LAW ON MEDICINAL PRODUCTS

I GENERAL PROVISIONS

Article 1

This Law regulates the conditions for placing on the market, manufacturing, distribution, pharmacovigilance, control, and clinical trials of medicinal products for human use and for veterinary use (hereinafter: veterinary medicinal product), the use of veterinary medicinal products, as well as the competences of sale relevant authorities in the field of medicinal products.

Article 2

The provisions of this Law shall apply to medicinal products for human use and veterinary medicinal products intended to be placed on the market, which are prepared industrially or manufactured by a method involving an industrial process.

The provisions of this Law shall also apply to the manufacture of medicinal products for human use intended exclusively for export, as well as to intermediate products, active substances, and excipients.

In addition to veterinary medicinal products referred to in paragraph 1 of this Article, the provisions of this Law concerning:

1) the issuance of good manufacturing practice certificates and the requirements for importers, manufacturers, and distributors, shall also apply to active substances used as starting materials in veterinary medicinal products;
2) the issuance of good manufacturing practice certificates, veterinary prescriptions, obligations on record keeping by owners and keepers of food-producing animals , the collection and disposal of waste of veterinary medicinal products, the advertising of veterinary medicinal products subject to veterinary prescription, and inspection, control, and prohibition of supply or distribution of veterinary medicinal products, shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens or antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link;
3) provisions of this Law relating to Articles 255 to 264 and Articles 275, 309, 310, 311, 336 shall apply to veterinary medicinal products intended for animals which are exclusively kept as pets: aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits, provided that such veterinary medicinal products are not subject to a veterinary prescription.
4) provisions of this Law related to the supply and use of veterinary medicinal products shall also apply to:

   – substances with anabolic, anti-infective, antiparasitic, anti-inflammatory, hormonal, narcotic, or psychotropic properties that may be used in animals;
   – veterinary medicinal products prepared in a pharmacy or by a person permitted to do so under national law, in accordance with a veterinary prescription for an

individual animal or a small group of animals (magistral veterinary medicinal products);
- veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end user (officinal veterinary medicinal products).

Where a product, by its definition and characteristics, may fall within the definition of a medicinal product for human use and within the definition of product subject to separate legislation, the provisions of this Law shall apply.

Where a veterinary medicinal product referred to in paragraph 1 of this Article, by virtue of its definition and characteristics, may simultaneously be considered a veterinary medicinal product and a product governed by legislation on biocidal products or feed additives for animals, the provisions of this Law shall apply.

In the case referred to in paragraph 5 of this Article, a product or group of products shall be considered a veterinary medicinal product if such designation has been established by a specific decision of the European Commission.

The list of products or product groups referred to in paragraph 6 of this Article shall be published by the Institute for medicines and medical devices (hereinafter: the Institute) and the administrative authority competent for veterinary affairs (hereinafter: the Administration) on their official websites.

Article 3

The provisions of this Law concerning medicinal products for human use shall not apply to:

1) any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the magistral formula)

2) any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula);

3) medicinal products intended for research and development, except those used in clinical trials but without prejudice to the provisions of the Regulation 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC (hereinafter: Regulation (EU) No 536/2014);

4) intermediates intended for further processing by an authorised manufacturer;

5) any radionuclides in the form of sealed sources;

6) whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a method involving an industrial process;

7) advanced therapy medicinal products, as defined in Article 11 of this Law, which is prepared on a non-routine basis according to specific quality standards, used in a hospital under the professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient in Montenegro.

Manufacturing of products referred to in paragraph 1 item 7 of this Article shall be authorised by the Institute which shall ensure that national traceability and pharmacovigilance requirements as well as the specific quality standards referred to in this paragraph are equivalent to those provided for at EU level in respect of advanced therapy medicinal products for which authorisation is required pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (hereinafter: Regulation (EC) No 726/2014).

The provisions of this Law shall not apply to matters regulated by special legislation, including:

1) rules for the radiation protection of persons undergoing medical examination or treatment, or from the rules laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation and protection against ionizing radiation for medical purposes.

2) exchange of therapeutic substances of human origin;

3) pricing of medicinal products reimbursed from compulsory health insurance, on the basis of health, economic and social conditions;

4) prohibitions or restrictions on the sale, supply or use of medicinal products such as contraceptives or abortifacients;

5) prohibitions or restrictions the use of any specific types of human or animal cells or the sale, supply or use of medicinal products containing or consisting of or derived from these cells.

The Institute shall communicate the national legislation related to intermediates referred to in paragraph 1 item 4 of this Article to the Commission and notify the European Commission of the national provisions referred to in paragraph 3 of this Article.

Article 4

The provisions of this Law concerning veterinary medicinal products shall not apply to:

1) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;
2) veterinary medicinal products based on radioactive isotopes;
3) feed additives;
4) veterinary medicinal products intended for research and development;
5) medicated feed and intermediates for medicated feed.

Article 5

The independent regulatory authority in the field of medicinal products shall be the Institute, which exercises public competences in accordance with this Law and the law regulating medical devices.

Article 6

The terms used in this Law in the masculine grammatical form for natural persons shall be deemed to include the same terms in the feminine grammatical form.

Article 7

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

1) **Active substance** is any substance or mixture of substances intended for use in the manufacture of a medicinal product, and that, when used in the production of a medicinal product, becomes an active ingredient of that product, intended to exert a pharmacological, immunological, or metabolic action for the purpose of restoring, correcting or modifying physiological functions or making a medical diagnosis;
2) **Active substance of a veterinary medicinal product** is any substance or mixture of substances intended for use in the manufacturing of a veterinary medicinal product which, when used in its manufacturing, becomes an active ingredient of that medicinal product;
3) **Antimicrobial resistance** is the ability of a microorganism to survive or grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;
4) **Antimicrobial substance** is a substance with a direct action on microorganisms, used for the treatment or prevention of infections or infectious diseases, including antibiotics, antivirals, antifungals, and antiprotozoals;
5) **Antiparasitic** means a is that kills or interrupts the development of parasites and is used for the treatment or prevention of infections, infestations, or diseases caused or transmitted by parasites, including substances with repelling activity;
6) **Antibiotic** is a substance with a direct activity on bacteria that is used for the treatment or prevention of infections or infectious diseases;
7) **European Union herbal monograph** is the 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);
8) **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;
9) **Bioavailability** is the rate and extent to which the active substance is absorbed from the pharmaceutical form and becomes available in the systemic circulation or excreta;

10) **Bioequivalence** is a condition where two medicinal products are pharmaceutical equivalents or pharmaceutical alternatives and their bioavailability, after administration in the same molar dose, is such that their efficacy and safety can be expected to be essentially the same;
11) **Investigator's brochure** is a compilation of clinical and non-clinical data on the investigational medicinal product relevant to the study of the product in humans;
12) **Centralised procedure (hereinafter: CP)** is the procedure for the granting of a marketing authorisation valid in all EU Member States, conducted by the European Medicines Agency;
13) **Decentralised procedure (hereinafter: DCP)** is the procedure for granting a marketing authorisation in the EU for a medicinal product that has not yet been authorised in the Union and is to be placed on the market in more than one Member State, and for which the centralised procedure is not mandatory;
14) **Auxiliary medicinal product** is a medicinal product used in a clinical trial as described in the clinical trial protocol, but not as an investigational medicinal product;
15) **European Medicines Agency (hereinafter: EMA)** is the agency of the European Union established under Regulation (EC) No 726/2004 for the authorisation and supervision of medicinal products for human and veterinary use;
16) **Ethics Committee** is an independent body in Montenegro, appointed by the national health authority, responsible for giving opinions on clinical trial applications in accordance with this Law , taking into account the views of laypersons, in particular patients or patients' organisations;
17) **Epidemiological unit** is a group of animals with the same likelihood of exposure to a disease agent;
18) **Pharmacovigilance** means the science and activities relating to the detection, assessment, understanding, prevention, and response to adverse reactions i.e. adverse events, or other problems related to a medicinal product;
19) **Falsified medicinal product** is any medicinal product with a false representation of:

- its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients, including excipients, and the strength of those ingredients;
- its source, including its manufacturer, its country of manufacturing, country of origin, or its marketing authorisation holder; or
- its history, including the records and documents relating to the distribution channels used.

This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.

20) **Pharmaceutical quality system** is the total sum of the organised arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use;
21) **Pharmaceutical equivalents** is medicinal products containing the same amount of the same active substance(s) in the same pharmaceutical form intended for the same route of administration and meeting the same or comparable standards;
22) **Pharmaceutical alternatives** is medicinal products that contain the same active substance(s), but in a different chemical form (such as salts or esters), pharmaceutical form, or strength;
23) **Pharmaceutical form** is the form in which a medicinal product is presented (e.g. tablet, capsule, ointment, injection solution);
24) **Pharmacovigilance system master file (hereinafter: PSMF)** is a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products;

25) **Principal investigator** is the investigator responsible leader of a team of investigators conducting a clinical trial at a clinical trial site;
26) **Generic medicinal product for human use** is a medicinal product which has the same qualitative and quantitative composition in active substance(s) and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance shall be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines;
27) **Investigational medicinal product** is a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial;
28) **Investigator** is an individual responsible for the conduct of a clinical trial at a clinical trial site;
29) **Subject** is an individual who participates in a clinical trial, either by recipient of an investigational medicinal product or by being part of the control group;
30) **Informed consent** is a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial;
31) **Clinical trial report** is a report of a clinical trial presented in a searchable, standardised format, submitted as part of the application for a marketing authorisation;
32) **Strength of a medicinal product** is the content of the active substances, expressed quantitatively per dosage unit, per unit of volume or weight according to the pharmaceutical form;
33) **Quality of a medicinal product** is a property determined by testing all ingredients of the product, and representing the acceptable physical, chemical, biological, pharmaceutical-technological, and other characteristics, in accordance with the marketing authorisation dossier;
34) **Clinical study** is any investigation in relation to humans with the objective of ascertaining the safety and/or efficacy of those medicinal products, intended:

- to discover or verify clinical, pharmacological or pharmacodynamic effects of one or more medicinal products;
- to identify any adverse reactions to one or more medicinal products; or
- to study absorption, distribution, metabolism, and excretion of one or more medicinal products;

35) **Clinical trial** is a clinical study which fulfils any of the following conditions:

- the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice in Montenegro or in the EU Member State concerned;

- the decision to prescribe the investigational medicinal product is taken together with the decision to include the subject in the clinical study; or
- diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects;

36) **Clinical trial of a veterinary medicinal product** is a study which aims to examine the safety and efficacy of a veterinary medicinal product under normal conditions of animal husbandry or as part of normal veterinary practice, for the purpose of obtaining or amending a marketing authorisation or a change thereof;
37) **Withdrawal period** is the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal, which under normal conditions of use ensures that such foodstuffs do not contain residues in quantities harmful to human health;
38) **European Union reference dates list (hereinafter: EURD list)** is a list of active substances and combinations thereof, specifying reference dates, submission frequency of periodic safety update reports, and whether periodic safety update reports are required, based on decisions of the EMA's Committee for medicinal products for human use (hereinafter: CHMP), the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (hereinafter: CMDh), based on advice of the Pharmacovigilance risk assessment committee (hereinafter: PRAC);
39) **Medical prescription** is a prescription issued by a qualified and authorised healthcare professional in accordance with the law;
40) **Magistral medicinal product** is a medicinal product prepared in a pharmacy in accordance with a prescription for an individual patient, based on pharmacopoeia or other official formulas;
41) **Medication error** is an unintentional mistake in prescribing, dispensing, or administering a medicinal product by a healthcare professional or patient;
42) **Intermediate product** is a partly processed material that shall undergo further processing steps to become a finished medicinal product;
43) **Clinical trial site** is a facility where a clinical trial is conducted, meeting the requirements laid down by this Law;
44) **Metaphylaxis** is the administration of a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick animals and controlling the spread of the disease to animals in close contact and at risk and which may already be subclinically infected;
45) **Name of the medicinal product** is either an invented name not be liable to confusion with the common name, a common name or a scientific name accompanied by a trademark or the name of the marketing authorisation holder in Montenegro or the EU.
46) **Adverse reaction** is any noxious and unintended response to a medicinal product;
47) **Unexpected adverse reaction** is an adverse reaction whose nature, severity or outcome is not consistent with the summary of product characteristics;
48) **Adverse event** is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product, which does not necessarily have a causal relationship with the treatment (e.g. abnormal laboratory finding, symptom, or disease temporally associated with use of the medicinal product);
49) **Unexpected serious adverse reaction** is a serious adverse reaction, the nature, severity or outcome of which is not consistent with the reference safety information;
50) **Unauthorised use (hereinafter: Off-label use)** is the use of a medicinal product that is not in accordance with the approved summary of product characteristics;

51) **Unmet medical needs** is conditions for which no satisfactory method of diagnosis, prevention or treatment is authorised in Montenegro, or where a medicinal product offers a significant therapeutic advantage over existing methods;
52) **Non-interventional study** is a clinical study other than a clinical trial;
53) **Serious adverse reaction** is an adverse reaction which results in: death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, congenital anomaly or birth defect;
54) **Serious adverse event** is any untoward medical occurrence that at any dose requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, results in a congenital anomaly or birth defect, is life-threatening, or results in death;
55) **Labelling** is the information on the immediate or outer packaging of a medicinal product;
56) **Risk-benefit balance of a medicinal product for human use** is an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks, including any risk to the health of the patient or public health relating to the quality, safety or efficacy of the product;
57) **Risk-benefit balance of a veterinary medicinal product** is an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the following risks relating to the use of that product:
    – any risks relating to the quality, safety or efficacy as regards animal or human health;
    – any risk of undesirable effects on the environment;
    – any risk relating to the development of resistance;
58) **Orphan designation** is a status granted by the European Commission to a medicinal product intended for the treatment of a rare disease, based on the opinion of the EMA's Committee for Orphan Medicinal Products (COMP);
59) **OCABR certificate (Official Control Authority Batch Release Certificate)** is a certificate confirming that a batch of an immunological medicinal product or a product derived from human blood or plasma has been tested by an Official Medicines Control Laboratory in accordance with the guidelines for the OCABR procedure;
60) **Authorised investigational medicinal product** is a medicinal product for human use that has been granted a marketing authorisation in Montenegro or in an EU Member State or by the EMA, irrespective of changes to the labelling of the medicinal product, which is used as an investigational medicinal product;
61) **Authorised auxiliary medicinal product** is a medicinal product for human use that has been granted a marketing authorisation in Montenegro or in an EU Member State or by the EMA, irrespective of changes to the labelling of the medicinal product, which is used as an auxiliary medicinal product;
62) **Limited market** is the market for one of the following types of veterinary medicinal products:
    – intended for the treatment or prevention of diseases that occur infrequently or in limited geographically areas;
    – intended for animal species other than cattle, sheep for meat production, pigs, chickens, dogs, and cats;
63) **Excipient** is any constituent of a medicinal product other than the active substance and the packaging material;

64) **Post-authorisation safety study (hereinafter: PASS)** is any study relating to an authorised medicinal product for human use, conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or measuring the effectiveness of risk management measures;
65) **Medication misuse** is the unintentional, inappropriate use of a medicinal product not in accordance with the approved product information;
66) **Brokering of medicinal products** is all activities relating to the sale or purchase of medicinal products for human use, except for wholesale distribution, that do not include physical handling of the products and consist of negotiating independently and on behalf of another legal or natural person;
67) **Representative of the marketing authorisation holder** or the local representative, is a natural or legal person designated by the marketing authorisation holder to represent him in the Member State concerned;
68) **Periodic safety update report (hereinafter: PSUR)** is a pharmacovigilance report for an authorised medicinal product for human use, containing an update of its safety profile, submitted by the marketing authorisation holder after the product is authorised;
69) **Risk management plan (hereinafter: RMP)** is a detailed description of the risk management system;
70) **Manufacturer** is any natural or legal person engaged in one or more stages of the manufacture of a medicinal product and holding a manufacturing authorisation;
71) **Starting material** is any substance used in the manufacture of a medicinal product, excluding the packaging material;
72) **Mutual recognition procedure (hereinafter: MRP)** is a procedure for the granting of a marketing authorisation that, following initial authorisation in a reference Member State, is conducted simultaneously in that and other EU Member States involved in the procedure, and is mandatory for products not subject to the centralised procedure and intended to be marketed in more than one EU Member State;
73) **Subsequent recognition of marketing authorisations** is a procedure for granting a marketing authorisation for a veterinary medicinal product that has already been authorised in other EU Member States following a DCP or MRP;
74) **Clinical trial protocol** is a document that describes the objectives, design, methodology, statistical considerations, and organisation of a clinical trial, and includes the original version and all successive versions and modifications;
75) **Manufacture of investigational medicinal products** is the total or partial process of manufacturing a medicinal product for human use intended for use in a clinical trial, including various processes of dividing, packaging, labelling, and masking (blinding).
76) **Start of a clinical trial** is the first act of recruitment a potential subject for a specific clinical trial, unless defined differently in the clinical trial protocol;
77) **Early termination of a clinical trial** is the premature end of a clinical trial due to any reason before the conditions specified in the protocol are complied with;
78) **Temporary halt of a clinical trial** is an interruption of a clinical trial not provided in the protocol of the conduct of a clinical trial by the sponsor with the intention of the sponsor to resume it;
79) **Prophylaxis** is the administration of a medicinal product to an animal or a group of animals before clinical signs of disease, in order to prevent the occurrence of disease or infection;

80) **Pre-clinical study** is a study not covered by the definition of a clinical trial, which aims to investigate the safety and efficacy of a veterinary medicinal product for the purpose of obtaining or amending a marketing authorisation or a change thereof;
81) **Letter of access** is a document signed by the data owner or their representative, stating that the data may be used for the benefit of the applicant in relation to the competent authorities, in accordance with this Law;
82) **Signal management process** is a process for performing active surveillance of pharmacovigilance data for veterinary medicinal products in order to assess the pharmacovigilance data and determine whether there is any change to the benefit-risk balance of those veterinary medicinal products, with a view to detecting risks to animal or public health or protection of the environment;
83) **Reference medicinal product** is a medicinal product authorised or previously authorised in an EU Member State on the basis of a complete dossier on quality, safety, and efficacy;
84) **Risk related to the use of a medicinal product** is any risk relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health, as well as any risk of undesirable effects on the environment;
85) **Reference Member State** is the Member State of the European Union responsible for preparing the assessment report on a medicinal product in DCP or MRP or in a procedure for subsequent recognition;
86) **Outer packaging** is the packaging into which is placed the immediate packaging;
87) **Summary of product characteristics** is a summary of the scientific information on a medicinal product, approved during the marketing authorisation procedure, intended for healthcare professionals or veterinary personnel;
88) **Risk management system (hereinafter: RMS)** is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product for human use, including the assessment of the effectiveness of those activities and interventions;
89) **Pharmacovigilance system** is a system used by the marketing authorisation holder and the Institute to fulfil the tasks and responsibilities listed in Title VII of this Law and designed for monitoring the safety of authorised medicinal products and detect any change to their risk-benefit balance;
90) **Good manufacturing practice guidelines (hereinafter: GMP guidelines)** is a system of rules for ensuring the quality of medicinal products, by guaranteeing consistent production, import and control in accordance with quality standards appropriate for their intended use;
91) **Good distribution practice guidelines for medicinal products for human use (hereinafter: GDP guidelines)** is a system of guidelines ensuring that the quality of medicinal products is maintained throughout all stages of the supply chain, from the site of manufacture to the pharmacist or other authorised dispenser;
92) **Good distribution practice guidelines for active substances for medicinal products for human use** (hereinafter: GDP guidelines for active substances) is specific good distribution practice guidelines applicable to importers and distributors of active substances intended for use in human medicinal products;
93) **Good pharmacovigilance practice guidelines (hereinafter: GVP guidelines)** is a set of guidelines for implementing pharmacovigilance, applicable to marketing authorisation holders and competent regulatory authorities;
94) **Good clinical practice guidelines (hereinafter: GCP guidelines)** is a set of detailed ethical and scientific quality requirements for designing, conducting, performing, monitoring, auditing, recording, analysing and reporting clinical trials ensuring that

the rights, safety and well-being of subjects are protected, and that the data generated in the clinical trial are reliable and robust;

95) **Batch** is a defined quantity of starting material, packaging material or product manufactured in a single process or series of processes so that it is expected to be homogeneous. In the case of continuous manufacture, the batch corresponds to a defined fraction of the production, characterised by its intended homogeneity;

96) **Certificate of pharmaceutical product (hereinafter: CPP)** is a document issued by the competent authority of the exporting country, in accordance with the recommendations of the World Health Organization (hereinafter: WHO);

97) **Substantial modification** is any change made to a clinical trial after its approval, which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the trial;

98) **Sponsor** is an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial;

