 paragraphs 2 to 5 of this Rulebook and paragraph 1 of this Article shall be provided in Montenegrin.

The information referred to in paragraph 2 of this Article may also be presented in multiple languages, provided that the same information is given in all languages used. The marketing authorisation holder shall be responsible for ensuring the consistency and accuracy of the information across all languages used.

If the medicinal product is not intended for direct supply to the patient, or in the event of serious supply issues, the Institute may, by means of measures it considers necessary for the protection of public

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health, grant an exemption from the requirement for certain information to be included on the labelling and in the package leaflet.

### **Article 30**

The inclusion of the package leaflet, in the cases referred to in Articles 25 and 26 of this Rulebook, shall be ensured by the manufacturer or the holder of the wholesale distribution authorisation.

### **Article 31**

The outer packaging and the container of a medicinal product containing radionuclides shall be labelled in accordance with the regulations on the safe transport of radioactive materials as prescribed by the International Atomic Energy Agency.

The labelling on the protective packaging of a medicinal product containing radionuclides shall include the information specified in Article 20 of this Rulebook. In addition, the labelling on the protective packaging shall contain a full explanation of the markings indicated on the vial and, where necessary, the amount of radioactivity per dose or per vial and the number of capsules or, in the case of liquids, the volume in millilitres, with the corresponding time and date.

The following information shall be provided on the vial:

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

The Institute shall ensure that the packaging of a radiopharmaceutical, radionuclide generator, radionuclide kit or radionuclide precursor is accompanied by detailed instructions for use. The text of such instructions shall be prepared in accordance with Article 28 of this Rulebook and shall include precautions to be taken by the user or patient during preparation and administration of the medicinal product, as well as specific precautions regarding the disposal of the packaging and any unused contents.

### **Article 32**

Medicinal products intended for clinical trials shall be labelled in accordance with the regulations governing clinical trials of medicinal products.

### **Article 33**

A homeopathic medicinal product shall be labelled in accordance with Articles 21 to 27 of this Rulebook, with a clear and legible indication of its homeopathic nature.

In addition to clear statement "homeopathic medicinal product", the labelling and, where necessary, the package leaflet of a homeopathic medicinal product shall contain the following information:

- 1) scientific name of the homeopathic stock(s), followed by the degree of dilution using the symbols of the pharmacopoeia; if the homeopathic product consists of two or more homeopathic stocks, a new name for the medicinal product may be added to the labelling in addition to the scientific names of the stocks;
  - 2) name and address of the holder of the registration for the homeopathic medicinal product and, where applicable, the manufacturer;
  - 3) method of administration and, if necessary, route of administration;
  - 4) the expiry date (month and year)
  - 5) pharmaceutical form
  - 6) contents of the packaging
  - 7) special storage precautions, if applicable
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- 8) special warning applicable to the product, if necessary
  - 9) batch number
  - 10) registration number
  - 11) the statement: “homeopathic medicinal product without approved therapeutic indications”;
  - 12) a warning advising the user to consult a doctor if symptoms persist during the use of the homeopathic medicinal product.

#### **Article 34**

In addition to Article 68 paragraph 2, Article 70 paragraphs 2, 4 and 5, Articles 71, 72, 74 and 75 of the Law and Articles 21, 23, 28 and 29 of this Rulebook, the labelling of a registered traditional herbal medicinal product shall contain the following statement:

- 1) that the medicinal product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use;
- 2) that the user should consult a doctor or pharmacist if symptoms persist during use of the medicinal product or if adverse reactions not listed in the package leaflet occur.

### **IV CONTENTS OF THE APPLICATION AND REQUIRED DOCUMENTATION FOR VARIATIONS OF MARKETING AUTHORISATION**

#### **Article 35**

The marketing authorisation holder shall, in accordance with the Law, follow scientific and technical developments in the field, pharmacovigilance data and other relevant information concerning the medicinal product, and shall notify the Institute of any new findings related to the assessment of the quality, safety and efficacy of the medicinal product; the marketing authorisation holder shall submit an application for the variation of the marketing authorisation in line with new findings concerning the medicinal product.

#### **Article 36**

The variations referred to in Article 35 of this Rulebook may include:

- 1) minor variations – variations of type IA, IAin and type IB;
- 2) major variations – variations of type II; and
- 3) variations requiring a new marketing authorisation, which represents an extension of the existing authorisation and shall be submitted as a new application.

The variations referred to in paragraph 1 of this Article shall be classified in accordance with the Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use, Commission Delegated Regulation (EU) 2024/1701 amending Regulation No 1234/2008 with regard to the examination of variations to the terms of marketing authorisations for medicinal products for human use, and Guideline on the details of the various categories of variations, the implementation of the procedures laid down in Chapters II, IIa, III and IV of Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human and veterinary use, as well as the documentation to be submitted pursuant to those procedures (C/2025/5045).

#### **Article 37**

Type IA variations are variations that either have no impact or have minimal impact on the quality, safety or efficacy of the medicinal product, and shall be notified to the Institute by the marketing authorisation holder within 12 months following their implementation (“Do and Tell” procedure).

