Pursuant to Article 34 paragraph 10 and Article 52 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 THE REGISTRATION OF HOMEOPATHIC AND TRADITIONAL HERBAL MEDICINAL PRODUCTS

I GENERAL PROVISIONS

Article 1

This Rulebook shall prescribe detailed manner of submission, the content of the application and required documentation, as well as detailed conditions, content of documentation and the procedure for registration of homeopathic and traditional herbal medicinal products.

Article 2

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

Article 3

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

1) **homeopathic medicinal product for human use** is a medicinal product prepared from substances called homeopathic stocks, in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the EU Member State. Homeopathic medicinal product for human use may contain a number of active principles;
2) **traditional herbal medicinal product** is a medicinal product based on scientific principles and resulting from tradition or other traditional therapeutic approaches;
3) **herbal medicinal product** is any medicinal product, exclusively containing as active ingredients one or more herbal substances, or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations;
4) **herbal substance** means all mainly whole, fragmented or cut plant, plant parts, algae, fungi or lichen in an unprocessed, usually dried form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);
5) **herbal preparation** is a preparation obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. Herbal preparations also include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;
6) **European Union herbal monograph** is a scientific opinion of the Committee on Herbal Medicinal Products (hereinafter: HMPC) of the European Medicines Agency (EMA) on the safety and efficacy data for a herbal substance and its

preparations intended for medical use, including all necessary information on indications, target population, and safety (e.g. adverse reactions, drug interactions);

7) **Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products** is the list prepared by the HMPC containing data on indications, strength, dosage, route of administration, and other relevant information for the safe use of herbal substances in traditional herbal medicinal products;
8) **corresponding medicinal product** is a medicinal product characterised by having the same active ingredients, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration as the medicinal product for which the application for registration is submitted;
9) **HMPC** is a committee at the European Medicines Agency (EMA) which prepares the list referred to in item 7 of this paragraph.

II REGISTRATION OF HOMEOPATHIC MEDICINAL PRODUCT

Article 4

Homeopathic medicinal product shall be registered via simplified procedure.

The application for registration of homeopathic medicinal product via simplified procedure shall be submitted to the Institute for Medicines and Medical Devices (hereinafter: the Institute), along with a completed application form.

The applicant for registration and the holder of the registration of a homeopathic medicinal product shall have their headquarters in Montenegro.

The application referred to in paragraph 2 of this Article may also be submitted by a natural or legal person having a headquarters in the European Union.

The application referred to in paragraph 2 of this Article shall be submitted on a form containing the following data:

1) name of a medicinal product;
2) name of homepathic stock(s);
3) pharmaceutical form, route of administration; information about the packaging, degree of dilution;
4) data on the composition of homeopathic medicinal product;
5) data on the manufacturer of the medicinal product (name, address and manufacturing site);
6) proposal of the dispensing mode of the medicinal product;
7) date and signature of a person responsible for the registration procedure.

The application referred to in paragraph 2 of this Article may relate to one pharmaceutical form in several different degrees of dilution and packaging sizes prepared from the same homeopathic stock.

The application form referred to in paragraph 2 of this Article shall be published on the webpage of the Institute.

The application referred to in paragraph 2 of this Article shall be accompanied by appropriate documentation and proof that the prescribed fees have been paid.

Article 5

The application referred to in Article 4 paragraph 2 of this Rulebook shall be accompanied by documentation in the form of a Common Technical Document (hereinafter:

CTD dossier), with specific requirements for homeopathic medicinal products, in accordance with special provisions on the application of Modules 3 and 4 to homeopathic medicinal products, in accordance with the regulation governing the conditions for granting a marketing authorisation.