99) **Suspension of a clinical trial** is an interruption of a clinical trial issued by the Institute or by the competent authority of an EU Member State;

100) **Common name** is the International Non-proprietary Name (hereinafter: INN) recommended by the World Health Organization, or, if one does not exist,. the name generally used;

101) **Immediate packaging** is the packaging immediately in contact with the medicinal product;

102) **Package leaflet** is a document containing information for the user which accompanies the medicinal product and which contains information for the safe and efficacious use of the product;

103) **Usual clinical practice** is the regime typically followed to treat, prevent, or diagnose a disease or a disorder;

104) **Aquatic species** means animals of the following species, at all life stages, including eggs and gametes:

- fish belonging to the superclass *Agnatha* and classes *Chondrichthyes*, *Sarcopterygii* and *Actinopterygii*;
- aquatic molluscs belonging to the phylum *Mollusca*;
- aquatic crustaceans belonging to the subphylum *Crustacea*;

105) **Abuse of medicinal product** is the persistent or sporadic, intentional excessive use of a medicinal product, accompanied by harmful physical or psychological effects;

106) **Concerned Member State** is an EU Member State in which a clinical trial application or a substantial modification thereof has been submitted;

107) **End of a clinical trial** is the date of the last visit of the last subject or at a later point in time as defined in the protocol;

108) **Food-producing animals** means animals that are bred, kept, slaughtered or harvested for the purpose of producing food;

109) **Compassionate use** is the use of a medicinal product for human use containing a new active substance that represents significant therapeutic, scientific or technical innovation, and is either undergoing the marketing authorisation process in the EU or is under clinical investigation for that purpose, for the treatment of patients with serious diseases that cannot be satisfactorily treated with an authorised medicinal product in Montenegro, the EU, EEA countries or countries with mutual recognition agreements;

110) **EudraVigilance database** is the EU database and network for managing safety data on authorised medicinal products, established and maintained by the EMA in cooperation with the EU Member States and the European Commission, in accordance with Article 24 of Regulation (EC) No 726/2004;
111) **List of medicinal products under additional monitoring** is the list established, maintained, and published by the EMA in cooperation with EU Member States, in accordance with Article 23 of Regulation (EC) No 726/2004;
112) **EudraGMDP database** is the European Union database established and maintained by the EMA in accordance with Article 111 paragraph 6 of Directive 2001/83/EC for human medicinal products and Article 91 of Regulation (EU) 2019/6 for veterinary medicinal products and repealing Directive 2001/82/EC;
113) **EU clinical trial number (EudraCT number)** is the unique identification number assigned to each clinical trial conducted in the EU;
114) **Public service obligation** is the obligation placed on wholesalers and marketing authorisation holders to guarantee permanently and adequate range of medicinal products to meet the requirements of a specific geographical area, and to deliver the supplies requested within a very short time over the whole of the area in question;
115) **Biological substance** means a substance produced or extracted from a biological source, whose characteristics and quality are determined by a combination of physicochemical-biological testing and knowledge of the production process and its control;
116) **Generic veterinary medicinal product** means a veterinary medicinal product which has the same qualitative and quantitative composition off active substances and the same pharmaceutical form as the reference veterinary medicinal product, and with regard to which bioequivalence with the reference medicinal product has been demonstrated;
117) **Control** means is any task performed by a competent authority to verify compliance with this Law;
118) **Veterinary prescription** means a document issued by a veterinarian for a veterinary medicinal product or a medicinal product for human use intended for its use in animals;
119) **Placing on the market** means the first making available of a medicinal product on the territory of Montenegro;
120) **Potential serious risk to human or animal health, or to the environment** means a situation where there is a significantly high probability that a serious hazard resulting from the use of a veterinary medicinal product will affect human or animal health or the environment;
121) **Substance** means any matter irrespective of origin which may be:

– of human origin (e.g. blood and blood products);
– of animal origin (e.g. microorganisms, animals, parts of organs, animal secretions, toxins, extracts, blood derivatives);
– of plant origin (e.g. micro-organisms, plants, parts of plants, vegetable secretions and extracts);
– of chemical origin (e.g. chemical elements, naturally occurring chemical substances and chemical products obtained by chemical change or synthesis);

122) **Parallel import of medicinal product for human use** is the import into Montenegro of a medicinal product that is authorised in the exporting country and is essentially similar to a medicinal product authorised in Montenegro, or under a MRP

or DCP, and which has been imported from one EU Member State to another on the basis of a parallel import authorisation issued by the competent authority;

123) **Parallel wholesale distribution of medicinal product for human use** is the entry of a medicinal product into Montenegro which is authorised under the CP from one EU Member State to another;

124) **EUMRA** is a mutual recognition agreement concluded with EU Member States;

125) **Marketing Authorisation Holder** is physical or legal person seated in Montenegro which obtains marketing authorisation issued by the Institute**.**

126) **Low-intervention clinical trial** is a clinical trial which fulfils all of the following conditions:

– the investigational medicinal products, excluding placebos, are authorised;
– according to the protocol of the clinical trial:
  a) the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or
  b) the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and
– the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;

127) **Minor** is a subject who is, according to the law, under the age of legal competence to give informed consent.

128) **Incapacitated subject** is a subject who is, for reasons other than the age of legal competence to give informed consent, incapable of giving informed consent according to the law. For the purposes of this Law, a subject who falls under the definition of both minor and incapacitated subject shall be deemed to be an incapacitated subject.

129) **Legally designated representative** is a natural or legal person, authority or body which, according to the law, is empowered to give informed consent on behalf of a subject who is an incapacitated subject or a minor;

130) **inspection of a clinical trial** is the act by the Institute of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the Institute to be related to the clinical trial and that may be located at the clinical trial site, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the Institute sees fit to inspect.

131) **clinical study report** is a report on the clinical trial presented in an easily searchable format, prepared in accordance with the Article 34 paragraph 10 if this Law and accompanying an application for marketing authorisation.

II MEDICINAL PRODUCTS

Article 8

A medicinal product for human use is:

1) any substance or a combination of substances presented as having properties for treating or preventing disease in human beings, or

2) a substance or combination of substances which may be used or administered to human beings either with a view to restoring, correcting or modifying physiological functions

by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Article 9

A biological medicinal product for human use is a product whose active substance is a biological substance produced or extracted from a biological source, and whose properties and quality are determined by a combination of physicochemical and biological testing, together with knowledge of its production process and control (immunological medicinal products, medicinal products derived from human blood or plasma, advanced therapy medicinal products).

Article 10

An immunological medicinal product for human use is any medicinal product consisting of vaccines, toxins, serums or allergen products.

Vaccines, toxins and serums shall cover, in particular:

1) agents used to produce active immunity (e.g. cholera vaccine, BCG, poliomyelitis vaccines, smallpox vaccine);

2) agents used to diagnose the state of immunity, including in particular tuberculin, and tuberculin PPD, toxins for the Schick and Dick test, brucellin;

3) agents used to produce passive immunity (e.g. diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin).

An allergen product is any medicinal product intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.

Article 11

An advanced therapy medicinal product for human use includes:

1) gene therapy medicinal products,
2) somatic cell therapy medicinal products, and
3) tissue-engineered products.

Where an advanced therapy medicinal product contains viable cells or tissues, the pharmacological, immunological or metabolic action of those cells or tissues shall be considered the principal mode of action of the product.

An advanced therapy medicinal product that contains both autologous (emanating from the patient himself) or allogeneic (coming from another human being) cells or tissues shall be considered to be intended for allogeneic use.

A medicinal product which may fall within the definition of a tissue engineered product and within the definition of a somatic cell therapy medicinal product shall be considered as a tissue engineered product.

A medicinal product which may fall within the definition of a somatic cell therapy medicinal product or a tissue engineered product, and a gene therapy medicinal product, shall be considered as a gene therapy medicinal product.

A gene therapy medicinal product is a medicinal product that:

1) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;
2) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.

Gene therapy medicinal products shall not include vaccines against infectious diseases.

A somatic cell therapy product is a medicinal product that:

1) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;
2) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.

A tissue engineered product is a product that:

1) contains or consists of engineered cells or tissues; and
2) is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing human tissue.

A tissue engineered product may contain viable or non-viable cells or tissues of human or animal origin, or both, as well as additional substances such as cellular products, bio-molecules, bio-materials, chemical substances, scaffolds or matrices.

Products containing exclusively non-viable human or animal cells and/or tissues, and which do not act principally by pharmacological, immunological or metabolic action, shall not be considered tissue-engineered products.

Cells or tissues shall be considered engineered if they fulfil at least one of the following conditions:

1) they have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant to the intended regeneration, repair or replacement are achieved; or
2) they are not intended to be used for the same essential function(s) in the recipient as in the donor.

Within the meaning of paragraph 12 point 1 of this Article the following shall not be considered substantial manipulations: cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilisation, irradiation, cell separation, concentration or purification, filtering, lyophilisation, freezing, cryopreservation and vitrification.

Article 12

Advanced therapy investigational medicinal product means an investigational medicinal product which is an advanced therapy medicinal product as defined in Article 11 of this Law.

Article 13

A combined advanced therapy medicinal product is an advanced therapy medicinal product that incorporates, as an integral part of the product, one or more medical devices or one or more active implantable medical devices within the meaning of the law governing medical devices and whose cellular or tissue part contains viable cells or tissues, or non-viable cells or tissues and which effect on the human body is considered primary in relation to that of the medical devices.

Article 14

A medicinal product derived from human blood or plasma is a product prepared industrially and based on components of human blood, in particular albumin, coagulation factors, and immunoglobulins of human origin.

Whole blood and blood components intended for transfusion shall not be considered medicinal products within the meaning of this Law.

Article 15

A radiopharmaceutical is a medicinal product which, when ready for use, contains one or more radionuclides (radioactive isotopes) intended for medical purpose.

A radionuclide generator means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or any other method, and used for the preparation of a radiopharmaceutical.

A radiopharmaceutical kit means a preparation to be reconstituted or combined with radionuclides to produce a radiopharmaceutical, usually prior to its administration.

A radionuclide precursor means any other radionuclide produced for the radio-labelling of another substance prior to administration.

Article 16

A 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.

A 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).

A 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.

Article 17

A traditional herbal medicinal product is a medicinal product based on scientific principles and resulting from tradition or other traditional therapeutic approaches.

Article 18

A 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.

A homeopathic medicinal product for human use may contain a number of active principles.

Article 19

Galenic medicinal product for human use is a medicinal product prepared in accordance with the manufacturing procedures of current pharmacopoeias, valid magistral formulas or standard recipes from professional pharmaceutical manuals, as well as in line with the guidelines of Good Compounding Practice for galenic preparations.

Galenic medicinal products for human use may be prepared in a galenic laboratory and in a galenic laboratory of a pharmacy that operates at the primary healthcare level provided that the preparation is carried out in small quantities that do not exceed 300 finished individual packs per batch.

A galenic medicinal product prepared in a galenic laboratory is intended for sale or supply to pharmacies and other healthcare institutions.

A galenic medicinal product prepared in the galenic laboratory of a pharmacy is intended for dispensing, sale, or use and administration to patients of that pharmacy, or of a pharmacy that is part of another healthcare institution providing primary healthcare services, as well as in an appropriate veterinary institution with which the pharmacy, in whose galenic laboratory the product was prepared, has concluded a supply agreement for a specific quantity of that galenic medicinal product.

A galenic veterinary medicinal product may be prepared in quantities of up to 100 finished individual packages per batch.

Preparation of a galenic medicinal product in the quantities referred to in paragraphs 2 and 5 of this Article shall not be considered manufacturing within the meaning of this Law.

Article 20

Galenic medicinal product may also be prepared in the galenic laboratory of a secondary or tertiary healthcare institution (hereinafter: galenic laboratory of the hospital pharmacy), in quantities necessary for ensuring the medical treatment of the patients of that institution.

Exceptionally from the paragraph 1 of this Article, based on a supply agreement of the certain quantity of the galenic medicinal product, supply of other secondary or tertiary healthcare institutions for the needs pf patients of those institutions shall be done, subject to prior approval by the Ministry of Health (hereinafter: the Ministry).

Where a pharmacy referred to in article 19 paragraph 2 supplies another healthcare or veterinary institution under a valid agreement in accordance with this law for the needs of patients and users of that healthcare or veterinary institution, such supply shall be considered retail supply in accordance with the law.

Preparation of an galenic medicinal product in a hospital pharmacy shall not be considered manufacture within the meaning of this Law.

Galenic medicinal products prepared in accordance with paragraph 1 of this article shall not be placed on the wholesale or retail market.

Each batch of an galenic medicinal product referred to in paragraph 1 of this Article shall be accompanied by a certificate of analysis issued by a laboratory meeting the requirements for quality control of medicinal products.

The Ministry shall prescribe the detailed conditions for the premises, staff, and equipment, as well as other requirements necessary for the preparation of galenic medicinal products in galenic laboratory, galenic laboratory of the pharmacy, or galenic laboratory of the hospital pharmacy

Article 21

The Ministry shall publish the Guidelines on Good preparation practice for galenic medicinal products on its official website.

Article 22

A veterinary medicinal product means any substance or combination of substances that fulfils at least one of the following conditions:

1) it is presented as having properties for treating or preventing disease in animals;
2) it is intended for administration to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;
3) it is intended for use in animals for the purpose of making a medical diagnosis;

4) it is intended to be used to euthanise animals.

Article 23

A biological veterinary medicinal product is a veterinary medicinal product whose active substance is a biological substance.

Article 24

An immunological veterinary medicinal product is a veterinary medicinal product intended for administration to animals in order to produce active or passive immunity or to diagnose its state of immunity.

Article 25

A veterinary medicinal product for novel therapy means a product that includes one or more of the following:

1) a veterinary medicinal product specifically developed for gene therapy, regenerative medicine, tissue engineering, therapy based on blood components, or bacteriophage therapy;
2) a veterinary medicinal product developed using nanotechnology;
3) any other type of therapy that falls under the definition of emerging veterinary medicinal technologies.

Article 26

A homeopathic veterinary medicinal product means a product prepared from substances referred to as homeopathic stocks, according to a homeopathic manufacturing procedure described in the European Pharmacopoeia or, in its absence, in an official pharmacopoeia of an EU Member State or in the national pharmacopoeia.

Article 27

Veterinary medicinal products containing narcotic or psychotropic substances shall, in addition to this Law, be subject to the provisions of a special Law.

III MARKETING AUTHORISATION FOR MEDICINAL PRODUCTS FOR HUMAN USE

1. Obligation to obtain a marketing authorisation for a medicinal product

Article 28

No medicinal product may be placed on the market in Montenegro unless a marketing authorisation (hereinafter: authorisation) has been issued by the Institute for Medicines and Medical Devices (hereinafter: the Institute), in accordance with this Law.

In Montenegro, a medicinal product may also be placed on the market if it has been granted a marketing authorisation by the European Commission under the centralised procedure in accordance with Regulation (EC) No 726/2004.

Once a medicinal product has been granted an initial marketing authorisation in Montenegro or in the European Union, any additional strengths, pharmaceutical forms, routes of administration, presentations, as well as any variations and extensions, shall also be granted an authorisation in accordance with paragraph 1 of this Article and included in the original marketing authorization. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation,, in particular in the case referred to in Article 35 of this Law.

A marketing authorisation shall also be required for radionuclide generators, kits, radiopharmaceuticals, radionuclide precursors and industrially manufactured radiopharmaceuticals.

Homeopathic and traditional herbal medicinal products may be placed on the market if they are registered or authorised in accordance with Articles 41, 42, 43 and 44 of this Law.

Homeopathic medicinal products referred to in Article 41 of this Law shall be subject to a special simplified registration procedure, in accordance with the conditions laid down in this Law.

An authorization to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Law.

No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a medicinal product may be taken except on the grounds set out in Articles 82 and 131 of this Law

Article 29

Exceptionally, the Institute issues an approval for the import of a medicinal product for which a manufacturing authorisation has not been issued in the following cases:

1) the medicinal product is intended for a specific patient or group of patients,

2) medically justified needs for the protection of public health, based on the request of a health institution

3) in the event of an epidemic, epizootic, natural disaster or other emergency situations in accordance with this law

4) the import of a donation or humanitarian aid medicinal product, including. a donation program in the EU,

5) a medicinal product for scientific research,

6) for compassionate use

In the case referred to in paragraph 1 item 3 of this Article, marketing authorisation holders, manufacturers and healthcare professionals shall not be liable for any damage resulting from the use of a medicinal product for which a marketing authorisation has not been issued or from off-label use of the authorised medicinal product, when such use is recommended by the Ministry.

The provision of paragraph 2 of this Article does not apply to the liability of the marketing authorisation holder and the manufacturer for quality deficiencies of the medicinal product.

The Government of Montenegro (hereinafter: the Government) shall take measures for the supply of medicinal products in the cases referred to in paragraph 1 item 3 of this Article and may prescribe a method, procedure and conditions for granting approval for the procurement or import of medicinal products different from the conditions prescribed by this Law.

The content of the application and supporting documentation, as well as the conditions and method of granting approval for the import of medicinal products referred to in paragraph 1 of this Article, shall be prescribed by the Institute, with the approval of the Ministry.

Article 30

The Institute may, in accordance with this Law and to fulfil special needs, exclude from the provisions of this Law medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.

The Institute may temporarily authorise the distribution of an unauthorised medicinal product in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

Without prejudice to paragraph 1, marketing authorisation holders, manufacturers and health professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised indications or from the use of an unauthorised medicinal product, when such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not national or authorization in EU has been granted.

Liability for defective products in accordance with the special law, shall not be affected by paragraph 3 of this Article.

Article 31

In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State, the Institute may, for justified public health reasons, authorise the placing on the market in Montenegro of the said medicinal product.

Such authorisation shall be valid for a maximum of three years.

Prior to granting a marketing authorisation under paragraph 1, the Institute:

1) shall notify the marketing authorisation holder in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned;

2) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 60 paragraph 1 of this Law and of the marketing authorisation in force in respect of the medicinal product concerned.

The Institute shall inform the European Commission if any medicinal product is authorised or ceases to be authorised, under this Article, indicating the name and address of the authorisation holder.

When the Institute avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Law are complied with, in particular those referred to in Articles 76, 85, 86, Articles 146 to 169, Articles 206 to 217 and Article 346 of this Law.

The Institute may decide that full compliance with the requirements concerning the labelling and the package leaflet in the Montenegrin language or several languages provided that the same particulars appear in all the languages used, shall not apply to medicinal products authorised under paragraph 1 of this Article.

Detailed conditions and procedures for granting marketing authorisation under paragraph 1 of this Article shall be defined by the Institute, subject to the approval of the Ministry.

Article 32

A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorized to use such medicinal products in an approved health care establishment exclusively from authorized radionuclide generators, kits or radionuclide precursors in accordance with the manufacturer's instructions, under the special law.

2. Application for marketing authorisation of a medicinal product

Article 33

The application for the granting of a marketing authorisation for a medicinal product shall be submitted to the Institute.

The applicant referred to in paragraph 1 of this Article may be a natural or legal person established in Montenegro.

The applicant referred to in paragraph 1 of this Article may also be a natural or legal person established in the European Union.

The applicant referred to in paragraph 1 of this Article shall employ a person responsible for marketing authorisation procedures, including submission, variation, and renewal of the marketing authorisation, under a full-time employment contract.

The applicant shall also appoint a qualified person responsible for pharmacovigilance.

The qualified person responsible for pharmacovigilance may be employed directly or otherwise engaged by the marketing authorisation holder.

The qualified person responsible for pharmacovigilance shall hold a degree in pharmacy, medicine, dentistry or veterinary medicine, with evidence of appropriate training in pharmacovigilance and shall be available 24 hours a day and reside in Montenegro.

The marketing authorisation holder shall be responsible for placing the medicinal product on the market and for its continued regulatory compliance under this Law.

The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.

The applicant shall be responsible for the accuracy of the data contained in the documentation submitted in the application procedure.