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Within the timeframe referred to in paragraph 1 of this Article, the marketing authorisation holder may submit a notification covering multiple type IA variations implemented during the previous 12 months – Annual Reporting.

Type IAin variations shall be notified to the Institute immediately after their implementation by the marketing authorisation holder.

### **Article 38**

Type IB variations are variations that do not qualify as type IA, IAin or type II variations, nor as variations requiring a new marketing authorisation.

For Type IB variations, the marketing authorisation holder shall submit an application for approval to the Institute prior to implementation.

The “Tell, Wait and Do” procedure shall apply to variations referred to in paragraph 1 of this Article, in accordance with the Commission Regulation and Guideline referred to in Article 35 paragraph 2 of this Rulebook.

### **Article 39**

Type II variations are variations that may have a significant impact on the quality, safety or efficacy of the medicinal product.

For type II variations, the marketing authorisation holder shall submit an application for approval to the Institute prior to implementation.

### **Article 40**

The marketing authorisation holder shall submit a new application for a marketing authorisation to the Institute for variations that constitute an extension of the marketing authorisation ("extension line" applications), in particular for variations relating to:

- 1) the active substance;
- 2) the strength, pharmaceutical form, and route of administration.

### **Article 41**

Along with the variation notification or approval application, the applicant shall submit the following documentation:

- 1) a completed application form signed by a responsible person of the applicant;
- 2) documentation relating to the variation, providing sufficient information for its evaluation;

and

- 3) proof that prescribed fees have been paid.

The application form referred to in paragraph 1 item 1 of this Article shall be published on the official webpage of the Institute and completed in accordance with the Instructions for completing the application form and preparing the documentation for the procedure of variation notification and approval.

### **Article 42**

For a variation notification/approval application concerning a medicinal product that has been granted marketing authorisation in Montenegro under the accelerated procedure in accordance with Article 52 of the Law, the applicant shall, in addition to the documentation prescribed by this Rulebook, submit the following:

1. identical variation documentation (variation package) as approved under the Centralised Procedure (CP), Mutual Recognition Procedure (MRP), or Decentralised Procedure (DCP);
  2. variation approval in CP, MRP or DCP (i.e. Approval/Opinion for Type II variations, or Acknowledgement of receipt and Notification for Type IA, IAin, and Type IB variations);
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3. assessment report issued by the EMA or by the reference Member State in the DCP or MRP, for Type IB and Type II variations.

#### **Article 43**

The marketing authorisation holder shall immediately notify the Institute of any urgent safety measures undertaken due to a risk to public health.

An urgent safety measure is a temporary modification of the terms of the marketing authorisation based on new information affecting safe use of the medicinal product.

If the Institute raises no objections to urgent safety measures referred to in paragraphs 1 and 2 of this Article, or does not provide a response to the marketing authorisation holder, the marketing authorisation holder shall implement the variation within 24 hours from the moment the notification was submitted to the Institute.

In case of a risk referred to in paragraph 1 of this Article, the Institute may also require the marketing authorisation holder to implement urgent safety measures.

The marketing authorisation holder shall submit to the Institute a completed variation application form with required documentation immediately upon implementation of the urgent safety measures referred to in paragraph 1 of this Article, and no later than 15 days following implementation.

#### **Article 44**

Following the approval of a variation of the medicinal product documentation, a medicinal product manufactured and placed on the market in Montenegro in accordance with previously approved data and documentation may remain on the market until the expiry date, unless the Institute, in the course of the variation approval procedure, adopts a different decision, in which case the applicant shall be informed accordingly.

### **V TERMINATION OF THE MARKETING AUTHORISATION FOR A MEDICINAL PRODUCT**

#### **Article 45**

The Marketing Authorisation Holder shall, in accordance with Article 82 of the Law, submit to the Institute an application for the termination of the marketing authorisation for a medicinal product, using the application form published on the Institute's website.

The application referred to in paragraph 1 of this Article shall be submitted separately for each pharmaceutical form, strength, and packaging size of the medicinal product.

The application referred to in paragraph 1 of this Article shall be accompanied by proof of payment of prescribed fees and any other documentation required by the Institute.

### **VI TRANSITIONAL AND FINAL PROVISIONS**

#### **Article 46**

The provisions of Article 21 paragraph 1 item 15 and Article 28 paragraph 2 item 6.6 in the part „EU Member States“ and item 7 of this Rulebook shall apply from the date of accession of Montenegro to the European Union.

#### **Article 47**

The provisions of Articles 25 and 26 of this Rulebook shall apply until the date of accession of Montenegro to the European Union.

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#### **Article 48**

On the date of entry into force of this Rulebook, the Rulebook on detailed conditions for granting marketing authorisation for medicinal products (“Official Gazette of Montenegro”, No 21/16 and 55/19) and the Rulebook on the contents and method of labelling the outer and immediate packaging of a medicine and contents of the package leaflet (“Official Gazette of Montenegro” No 21/16 and 67/18) shall cease to apply.

#### **Article 49**

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

In Podgorica, 2026

CHAIR OF THE STEERING COMMITTEE

No:

dr Jovan Milić, specialist in ophthalmology

\* This Rulebook transposes the provisions of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as well as the Annexe I to this Directive