The documentation referred to in paragraph 1 of this Article shall contain the following:

1) scientific name or other name given in a pharmacopoeia for the homeopathic stock(s), stating different routes of administration, pharmaceutical forms and degrees of dilution for which registration is sought;

2) data that describe how homeopathic stock or stocks have been obtained and their quality controlled and bibliographic data justifying its/their homeopathic use;

3) data on manufacture and quality control of each pharmaceutical form and a description of the method of dilution and potentisation;

4) manufacturing authorization issued by the competent authority in the country of manufacturer and a certificate on Good Manufacturing Practice (hereinafter GMP Certificate) issued by the competent authority in one of the EEA countries or countries having a Mutual Recognition Agreement with the EU, or a certificate issued by the Institute;

5) list of countries in which the medicinal product is registered or authorised for marketing, in which the application has been withdrawn or rejected stating the reasons for such decision, as well as a list of countries where the medicinal product is on the market;

6) a copy of the registration certificate or authorisation for the same homeopathic medicinal product in European Union Member States;

7) one, or more mock-ups of the outter and immediate packaging of a medicinal product for which the registration is sought;

8) data on stability of the medicinal product.

Provisions of the Module 3 referred to in paragraph 1 of this Article shall apply to submitted documents, with followwing modifications:

1) terminology - Latin name of the homeopathic stock shall be in accordance with the Latin title of the European Pharmacopoeia, or in the absence thereof, with the official pharmacopoeia of the Member State of the European Union; if applicable, traditional name used in the European Union should be stated;

2) control of starting materials – documentation on starting substances, i.e. all materials used including raw materials and intermediates in the preparation of the final dilution included in the finished medicinal product, shall be supplemented with additional data on the homeopathic stock. General quality requirements shall apply to all starting materials and raw materials as well as to all stages of the manufacturing process up to the final dilution included in the finished medicinal product. Where possible, determination of the content of toxic components shall be carried out even if the quality of the final dilution cannot be controlled due to a high degree of dilution. Each stage of the manufacturing process, from starting materials to the final dilution included in the finished medicinal product, shall be described in detail. In the case of dilutions, dilution methods shall be performed in accordance with homeopathic manufacturing methods described in the European Pharmacopoeia or the official pharmacopoeia of a European Union Member State;

3) quality control of the finished medicinal product – general quality requirements shall also apply to homeopathic medicinal products, and each exception shall be fully justified by the applicant. It is necessary to identify and determine the content of all the toxicologically relevant ingredients. If it is not possible to carry out the identification and determination of the content of the toxicologically relevant ingredients due to, for example, high degree of dilution in a finished product, the quality shall be demonstrated by complete validation of the manufacturing process and dilution process;

4) stability testing - It is necessary to demonstrate the stability of the finished medicinal product. Stability data on homeopathic stocks are generally transferable to dilutions/triturations. If it is not possible to carry out the identification and determination of the content of active substance due to high degree of dilution, stability data of the pharmaceutical form may be considered.

Requirements for pharmacological-toxicological documentation relate to the usual data on safety that include data on pharmacodynamics, pharmacokinetics and toxicology.

The provisions of Module 4 referred to in paragraph 1 of this Article shall apply in such manner that any omission of data shall be justified, i.e. justification shall be provided why the evidence of an acceptable level of safe use may be accepted despite missing testings.

The documentation referred to in paragraph 1 of this Article shall be submitted separately for each pharmaceutical form.

The applicant shall, at the request of the Institute, submit samples of medicinal products required for laboratory quality control.

Article 6

The decision on registration of a homeopathic medicinal product shall have a 5-year validity period from the date of issuance.

The decision on registration of a homeopathic medicinal product shall, inter alia, contain the name of the homeopathic stock(s) and the degree of dilution.

Article 7

The holder of the registration of a homeopathic medicinal product shall notify the Institute of the date of placing the medicinal product on the market in Montenegro for each pharmaceutical form, type and packaging size of the medicinal product, within 15 days from the date of placing the homeopathic medicinal product on the market.

The holder of the registration of a homeopathic medicinal product shall notify the Institute at least 60 days before the cessation of placing the medicinal product on the market, either temporarily or permanently, except in extraordinary circumstances.

The notification of placing the medicinal product on the market referred to in paragraph 1 of this Article shall be submitted on a form published on the webpage of the Institute.