Article 34

The application for a marketing authorisation shall be accompanied by the following particulars and documents:

1) name or corporate name and registered address of the applicant and, where applicable, of the manufacturer;
2) name of the medicinal product;
3) qualitative and quantitative particulars of all the constituents, including the INN if it exists, or relevant chemical name;
4) evaluation of the potential environmental risks posed by the medicinal product (the environmental impact of the product shall be on a case by-case basis, specific arrangements to limit it shall be envisaged).
5) description of the manufacturing method;
6) therapeutic indications, contra-indications and adverse reactions;
7) posology, pharmaceutical form, method and route of administration and expected shelf life;
8) reasons for any precautionary and safety measures to be taken for the for the storage, handling, administration, and disposal of the waste products, together with an indication of potential risks presented by the medicinal product for the environment;
9) description of control methods employed by the manufacturer;
10) a written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the active substance with GMP guidelines, by conducting an audit in accordance with this Law, including date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles and guidelines of good manufacturing practice;
11) results of:
    – pharmaceutical (physicochemical, biological, or microbiological) tests,

– pre-clinical (toxicological and pharmacological) tests,
– clinical trials;

12) a summary of the applicant's pharmacovigilance system containing:
– proof of employment or otherwise engagement qualified person for pharmacovigilance,
– the contact details of the qualified person for pharmacovigilance,
– a declaration that the applicant has provided all necessary resources for fulfilling pharmacovigilance obligations,
– a reference to the location where the PSMF for the medicinal product is kept;
13) RMP including a description of the RMS which the applicant will introduce for the medicinal product concerned together with a summary thereof;
14) a statement confirming that clinical trials conducted outside the EU meet ethical standards in accordance with EU regulations;
15) summary of product characteristics (SmPC), mock-ups of outer and inner packaging, and package leaflet prepared in accordance with this Law;
16) manufacturing authorisation;
17) Copies of:
– any marketing authorisations issued in EU member states or in a third country, summaries of safety data including the data contained in PSUR, if available, and suspected adverse reactions reports, together with a list of those countries in which an application has been submitted and is under review,
– the summary of product characteristics submitted by the applicant in the marketing authorisation procedure ongoing in a member state of the European Union or the summary approved by the competent authority of a Member State of the European Union, as well as the package leaflet submitted in the marketing authorisation procedure ongoing in a member state of the European Union or the leaflet approved by the competent authority of a member state of the European Union;
– details of any decision to refuse marketing authorisation in an EU member state or third country, and the reasons for such a decision;
18) a copy of the European Commission decision designating the product as an orphan medicinal product, with the related EMA opinion.

The documentation concerning the results of the pharmaceutical and pre-clinical tests and the clinical trials referred to in item11 of the first paragraph of this article shall be accompanied by reports drawn up and signed by experts with necessary technical or professional qualifications, which shall be set out in a brief curriculum vitae.

Experts referred to in paragraph 2 shall justify any use of scientific literature under Article 36, in line with this Law.

The detailed summaries shall form part of the file which the applicant submits to the Institute.

In addition to the documentation under paragraph 1 of this article, for medicinal products falling within the scope of Annex to Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, a copy of the EC decision shall be provided.

RMS from item 13 of paragraph 1 of this article shall be proportionate to the identified and potential risks and to the need for post-authorisation safety data.

At the request of the Institute, the applicant shall submit product samples and standards needed for quality control of the medicinal product.

The data and documentation referred to in paragraph 1 shall be updated as necessary.

The Institute, when assessing a marketing authorisation, does not assess possible infringements of intellectual or industrial property rights.

Detailed requirements for the submission of the application, its content, and required documentation shall be prescribed by the Institute, with the approval of the Ministry.

Article 35

By way of derogation from Article 34 paragraph 1 item 11 of this Law and without prejudice to the provisions governing industrial and commercial property -rights the applicant shall not be required to provide results of preclinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised in Montenegro or in the European Union for not less than eight years before the date of submission of the application.

A generic medicinal product authorised in accordance with paragraph 1 of this Article shall not be placed on the market in Montenegro until ten years have elapsed from the initial authorisation of the reference medicinal product in Montenegro or in the European Union.

The period referred to in paragraph 2 may be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies..

The provision of paragraph 1 of this Article shall also apply if the reference medicinal product reference medicinal product was not authorised in Montenegro, in which case the applicant for the generic medicinal product shall indicate in the application form the EU Member State in which the reference medicinal product is or has been authorised.

If the reference medicinal product referred to in paragraph 1 of this Article has or has had a marketing authorisation issued in Montenegro, the Institute shall, at the request of the competent authority of a European Union Member State, provide within 30 days a confirmation that the reference medicinal product has or has had a marketing authorisation in Montenegro, including information on the full composition of the reference medicinal product and, if necessary, other relevant documentation.

In addition to the provisions of paragraphs 1 to 4 of this Article, where an application is made for a new indication for a well-established substance, a non-cumulative period of one-year of data exclusivity shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.

Where the medicinal product does not fall within the definition of a generic medicinal product in accordance with this Law or where the bioequivalence cannot be demonstrated through bioavailability studies or in cases of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form, or route of administration vis-à-vis the reference medicinal product, the results of the appropriate pre-clinical tests or clinical trials shall be provided.

Where a biological medicinal product which is similar to a reference biological product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or differences in manufacturing processes compared to the reference biological product, the applicant shall submit the results of appropriate pre-clinical tests or clinical studies relating to these conditions.

The type and quantity of supplementary data to be provided shall comply with the relevant criteria stated in the regulation on detailed conditions for granting marketing authorisation for medicinal products and the related detailed guidelines.

The applicant referred to in paragraph 8 of this Article shall not be required to provide the results of other tests and trials from the reference medicinal product's dossier.

Conducting of the necessary studies and trials referred to in this Article, as well as the consequential practical requirements, shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products in accordance with applicable law.

Article 36

By way of derogation from Article 34 paragraph 1 item 11 of this Law, and without prejudice to the provisions governing the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests or clinical trials if he can demonstrate that the active substance of the medicinal product have been in well-established medicinal use in Montenegro or the European Union for at least ten years, with recognised efficacy and acceptable level of safety in terms of the conditions referred to in the article 34 paragraph 10 of this Law.

In the case referred to in paragraph 1 of this Article, the test and trial results shall be replaced by appropriate scientific literature.

Article 37

In addition to the data referred to in Article 34 and Article 35 paragraphs 1 to 5 of this Law, the application for a marketing authorisation of a radionuclide generator shall contain:

1) a general description of the system together with a detailed description of the system components which may affect the composition or quality of the daughter nuclide preparation;
2) qualitative and quantitative particulars of the eluate or the sublimate.

Article 38

In the case of medicinal products containing active substances used in the composition of authorised medicinal products in Montenegro or the European Union but not hitherto used in combination for therapeutic purposes, the results of new pre-clinical tests or new clinical trials relating to that combination shall be provided, in accordance with Article 34 paragraph 1 item 11 of this Law but it shall not be necessary to provide scientific references relating to each individual active substance.

Article 39

In the procedure for granting a marketing authorisation, the Institute shall verify that manufacturers and importers of medicinal products coming from third countries are able to carry out manufacture in accordance with the information referred to in Article 34 paragraph 1 item 5 of this Law and/or to carry out quality control in accordance with the methods described in the information referred to in Article 34 paragraph 1 item 9 of this Law.

Where, in certain cases, manufacturers or importers referred to in paragraph 1 of this Article have entered into a contract with another natural or legal person for the performance of certain stages of manufacturing and/or quality control, the Institute shall verify that such natural or legal person complies with the requirements for manufacturing in accordance with the information referred to in Article 34 paragraph 1 item 5 and/or performs quality control in accordance with the test methods specified in the information referred to in Article 34 paragraph 1 item 9 of this Law.

Article 40

Following the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

3. Application for registration or marketing authorisation of a homeopathic medicinal product and a traditional herbal medicinal product

Article 41

A homeopathic medicinal product shall be registered through a simplified procedure if:

1) they are administered orally or externally;
2) no specific therapeutic indications or data implying such indications are stated on the packaging;
3) there is a sufficient degree of dilution to guarantee the safety of the medicinal product, as well as the medicinal product may not contain either more than one part per 10.000 of the mother tincture, or more than 1/100 of the smallest dose used in allopathic (conventional) medicine for active substances which, whose presence in an allopathic medicinal product, results in the obligation to submit a doctor's prescription, in accordance with this Law.

When registering a homeopathic medicinal product, the Institute shall determine the classification for the dispensing of the medicinal product.

Article 42

An application for the simplified registration of a homeopathic medicinal product may be submitted for a series of medicinal products derived from the same homeopathic stock or stocks.

In order to demonstrate the pharmaceutical quality and batch-to-batch homogeneity of a specific homeopathic medicinal product, the following documents shall be submitted along with the application referred to in paragraph 1 of this Article:

1) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, including data on the various routes of administration, pharmaceutical forms and the degree of dilution to be registered;
2) documentation describing how the homeopathic stock or stocks is/are obtained and controlled, and demonstrating its/their homeopathic use, on the basis of an adequate bibliographic data;
3) documentation on the manufacture and quality control for each pharmaceutical form, including a description of the method of dilution and potentization;
4) manufacturing authorization;
5) a copy of the registration certificate or marketing authorization for the same homeopathic medicinal product in European Union Member States;
6) one or more mock-ups of the outer and immediate packaging of the medicinal product to be registered;
7) data concerning the stability of the medicinal product.

The provisions of this Law governing conditions and procedures for granting a marketing authorisation shall apply by analogy to the registration of homeopathic medicinal products under the simplified procedure, with the exception of the proof of evidence of therapeutic efficacy.

Article 43

The Institute may establish specific requirements for preclinical tests and clinical trials of homeopathic medicinal products, in line with the principles and characteristics of homeopathy as applied in Montenegro.

In the case referred to in paragraph 1 of this Article, the Institute shall notify the European Commission.

Articles 146 to 169 of this Law shall apply to homeopathic medicinal products, with the exception of those referred to in Article 41 of this Law.

Article 44

A traditional herbal medicinal products shall be registered via a simplified registration procedure if:

1) they have indications exclusively appropriate to traditional herbal medicinal products, which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;
2) they are exclusively for administration in accordance with a specified strength and posology;
3) they are an oral, external and/or inhalation preparation;
4) the product has been in traditional medicinal use for at least 30 years before the date of application, of which at least 15 years within the European Union;
5) the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

If a traditional herbal medicinal product contains vitamins or minerals for the safety of which there is well-documented evidences, shall not prevent the product from being eligible for registration provided their action is only auxiliary to the action of the active herbal ingredients regarding the specified claimed indication(s).

If the Institute determines that a traditional herbal medicinal product or a homeopathic product fulfils the criteria for marketing authorisation or simplified registration, the relevant provisions of this Law governing marketing authorisation or homeopathic registration shall apply accordingly.

Article 45

The applicant and registration holder of a traditional herbal medicinal product shall be established in Montenegro.

An application for registration of a traditional herbal medicinal product may be submitted by a natural or legal person established in the European Union.

In order to obtain traditional-use registration, the applicant shall submit an application to the Institute.

The application referred to in paragraph 1 of this article shall be accompanied by:

1) data and documentation:
   - from article 34 paragraph 1 point 1 to 9 and points 15 and 16 of this Law,
   - results of preclinical studies (toxicological and pharmacological),
   - a summary of product characteristics, without inclusion of clinical data,
   - in case of combination of active substances referred to in Article 16 or Article 44 paragraph 2 of this Law, the information under article 44 paragraph 1 item5 of this Law relating to combination as such; if the individual active ingredients are not sufficiently known, the data shall also relate to the individual active ingredients;
2) information on any marketing authorisation or registration obtained by the applicant in an EU Member State or in a third country, as well as details on any decision to refuse to grant an authorisation or registration, including the reasons for any such decision;

3) bibliographic or expert evidence that the medicinal product in question, or a corresponding product, has been in medicinal use for at least 30 years preceding the date of the application, of which at least 15 years within the European Union;
4) a bibliographic review of safety data together with an expert report; and, upon request by the Institute, any additional data necessary for assessing the safety of the medicinal product.

A corresponding medicinal product referred to in item 3 of paragraph 4 of this Article is 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.

The requirement to demonstrate medicinal use referred to in paragraph 3 item 3 of this article is satisfied even where the marketing of the product has not been based on a specific authorisation or where the number or quantity of ingredients of the medicinal product has been reduced during that period.

An application for simplified registration may also be submitted for a traditional herbal medicinal product used in the European Union for less than 15 years, provided that it meets the other registration requirements under this Law and is covered by a European Union herbal monograph or consists of herbal substances, preparations, or combinations listed on the EU list of herbal substances and preparations for use in traditional herbal medicinal products.

Where a medicinal product has been used in the EU for less than 15 years but meets the other requirements for simplified registration, the Institute, to which the application has been submitted, shall refer that application to the HMPC and provide the relevant documentation supporting the referral.

When taking its final decision on application referred to in paragraph 8 of this Article, the Institute shall take into account herbal monography established by the HMPC after assessment that application is justified.

Article 46

If an application for registration relates to a herbal substance, preparation or combination included in a European Union herbal monograph or the EU list of herbal substances and combinations for use in traditional herbal medicinal products, the data referred to in Article 45 paragraph 3 item1 indents 2, 3, and 4 of this Law shall not be submitted and the provisions of Article 48 paragraph 1 points 3 and 4 of this Law shall not apply.

If the relevant herbal substance, preparation or combination ceases to be included in the EU herbal monograph or the EU list, the herbal medicinal products containing it shall be revoked from the register unless the applicant submits the data and documentation referred to in Article 45 paragraph 4 of this Law within three months.

Article 47

When registering a traditional herbal medicinal product, the Institute shall take into account whether the product has been registered in any EU Member State.

The provisions of this Law governing DP and MRP procedures for granting marketing authorisations shall apply mutatis mutandis to the simplified registration of a traditional herbal medicinal product consisting of herbal substances, preparations, or combinations included in a European Union herbal monograph or on the EU list of herbal substances.

Article 48

The application for simplified registration of a traditional herbal medicinal product shall be refused if the requirements of Articles 44 and 45 of this Law are not met, or if at least one of the following conditions is fulfilled:

1) the qualitative and/or quantitative composition is not as declared;
2) the indications do not comply with the conditions for registration;
3) the medicinal product could be harmful under normal conditions of use;
4) the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience;
5) the pharmaceutical quality of the product is not satisfactorily demonstrated.

The Institute shall notify the applicant, the European Commission and any other competent authorities that requests of any decision they take to refuse registration of a traditional herbal medicinal product, including the reasons for the refusal.

Article 49

In addition to the labelling and package leaflet requirements applicable to medicinal products under this Law, the labelling and package leaflet for a traditional herbal medicinal product shall also include:

1) a statement that the product is a traditional herbal medicinal product for use in the specified indication(s) exclusively, based upon long-standing use; and
2) a warning that the user should consult a doctor or pharmacist if symptoms persist during the use of the medicinal product, or if any adverse effects not mentioned in the package leaflet occur.

The Institute may require that the labelling and the user package leaflet shall also state the nature of the tradition in question.

Article 50

Provisions of Articles 3 paragraph 1 item 1 and 2 and paragraph 3 item 4, Articles 28 paragraphs 1 and 2, Article 34 paragraph 1 item 9 and paragraphs 2 and 3, Article 39, Article 53 paragraphs 1 to 5, Article 63 paragraphs 1 and 2, Article 67 paragraphs 1 and 3, Article 77 paragraphs 1, 2, 3, 6 and 7, Article 80, Article 85, Articles 90 to 113, Article 131, Article 139 paragraph 2, Article 146 to 169 and Article 347of this Law shall apply by analogy to homeopathic and traditional use registration of medicinal products granted in accordance with this Law.

The Institute shall communicate to other Member States all the information necessary to guarantee the quality and safety of homeopathic medicinal products manufactured and

marketed within the EU, and in particular the information referred to in Articles 126 and 127 of this Law.

Article 51

Homeopathic and traditional herbal medicinal products registered under the simplified registration procedure shall be entered in the Register of Homeopathic Medicinal Products and the Register of Traditional Herbal Medicinal Products, which are maintained by the Institute in electronic form.

Article 52

The detailed conditions, documentation requirements, and procedure for the registration of homeopathic and traditional herbal medicinal products shall be prescribed by the Institute, with the approval of the Ministry.

4. Marketing authorisation

Article 53

The Institute shall decide on the granting of a marketing authorisation within a maximum 210 days from the date of submission of a valid application.

The Institute shall assess whether the application for marketing authorisation is valid within 30 days from the date of receipt of the application.

If the application is not complete, the Institute shall notify the applicant and set a deadline for correcting the deficiencies, which may not exceed 30 days.

By way of derogation from paragraph 3 of this Article, in justified cases and at the request of the applicant, the Institute may extend the deadline for correcting deficiencies by an additional 30 days.

In the procedure for granting a marketing authorisation for a medicinal product, when assessing whether the conditions for granting the authorisation are fulfilled in accordance with this Law, the Institute may:

1) perform testing of the medicinal product, its starting materials, and, where necessary, its intermediate products or other constituents in its authorised quality control laboratory, or accept the results of quality control performed by another Official Medicines Control Laboratory (hereinafter: OMCL), in order to determine whether the control methods employed by the manufacturer, and described in the application for marketing authorisation, are satisfactory;
2) where necessary, require the applicant to supplement the documentation submitted with the application for marketing authorisation within a specified time limit, which shall not exceed 180 days.

In the case that the Institute, during the assessment of the request, in accordance with paragraph 3 and paragraph 5, item 2 of this Article, requests additional data and explanations from the applicant, the time period referred to in paragraph 1 of this Article

shall not include the time required for the applicant to submit the requested data and explanations to the Institute, that is, the time from the day the Institute requests additional data from the applicant until the day such data is submitted.

Article 54

If the application for marketing authorisation refers to a medicinal product that has already received a marketing authorisation in the European Union through the CP, MRP or DCP, or if the product is of public health interest, particularly in terms of therapeutic innovation, the applicant may request accelerated assessment, with a written justification.

In such cases, the Institute shall issue the marketing authorisation within 150 days from the receipt of a complete application.

The application shall be accompanied by the documentation specified in Article 34 of this Law, along with a declaration from the responsible person attesting that the submitted documentation is identical to that on the basis of which the authorisation was granted through CP, MRP, or DCP.

If the application for accelerated assessment is incomplete, the Institute shall notify the applicant and set a deadline for correcting the deficiencies, not exceeding 30 days.

Exceptionally, in justified cases and at the applicant's request, the Institute may extend the deadline for an additional 30 days.

The time referred to in paragraph 2 does not include the period required for the applicant to provide the requested data i.e., the time between the Institute's request and submission of the data.

Article 55

The granting of a marketing authorisation for the same medicinal product in two or more EU Member States shall be conducted in accordance with the provisions of this Law governing MRP and DCP.

If the Institute determines that an application for the same medicinal product is under review in another EU Member State, it shall not evaluate the application, and shall notify the applicant that the procedure will follow the rules set out in paragraph 1 of this Article.

If the Institute is informed in accordance with Article 34 paragraph 1 that another EU Member State has granted a marketing authorisation for a product for which an application has also been submitted in Montenegro, it shall reject the application, unless Institute itself it is the competent authority evaluating the product under paragraphs 1 and 2 of this Article.

Article 56

A marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:

1) to take certain measures to ensure safe use of the medicinal product, to be included in the RMS;
2) to conduct post-authorisation safety studies;
3) to comply with obligations on the recording or reporting of suspected adverse reactions which are stricter than the general obligations established by this Law;
4) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;
5) the existence of an adequate pharmacovigilance system;
6) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. The obligation to carry out such studies shall be based on scientific guidelines or European Commission acts.

The marketing authorisation shall lay down deadlines for the fulfilment of these conditions where necessary.

If the marketing authorisation holder fails to fulfil any condition set in accordance with paragraph 1 of this Article, the Institute shall take appropriate measures, which may include suspension, variation or revocation of the marketing authorisation, in a proportionate manner and on the basis of the actual risks.

Article 57

The Institute may grant a conditional marketing authorisation for certain categories of medicinal products to address unmet medical needs of patients or when it is in the interest of public health, based on a reasoned request by the applicant.

A conditional marketing authorisation may be granted for:

1) a medicinal product aim at the treatment, prevention, or medical diagnosis of a seriously debilitating or life-threatening disease;
2) a medicinal product to be used for emergency situations, in response to a public health threat recognised by the World Health Organization (WHO) or a competent authority, body, or institution of the European Union or Montenegro;
3) a medicinal product with orphan designation;
4) other medicinal products of public health interest.

The application for conditional marketing authorisation shall be submitted with the documentation and data referred to in Article 34 of this Law and if the applicant is unable to submit comprehensive clinical data on the safety and efficacy of the medicinal product, the Institute may grant a conditional authorisation if the following conditions are met:

1) the risk-benefit balance of the medicinal product is positive;
2) the applicant is likely will be in a position to provide comprehensive clinical data;
3) the unmet medical needs will be addressed;
4) the benefit to the public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

A person interested in submitting a request for conditional authorisation may ask the Institute for the information on whether a specific medicinal product, developed for certain therapeutic indications, meets the conditions laid out in paragraphs 1 and 2 of this Article.

Article 58

In the conditional marketing authorisation, the Institute shall define specific obligations for the authorisation holder and set deadlines for fulfilling these obligations, which may include the obligation to:

1) complete ongoing clinical trials or conduct new studies, with a view to confirming that the risk-benefit balance is positive
2) provide the additional data referred to in Article 57 paragraph 2 of this Law;
3) collect pharmacovigilance data.

The specific obligations and deadlines referred to in paragraph 1 shall be published by the Institute on its official website.