Article 8

The Institute may reject an application for registration of a homeopathic medicinal product, if the applicant fails to submit data, documents, samples or other materials in accordance with the Law, and also if it determines that:

1) the information contained in or submitted with the registration application is incorrect;
2) that the medicinal product is harmful under normal conditions of use;
3) that the qualitative or quantitative composition of the medicinal product does not correspond to the one declared by the applicant,
4) the labelling or package leaflet is not in accordance with the provisions of the Law.

Article 9

The holder of the registration of a homeopathic medicinal product shall submit to the Institute an application for amendments to the data on the grounds of which the homeopathic medicinal product was registered, as well as amendments to the documentation submitted along with the registration application, as well as consequential changes to the package leaflet, where applicable.

Along with the application for amendments referred to in paragraph 1 of this Article, the holder of the registration shall, in addition to the data subject to amendments, provide the number and date of the first registration and the latest renewal of registration (if applicable).

Article 10

The holder of the registration shall submit to the Institute an application for renewal of registration no later than nine months before the expiry of the validity period of the registration decision.

The registration may be renewed for a further five years or for an unlimited period, based on a reassessment of the risk-benefit balance.

If the renewal application is not submitted within the time-limit referred to in paragraph 1 of this Article, the registration shall be deemed not to be renewed, and the holder shall submit a new application for registration, and the medicinal product may not be placed on the market until a new decision is issued.

In addition to data referred to in paragraphs 4 and 5 of this Rulebook, the registration holder shall, along with the application for renewal, provide the number and date of the first registration (where applicable), with documentation relating to the renewal.

At the request of the Institute, the applicant for the renewal shall submit the samples of medicinal products required for laboratory quality control.

A medicinal product the registration of which has expired and not been renewed may remain on the market until its expiry date, but no longer than 180 days after expiry of the registration validity period.

Article 11

Documentation referred to in Article 10 paragraph 4 of this Rulebook shall contain the following:

1) updated administrative data referred to in paragraph 5 of this Rulebook;
2) chronological list of approved and submitted amendments during the validity period of the registration of homeopathic medicinal product;
3) review the data on the safety of homeopathic medicine in the past five years.

Article 12

The decision on registration of a homeopathic medicinal product may be suspended or revoked at the request of the registration holder or if the Institute determines that:

1) the risk-benefit balance of the medicinal product is not favourable under the prescribed conditions of use;
2) the medicinal product may be harmful under normal conditions of use;
3) the qualitative or quantitative composition of the medicinal product does not correspond to the declared composition;
4) any data or information submitted with the application for registration of the homeopathic medicinal product is incorrect,
5) that the medicinal product placed on the market does not comply with the conditions specified in the decision on the registration, or does not comply with other conditions prescribed by the Law and subordinate legislation;
6) the registration holder no longer meets the conditions prescribed by the Law and subordinate legislation;
7) the medicinal product has not been marketed in Montenegro for three years from the date of registration, i.e. that, after being placed on the market for a

certain period following the registration, has not been marketed for three consecutive years;

8) in other justified cases determined by the Institute.

In the case referred to in paragraph 1 of this Article, the Institute may order the withdrawal of the homeopathic medicinal product from the market.

II REGISTRATION OF TRADITIONAL HERBAL MEDICINAL PRODUCT

Article 13

A traditional herbal medicinal product shall be registered via simplified procedure.

The application for registration of a traditional herbal medicinal product via simplified procedure shall be submitted to the Institute, along with a completed application form.

The applicant for registration and the holder of the registration of a traditional herbal medicinal product shall have their headquarters in Montenegro.

The application referred to in paragraph 2 of this Article may also be submitted by a natural or legal person having a headquarters in the European Union.

The application referred to in paragraph 2 of this Article shall be submitted on a form containing the following data:

1) name of the medicinal product;
2) pharmaceutical form, route of administration, information on the packaging;
3) data on the composition of the traditional herbal medicinal product (name and quantity of active substances and proposal of traditional indications);
4) data on the manufacturer of the medicinal product (name, address and manufacturing site);
5) date and signature of the person responsible for the registration procedure.

The application referred to in paragraph 2 of this Article shall be submitted for each pharmaceutical form, strength and packaging size of the traditional herbal medicinal product.

The application form referred to in paragraph 2 of this Article shall be published by the Institute on its website.