If the marketing authorisation holder fulfils the specific obligations referred to in paragraph 1, the Institute shall issue a standard marketing authorisation valid for five years, in accordance with this Law.

Article 59

In exceptional circumstances, only for a medicinal product of particular interest to human health, after consultation with the applicant, the Institute may issue a medicinal product authorisation subject to certain conditions, in particular those relating to the safety of the medicinal product, with the obligation to inform the Institute of any incident relating to the use of the medicinal product and the measures to be taken (hereinafter referred to as: authorisation under special circumstances).

The marketing authorisation under exceptional circumstances may be granted only when the applicant can show that he is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, in accordance with Article 34 of this Law, for objective, verifiable reasons.

Continuation of the marketing authorisation under exceptional circumstances shall be linked to the Institute's annual reassessment of these conditions.

Article 60

In the procedure for granting a marketing authorisation, the Institute shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and pre-clinical tests, the clinical trials, the risk management system and the pharmacovigilance system of the medicinal product concerned, which shall be updated whenever new information becomes available which is important for the evaluation of the quality, safety or efficacy of the medicinal product concerned.

The report referred to in paragraph 1 of this Article shall contain a justification for each requested indication, as well as a summary written in language understandable to the public, including a dedicated section relating to the conditions of use of the medicinal product.

The summary report from paragraph 1 shall be published by the Institute on its official website without delay, excluding any information of a commercially confidential nature.

Article 61

After the granting of a marketing authorisation, the Institute may impose an obligation on the marketing authorisation holder:

1) to conduct a PASS, if there is a concerns about the risk of an authorised medicinal product. If the same concern s apply to more than one medicinal product, the Institute may, following consultation with the PRAC, encourage the marketing authorisation holders concerned to conduct a joint PASS;
2) to conduct a post-authorisation efficacy study, when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly, in which case the obligation shall be based on appropriate scientific guidelines of the European Commission.

The imposition obligations referred to in paragraph 1 of this article, including objectives and deadlines for the conduct and submission of studies, shall be set by the Institute with a detailed justification.

If the obligations referred to in paragraph 1 are imposed, the marketing authorisation holder has the right, within 30 days of receiving the Institute's decision, to request the opportunity to present written observations, and the Institute shall set a deadline for doing so.

The institute may, acting on the observations referred to in paragraph 3 of this Article, withdraw or confirm the obligations imposed under paragraph 1.

If the Institute confirms the obligation under paragraph 1, it shall amend the marketing authorisation by including that obligation as a condition of marketing authorisation.

In the case referred to in paragraph 5, the marketing authorisation holder shall update the RMS accordingly.

Article 62

The marketing authorisation holder shall incorporate into the Risk Minimisation System all conditions, special circumstances, and obligations set out in the marketing authorisations referred to in Articles 56 to 59 of this Law.

The Institute shall notify the European Medicines Agency (EMA) of the marketing authorisations referred to in Articles 56 to 59 of this Law.

Article 63

After a marketing authorisation has been granted, the marketing authorisation holder shall:

1) monitor the latest scientific and technological progress in respect of manufacturing process and quality control, or the description of manufacturing methods and analytical techniques provided in the application, and implement any changes necessary to ensure the product is manufactured and controlled in accordance with generally accepted scientific methods;
2) without delay, provide the Institute with any new information that may lead to an amendment of the data or documentation in accordance with this Law;
3) forthwith inform the Institute of any prohibition or restriction imposed by competent authorities in any country in which the medicinal product is marketed, and of any other new information which might influence the evaluation of the benefits and risks of the medicinal product concerned, including both positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation;
4) ensure that the product information is kept up to date with the current scientific knowledge, including the conclusions of the assessment and recommendations made public in the European Union;
5) without delay and in full, submit to the Institute data demonstrating that the risk-benefit balance remains favourable, in order to be able to continuously assess the risk-benefit balance;
6) submit a copy of the PSMF to the Institute whenever requested, within seven days after receipt the request.

The changes referred to in paragraph 1, item1 of this Article shall be approved by the Institute in accordance with this Law.

In the cases referred to in paragraph 1 of this article, the Institute may require the marketing authorisation holder to submit an application for a variation of the marketing authorisation.

Article 64

After the marketing authorisation has been granted, the marketing authorisation holder shall notify the Institute of the date on which the medicinal product is placed on the market in Montenegro, for each pharmaceutical form and pack size and, within 15 days from the date of placing the product on the market, using the notification form published on the Institute's official website.

Article 65

If a medicinal product ceases to be placed on the market, either temporarily or permanently, or if its placing on the market is to be discontinued, the marketing authorisation holder shall notify the Institute at least 60 days in advance, except in cases of urgent recall or other exceptional circumstances.

In the case referred to in paragraph 1 of this Article, the marketing authorisation holder shall inform the Institute of the reasons for interruption of supply, and shall also notify the Ministry of Health and the Health Insurance Fund of Montenegro, if the medicinal product is prescribed or dispensed at the expense of compulsory health insurance funds.

Article 66

Upon request of the Institute, particularly in the context of pharmacovigilance, the marketing authorisation holder shall provide all data relating to the volume of sales of the medicinal product, and any data in his possession relating to the volume of prescriptions.

Article 67

A marketing authorisation shall be valid for a period of five years.

A conditional marketing authorisation shall be issued for a period of 12 months.

The granting of a marketing authorisation does not release the manufacturer or the marketing authorisation holder from civil or criminal liability under applicable law.

Article 68

The following documents shall form an integral part of the marketing authorisation:

1) the approved summary of product characteristics;
2) the labelling;
3) the package leaflet.

Medicinal products labelled and accompanied by a package leaflet in accordance with this Law shall not be prohibited or impeded from being placed on the market on grounds related to labelling or the package leaflet.

The marketing authorisation shall also include a list of all sites for batches release of the medicinal product placed on the market of Montenegro.

Article 69

The Institute shall inform the marketing authorisation holder of the approved summary of product characteristics upon the granting of the marketing authorisation.

The Institute is responsible for ensuring that the information contained in the approved summary of product characteristics are consistent with the data accepted during the authorisation procedure, whether initially or subsequently.

For a marketing authorisation granted under Article 35 of this Law, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included..

For a conditional marketing authorisation, the summary of product characteristics and the package leaflet shall contain a statement that the authorisation was granted under conditional terms.

Article 70

Every medicinal product placed on the market shall be labelled in accordance with the granted marketing authorisation.

The data on the outer and inner packaging and the package leaflet shall be easily legible, clearly comprehensible and indelible.

In the case of medicinal products with orphan designation, the labelling information may, upon a duly justified request, be provided in only one official language of the European Union.

The name and strength of the medicinal product if the product has more than one strength shall also be stated in Braille format on the packaging.

By way of derogation from paragraph 4 of this Article, the name and strength in Braille are not required for medicinal products authorised solely for hospital use under healthcare professional supervision, or for investigational medicinal products.

At the request of a patient organisation, the marketing authorisation holder shall make the package leaflet available in a format adapted for blind and partially-sighted persons.

In the case when it is necessary for the protection of the public interest, the Ministry may require that the medicinal product be marked with additional labels.

The detailed conditions for marking the medicinal product with additional labels shall be prescribed by the Ministry.

Article 71

Medicinal products subject to prescription, except for radiopharmaceuticals, shall bear safety features on the packaging that enable persons involved in wholesale and retail distribution to verify the authenticity of the product and to identify each individual pack.

By way of derogation from paragraph 1 of this Article, a medicinal product subject to prescription is not required to bear safety features if it is included on the list of exempt products determined by the European Commission.

Medicinal products not subject to prescription are not required to bear safety features unless included on the list of products that shall bear such features, as determined by the European Commission based on an assessment of the risk of falsification.

In addition to the products in paragraphs 1 and 3, the Institute may require other medicinal products to bear safety features if:

1) they are medicinal products subject to prescription or financed through compulsory health insurance, for the purposes of health insurance or pharmacovigilance;
2) there is a need to ensure patient safety.

For the purposes of health insurance, pharmacovigilance, or pharmacoepidemiology, the Institute may use data from EU systems containing information on safety features and enabling verification of authenticity and identification of medicinal products.

The Institute shall notify the European Commission of medicinal products not subject to prescription hat are assessed to be at risk of falsification.

The Institute may also notify the Commission of medicinal products deemed not at risk of falsification, based on the following criteria:

1) the price and sales volume of the medicinal product;
2) the number and frequency of previous cases of falsification being reported in the EU and third countries, and changes in their incidence;
3) the specific characteristics of the medicinal products concerned;
4) severity of the condition the medicinal product is intended to treat;
5) other potential public health risks.

The lists referred to in paragraphs 2 and 3 of this Article, as well as the list of medicinal products required to bear safety features, shall be published on the Institute's website.

More detailed conditions and the method of establishing the safety features system, as well as the list specifying medicinal products required to bear safety features and those not required to bear them shall be prescribed by the Ministry.

Article 72

Safety features shall not be removed or covered, either partially or entirely, unless the following conditions are met:

1) the manufacturing authorisation holder, prior to partly or fully removing or covering those safety features, verifies that, the medicinal product concerned is authentic and that it has not been tampered with;
2) the manufacturing authorisation holder has replaced the original safety features with safety features which are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering, and such replacement shall be conducted without opening the immediate packaging.

The safety features referred to in item 2 of paragraph 1 of this Article shall be considered equivalent if they:

1) comply with the requirements laid down in Article 71 paragraphs 1 to 3 of this Law;
2) they are equally effective in enabling the verification of authenticity, identification of the medicinal product, and providing evidence of tampering;
3) the replacement of safety features is conducted in accordance with applicable good manufacturing practice for medicinal products;
4) the replacement is carried out under supervision by the Institute.

The manufacturing authorisation holder shall be regarded as responsible for the procedures and therefore held liable for damages in the cases and under the conditions set forth in the special Law.

Article 73

The package leaflet shall be consistent with the approved summary of product characteristics and written in the Montenegrin language.

In the case of a medicinal product not intended for direct dispensing to the patient, or where there are serious supply issues, the Institute may, at the request of the marketing authorisation holder, approve, either in whole or in part, that the labelling and package leaflet for a specific batch and quantity of the medicinal product do not have to be in the Montenegrin language.

Article 74

One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the Institute along with marketing authorisation application submitted.

The draft package leaflet shall be accompanied by the results of a user consultation, conducted in collaboration with the target patient groups.

The Institute shall refuse the application for marketing authorisation if the labelling or package leaflet do not comply with the provisions prescribed by this Law or are not in accordance with the particulars listed in the summary of product characteristics.

All proposed changes to an aspect of the labelling or the package leaflet not related to the with the summary of product characteristics shall be submitted to the Institute.

If the Institute have not opposed a proposed change within 90 days following proposal referred to in paragraph 4 of this Article, the applicant may put the change into effect.

The fact that the Institute do not refuse a marketing authorization pursuant to Article 34 paragraph 1 item 15 of this Law or a change to the labelling or the package leaflet pursuant to paragraph 4 of this Article does not alter the general legal liability of the manufacturer and the marketing authorization holder.

Article 75

If the Institute determines that the labelling and package leaflet of a medicinal product on the market are not in compliance with this Law and the marketing authorisation, the Institute shall issue a warning to the marketing authorisation holder, requiring alignment within a specified time period.

If the marketing authorisation holder upon the warning fails to comply within the deadline referred to paragraph 1 of this article , the Institute shall suspend the marketing authorisation until compliance is achieved.

Article 76

The detailed content of the marketing authorisation, as well as the content of the summary products characteristics, labelling, and package leaflet, shall be prescribed by the Institute, with the approval of the Ministry.

5. Renewal, variation, transfer, and cessation of validity of a marketing authorisation for a medicinal product

Article 77

The application for renewal of a marketing authorisation valid for a five-year period shall be submitted to the Institute no later than nine months before its expiry.

In the procedure referred to in paragraph 1 of this Article, the re-evaluation of the risk-benefit balance, shall be carried out. In this context the marketing authorisation holder shall submit to the Institute a consolidated documentation on the quality, safety and efficacy of the medicinal product, including the evaluation of data contained in suspected adverse reaction reports and PSURs, as well as information on all variations implemented since the marketing authorisation was granted.

Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the Institute decides, on justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned, to proceed with one additional five-year renewal.

Following the submission of the application referred to in paragraph 1 of this Article, the marketing authorisation shall remain valid until the date of the issuing of the renewal decision , in accordance with this Law.

The marketing authorisation holder shall place the medicinal product on the market in accordance with the renewed authorisation within 12 months from the date of renewal.

The provisions of Articles 53 and 54 of this Law shall apply accordingly to the renewal procedure.

If the marketing authorisation holder does not intend to renew the marketing authorisation, they shall notify the Institute within the deadline referred to in paragraph 1 of this Article.

Instructions for submitting the application referred to in paragraph 1 and the accompanying documentation shall be published by the Institute on its official website.

Article 78

The application for renewal of a conditional marketing authorisation shall be submitted to the Institute no later than six months before expiry, together with an interim report on the fulfilment of specific obligations set out in the authorisation.

The Institute shall assess the application on the basis of a re-confirmation of the risk-benefit balance, taking into account the specific obligations and deadlines set out in the conditional marketing authorisation, and shall decide whether to maintain or amend those obligations.

The decision referred to in paragraph 2 of this Article shall be published on the Institute's website.

The Institute shall decide on the application referred to in paragraph 1 of this Article within 90 days of receiving a complete application.

Following the submission of the renewal application, the conditional marketing authorisation shall remain valid until the renewal decision is issued in accordance with this Law.

At the request of the Institute, either immediately or at least every six months from the date of granting or renewing the conditional authorisation, the marketing authorisation holder shall submit a PSUR.

If the holder of a conditional marketing authorisation does not intend to apply for renewal, they shall notify the Institute within the deadline referred to in paragraph 1 of this Article.

Article 79

The Institute shall refuse an application for a marketing authorisation if, after assessment of the data and documentation as required by this Law, it determines that:

1) the risk-benefit balance of the medicinal product is not considered to be favourable;
2) its therapeutic efficacy is insufficiently substantiated by the applicant;
3) its qualitative and quantitative composition is not as declared;
4) the documentation submitted in support of the application do not comply with the requirements set out in this Law;
5) other cases as prescribed by this Law.

A refusal of an application for the granting or renewal of a marketing authorisation shall constitute a prohibition on placing the medicinal product on the market in the territory of Montenegro.

The Institute shall publish on its official website information on rejected applications for marketing authorisation and renewal, including the reasons for rejection.

Article 80

A variation to a marketing authorisation (hereinafter: variation) shall mean an amendment to:

1) the content or data from the documentation submitted with the application for marketing authorisation in accordance with the Article 7 paragraph 1 items 26 and 83 and Articles 34 to 38 of this Law.

2) the terms set out in the decision granting the authorisation, including the summary of product characteristics, and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or package leaflet related to changes to the summary of the product characteristics.

The marketing authorisation holder shall submit an application for variation to the Institute.

The Institute shall decide on the application referred to in paragraph 2 of this Article within 180 days from receipt of a complete application.

The Institute shall assess the completeness of the application referred to in paragraph 2 of this Article within 30 days, and if incomplete, shall notify the applicant and set a deadline of no more than 30 days to correct deficiencies.

By way of derogation from paragraph 4 of this article, for justified reasons and upon request by the applicant, the Institute may extend this deadline by an additional 30 days.

The time period referred to in paragraph 3 of this Article does not include the time taken by the applicant to respond to requests for additional data, from the day the Institute makes the request until the day the data are received.

A marketing authorisation holder may submit one application for the same variation affecting multiple marketing authorisations.

The procedures for examination of application referred to in paragraph 2 of this Article shall be proportionate to the risk and impact of the variations and these procedures shall range from those allowing implementation only after approval based on a complete scientific assessment, to those allowing immediate implementation and subsequent notification to the competent authority by the marketing authorisation holder.

Variations shall be classified in different categories, depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned, ranging from changes that have highest potential impact to changes that have no or minimal impact thereon.

If the approved variation requires changing the data in the summary of product characteristics and/or labelling and/or package leaflet, the Institute shall, along with the approved variation, also approve a new amended summary of the product characteristics and/or labelling and/or package leaflet.

The content of the application from paragraph 2 of this article and supporting documentation shall be determined by the Institute, with the approval of the Ministry.

Article 81

The marketing authorisation holder may submit to the Institute a request to transfer the marketing authorisation to another person who fulfils the requirements referred to in Article 33 of this Law, with the consent of that person.

The Institute shall assess the completeness of the application for the transfer of the marketing authorisation within 30 days from the date of receipt.

The Institute shall issue a decision approving or rejecting the request for the transfer of the marketing authorisation within 30 days of receiving a complete application.

The transfer of the marketing authorisation is not considered a variation.

A medicinal product for which the authorisation has been transferred to a new holder may remain on the market until the expiry date, but for no longer than 18 months from the date of the decision approving the transfer, in accordance with the data from the original marketing authorisation.

Instructions for submitting the request referred to in paragraph 1 of this Article and the supporting documentation shall be published by the Institute on its official website.

Article 82

A marketing authorisation shall cease to be valid upon the expiry of the authorised period, at the request of the marketing authorisation holder, or upon issuance of a revocation decision.

The Institute shall suspend, revoke, or amend a marketing authorisation if it determines that:

1) the medicinal product is harmful or lacks therapeutic efficacy;
2) the risk-benefit balance is not favourable;
3) the qualitative and quantitative composition of the medicinal product does not correspond to the documentation;
4) the authorisation was granted based on incomplete or inaccurate data;
5) particulars supporting the application in terms of Article 34, Article 35, Article 36, Article 38 and Article 40 of this Law are incorrect or have not been amended in accordance with Article 63 of this Law, or the conditions referred to in Articles 56, 59 or 61 of this Law are not met, or the controls referred to in Article 139 paragraph 2 of this Law have not been carried out;
6) manufacturing and testing were not conducted in compliance with this Law, or for a category of preparations or all preparations where any one of the requirements laid down in Article 92 is no longer met;
7) the product placed on the market does not conform to the terms of the granted marketing authorisation.

The provision of the paragraph 2 item 5 of this Article shall also apply in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to Article 32 item 4), or where controls are not carried out in compliance with the control methods described Article 34 item 9) of this Law.

Therapeutic efficacy is considered insufficient if it is established that the intended therapeutic outcomes cannot be achieved with the medicinal product.

The Institute shall revoke a marketing authorisation ex officio if:

1) the medicinal product has not been placed on the market in Montenegro within three years after the granting of the authorisation;
2) the product was placed on the market but has not been available for three consecutive years.

In the case referred to in paragraph 5 of this Article, the Institute shall inform the Ministry or the state administration body responsible for veterinary affairs of its intention to revoke the marketing authorisation, and they may, for reasons of public health protection, propose the Institute not to revoke the authorisation.

A medicinal product whose marketing authorisation has ceased to be valid may remain on the market until the expiry date and maximum 18 months, provided the authorisation did not cease due to issues related to quality, safety, or efficacy.

A medicinal product whose marketing authorisation has ceased to be valid may no longer be manufactured or imported as of the date the authorisation ceases to be valid.

Article 83

The Institute shall, without delay, publish on its website information on granted marketing authorisations together with the approved summaries of product characteristics, package leaflets and specific obligations or conditions under which conditional marketing authorisations have been granted, including the deadlines for the fulfilment of such obligations or conditions, as well as information on marketing authorisations that have ceased to be valid.

6. Verification of compliance with requirements

Article 84

The applicant is obliged, during the marketing authorisation procedure, to provide evidence that a manufacturer without a registered seat in Montenegro complies with the requirements of the GMP guidelines.

Compliance with the requirements from paragraph 1 of this Article shall be proven by submitting a document conformity assessment with GMP guidelines (hereinafter: GMP certificate), issued by the competent authority of an EEA Member State or EUMRA, or by a GMP conformity assessment carried out by the Institute.

By way of derogation from paragraph 2 of this Article, based on a risk assessment of potential non-compliance of the manufacturer with GMP guidelines, the Institute may decide to carry out an inspection to verify compliance with the GMP requirements set out in paragraph 1 of this Article and issue a GMP certificate.

7. Classification of medicinal products

Article 85

In the procedure for issuing a marketing authorisation, the Institute shall determine the dispensing regime of the medicinal product, classifying it as medicinal product subject to

medical prescription or a medicinal product not subject to medical prescription, based on established criteria.

In the procedure for granting, renewal or variation of a marketing authorisation, the Institute may determine sub-categories for medicinal products which are available on medical prescription only, as follows:

1) medicinal products subject to renewable or non-renewable medical prescription;
2) medicinal products subject to special medical prescription;
3) medicinal products subject to restricted medical prescription, reserved for use in certain specialised areas.

The Institute shall publish a list of medicinal products that are subject to medical prescription in Montenegro on its official website.