The application referred to in paragraph 2 of this Article shall be accompanied by appropriate documentation and evidence that the prescribed fees have been paid.

Article 14

The application referred to in Article 13 paragraph 2 of this Rulebook shall be accompanied by documentation in the form of a CTD dossier, with specific requirements for traditional herbal medicinal products, in accordance with special provisions on the application of Module 3 applicable to herbal medicinal products, in accordance with the regulation governing the conditions for granting a marketing authorisation.

The documentation referred to in paragraph 1 of this Article shall contain the following:

1) name or business name and address of the applicant and, where applicable, the manufacturer;

2) name of the medicinal product;

3) qualitative and quantitative composition of all constituents of the medicinal product, including the international non-proprietary name (INN) recommended by the World Health Organization, where available, or another appropriate name, which for a herbal substance shall include the scientific name of the plant (genus, species, subspecies, author) and the plant part

used, and as for a herbal preparation also the ratio of herbal substance to preparation and the extraction solvent(s);

4) an assessment of the risk the medicinal product may pose to the environment (the impact of the medicinal product on the environment shall be assessed on a case-by-case basis and specific arrangements to limit such impact shall be envisaged);

5) description of the manufacturing process;

6) therapeutic indications, contra-indications and adverse reactions;

7) posology, pharmaceutical form, method and route of administration and expected shelf life;

8) reasons for precautionary measures to be taken for the storage of the medicine, its administration to patients and for the disposal of waste products, stating potential risks presented by the medicinal product to the environment;

9) description of the testing methods used by the manufacturer;

10) results of pre-clinical (toxicological and pharmacological) studies;

11) summary of product characteristics without clinical data, mock-ups of outer and immediate packaging and package leaflet;

12) if the medicinal product contains a combination of active substances referred to in Article 16 or Article 44 paragraph 2 of the Law, the data referred to in Article 44 paragraph 1 item 5 of the Law relating to that combination, and where specific active substances are not sufficiently known, also data relating to individual active substances;

13) a manufacturing authorisation issued by the competent authority in the country of the manufacturer and a GMP certificate (hereinafter: GMP certificate) issued by a regulatory authority of an EEA country or a country having a Mutual Recognition Agreement with the EU, or a certificate issued by the Institute;

14) a list of countries in which the medicinal product is registered or authorised for marketing, countries in which the application has been withdrawn or rejected stating the reasons for such decision, as well as a list of countries where the medicinal product is on the market;

15) bibliographic (literature) or expert evidence that the medicinal product in question or a corresponding medicinal product has been in medicinal use for at least 30 years prior to submission of the application, including at least 15 years within the European Union Member States;

16) an overview of bibliographic data accompanied by an expert report on safety of use, and at the request of the Institute, other data necessary for safety assessment.

The condition to demonstrate medical use from paragraph 1 point 15 of this Article shall be deemed to be met even when placing of the medicinal product on the market was not based on a specific marketing authorisation, as well as when the number or quantity of the medicinal product's constituents was reduced during that period.

An application for registration via simplified procedure may also be submitted for a traditional herbal medicinal product that has been used in the European Union for less than 15 years if the medicinal product in question meets other requirements for registration in accordance with the Law and if there is a herbal monograph of the European Union or the herbal medicinal product consists of herbal substances, their preparations or combinations for use in traditional herbal medicinal products that are included in the List of herbal substances, their preparations and combinations for use in traditional herbal medicinal products.

The specific requirements from paragraph 1 of this Article shall apply to:

1) requirements for herbal substance and herbal preparation;

2) requirements for herbal medicinal products.

Requirements for herbal substance and herbal preparation shall include the following:

- data related to nomenclature of the herbal substance: the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the description of the herbal substance, the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code;
- data related to nomenclature of the herbal preparation: the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the description of the herbal preparation, the ratio of the herbal substance to the herbal preparation, the extraction solvent(s), the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code;
- data related to the structure for herbal substance and herbal preparation (where applicable): the physical form, the description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereo-chemistry) as well as other constituents;
- data on the manufacturer of the herbal substance: the name, address, and responsibility of each suppliers, including contracted ones, and each site involved in specific manufacturing processes, i.e. processes that involve collection and testing of the herbal substance
- data on the manufacturer of the herbal preparation: name, address and responsibility of all suppliers, including contractual suppliers, each sites involved in specific manufacturing processes i.e. processes that involve collection and control processes of the herbal preparation
- data on the manufacturing process and process controls for the herbal substance: manner of plant production and plant collection, including the geographical source of the medicinal plant and cultivation, harvesting, drying and storage conditions;
- data on the manufacturing process and process control for herbal preparation: stating information that adequately describes the manufacturing of the herbal preparation, including data on solvents and reagents, purification stages and standardization;
- a brief description of the development of the manufacturing process of the herbal substance and herbal preparation, taking into account the method and route of administration. It is also necessary to take into account the results of the comparison of the phytochemical composition of the herbal substances and herbal preparations listed in the literature and the composition of the herbal substances and herbal preparations contained in the traditional herbal medicinal product for which an application for entry in the Register is submitted, if applicable;
- elucidation of the structure and other characteristics of the herbal substance including information on the botanical, macroscopical, microscopical, phyto-chemical characterisation, and biological activity, where appropriate;
- elucidation of the structure and other characteristics of the herbal preparation along with information on the phytochemical composition and physicochemical characterisation, and biological activity if necessary;
- specifications for the herbal substance and herbal preparations, where applicable;
- data on the analytical procedures used for testing the herbal substance and herbal preparation, where applicable;
- data on the validation of analytical procedures used for testing the herbal substance and herbal preparation, where applicable;
- data on batches and results of batch analyses for the herbal substance and herbal preparation including those for pharmacopoeial substances;
- justification for the specifications of the herbal substance and herbal preparations, where applicable;
- data on the reference standards or reference materials used for testing of the herbal substance and herbal preparation, where applicable;
- where the herbal substance or the herbal preparation is subject to a European

Pharmacopoeia monograph, the applicant may submit certificate of suitability granted by the European Directorate for the Quality of Medicines EDQM).

The requirements for herbal medicinal products shall refer to the submission of a brief description of the development of the herbal medicinal product formulation, taking into account proposed method and route of administration. Where applicable, the results of comparative phyto-chemical composition studies of products stated in the literature and the products for which the application is submitted shall also be taken into account.

Article 15

If the application for registration of a traditional herbal medicinal product refers to a herbal substance, herbal preparation or their combination from a European Union herbal monograph or from the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, the data referred to in Article 14 paragraph 2 items 14), 15) and 16) of this Rulebook shall not be submitted and the provisions of Article 16 paragraph 1 items 3) and 4) of this Rulebook shall not apply.

If a herbal substance, herbal preparation or their combination is no longer included in the European Union herbal monograph or in the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, the registration of herbal medicinal products containing that substance shall be revoked unless the data and documentation referred to in Article 14 paragraph 2 of this Rulebook are submitted within three months.

Article 16

An application for registration of a traditional herbal medicinal product via simplified procedure shall be rejected if the requirements referred to in Article 44 of the Law and the documentation referred to in Article 14 paragraph 2 of this Rulebook have not been fulfilled or submitted, or if:

1) qualitative or quantitative composition does not correspond to the declared composition;
2) indications are not in accordance with the requirements for registration;
3) medicinal product could be harmful under normal conditions of use;
4) data on traditional use are insufficient, particularly if pharmacological effects or efficacy are not sufficiently plausible based on long-term use and experience;
5) pharmaceutical aspect of the quality of the medicinal product has not been adequately demonstrated.

The Institute shall notify the applicant, the European Commission and other competent authorities requesting such information of any decision rejecting the application for registration of a traditional herbal medicinal product and also provide the reasons for such decision.

Article 17

The decision on registration of a traditional herbal medicinal product shall be issued for 5-year validity period from the date of issuance.

Article 18

The holder of the registration of a traditional herbal medicinal product shall notify the Institute of the date of placing the medicinal product on the market in Montenegro for each pharmaceutical form, type and packaging size of the medicinal product, within 15 days from the date of placing the medicinal product on the market.