The list referred to in paragraph 3 shall be updated every 12 months.

Upon becoming aware of new facts, the Institute shall review and, if necessary, amend the classification of the medicinal product, in accordance with the prescribed criteria.

If the Institute approves a change in classification based on significant preclinical or clinical studies, those study results may not be used in support of another applicant's or marketing authorisation holder's request for a classification change for a product containing the same active substance within 12 months of the first reclassification.

The Institute shall notify the European Commission annually about changes to the list referred to in paragraph 3 of this Article.

A person authorised to prescribe medicinal products under the law may not be the owner or co-owner of a pharmacy.

It is prohibited to dispense or sell a medicinal product contrary to the prescription regime established in the marketing authorisation.

A person who dispenses or sells a medicinal product contrary to paragraph 1 of this Article shall have their license temporarily revoked by the competent chamber, in accordance with the law.

The criteria for classification of medicinal products, the manner of prescribing and dispensing, and the content and format of the medical prescription shall be prescribed by the Ministry.

Article 86

A medicinal product may be used off-label, i.e., for indications, doses, routes of administration, or patient age groups not specified in the labelling or summary of product characteristics.

A medical specialist in the relevant field may prescribe a medicine for off-label use if:

1) based on professional and scientific knowledge, they conclude the product is safe and appropriate for the patient;
2) they possess sufficient experience-based evidence of the product's safety and efficacy for the intended indication.

In the case described in paragraph 2, the prescribing physician shall bear responsibility for the off-label use and for monitoring the patient's treatment.

8. Mutual recognition procedure and decentralised procedure

Article 87

If, in the case of the issuance of a medicinal product authorisation in more than one Member State of the European Union, an application is submitted to the Institute, and the applicant requests that Montenegro be the reference state, the Institute shall prepare a report on the assessment of the medicinal product documentation.

In the case referred to in paragraph 1 of this Article, the applicant shall submit to the Institute identical documentation on the medicinal product submitted in other Member States of the European Union.

The documentation referred to in paragraph 2 of this Article shall include the data referred to in Articles 34, 35, 36 and 38 of this Law, as well as a list of the Member States of the European Union in which the application was submitted.

If, at the time of submitting the application referred to in paragraph 1 of this Article, a medicinal product authorisation has already been issued in Montenegro as the reference state, the medicinal product authorisation holder may submit a request to the Institute to prepare a new assessment report on the medicinal product documentation or, if necessary, to update the existing report.

The Institute shall prepare the report referred to in paragraph 4 of this Article within 90 days from the date of receipt of the complete application and submit it, along with the approved summary of product characteristics, package leaflet and labelling, to the other Member States of the European Union participating in the medicinal product authorisation procedure and to the applicant.

If, at the time of submitting the application referred to in paragraph 1 of this Article, a medicinal product authorisation has not been issued, the applicant requesting that Montenegro be the reference state may submit a request to the Institute to prepare a draft assessment report on the medicinal product documentation, as well as draft summary of product characteristics, package leaflet and labelling.

The Institute shall prepare the report referred to in paragraph 6 of this Article within 120 days from the date of receipt of the complete application and submit it to the other Member States participating in the medicinal product authorisation procedure and to the applicant.

Upon receipt of the notification from other European Union Member States participating in the medicinal product authorisation procedure, by which those states approve the assessment report of the medicinal product documentation, the summary of the medicinal

product characteristics, the package leaflet and the labelling, the Institute, in the case where Montenegro is the reference state, shall record the agreement of all Member States participating in the medicinal product authorisation procedure and shall inform the applicant thereof.

The Institute shall issue a decision on the issuance of a medicinal product authorisation, in accordance with the approved report on the assessment of the medicinal product documentation, the summary of the medicinal product characteristics, the package leaflet and the labelling, within 30 days from the date of recording the agreement referred to in paragraph 8 of this Article.

In the case where Montenegro is another Member State of the European Union participating in the medicinal product authorisation procedure, the Institute shall submit the notification approving the report assessment of the medicinal product documentation, the summary of the medicinal product characteristics, the package leaflet and the labelling to the reference Member State within 90 days from the date of receipt of the documentation referred to in paragraphs 2 and 3 of this Article.

Article 88

If the Institute, due to a possible serious risk to human health, cannot approve the assessment report of the medicinal product documentation, the summary of product characteristics, the package leaflet and the labelling within the period referred to in Article 87, paragraph 10 of this Law, it shall explain in detail the reasons for disagreement to the reference Member State, other European Union Member States participating in the procedure for issuing a medicinal product authorisation and to the applicant.

The Institute shall, without delay, submit the reasons for disagreement to the CMDh.

The Institute shall determine the possible serious risk referred to in paragraph 1 of this Article in accordance with the guidelines of the European Commission.

If Montenegro is the reference State, and within 60 days from the date of submission of the reasons for disagreement referred to in paragraph 1 of this Article the European Union Member States reach an agreement, the Institute shall record the agreement, issue a medicinal product authorisation and inform the applicant thereof.

If, in the case referred to in paragraph 4 of this Article, no agreement is reached, the Institute shall, without delay, inform the EMA, for the purpose of conducting further proceedings in accordance with the relevant regulations of the European Union, to submit to it a detailed report on the reasons for the failure to reach an agreement between the European Union Member States, as well as to submit that report to the applicant.

After submitting the report referred to in paragraph 5 of this Article to the applicant, the Institute shall, without delay, submit to the EMA the documentation referred to in Article 87, paragraphs 1 and 2 of this Law.

In the case referred to in paragraph 5 of this Article, if the Institute has acknowledged and approved the assessment report of the medicinal product documentation, the draft summary of the medicinal product characteristics, the package leaflet and the labelling, it may, at the

request of the applicant, issue a medicinal product authorisation without waiting for the outcome of the proceedings before the EMA and regardless of the outcome of that proceedings.

Article 89

The provisions of Article 88, paragraphs 5, 6, and 7 of this Law shall not apply to homeopathic medicinal products registered through the simplified registration procedure.

The provisions of this Law relating to the MRP and DCP shall not apply to homeopathic medicinal products referred to in Article 43 paragraph 1 of this Law.

IV MANUFACTURE AND IMPORTATION OF MEDICINAL PRODUCTS FOR HUMAN USE

Article 90

Manufacturing of a medicinal product is a public service obligation.

Manufacturing of a medicinal product in Montenegro shall be carried out only by a legal or natural person holding a manufacturing authorisation, issued by the Institute in accordance with this Law.

The manufacturing authorisation may cover the entire manufacturing process or individual stages thereof, as well as operations such as division, packaging, and labelling.

A manufacturing authorisation shall also be issued for:

1) medicinal products intended for clinical trials or exclusive export;
2) importation of medicinal products from third countries.

A manufacturing authorisation is not required for the preparation, division, and labelling of a medicinal product intended exclusively for distribution to the patient when performed by a pharmacist in a pharmacy or by another person in accordance with the law.

If the manufacturer does not carry out quality control independently but outsources this activity to another entity, that entity does not need a manufacturing authorisation, but shall hold a valid GMP certificate in accordance with this Law.

Article 91

The manufacture of a medicinal product is prohibited if:

1) the medicinal product has not been granted a marketing authorisation;
2) the activity is performed by a person without a manufacturing authorisation;
3) the medicinal product is not manufactured in accordance with the granted manufacturing authorisation;
4) the medicinal product lacks appropriate quality control documentation;
5) the medicinal product is falsified.

Article 92

An application for a manufacturing authorisation shall be submitted to the Institute.

The application shall be accompanied by:

1) a list of medicinal products and pharmaceutical forms which are to be manufactured;
2) the name and registered address of the manufacturer, including all manufacturing and/or quality control sites;
3) a description of the manufacturing process or part thereof, including procedures for division, packaging, and labelling of the medicinal product for which the authorisation is requested;
4) evidence that appropriate premises and equipment are in place for the manufacturing, quality control, and storage of medicinal products, in accordance with this Law;
5) evidence that at least one qualified person referred to in Article 98 of this Law is employed;
6) other relevant information necessary for obtaining the manufacturing authorisation, in accordance with this Law.

Article 93

The Institute shall issue a decision on the application for a manufacturing authorisation within 90 days of receipt of a complete application.

If the application is incomplete, the Institute shall inform the applicant and set a deadline to rectify the deficiencies.

The Institute may request additional information about the data submitted under Article 92 of this Law, including details concerning the Qualified Person.

In cases referred to in paragraphs 2 and 3 of this Article, the period referred to in paragraph 1 shall not include the time required for the applicant to provide the requested data, calculated from the date the Institute makes the request until the date the data are submitted.

Article 94

The provisions of Articles 61, 62 and 63 of the Regulation 536/2014, shall apply to authorised investigational medicinal products only as regards any modification of such products not covered by the marketing authorization

Article 95

The Institute shall grant a manufacturing authorisation only after verifying compliance prescribed conditions through an inspection carried out in accordance with this Law.

The manufacturing authorisation shall apply exclusively to the medicinal products, pharmaceutical forms, and manufacturing sites specified in the application.

The manufacturing authorisation may be granted with specific conditions in order to ensure the fulfilment of obligations defined either at the time of granting the authorisation or at a later date.

In cases referred to in paragraph 3, the manufacturer shall fulfil the specified conditions within the timeframe set by the Institute and shall inform the Institute upon completion.

If the manufacturer fails to meet the conditions referred to in paragraph 3, the Institute shall revoke the manufacturing authorisation.

Manufacturing authorisation for medicinal products containing narcotic drugs and psychotropic substances shall be issued in accordance with this and a special law.

Article 96

The manufacturer is responsible for the quality, of the medicinal product being produced.

This responsibility also applies to the manufacturer responsible for batch release and to the marketing authorisation holder.

The holder of the manufacturing authorisation shall ensure at minimum and in accordance with the scope of the manufacturing authorization:

1) to have at his disposal employed qualified person responsible for batch release;
2) to have at his disposal employed person responsible for manufacturing and a person responsible for quality control, both meeting the qualification requirements prescribed with this his Law;
3) to dispose only those medicinal products for which a valid marketing authorisation has been issued, unless otherwise provided by this Law;
4) to give prior notice to the Institute of any changes he may wish to make to manufacturing conditions from Article 92 of this Law, and the Institute shall, in any event, be immediately informed if the qualified person is replaced unexpectedly;
5) unrestricted access for the Institute and, where applicable, the competent authority of an EU Member State, to the manufacturing premises;
6) to enable to the qualified person
7) independence in performing their duties, and all necessary resources to ensure such independence;
8) use of only those active substances that:
    - are manufactured in compliance with GMP guidelines for active substances,
    - are distributed in accordance with GDP guidelines for active substances,
    - originate from manufacturing and distribution sites that are subject to audit, conducted either by the holder themselves or by another party on their behalf under a contract, without prejudice to the holder's legal responsibility under this Law;
9) immediate notification to the Institute and the marketing authorisation holder if the manufacturer becomes aware of, or suspects, falsification of medicinal products covered by the manufacturing authorisation, regardless of whether they were lawfully or unlawfully distributed;

10) verification that the manufacturers, importers, and wholesalers from whom active substances are procured are registered with the Institute, or with the competent authority of the EU Member State where they are established;
11) verification of the authenticity and quality of active substances and excipients.

The holder of the manufacturing authorisation shall ensure that excipients are of suitable quality for use in medicinal products by ascertaining appropriate GMP guidelines, assessed through a formalised risk assessment in accordance with applicable guidelines. Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects.

The holder of the manufacturing authorisation shall document the measures taken pursuant to paragraph 4 of this Article.

The holder of the manufacturing authorisation shall ensure that the relevant Good Manufacturing Practices defined under paragraph 4 are implemented and maintained.

Article 97

The manufacturer shall:

1) operate in compliance with the manufacturing authorisation, GMP guidelines, and GDP guidelines;
2) ensure that the manufacturing process of a medicinal product with a marketing authorisation is carried out in line with the approved documentation submitted during the authorisation procedure;
3) regularly review manufacturing methods in light of scientific and technological advancements;
4) establish and implement an effective pharmaceutical quality assurance system, involving the active participation of management and staff across different departments.

An importer of a medicinal product shall demonstrate that the imported product from third countries is manufactured in accordance with standards that are at least equivalent to the GMP standards established in the European Union, and that the product is manufactured by authorised manufacturers.

Article 98

The manufacturer shall employ at least one qualified person in accordance with the conditions referred to in Article 99 of this Law, on a full-time basis, permanently and continuously at his disposal.

The qualified person shall possess a relevant university degree in pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology, and have appropriate practical experience.

If the manufacturer is a natural person who meets the qualifications in paragraph 2, they may personally perform the duties of the qualified person responsible for batch release.

The Institute shall verify whether the person referred to in paragraph 1 of this Article meets the requirements referred to in paragraphs 1 and 2 of this Article and shall enter the person in the register of qualified persons.

The detailed educational and practical experience requirements for the qualified person, as well as the conditions and method of conducting the verification referred to in paragraph 4 of this Article, shall be prescribed by the Institute, with the approval of the Ministry.

Article 99

The qualified without prejudice to his relationship with the holder of the manufacturing authorization, shall ensure that:

1) each batch of a medicinal product manufactured in Montenegro has been manufactured and quality controlled in compliance with this Law and in accordance with the requirements of the marketing authorisation;
2) in the case of medicinal product is coming from third countries, irrespective of whether the product has been manufactured in the EU, each batch undergoes complete qualitative and quantitative analysis of all active substances, as well as all other tests or checks necessary to ensure compliance with the requirements of the marketing authorisation.

In the case of medicinal products intended to be placed on the Montenegrin or EU market, the qualified person shall ensure that safety features are affixed on the outer packaging in accordance with this Law.

The batches of medicinal products which have undergone quality control from paragraph 1 and 2 of this article in an EU Member State, and is already placed on the EU market, shall be exempt from the controls in Montenegro, provided that a control report signed by the qualified person of that Member State is submitted.

In the case of medicinal products imported from a third country where appropriate arrangements have been made by the EU with the exporting country to ensure that manufacturer of the medicinal product applies standards of good manufacturing practice at least equivalent to those laid down by EU and that quality control is performed in the exporting country, the qualified person in Montenegro may be relieved from conducting quality control.

In all cases and particularly where the medicinal products are released for sale, the qualified person shall, simultaneously with the actions taken, keep records that each production batch has been manufactured and controlled in compliance with paragraphs 1 to 4 of this Article, or record it in another appropriate manner.

The manufacturer and the qualified person shall retain the records, or appropriate documentation referred to in paragraph 5 of this Article for a minimum of five years, and make it available to the Institute upon request.

Article 100

The manufacturer shall promptly notify the Institute of any changes in the location of manufacturing, quality control or batch release, as well as any changes to the qualified person responsible for batch release, or persons responsible for manufacturing or quality control, including significant changes to premises or equipment.

The manufacturer shall also investigate and document, and promptly notify the Institute of, any deviations in the manufacturing process or any other event that may raise doubts about the quality, safety, or efficacy of the medicinal product.

In the cases referred to in paragraphs 1 and 2, the Institute may suspend or prohibit manufacturing and wholesale distribution, or order a recall of the product from the market, in accordance with this Law.

The manufacturer shall, upon the Institute's request, submit a report on manufacturing activities, stock levels, and sales volume for each individual medicinal product (per packaging) in Montenegro.

The report from paragraph 4 constitutes a trade secret, while aggregated data on total medicine sales shall be publicly available.

The manufacturer or holder of the manufacturing authorisation shall ensure continuous supply of the market with medicinal product in accordance with manufacturing authorisation.

The Institute shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of specific viral contamination.

In the case referred to in paragraph 7 of this Article, manufacturers shall notify the Institute of the method used to reduce or eliminate pathogenic viruses that may be transmitted by medicinal products derived from human blood or human plasma.

In the case referred to in paragraph 7 of this Article, the Institute may submit samples of the bulk product and/or medicinal product for testing to a laboratory designated for that purpose, either during the examination of the application in accordance with Article 53, paragraphs 2 to 5 of this Law or after the authorisation for the medicinal product has been granted.

Article 101

If a holder of the manufacturing authorisation requests a change in any of the particulars referred to in Article 92 paragraph 2 of this Law, he shall submit a request to the Institute to amend or supplement the manufacturing authorisation.

If the request referred to in paragraph 1 of this Article is incomplete, the Institute shall inform the applicant and set a deadline to rectify the deficiencies.

The Institute may request additional information concerning the particulars referred to in Article 92 of this Law and regarding the qualified person responsible for batch release.

The Institute shall decide on the request referred to in paragraph 1 within 30 days of receipt of a complete application.

By way of derogation from paragraph 4 of this Article, in justified cases, the time limit for the decision may be extended by an additional 60 days.

In the cases referred to in paragraphs 2 and 3, the time limits in paragraphs 4 and 5 shall exclude the period between the Institute's request for additional data and the applicant's response.

If the approved change in the data referred to in paragraph 1 of this Article requires a change in the authorisation, the Institute shall issue a new manufacturing authorisation and update the Register of manufacturers.

If the approved change in the data referred to in paragraph 1 of this Article does not require a change in the authorisation, the Institute shall approve the change by written notification.

Article 102

A decision that a manufacturing authorisation shall cease to be valid may be issued upon the request of the manufacturer, or ex officio.

The Institute may, by decision, suspend or revoke a manufacturing authorisation, or suspend or revoke a marketing authorisation, if the manufacturer:

1) does not conduct manufacturing in accordance with the terms of the authorisation, or no longer fulfils the conditions laid down in this Law;
2) fails to comply with obligations imposed at the time of granting or after the granting of the manufacturing authorisation within the prescribed timeframe;
3) does not have a valid GMP certificate in accordance with this Law;
4) in other justified cases, as prescribed by law.

In addition to the measures under Article 131 of this Law, the Institute may temporarily suspend the manufacture or import of medicinal products from third countries or suspend or revoke the manufacturing authorisation for a group of medicinal products or all medicinal products, in case of non-compliance with Articles 95, 96 paragraph 3, 99 and 139 paragraph 2 of this Law.

Upon adoption of the decision referred to in paragraphs 2 and 3, the manufacturing authorisation or marketing authorisation shall cease to be valid either temporarily or permanently, as specified in the decision.

Article 103

The Institute, with the approval of the Ministry, shall prescribe the detailed conditions, content of the application, and supporting documentation required for the issuance of a manufacturing authorisation.

Article 104

The manufacture of active substances used as starting materials in the manufacture of medicinal products includes both total and partial manufacturing process, or the import of an active substance used as starting materials (materials from which the active substances are produced or derived, in accordance with this Law), as well as processes of dividing up, packaging or presentation prior to its incorporation into a medicinal product, including repackaging or re-labelling.

Article 105

A legal or natural person established in Montenegro engaged in the manufacture, import, or distribution of active substances shall be registered in the Register of manufacturers, importers, and distributors of active substances.

The application for registration referred to in paragraph 1 shall be submitted to the Institute no later than 60 days before the planned start of the activity referred to in paragraph 1 of this Article.

The application referred to in paragraph 2 of this Article shall include at least:

1) the name and address of the applicant, including business name or, where applicable, full name and permanent address;
2) data on the active substances which are to be imported, manufactured or distributed;
3) particulars regarding the premises and the technical equipment for their activity.

As part of the registration procedure, the Institute may, based on a risk assessment, decide to carry out an inspection and shall notify the applicant in writing within 60 days of receiving a complete application.

In the case referred to in paragraph 4 of this Article, the applicant shall not commence the activity referred to in paragraph 1 of this Article before the inspection has been carried out.

If the Institute does not notify the applicant about the inspection within the period referred to in paragraph 4 of this Article , the applicant may commence the activity.

The Institute shall issue a decision of an approval on the registration or rejection of registration in the register referred to in paragraph 1 of this Article within 60 days from the date of receipt of a complete application, or from the date of the conducted inspection.

The person referred to in paragraph 1 shall communicate annually to the Institute of authority an inventory of the changes to the data in paragraph 3 and shall immediately notify the Institute of any changes that may affect the quality or safety of the active substance.

If the changes may affect the quality or safety of the active substance, the person referred to in paragraph 1 of this Article shall submit a request to amend the registered data.

The Institute shall decide to approve or reject requested changes within 30 days from receipt of a complete application referred to paragraph 9 of this article.

At the request of an interested party with a legitimate legal interest, the Institute shall issue a certificate of the publicly available data entered in the register referred to in paragraph 1 of this Article.

The conditions for the manufacture, import, and distribution of active substances, the content of the application, and amendments to the registration referred to in paragraph 1 of this Article shall be laid down by the Institute, with the approval of the Ministry.

Article 106

The manufacture, import, and distribution of active substances, including those intended for export, shall comply with the GMP guidelines and with GDP guidelines for active substances, as applicable.

The Institute shall assess compliance referred to in paragraph 1 of this Article and issue a GMP certificate or a GDP certificate for active substances in accordance with this Law.

Importation of active substances from third countries may be conducted only if:

1) the active substances have been manufactured in accordance with standards of good manufacturing practice that are at least equivalent to those of the EU; and
2) the active substances are accompanied by a written confirmation from the competent authority of the exporting third country stating that of the following:
    - the standards of good manufacturing practice applicable to the manufacturing site of the exported active substance are at least equivalent to those laid down in EU.
    - the manufacturing site concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU;
    - in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Institute and/or the EU.

This written confirmation referred to in paragraph 3 item 2 of this Article shall be without prejudice to the obligations set out in the article 34 and article 96 paragraph 3 item 7 and paragraphs 4, 5, and 6 of this Law.

The confirmation requirement referred to in paragraph 3 item 2 shall not apply to third countries which are on the list of countries for which the European Union has determined that the legislative framework, control and inspection measures applied to active substances ensure a level of public health protection that is at least equivalent to the level of public health protection in the European Union. .

By way of derogation from paragraph 3 item 2 of this Article and if it is necessary to ensure the availability of medicinal products, and the competent authority of an EU Member State has inspected the manufacturing site and confirmed compliance with GMP guidelines, the Institute may allow import without written confirmation, provided that the GMP certificate is still valid and that the Member State did not require such confirmation.

In the case referred to in paragraph 6 of this Article, the Institute shall communicate it to the Commission.

Article 107

The Institute shall assess compliance with GMP guidelines for the manufacture of medicinal products and active substances in Montenegro and shall issue a GMP certificate for each manufacturing site, quality control site, and site of batch release.

The compliance assessment referred to in paragraph 1 of this Article shall be carried out through inspections, in accordance with the law and the Compilation of Union Procedures on Inspections and Exchange of Information, based on applications submitted by manufacturers and the annual inspection plan prepared by the Institute by the end of the current calendar year for the next.

The Institute shall issue a GMP certificate within 90 days from the last day of the inspection, provided that all requirements under this Law are fulfilled.

The period referred to in paragraph 3 of this Article does not include the time required for the applicant to provide the Institute with the requested information, that is, the period from the day the Institute requests additional information from the applicant until the day such information is submitted.

GMP certificates, as a rule, are issued for a period of up to three years from the last day of inspection.

If non-compliance with the GMP guidelines is identified, the Institute may suspend or revoke the GMP certificate, or issue a statement of non-compliance.

The translated Compilation from paragraph 2 of this article shall be published on the Institute's official website.

Manufacturers of medicinal products or active substances shall obtain prior approval from the Institute for any foreign inspection of the manufacturing site aimed at verifying GMP compliance.

The Institute may require a manufacturer established in a third country to undergo a good manufacturing practice inspection, without prejudice to any arrangements concluded between Montenegro and that third country.

Importers of veterinary medicinal products shall ensure, prior to placing such products on the market in Montenegro, that the manufacturer established in a third country holds a certificate of good manufacturing practice issued by a competent authority, or, where Montenegro has concluded an arrangement with that third country, an equivalent confirmation.

Article 108

The Institute may conduct extraordinary inspections to assess compliance, in addition to the regular inspections from Article 107 paragraph 1 of this Law.

Extraordinary inspections may be carried out ex officio or upon request, in cases such of a suspicion of quality or safety issues with the medicinal product or active substance; adverse event reports or manufacture errors and in other circumstances that may affect the quality or safety of the medicinal product.

Following such extraordinary inspections, the Institute may suspend or revoke a GMP certificate or issue a statement of non-compliance with GMP guidelines.

Article 109

The manufacturing authorisation, GMP certificate, GMP compliance report, statement of non-compliance with GMP guidelines, registration certificate from the Register of Manufacturers, Importers, and Distributors of Active Substances, as well as the GDP certificate for active substances, shall be issued using the standardised templates.

Templates referred to paragraph 1 of this article are established by the EU and EMA acts and published on the Institute's official website, in both Montenegrin and English.

Article 110

The Institute shall maintain an electronic register of issued manufacturing authorisations (hereinafter: Register of manufacturers).

Upon request of the manufacturer or another legal or natural person with a legitimate legal interest, the Institute shall issue a certificate on publicly available the data held in the Register of manufacturers.

Article 111

The Institute shall publish on its official website:

1) information on registered manufacturers, importers, and distributors of active substances;
2) regularly updated GMP guidelines, GMP guidelines for active substances, GDP guidelines for active substances, and guidelines on formal risk assessment in accordance with the applicable European Union guidance;
3) data on issued, suspended, or revoked manufacturing authorisations;
4) data on issued, suspended, or revoked GMP certificates;
5) data on GDP certificates for active substances.

The information referred to in items 1, 3, and 4 of paragraph 1 of this Article shall be entered by the Institute into the EudraGMDP database.

Article 112

At the request of the manufacturer, the exporter or the authorities of an importing third country, the Institute shall certify that a manufacturer of medicinal products is in possession of the manufacturing authorization.

When issuing certificates from paragraph 1 of this Article the Institute shall comply with the following conditions:

1) it shall have regard to the prevailing administrative arrangements of the World Health Organization;

2) for medicinal products intended for export which are already authorized in Montenegro, it shall supply the summary of the product characteristics as approved in accordance with Article 69 of this Law.

When the manufacturer is not in possession of a marketing authorization he shall provide the Institute with a declaration explaining why no marketing authorization is available.

Article 113

The provisions of this Law concerning manufacture shall apply mutatis mutandis to the importation of medicinal products from third countries.

V WHOLESALE DISTRIBUTION AND BROKERING

Article 114

The distribution of medicinal products is a public service obligation and it is conducted as wholesale distribution and retail distribution.

Wholesale distribution includes procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public.

Wholesale distribution is subject to the possession of an authorisation to engage in activity as a wholesaler in medicinal products, stating the premises located on their territory for which it is valid, and it may be performed by:

1) legal or natural persons established in Montenegro who hold a wholesale distribution authorisation (hereinafter: wholesaler);
2) manufacturers established and authorised in Montenegro, for medicinal products covered by the manufacturing authorization.

Wholesale is carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorized or entitled to supply medicinal products to the public.

At the request of the Commission or any Member State, the Institute shall provide all appropriate information concerning the individual authorisations which they have granted under paragraph 3 of this Article.

Only medicinal products that have been granted a marketing authorisation or registered in accordance with this Law, as well as medicinal products referred to in Article 30 of this Law, may be included in wholesale distribution in Montenegro.

The wholesale distribution of donated or humanitarian aid medicinal products is also considered wholesale distribution.

Retail distribution includes dispensing and sale of medicinal products directly to public.

Retail distribution shall be conducted in accordance with special legislation.

Article 115

Wholesale distribution of a medicinal product is prohibited if:

1) the product does not have a marketing authorisation, or has not been granted import approval in accordance with this Law;
2) the product was manufactured by a person without a manufacturing authorisation;
3) the distributor does not hold a wholesale distribution authorisation issued in accordance with this Law;
4) the product is not labelled in accordance with this Law;
5) the shelf life has expired, or a quality defect has been identified indicating that risk outweighs benefit under this Law;
6) the product is falsified;
7) the product is sold through sale at distance.

The Institute shall take all necessary measures to prevent the placing on the market and entry into the supply chain of medicinal products found within the European Union that have been imported but are not intended for placing on the market within the European Union, and for which there is suspicion of falsification.

The Institute shall organise meetings with competent authorities, healthcare institutions, patient associations, and, where necessary, with officials and inspectors of EU Member States, in order to make publicly available all information about measures taken to prevent and combat falsified medicinal products.

Article 116

A wholesaler shall carry out wholesale distribution in accordance with the wholesale distribution authorisation and GDP guidelines.

Possession of an authorization to engage in activity as a wholesaler in medicinal products shall not release from the obligation to possess a manufacturing authorization and to comply with the conditions prescribed by this Law, even where the manufacturing or import business is secondary.

A wholesaler may entrust specific wholesale distribution activities to another authorised wholesaler.

Transportation activities may also be entrusted to a legal or natural person who is not a wholesaler, but who is registered for that activity in accordance with the law and complies with GDP guidelines.

The Institute shall enter information on wholesale distribution authorisations into the EudraGMDP database.

A manufacturer or wholesaler may import medicine samples, substances, or other materials necessary for the marketing authorisation procedure, based on the opinion of the Institute, in accordance with this Law.

Article 117

The Institute shall decide on the application for a wholesale distribution authorisation within 90 days from the date of receipt of a complete application.

In the procedure of issuing wholesale distribution authorisation, the Institute may conduct the inspection supervision.

If the application is incomplete, the Institute shall notify the applicant in writing and specify a deadline for rectifying the deficiencies.

The time period referred to in paragraph 1 of this Article shall exclude the period during which the applicant is responding to the Institute's request for additional data.

Article 118

In order to obtain the distribution authorization, applicants shall fulfil the following minimum requirements:

1) they shall have suitable and adequate premises, installations and equipment, so as to ensure proper conservation and distribution of the medicinal products;
2) employment of a person responsible for wholesale distribution;
3) other qualified personnel;
4) fulfilment of any additional requirements under this Law.

The person responsible for wholesale distribution is accountable for the implementation of GDP guidelines.

This person shall have a university degree in pharmacy.

The wholesaler shall conclude a full-time employment contract with the person responsible for wholesale distribution and ensure their continuous and permanent availability.

The requirements under paragraph 4 of this Article shall also be met by customs warehouses storing medicinal products, operating in accordance with customs legislation.

The Institute shall issue an opinion on whether the conditions under paragraph 5 are fulfilled.

Article 119

Holders of the wholesale distribution authorization shall fulfil the following minimum requirements:

1) they shall make the premises, installations and equipment referred to in Article 118 paragraph 1 item 1, accessible at all times to the persons responsible for inspecting them in accordance with this Law;
2) they shall obtain their supplies of medicinal products only from persons who are themselves in possession of the wholesale distribution authorisation or from authorised manufacturers;
3) they shall supply medicinal products only to persons who are themselves in possession of the distribution authorization or who are authorized to dispense medicinal products in Montenegro under a separate law;
4) they shall verify that the medicinal products received are not falsified by checking the safety features on the outer packaging and through other means, in accordance with this Law;
5) they shall have an emergency plan which ensures effective implementation of any recall from the market ordered by the Institute, or carried out in cooperation with the authorised manufacturer or marketing authorization holder for the medicinal product concerned;
6) they shall keep records either in the form of purchase/sales invoices or on computer, or in any other form, giving for any transaction in medicinal products received, dispatched or brokered at least the following information: date, name of the medicinal product, quantity received, supplied or brokered, name and address of the supplier or consignee, as appropriate, batch number of the medicinal products at least for products bearing the safety features in accordance with this Law;;
7) they shall keep the records referred to in item 6 of this paragraph during inspections, available to the Institute, for inspection purposes, for a period of five years;
8) they shall comply with GDP guidelines;
9) they shall maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;
10) they shall immediately inform the Institute, health inspectorate, and, where applicable, the marketing authorisation holder, of medicinal products they receive or are offered which they identify as falsified or suspect to be falsified.

If a wholesaler procures a medicine from another wholesaler, they shall verify compliance with GDP guidelines, including verifying whether the supplying wholesaler holds a valid wholesale distribution authorisation.

If the wholesaler procures medicinal products from a manufacturer or importer, they shall verify that the manufacturer/importer holds a valid manufacturing authorisation.

If the wholesaler procures medicinal products through brokering, they shall verify that a natural or legal person carrying out brokering activities (hereinafter: broker) meets the requirements set out in this Law.

Article 120

In addition to the requirements of this Law, any person performing wholesale distribution of medicinal products derived from blood, radiopharmaceuticals, immunological medicinal products or medicinal products containing narcotic drugs and psyhotropic substances, shall comply with the special provisions laid down in a special law.

Wholesale distribution of medicinal products containing narcotic drugs shall be conducted in accordance with this and the relevant special law.

Article 121

Persons who, in accordance with a special law, carry out pharmacy activities in Montenegro may offer for sale at distance over the internet non-prescription medicinal products, whereby they are obliged to submit the following data to the Institute: name and surname, or the name of the person, address of the place where the medicinal products are sold, date of commencement of sales activities, website used for that purpose and other information necessary for the identification of the website in question.

The medicinal products referred to in paragraph 1 of this Article shall be approved in the Member State of destination.

The website referred to in paragraph 1 of this Article shall contain at least the following: contact details of the Institute, website of the Institute with data on legal and natural persons offering medicinal products for sale at distance and a common logo in the form prescribed for the European Union, clearly displayed on each website related to the offer of medicinal products for sale at distance and the website providing the list of persons offering medicinal products for sale at distance.

The Institute's website shall contain the following: information on national regulations governing the sale at distance of medicinal products via the Internet, including information on differences in the classification and conditions for dispensing medicinal products that may exist between the Member States of the European Union, information on the purpose of the common logo, a list of persons selling medicinal products via Internet, general information on the risks associated with medicinal products sold illegally to the public via unauthorized information social services and the address of the EMA website with information on the sale at distance of medicinal products.

More detailed conditions for sale at distance of medicinal products via the Internet shall be prescribed by the Institute, with the approval of the Ministry.

Article 122

Persons authorised to perform wholesale distribution of medicinal products under this Law, as well as the marketing authorisation holder shall ensure adequate and continuous supply of medicinal products to entities authorised to supply or dispense medicinal products in Montenegro, in order to meet patient needs.

The wholesale distribution authorisation holder shall, for the purpose of protecting the health and life of patients, ensure the supply of medicinal products to healthcare institutions at

their request, within the shortest possible time frame, depending on the availability of the medicinal product and in accordance with its wholesale distribution authorisation.

Authorised wholesalers and marketing authorisation holders shall maintain sufficient stocks of medicinal products, and timely initiate procurement, importation, and quality control certification to avoid interruptions in the medicine supply chain.

Persons authorised to perform wholesale distribution of medicinal products in accordance with this Law, as well as the marketing authorisation holder, shall, depending on the availability of the medicinal product and in accordance with its wholesale distribution authorisation, be obliged, upon request of the Ministry and within the specified timeframe, to supply any other authorised medicine in Montenegro, as well as medicinal products referred to in Articles 29, 30, or 31 of this Law.

The marketing authorisation holder, regardless of whether they are the distributor of the medicinal product or not, shall be required to keep records of all batches, quantities, and distributors of the medicinal product placed on the market in Montenegro.

Article 123

The Institute shall not impose on a holder of a wholesale distribution authorisation issued by an EU Member State any obligation related to the supply of persons authorised to supply or dispense medicinal products, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities, particularly in terms of any public service obligation.

The supply referred to in paragraph 1 of this Article shall be carried out for the purpose of public health protection, in accordance with the rules on free movement of goods and market competition.

Article 124

For all supplies of a medicinal product, the wholesaler shall attach a document that includes at least the following information:

1) the date of delivery;
2) the name and pharmaceutical form of the medicinal product;
3) the quantity supplied;
4) the name and address of the supplier and consignor of the medicinal product;
5) batch number of the medicinal products at least for products bearing the safety features in accordance with this Law.

The Ministry shall take appropriate measures to ensure that persons authorised to supply or dispense medicinal products to end users in accordance with the law are able to provide information that makes it possible to trace the distribution path of every medicinal product.

The Ministry may take appropriate measures requiring wholesalers, healthcare institutions, and persons authorized to dispense medicinal products to end users to comply with all requirements necessary for monitoring the distribution chain for each medicinal product.

Article 125

Persons brokering medicinal products may engage in medicinal product brokering if they have their residence or headquarters in an EU Member State and are registered in the Register of Brokers in accordance with this Law.

Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a marketing authorisation granted pursuant to Regulation (EC) No 726/2004 or by the competent authorities of a Member State in accordance with the Directive 2001/83/EC.

The application for registration shall be submitted to the Institute and shall include in particular: the name and surname or company name of the applicant, business name and address of residence or headquarters, as well as contact information in the European Union that allows the competent authority to precisely identify, locate, communicate with, and supervise the applicant.

The provisions of Article 119 paragraph 1 points 5 to 10 of this Law shall apply mutatis mutandis to brokers.

During the registration procedure, the Institute may carry out an inspection, and shall inform the applicant in writing within 60 days of receiving a complete application.

In the case referred to in paragraph 5 of this Article, the applicant may not commence brokering activities until the inspection is completed.

If the Institute does not notify the applicant about an inspection within the period referred to in paragraph 5, the applicant may begin their brokering activity.

After the inspection, the Institute shall issue a decision on entry into the Register referred to in paragraph 1 of this Article or refusal of it within 60 days.

The Institute may carry out an inspection at any time in accordance with Article 346 of this Law and the law governing inspection supervision.

The broker shall promptly notify the Institute of any change in the data referred to in paragraph 3 of this Article.

The broker may only broker medicinal products that have been granted marketing authorisation in accordance with this Law and shall comply with GDP guidelines relating to brokers.

If the broker fails to operate in accordance with this Law, the Institute may prohibit their activity and remove the broker from the register referred to in paragraph 1 of this Article, and shall inform them accordingly.

Upon request of the broker or another natural or legal person with a legitimate legal interest, the Institute shall issue a certificate containing the data recorded in the Register referred to in paragraph 1 of this Article.

Article 126

The Institute shall verify GDP compliance of wholesale distribution operations and issue a GDP certificate (hereinafter: GDP certificate) confirming compliance with the GDP guidelines.

GDP compliance verification referred to in paragraph 1 of this Article shall be conducted through inspections, in accordance with the law and the Compilation of Union Procedures on Inspections and Exchange of Information, and based on applications submitted by wholesalers and the annual inspection plan prepared by the Institute by the end of the current calendar year for the following one.

The Institute shall issue the GDP certificate within 90 days from the last day of the inspection, provided all legal requirements are fulfilled in accordance with this Law.

GDP certificates are typically issued for a period of up to five years.

If the compliance assessment reveals non-conformities, the Institute may suspend or revoke the GDP certificate, or issue a statement of non-compliance with GDP guidelines.

Article 127

Following the issuance of the GDP certificate, the Institute may carry out extraordinary GDP compliance inspections as referred to in Article 126 paragraph 1 of this Law.

Extraordinary inspections may be conducted either ex officio or upon request, in the event of: a report of suspected issues concerning the quality or safety of the medicinal product or active substance, a report of an incident or error in wholesale distribution of medicinal products or active substances, or any other situation that may raise doubts about or affect the quality and safety of the medicinal product.

Based on the findings of such extraordinary inspections, the Institute may suspend or revoke the GDP certificate, or issue a statement of non-compliance with GDP guidelines.

Article 128

The wholesale distribution authorisation, GDP certificate, GDP compliance report, and statement of non-compliance with GDP guidelines shall be issued using standardised templates.

Templates referred in paragraph 1 of this article are established by the European Union and the EMA acts and shall be published on the official website of the Institute, in both Montenegrin and English.

The detailed conditions for conducting wholesale distribution, including certain wholesale operations, delegation of specific wholesale activities, content of the application for a wholesale distribution authorisation and supporting documentation, and the method of issuing the wholesale distribution authorisation and GDP certificate, shall be prescribed by the Institute, with the approval of the Ministry.

Article 129

If there is a change in the conditions covered by the wholesale distribution authorisation, the wholesaler shall submit a request to amend or supplement the authorisation to the Institute.

If the request referred to in paragraph 1 is incomplete, the Institute shall notify the applicant and set a deadline to rectify the deficiencies.

The Institute shall decide on the request referred to in paragraph 1 of this Article within 30 days from the date of receipt of a complete application.

The time limit referred to in paragraph 3 of this Article shall exclude the period between the Institute's request for additional information and the applicant’s submission of the required data.

Article 130

A wholesale distribution authorisation shall cease to be valid upon request by the wholesaler or by decision to revoke the authorisation.

The Institute may suspend or revoke the wholesale distribution authorisation if the wholesaler:

1) does not conduct wholesale distribution in accordance with the issued authorisation or fails to submit a request for amendment in accordance with this Law;
2) no longer meets the conditions for wholesale distribution under this Law;
3) fails to rectify, within the specified timeframe, any deficiencies or non-conformities identified by the Institute;
4) does not fulfil the obligation of continuous supply of medicinal products for which the wholesale authorisation was granted, in accordance with the authorisation;
5) does not hold a valid GDP certificate in accordance with this Law;
6) distributes falsified medicinal products, or fails to notify the Institute and the marketing authorisation holder of suspected or confirmed falsification.

If the Institute revokes a wholesale distribution authorisation in accordance with paragraph 1 of this Article, it shall notify the customs authorities.

In the case referred to in paragraph 1 of this Article, the Institute shall, without delay, inform the EU Member States and the European Commission.

If the Institute determines that a wholesaler holding a wholesale distribution authorisation issued by another EU Member State no longer meets the conditions under which the authorisation was granted, it shall immediately notify the European Commission and that Member State.