The holder of the registration of a traditional herbal medicinal product shall notify the Institute at least 60 days before the cessation of placing the medicinal product on the market, either temporarily or permanently, except in extraordinary circumstances.

The notification referred to in paragraph 1 of this Article shall be submitted on a form published on the webpage of the Institute.

Article 19

The holder of the registration of a traditional herbal medicinal product shall submit to the Institute an application for amendments to the data, as well as amendments to the documentation submitted along with the application for registration, as well as consequential changes to the package leaflet, where applicable.

Together with the application for variations referred to in paragraph 1 of this Article, the holder of the registration shall, in addition to the data relating to the amendments, also provide the number and date of the first registration and latest renewal of registration (where applicable).

When a herbal substance, preparation or their combination is included in the Community list or after adoption of a European Union herbal monograph, the holder of the registration shall submit to the Institute an application for amendments to the registration and documentation submitted along with the application, where necessary.

Article 20

The holder of the registration of a traditional herbal medicinal product shall submit to the Institute an application for renewal of registration no later than nine months before the expiry of the validity period of the decision on registration.

The registration may be renewed for a further five years or for an unlimited period, based on a reassessment of the risk-benefit balance.

If the renewal application is not submitted within the time-limit referred to in paragraph 1 of this Article, the registration shall be deemed not to be renewed, and the holder shall submit a new application for registration, and the medicinal product may not be placed on the market until a new decision is issued.

Along with the renewal application, the holder of the registration shall, in addition to the data referred to in Article 13 of this Rulebook, provide the number and date of the first registration (where applicable), along with with documentation relating to renewal.

At the request of the Institute the applicant for the renewal of the registration of a traditional herbal medicinal product shall submit samples of the medicinal product required for laboratory quality control of the medicinal product.

A medicinal product the registration of which has expired and has not been renewed may remain on the market after expiry of the registration, until the expiry date of the medicinal product, but not longer than 180 days after expiry of the decision of the registration.

Article 21

The documentation referred to in Article 20 paragraph 4 of this Rulebook shall contain the following:

1) updated administrative data referred to in Article 14 of this Rulebook;

2) chronological list of approved and notified variations during the validity period of the registration;

3) an overview of safety data on the use of the traditional herbal medicinal product in for the past five years.

Article 22

The decision on registration of a traditional herbal medicinal product may be suspended or revoked at the request of the registration holder or if the Institute determines that:

1) risk-benefit balance of the medicinal product is not favourable under the prescribed conditions of use;
2) medicinal product may be harmful under normal conditions of use;
3) qualitative or quantitative composition does not correspond to the declared composition;
4) any data or information submitted with the registration application is incorrect;
5) medicinal product placed on the market does not comply with the conditions specified in the decision on the registration or other conditions prescribed by the Law;
6) registration holder no longer meets the requirements prescribed by the Law;
7) the medicinal product has not been marketed in Montenegro for three years from the date of registration, i.e. that, after being placed on the market for a certain period following the registration, has not been marketed for three consecutive years;
8) in other justified cases determined by the Institute.

In the case referred to in paragraph 1 of this Article, the Institute may order the withdrawal of the traditional herbal medicinal product from the market.

Article 23

Labelling of homeopathic and traditional herbal medicinal products shall be carried out in accordance with the Law.

III TRANSITIONAL AND FINAL PROVISIONS

Article 24

On the date of entry into force of this Rulebook, the Rulebook on more detailed conditions and manner of entering a medicine into the Register of traditional herbal medicines ("Official Gazette of Montenegro", No. 4/15) and the Rulebook on more detailed conditions and manner of entering a medicine into the Register of homeopathic medicinal products ("Official Gazette of Montenegro", No. 6/15) shall cease to be valid.

The provisions of Article 4 paragraph 4, Article 13 paragraph 4 and Article 16 paragraph 2 in the part relating to the European Commission shall apply from the date of accession of Montenegro to the European Union.

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

In Podgorica, 2026

No:

CHAIR OF THE STEERING COMMITTE

Dr Jovan Milić, specialist in oftalmology

* 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 Annex I to this Directive