Competent authority of the EU Member State that issued wholesale distribution authorisation referred to in paragraph 5 of this Article shall, upon taking necessary measures, inform the Institute and the European Commission of the decisions taken and the reasons for those decisions.

Article 131

The Institute shall take all appropriate measures to prohibit the placing on the market of a medicinal product and to withdraw a medicinal product from the market, if it determines that:

1) the medicinal product is harmful;
2) it lacks therapeutic efficacy;
3) the risk-benefit balance is not favourable;
4) the qualitative or quantitative composition of the product does not correspond to the data provided in the submitted documentation;
5) quality control of the product, its intermediates, or its composition has not been performed, or any other condition related to the granting of the manufacturing authorisation has not been fulfilled.

The Institute may limit the prohibition or withdrawal referred to in paragraph 1 to specific batches of the medicinal product.

Exceptionally, for a medicinal product that has been prohibited or withdrawn from the market in accordance with paragraphs 1 and 2 of this Article, the Institute may, during a transitional period, allow continued supply to patients already undergoing treatment with that product.

Article 132

A wholesaler who is not the marketing authorisation holder and is not in a contractual relationship with the marketing authorisation holder, and who intends to import a medicinal product from another EU Member State, shall notify the marketing authorisation holder in Montenegro and the Institute of their intention.

In the case referred to in paragraph 1 of this article, if the product is not authorised under the CP, the wholesaler shall submit a request for authorisation for parallel import to the Institute.

In the case referred to in paragraph 1 of this article, if the medicinal product is authorised under the CP, the wholesaler shall submit the notification to the marketing authorisation holder and the EMA.

In the case referred to in paragraph 3 of this article, the wholesaler shall notify the Institute of the intended parallel wholesale distribution no later than 15 days before the medicinal product is brought into Montenegro.

The Institute shall issue the authorisation for parallel import within 90 days from the date of receipt of a complete application.

During the authorisation procedure, the Institute may request additional documentation or justification, specifying a deadline for submission.

The period from paragraph 5 of this article shall exclude the time from when the Institute requests additional documentation or justification until the applicant submits it.

The provisions of paragraphs 5, 6, and 7 of this article shall apply mutatis mutandis in the case of amendments to the parallel import authorisation.

The costs of issuing or amending the authorisation for parallel import shall be borne by the applicant or holder of the authorisation.

A fee shall be payable to the EMA for checking that the conditions laid down in EU legislation on medicinal products and in the marketing authorisations are observed.

The Institute, shall prescribe the detailed conditions for parallel import and wholesale distribution under parallel import, the content of the request and accompanying documentation under paragraph 2, and the content of the authorisation for parallel import with the approval of the Ministry.

Article 133

The provisions of Article 114 paragraph 3 and Article 119 paragraph 1 item 3 of this Law do not apply to the export of medicinal products to third countries.

In cases of direct receipt of medicinal products from a third country that are not imported, Article 119 paragraph 1 points 2 and 4 of this Law shall not apply.

In the case referred to in paragraph 2 of this Article, the wholesaler shall ensure that medicinal products are procured only from entities that hold a wholesale distribution authorisation or are authorised to supply medicinal products in accordance with the laws of the third country.

Where the wholesaler supplies medicinal products to an entity in a third country, they shall ensure that delivery is made only to persons authorised for wholesale distribution or supply of medicinal products under the laws of that country.

The provisions of Article 124 paragraphs 1 and 2 of this Law shall apply to the supply of medicinal products to entities holding a wholesale distribution authorisation or authorised to supply medicinal products to the public in accordance with the regulations of third countries.

Article 134

The Institute shall establish and maintain the Register of issued, suspended, and revoked wholesale distribution authorisations (hereinafter: Register of wholesalers).

The Institute shall enter data from the Register of wholesalers into the EudraGMDP database.

Upon request of a wholesaler, importer, or another legal or natural person with a legitimate legal interest, the Institute shall issue a certificate containing the data held in the Register of wholesalers and the Register of importers.

Article 135

The Institute shall publish on its official website:

1) information on issued, suspended, and revoked GDP certificates;
2) information on issued, suspended, and revoked wholesale distribution authorisation;
3) regularly updated GDP guidelines, in accordance with the applicable guidelines of the European Union.

The Institute shall enter the data referred to in paragraph 1, item 1 of this Article into the EudraGMDP database.

Article 136

The Institute State shall take all the appropriate measures to ensure that decisions authorizing marketing, refusing or revoking a marketing authorization, cancelling a decision refusing or revoking a marketing authorization, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the EMA forthwith.

The marketing authorisation holder is obliged to notify the Institute forthwith of any action taken by the holder to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action. The marketing authorisation holder shall in particular declare if such action is based on any of the grounds set out in Article 82 or Article 131 paragraph 1 of this Law.

The marketing authorisation holder shall also make the notification pursuant to paragraph 2 of this Article in cases where the action is taken in a third country and where such action is based on any of the grounds set out in Article 82 or Article 131 paragraph 1 of this Law.

The marketing authorisation holder shall furthermore notify the EMA where the action referred to in paragraph 2 or 3 of this Article is based on any of the grounds referred to in Article 82 or Article 131 paragraph 1 of this Law.

The Institute shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 of this Article which may affect the protection of public health in third countries is forthwith brought to the attention of the World Health Organization, with a copy to the EMA.

Article 137

A person entering or leaving Montenegro may carry with them only those medicinal products necessary for personal use, or for the use of a minor or legally incapacitated family member travelling with them, or for the use of an animal travelling with them, in a quantity not exceeding a six-month supply, depending on the nature and duration of the illness affecting the person or animal.

When entering or leaving Montenegro, the person referred to in paragraph 1 shall present to the customs authority appropriate medical documentation proving that the medicine is for personal use by them, or the accompanying person or animal.

If the person is carrying medicinal products containing narcotic drugs, the provisions of the special law on controlled substances shall apply.

The person referred to in paragraph 1 of this Article may not receive the necessary medicinal products by mail or courier service.

VI QUALITY CONTROL OF MEDICINAL PRODUSTS FOR HUMAN USE

Article 138

The Institute may, either ex officio or upon request, perform quality control of a medicinal product to determine whether it meets the prescribed quality standards. This may be done through laboratory testing (hereinafter: laboratory control), and/or assessment of quality documentation (hereinafter: documentation control).

Laboratory control shall be carried out in accordance with the applicable European Pharmacopoeia, other recognised pharmacopoeias, validated analytical methods, or magistral formulas.

Documentation control is performed by assessing the appropriate batch documentation.

The quality of the medicinal product shall be established, recorded, and demonstrated at each stage of its manufacture and distribution, in accordance with the GMP guidelines.

Article 139

The Institute may perform laboratory control:

1) before placing the medicinal product on the market, including:
   – during the marketing authorisation procedure;
   – for the first batch after the marketing authorisation is granted;
   – in the context of renewals or variations of the marketing authorisation;
   – as mandatory testing of each batch of immunological medicinal products and blood- or plasma-derived medicinal products before being released into free circulation unless, in the case of a batch manufactured in another Member State, the competent authority of that Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications;
2) on products already placed on the market, including:
   – random sampling at least once during the validity period of the marketing authorisation or at least once every five years;
   – testing of each imported batch of medicinal products;
   – quality control of immunological medicinal products and medicinal products derived from human blood and human plasma;
   – as part of addressing identified issues on the market;
3) on magistral and galenic preparations.

The wholesaler and/or marketing authorisation holder, as well as manufacturer shall, upon request of the Institute, provide valid certificates of quality control for each batch of the

medicinal product and/or active substances, excipients, or intermediates, in accordance with Article 34 paragraph 1 item 9 of this Law.

For the purposes of the testing referred to in item 1, item 4 of this Article, the Institute may request from the manufacturer the manufacturing and control protocol, signed by the qualified person responsible for batch release.

The Institute may conduct quality control of any medicinal product if deemed necessary to ensure proper quality, provided that manufacturers and wholesalers are not put in unequal position.

Laboratory control shall be performed in accordance with the good practices for pharmaceutical quality control laboratories.

For specific quality controls the Institute may engage an OMCL or another authorised laboratory, and upon receiving the results, the Institute shall issue a certificate.

The results of laboratory control shall be considered confidential business information, except in cases where public disclosure is necessary to protect public health.

Article 140

When the Institute intends to conduct laboratory testing under Article 139 paragraph 1 item1 indent 4 of this Law—i.e., before placing a batch of an immunological medicinal product on the market to protect human and animal health—it shall notify the EU Member States where the product is authorised, as well as the European Directorate for the Quality of Medicines (EDQM).

The laboratory control from the paragraph 1 of this Article shall include all tests performed by the manufacturer on the finished product, in accordance with the documentation required by this Law.

By way of exception of paragraph 2 of this Article, the laboratory control may include only justified tests agreed between the EU Member States, and, where necessary, the EDQM.

For immunological veterinary medicinal products authorised via the centralised procedure (CP), the laboratory control may include only justified tests after obtaining the approval of the EMA.

The Institute shall notify the EU Member States where the medicinal product is authorised, the EDQM, the marketing authorisation holder, and, where necessary, the manufacturer, of the test results referred to in paragraph 1 of this Article.

If the batch of the immunological medicinal product is not compliant with the manufacturer’s manufacturing and control protocol or with the specifications listed in the marketing authorisation, the Institute shall take measures in accordance with the Law against the marketing authorisation holder and, if necessary, the manufacturer, and shall notify the EU Member States where the product is authorised.

The Institute recognises the OCABR certificate.

Article 141

The manufacturer and wholesaler shall enable the Institute to collect the necessary number of samples of medicinal products for the purpose of laboratory testing.

The costs of laboratory testing, including sample collection, shall be borne by the applicant for the quality control (i.e. marketing authorisation applicant, marketing authorisation holder, wholesaler, pharmacy, or veterinary establishment).

By way of exception of paragraph 2 of this Article, the cost of quality control referred to in Article 139 paragraph 1 item 2 indent 1 of this Law shall be borne by the Institute, or by the legal or natural person that submitted a request for testing to the competent inspectorate or the Institute, from the second time onward within a five-year period, provided it is confirmed that the product complies with the required quality standards.

Article 142

The Institute is obliged to issue a certificate of the performed quality control within 60 days from the day of sampling by the Institute, or the receipt of a complete request for quality control of the medicine, unless otherwise stipulated by this law.

In the case of documentation control, the Institute is obliged to issue a certificate of quality control performed within 30 days calculated from the date of receipt of the required batch documentation.

In the case of laboratory control referred to in Article 139, paragraph 6 of this Law, the Institute is obliged to issue a certificate of quality control within 120 days from the date the sample is provided to the engaged testing body.

In the case when the Institute is conducting laboratory control of each batch of medicine for vaccines, serums, toxins, allergens, medicinal products from blood and blood plasma, the Institute is obliged to issue a certificate of performed quality control within 60 days from the day of receiving the medicine samples.

If it is necessary to carry out laboratory control of starting materials and drug intermediates in the process of issuing a marketing authorisation for a medicinal product, as well as laboratory control in the process of renewing a marketing authorisation for a medicinal product, i.e. variations, the Institute is obliged to issue a certificate of quality control performed within 60 days from the date of receipt of the complete request.

In the deadline from paragraphs 1, 2, 4 and 5 of this article, the time required for the applicant to submit the requested data to the Institute is not counted, that is, the time from the day when the Institute requests additional data from the applicant to the date of delivery of that data.

Article 143

If, on the basis of quality control, it is determined that the medicinal product does not meet the required quality standard, the Institute shall issue a certificate of analysis confirming

the non-conformity and adopt a decision on suspension, prohibition, and withdrawal of the product batch from the market, taking all appropriate measures in accordance with this Law.

Article 144

The contents of the request for conducting quality control of a medicinal product and the accompanying documentation, the detailed manner of conducting quality control, the contents and issuance of the certificate, as well as the content and procedure for implementing necessary measures in the quality control process, shall be prescribed by the Institute, with the approval of the Ministry.

Article 145

The Institute shall establish a system to prevent any medicinal product posing a health risk from reaching the patient.

The system referred to in paragraph 1 of this Article includes the receipt and management of information regarding medicinal products suspected of being falsified, and information about quality defects in medicinal products.

This system referred to in paragraph 1 of this Article also enables the recall of a medicine or batch by the marketing authorisation holder and the recall of medicinal products from the market at the request of the Institute, from all relevant supply chain participants both during and outside working hours, including the recall from patients who have received the affected product, with the involvement of healthcare professionals when necessary.

Healthcare and veterinary professionals who come into contact with a medicinal product or patient/user, and legal or natural persons involved in manufacturing or wholesale distribution, are obliged to immediately notify the Institute in writing if they become aware of a quality defect.

In cases of suspected or confirmed falsified medicinal products, those referred to in paragraph 4 of this Article shall immediately notify the Institute, the competent inspection authority, the Administration, and the marketing authorisation holder.

If there is a doubt that medicinal products referred to in paragraph 1 pose a serious threat to public health, the Institute shall inform the entities listed in paragraph 3 of this Article and send an rapid alert to all EU Member States.

In case that these medicinal products referred in the paragraph 6 of this Article are already available to patients, the Institute shall, within 24 hours, issue an urgent public notice containing sufficient information about the suspected quality defect or falsified medicinal product and the risks involved, to ensure patients discontinue their use.

Patients or users of medicinal products may submit complaints to the Institute, upon which the Institute shall take appropriate measures in accordance with this Law.

The Institute shall keep records on complaints referred to in paragraph 8 of this Article.

VII. PHARMACOVIGILANCE OF MEDICINAL PRODUCTS FOR HUMAN USE

Article 146

The Institute and the marketing authorisation holder shall maintain a pharmacovigilance system in accordance with this Law.

The systems referred to in paragraph 1 of this Article shall be maintained in compliance with the on GVP guidelines.

The Institute shall publish the GVP guidelines on its official website.

The detailed conditions and method for managing the pharmacovigilance system referred to in paragraph 1 of this Article shall be prescribed by the Institute, with the approval of the Ministry.

Article 147

The Institute shall operate a pharmacovigilance system used to collect information on the risks of medicinal products as regards patients' or public health, particularly adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from off-label use, and adverse reactions associated with occupational exposure.

Through the pharmacovigilance system, the Institute shall conduct scientific assessment of all collected information, consider options for risk minimisation and prevention measures, and, where necessary, undertake appropriate regulatory actions in accordance with this Law.

The Institute shall conduct regular audits of its pharmacovigilance system referred to in paragraph 1 of this Article and submit an audit report to the European Commission every two years.

The Institute is obliged, at the request of the European Commission and under the coordination of the EMA, to participate in international harmonisation and standardisation of technical measures related to pharmacovigilance.

Article 148

As part of the pharmacovigilance system, the Institute shall:

1) maintain a record of all adverse reaction reports related to medicinal products occurring in Montenegro, reported by patients or healthcare professionals
2) involve patients and healthcare professionals in follow-up on submitted reports, as appropriate;
3) take measures to encourage reporting of suspected adverse reactions by patients and healthcare professionals, in collaboration with health professional chambers and patient or consumer organisations, as needed;
4) ensure that suspected adverse reactions may be reported through the official web-portal or by other means, with particular facilitation of reporting by patients;

5) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of adverse reaction reports;
6) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary;
7) ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in Montenegro which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product and batch number;
8) take measures to ensure that a marketing authorisation holder who fails to discharge its pharmacovigilance obligations under this Law is subject to effective, proportionate, and dissuasive penalties;
9) cooperate with marketing authorisation holders in identifying duplicate adverse reaction reports;
10) enter appropriate suspected adverse reaction reports related to medicinal products occurring in Montenegro into the WHO Collaborative Centre database (Uppsala Monitoring Centre).

For reports submitted by a marketing authorization holder the Institute may involve the marketing authorisation holder in the follow-up of the reports.

Marketing authorisation holders, patients, and healthcare professionals shall participate in the reporting of suspected adverse reactions in Montenegro.

In the case of medicinal products referred to in Article 29 of this Law, the wholesaler shall participate in the monitoring of suspected adverse reaction reports instead of the marketing authorisation holder.

The management of funds intended for pharmacovigilance activities, communication networks, and market surveillance shall remain under the constant supervision of the Institute, to ensure the independence of these activities.

Fees paid by the marketing authorisation holder under this Law shall not influence the independence of the Institute in exercising its pharmacovigilance responsibilities.

Article 149

The Institute shall establish and maintain an official website linked to the EMA's website.

The website of the Institute shall publish at least the following:

1) public assessment reports on the evaluation of medicinal product documentation, including summaries;
2) summaries of product characteristics and patient information leaflets;
3) RMP summaries for authorised medicinal products;
4) a list of medicinal products under additional monitoring;
5) information on how healthcare professionals and patients may report suspected adverse reactions, including electronic reporting options.

The Institute may assign additional monitoring status to medicinal products authorised in Montenegro which are not listed in the EU list of products under additional monitoring.

Article 150

The Institute shall:

1) electronically submit to the EudraVigilance database all suspected serious adverse reaction reports occurring in Montenegro, within 15 days of becoming aware of them;
2) electronically submit to EudraVigilance all suspected non-serious adverse reaction reports occurring in Montenegro, within 90 days of becoming aware of them;
3) cooperate with the EMA in identifying duplicate reports of suspected adverse reactions;
4) ensure that reports of adverse reactions resulting from medication errors reported to the Institute are available in EudraVigilance and to any authorities, bodies, organisations and/or institutions, responsible for patient safety in Montenegro. It shall also ensure that the authorities responsible for medicinal products in Montenegro are informed of any suspected adverse reactions brought to the attention of any other authority in Montenegro. These reports shall be appropriately identified in the standard forms referred to in Article 25 of Regulation (EC) No 726/2004 .

Marketing authorisation holders shall access suspected adverse reaction reports via the EudraVigilance database.

Until access to EudraVigilance is established, the Institute shall forward reports referred to in points 1 and 2 of this Article to the marketing authorisation holder within the same deadlines.

Article 151

The Institute may entrust certain pharmacovigilance activities specified in this Law to a competent authority of another EU Member State, subject to written approval from that authority.

In the case referred to in paragraph 1 of this Article, the Institute shall notify the European Commission, the EMA, and other EU Member States in writing and shall also publish this information on its official website.

Article 152

The marketing authorisation holder shall:

1) maintain a pharmacovigilance system for conducting scientific evaluation of all information, assessing risk minimisation and prevention measures, and taking appropriate action;
2) perform regular audits of the pharmacovigilance system and record major findings in the Pharmacovigilance System Master File (PSMF), ensuring preparation and implementation of relevant corrective actions.

The data referred to in paragraph 1 item 2 of this Article may be deleted from the PSMF after the corrective actions have been fully implemented.

Article 153

Within the framework of the pharmacovigilance system, the marketing authorisation holder shall:

1) ensure that the qualified person for pharmacovigilance referred to in Article 33 paragraphs 5, 6 and 7 of this Law is permanently and continuously available;
2) ensure that the qualified person for pharmacovigilance in the European Union is permanently and continuously available
3) maintain the PSMF and make it available upon request by the Institute;
4) implement a RMS for each medicinal product;
5) monitor the effectiveness of risk minimisation measures outlined in the RMP or laid down as conditions in the case of a conditional marketing authorisation, authorisation under exceptional circumstances, or an authorisation granted with obligations under this Law;
6) update the RMS and monitor pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance of medicinal products.

The qualified person for pharmacovigilance is responsible for establishing and maintaining the pharmacovigilance system in Montenegro.

The qualified person for pharmacovigilance referred to in paragraph 2 of this Article may also be responsible for pharmacovigilance activities in the European Union, or the marketing authorisation holder may appoint a separate qualified person for pharmacovigilance in the EU.

Qualified person referred to in paragraph 3 of this Article shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the EU pharmacovigilance system.

The marketing authorisation holder shall submit the name and contact details of the EU qualified person to the Institute and the Agency .

Certain pharmacovigilance tasks, including responsibilities of the qualified person for pharmacovigilance, may be contractually delegated to another legal entity, in accordance with GVP guidelines.

In the case referred to in paragraph 6 of this Article, the marketing authorisation holder shall retain responsibility for the accuracy and completeness of the PSMF and for fulfilling all obligations under the pharmacovigilance system.

The marketing authorisation holder shall perform a regular audit of his pharmacovigilance system. He shall place a note concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented.

Once the corrective actions have been fully implemented, the note referred to in paragraph 8 of this Article may be removed.

Article 154

For medicinal products granted marketing authorisation in the European Union before 21 July 2012, the marketing authorisation holder is not required to implement an RMS for each product.

By way of derogation from paragraph 1 of this article, the Institute may require the marketing authorisation holder to implement an RMS if there is a suspicion of risks that may affect the risk-benefit balance of the authorised product.

In the case referred to in paragraph 2 of this Article , the Institute shall oblige the marketing authorisation holder to submit a detailed description of the RMS they intend to establish for that product.

Obligations referred to in paragraphs 2 and 3 of this Article shall only be imposed in justified cases, by written decision and with specified deadlines for submitting the detailed RMS description.

Upon request, the Institute shall allow the marketing authorisation holder to submit written observations on the obligations from paragraphs 2 and 3 of this Article within 30 days from the date of receipt of the request.

The Institute shall decide on the obligation referred to in paragraphs 2 and 3 of this Article on the grounds of a written justification provided by the marketing authorisation holder.

If the Institute confirms the obligation referred to in paragraphs 2 and 3 of this Article, the marketing authorisation holder shall fulfil the obligation and submit a variation application to include the risk minimisation measures in the marketing authorisation as a condition.

Article 155

If the marketing authorisation holder make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal product, they shall notify the Institute at the same time or before to its publication.

The marketing authorisation holder shall ensure that information referred to in paragraph 1 of this Article is presented objectively and does not mislead.

Before publication, the marketing authorisation holder shall also submit the information referred to in paragraph 1 of this Article to the EMA and the European Commission.

Unless urgent public announcements are required for the protection of public health, the Institute shall inform other EU Member States, the EMA, and the European Commission at least 24 hours before publication.

In cooperation with the EMA, the Institute shall publish information on the safety of active substances contained in medicinal products authorised in Montenegro and at least one EU Member State.

The information referred to in paragraphs 4 and 5 of this Article shall be published in accordance with the legislation on personal data protection and confidential business information, unless disclosure is necessary for the protection of public health.

Article 156

The marketing authorisation holder shall:

1) maintain records of all suspected adverse reactions to medicinal products occurring in Montenegro, reported spontaneously by patients or healthcare professionals, or recorded during post-authorisation studies;
2) monitor and collect all information that may influence the risk-benefit assessment of the product and submit such information to the Institute without delay and as soon as possible;
3) until direct reporting to the EudraVigilance database is functional, forward to the Institute all reports of suspected serious adverse reactions occurring in Montenegro within 15 days of receipt;
4) until direct reporting to EudraVigilance is functional, submit to the Institute all non-serious adverse reaction reports occurring in Montenegro within 90 days of receipt;
5) establish a procedure for obtaining accurate and verifiable data necessary for the scientific evaluation of reports under points 3 and 4, and gather additional case information and submit it to the Institute until direct EudraVigilance reporting is functional;
6) until direct reporting to EudraVigilance is functional, upon request by the Institute, submit reports of serious and unexpected adverse reactions that occurred in the EU or in third countries within 15 days of request receipt;
7) maintain records of all suspected adverse reactions occurring in the EU or third countries.

By way of derogation from paragraph 1 item 7 of this Article, suspected adverse reactions occurring within clinical trials shall be recorded and reported in accordance with Article 193 of this Law.

For a medicinal product on the market in Montenegro without marketing authorisation, the obligations under paragraph 1 points 2 to 5 of this Law are assumed by the wholesaler authorised for import.

The marketing authorisation holder shall ensure that the data referred to in paragraph 1 points 1 and 7 of this Article are available at a single location within the EU.

The marketing authorisation holder may not refuse to consider reports of suspected adverse reactions submitted electronically or otherwise by patients or healthcare professionals.

The Institute shall not impose additional obligations on the marketing authorisation holder regarding adverse reaction reporting unless justified by pharmacovigilance-related reasons.

Article 157

The marketing authorisation holder shall electronically report to the EudraVigilance database:

1) all serious adverse reactions occurring in Montenegro, the EU, or third countries within 15 days of becoming aware of them;
2) all non-serious adverse reactions occurring in Montenegro, the EU, or third countries within 90 days of becoming aware of them.

For medicinal products containing active substances included in the EMA list of monitored medical literature, the marketing authorisation holder is not obliged to report reactions described in such literature but shall monitor all other medical literature and report any suspected adverse reactions.

The marketing authorisation holder shall establish a procedure for obtaining accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports and collect additional information to be submitted to the EudraVigilance database.

The marketing authorisation holder shall cooperate with the Institute, EMA, and EU Member States in identifying duplicate adverse reaction reports.

Article 158

The marketing authorisation holder shall pay a fee for the conduct of pharmacovigilance activities carried out by the Institute in accordance with this Law.

Article 159

The marketing authorisation holder shall electronically submit to the Institute and the EMA, PSUR containing:

1) summaries of data relevant for evaluating the benefits and risks of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;
2) a scientific evaluation of the risk-benefit balance based on all available data, including those from clinical trials in unauthorised indications and populations;
3) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder, including an estimate of the population exposed to the medicinal products.

By way of derogation from paragraph 1 of this Article, for marketing authorisations issued for generic or bibliographical applications, traditional herbal medicine registrations, and homeopathic medicine registrations, the marketing authorisation holder shall submit a PSUR only if:

1) it is explicitly required as a condition in the marketing authorisation;
2) it is requested by the Institute or EMA following the granting of the marketing authorisation, due to pharmacovigilance data or the absence of a PSUR for certain active substance.

The assessment reports of the requested periodic safety update reports shall be communicated to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment report for all marketing authorisations for medicinal products containing the same active substance and inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Article 160 paragraph 5 and Article 161 of this Law.

Article 160

The Institute shall determine the frequency of PSUR submission in accordance with the EURD list, during the marketing authorisation procedure.

Frequencies set at EURD list are applicable to products authorised nationally and shall be followed by marketing authorisation holders.

Marketing authorization holders are obliged to be aligned with EU reference dates published and to keep them aligned thereafter, by submitting a variations.

Marketing authorization holder may request determination or changes to frequencies set at EURD list for the following reasons:

1) public health;
2) to avoid a duplication of the assessment;
3) to achieve international harmonisation.

The PSURs submission dates, based on the established frequency, shall be calculated from the date of granting the marketing authorisation.

For medicinal products authorised before 21 July 2012, for which the frequency and dates of PSURs submission of the PSURs are not laid down as a condition to the marketing authorisation, the marketing authorisation holder shall submit PSURs without delay upon request by the Institute, or in accordance with the following frequency:

1) where a medicinal product has not yet been placed on the market, at least every 6 months following authorisation and until the placing on the market;
2) where a medicinal product has been placed on the market, at least every 6 months during the first 2 years following the initial placing on the market, once a year for the following 2 years and at three-yearly intervals thereafter.

The obligation to submit PSURs in accordance with paragraphs 3 and 4 of this Article shall apply until a different frequency or submission date is determined in the marketing authorisation or as per the EURD list.

The provisions of paragraphs 6 and 7 of this Article shall also apply to medicinal products authorised in only one EU Member State, not covered by paragraph 9 of this Article.

If different marketing authorisations have been issued for medicinal products containing the same active substance or the same combination of active substances, the PSUR submission frequency and dates referred to in paragraphs 1, 6, and 7 of this Article may be

changed and harmonised to enable a single assessment of PSUR and determine a Union reference date for submission.

Article 161

The Institute shall assess PSURs to determine whether there are new risks or whether risks have changed or whether there are changes to the risk-benefit balance of medicinal products

Based on the PSUR assessment, the Institute may adopt a decision on suspension or revoking of the marketing authorisation or may request the marketing authorisation holder to initiate a variation procedure in accordance with this Law.

The Institute may participate in the work of the CMDh for joint assessment of PSURs concerning more than one marketing authorisation.

If the outcome of the assessment under paragraph 3 of this Article affects a marketing authorisation granted under this Law, the Institute may, in accordance with the CMDh agreement or the European Commission's decision, adopt a decision on suspension or revoking of the marketing authorisation or require the initiation of a variation procedure under this Law.

Article 162

The Institute, in cooperation with the EMA, shall:

1) monitor the outcomes of risk minimisation measures contained in the RMP and the conditions referred to in Articles 56, 59, or 61 of this Law;
2) assess updates to risk management systems;
3) monitor data in the EudraVigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the risk-benefit balance.

The Institute shall inform the EMA and the marketing authorisation holder when new or changed risks are identified or when there is a shift in the risk-benefit balance.

If the marketing authorisation holder determines that new or changed risks exist, or that the risk-benefit balance has changed, they shall notify the Institute and the EMA.

Article 163

If, based on the evaluation of data from pharmacovigilance activities, there is a suspicion of a safety risk, the Institute shall notify other EU Member States, the European Commission, and the EMA that it:

1) considers the adoption of a decision to suspend or revoke the marketing authorisation;
2) considers prohibiting the supply of the medicinal product;
3) considers refusal of renewal of the marketing authorisation; or
4) is informed by the marketing authorisation holder that, on the basis of safety concerns, the medicinal product has been withdrawn from the market or has taken action to have

a marketing authorisation withdrawn or intends to take such action or has not applied for the renewal of a marketing authorisation.

At the time of notification referred to in paragraph 1 of this Article, the Institute shall give EMA all relevant scientific data and its assessment.

In the case referred to in paragraph 1 of this Article, the Institute shall notify the EU Member States, the European Commission, and the EMA if it considers that a new contraindication, dose restriction, or limitation of indications is required, with a description of the proposed measures and their rationale.

The notifications referred to in paragraphs 1 and 3 of this Article shall serve the purpose of initiating an urgent Union procedure in accordance with applicable EU legislation.

The Institute may, where it is necessary to take urgent action to protect public health, suspend the marketing authorisation and prohibit the use of the medicinal product in Montenegro pending the outcome of the Union procedure referred to in paragraph 4 of this Article, and shall notify the EU Member States, the European Commission, and the EMA within 24 hours.

Article 164

The marketing authorisation holder may conduct non-interventional PASS that involve the collection of safety data from patients and healthcare professionals, either on their own initiative or at the request of the Institute, in accordance with Articles 56 and 61 of this Law.

Provisions of this Article and Articles 165 and 166 1 of this Law are without prejudice to national and EU requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies.

The costs of conducting a non-interventional PASS shall be borne by the marketing authorisation holder.

Non-interventional PASS shall not be conducted in a manner that promotes the use of the medicinal product.

Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.

During the conduct of a non-interventional PASS, the marketing authorisation holder is obliged to monitor the collected data and assess its impact on the risk-benefit balance of the studied medicinal product.

The marketing authorisation holder shall notify the Institute and competent authority of the Member State in which the medicinal product has been authorised of any new information that may impact the risk-benefit balance of the product and shall undertake appropriate measures.

The Institute may require the marketing authorisation holder to submit the protocol and the progress reports of the non-interventional PASS.

The final report of the non-interventional PASS shall be submitted to the Institute within 12 months from the end of data collection.

If the results of the non-interventional PASS affect the marketing authorisation, the Institute shall take appropriate regulatory measures based on the evaluation of the results.

The obligation under paragraph 7 of this Article does not affect the obligation to submit PASS results as part of the PSUR in accordance with Articles 56 and 61 of this Law.

Article 165

For non-interventional PASS conducted in Montenegro and another EU Member State, the marketing authorisation holder shall submit to the Institute, prior to conducting the study, the protocol approved by the PRAC.

Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the PRAC, except for studies to be conducted in only one Member State that requests the study according to Article 61 of this Law.

For studies referred to in paragraph 2 of this Article, the marketing authorisation holder shall submit a draft protocol to the national competent authority of the Member State in which the study is conducted.

Within 60 days of the submission of the draft protocol the national competent authority or the PRAC, as appropriate, shall issue:

(1) a letter endorsing the draft protocol;

(2) a letter of objection, which shall set out in detail the grounds for the objection, in any of the following cases:

- it considers that the conduct of the study promotes the use of a medicinal product;

- it considers that the design of the study does not fulfil the study objectives; or

(3) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Directive 2001/20/EC.

The study may commence only when the written endorsement referred to in paragraph 4 item 1 has been issued.

Where a letter of endorsement as referred to in paragraph 4 item 1 has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol.

The marketing authorisation holder shall submit all substantial amendments to the protocol approved by PRAC to the Institute prior to their implementation.

Upon completion of the non-interventional PASS, the marketing authorisation holder shall submit to PRAC a final study report and summary of results within 12 months, unless PRAC grants an extension or a waiver in writing.

If the results of the PASS impact the marketing authorisation, the holder shall submit a variation application to the Institute.

Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the competent authority of the EU Member State or to the PRAC.

The obligation under paragraph 9 of this Article does not affect the obligation to submit PASS results within the PSUR under this Law.

Article 166

For non-interventional PASS conducted only in Montenegro, in accordance with Article 61 of this Law, the marketing authorisation holder shall submit a draft study protocol to the Institute.

The PASS may commence only after the written approval of the Institute.

Within 60 days from receiving the draft protocol referred to in paragraph 1 of this Article, the Institute shall:

1) issue approval for the protocol;
2) submit a reasoned objection if it considers that the study promotes the use of the product or that the design does not meet the objectives of the study; or
3) notify the marketing authorisation holder that a clinical trial, in accordance with Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, shall be conducted instead.

The marketing authorisation holder shall submit all significant amendments to the non-interventional PASS protocol to the Institute before their implementation, and the Institute shall evaluate them and approve or submit a reasoned objection to the marketing authorisation holder.

In the case referred to in paragraph 4 of this Article, the marketing authorisation holder shall inform Member States in which the study is conducted.

If the results of the non-interventional PASS impact the marketing authorisation in Montenegro, the Institute may suspend or revoke the authorisation or require the holder to submit a variation application.

Article 167

The Institute shall verify compliance of the marketing authorisation holder's pharmacovigilance system with GVP guidelines, in accordance with this Law.

If the Institute determines, based on the results verification referred to in paragraph 1 of this Article, that the marketing authorisation holder does not comply with the GVP guidelines, it shall notify the EU Member States, the EMA, and the European Commission.

Article 168

A healthcare professional shall:

1) notify the Institute, in writing, of any suspected adverse reaction, especially if it is serious or unexpected; in the case of vaccines for human use, the Institute of Public Health of Montenegro shall also be informed;
2) report to the Institute suspected serious adverse reactions within 30 days from the date of becoming aware of them and submit any additional relevant information subsequently, if needed;
3) report to the Institute any suspected serious adverse reaction resulting in death immediately, in writing or by telephone, with subsequent written confirmation;
4) when reporting suspected adverse reactions related to a biological medicinal product, provide, if available, the product name and batch number.

Article 169

A patient may report any suspected adverse reaction to medicinal products or vaccines to the Institute or to the marketing authorisation holder and as regards a minor or a legally incapacitated person, the report may be submitted by a parent, guardian, or other legal representative.

VIII. CLINICAL TRIALS OF MEDICINAL PRODUCTS FOR HUMAN USE

Article 170

A clinical trial may be conducted only if the rights, safety, dignity, and well-being of subjects are protected and prevail over all other interests, and if the design of the trial ensures the generation of reliable and robust data.

The conditions referred to in paragraph 1 of this Article shall be ensured and monitored throughout the duration of the clinical trial.

A clinical trial may commence only after approval for clinical trial conduct has been granted by the Institute.

All clinical trials must be designed, conducted, and reported in accordance with the principles of Good Clinical Practice (GCP).

Clinical trials of gene therapy medicinal products that could lead to modification of the genome of the subject's germline cells shall not be conducted.

Article 171

The provisions of this Law regulating clinical trials do not apply to the application of laws prohibiting or restricting the use of any particular type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of, or derived from such cells, or medicinal products used as abortifacients, or medicinal products containing narcotic substances within the meaning of relevant international conventions in force, such as the 1961 United Nations Single Convention on Narcotic drugs.

Article 172

A clinical trial of a medicinal product may be conducted by a sponsor who has obtained clinical trial authorisation in accordance with this Law.

The clinical trial shall be conducted in a healthcare institution, at the expense and upon request of the sponsor.

A clinical trial may also be conducted at the request of the Ministry or the Institute.

The sponsor is obliged to provide free of charge the investigational medicinal products as well as any medical devices required for their administration, where necessary.

Article 173

A clinical trial shall be subject to scientific and ethical review and shall be authorised in accordance with this Law.

The Ministry shall establish an Ethics Committee as a specific independent body.

The Ethics Committee shall consist of at least five members, of whom at least one member's primary field of interest shall not be in medical sciences, and at least one member shall be independent of the trial site; the remaining members shall be medical professionals.

The ethical review performed by Ethics committee may encompass aspects addressed in Part I of the assessment report for the authorisation of a clinical trial as referred to in Article 6 and in Part II of that assessment report as referred to in Article 7 of the Regulation (EU) 536/2014.

The Ethics Committee shall ensure the protection of the rights, safety, and well-being of subjects enrolled in clinical trials.

The protection of subjects' rights is ensured by issuing an opinion on the clinical trial protocol, the suitability of the investigator, and the appropriateness of conditions, methods, and documents used to inform subjects and obtain informed consent, in a transparent manner.

The costs of the Ethics Committee's work shall be borne by the applicant for clinical trial authorisation.

The Institute shall perform administrative and technical tasks for the Ethics Committee.

One payment for the assessment of the Institute and the Ethics Committee shall be payed by the applicant in accordance with Article 332 of this Law.

Guidelines on the required documentation for obtaining an Ethics Committee opinion shall be published on the websites of the Ministry and the Institute.

The detailed procedure for the work and decision-making of the Ethics Committee, the remuneration for its members, and other matters relevant to its functioning shall be prescribed by the Ministry.

Article 174

The Institute shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a clinical trial conducted on the territory of Montenegro are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.

The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the appropriate published on the web page of the Institute.

The Institute may not require any additional use of the system referred to in paragraph 1 of this Article from the sponsor for low-intervention clinical trials, if any possible damage that could be suffered by a subject resulting from the use of the investigational medicinal product in accordance with the protocol of that specific clinical trial on the territory of the Montenegro is covered by the applicable compensation system already in place.

The investigator shall be a medical doctor or a professionally qualified person appropriate for the clinical trial, who possesses the necessary expertise and experience in treating and caring for patients involved in the trial.

Other individuals involved in conducting the clinical trial shall have the requisite education, training, and experience to perform their duties in the trial.

The premises where the clinical trial is conducted shall be appropriate for clinical trial conduct, in accordance with the requirements of this Law.

Article 175

The application for clinical trial authorisation shall be submitted to the Institute by the sponsor with a headquarters in Montenegro, or by their representative based in Montenegro if the sponsor is foreign.

The applicant referred to in paragraph 1 of this Article shall have a person responsible for the clinical trial in Montenegro, who is permanently available.

The applicant referred to in paragraph 1 of this Article may withdraw the application at any time prior to the Institute’s decision.

Article 176

The Institute shall assess the completeness of the application for clinical trial authorisation within 10 days of its receipt and, if complete, issue a confirmation of receipt to the applicant.

If the application is incomplete, the Institute shall notify the applicant and provide a deadline of up to 10 days to remedy the deficiencies.

Within 5 days of the applicant addressing the deficiencies referred to in paragraph 2 of this Article, the Institute shall issue a confirmation of receipt of a complete application.

If the Institute does not notify the applicant within the time limits referred to in paragraphs 1 and 3 of this Article, the application shall be deemed complete.

If the applicant fails to remedy the deficiencies within the period referred to in paragraph 2 of this Article, the application shall be deemed to have ceased to be valid.

The Institute shall perform a scientific and technical evaluation of the clinical trial documentation and issue an assessment report within 45 days from the date of issuing the confirmation of receipt of a complete application.

By way of derogation from paragraph 6 of this Article, if the clinical trial involves advanced therapy medicinal products or investigational medicinal products obtained using recombinant DNA technology, controlled expression of genes encoding biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells, hybridoma techniques, or monoclonal antibody methods, the Institute may extend the decision period by an additional 50 days to allow expert consultation.

By way of derogation from paragraph 6 of this Article, for the purpose of obtaining additional information from the sponsor and evaluating it in accordance with this Law, the Institute may extend the assessment period by a maximum of 31 days.

In the case referred to in paragraph 8 of this Article, the Institute shall set a deadline of 12 days for the applicant to submit additional information, after which it shall prepare an assessment report within 19 days.

If the applicant fails to submit additional information within the period referred to in paragraph 9 of this Article, the application shall be deemed to have ceased to be valid.

Article 177

The Ethics Committee shall issue a reasoned opinion on the clinical trial within 45 days from the date of receiving the complete application for its opinion.

The provisions of Article 176 of this Law shall apply mutatis mutandis to the determination of application completeness by the Ethics Committee.

The reasoned opinion of the Ethics Committee shall be forwarded without delay to the applicant and the Institute.

Article 178

The Institute shall decide on the application for clinical trial authorisation based on the assessment report referred to in Article 176 paragraph 6 of this Law and the opinion of the Ethics Committee, within five days of receiving the report or opinion.

The Institute shall grant the clinical trial authorisation on the basis of a positive assessment report under Article 176 paragraph 6 and a positive opinion from the Ethics Committee.

Article 179

Employees of the Institute validating and assessing clinical trial applications or substantial amendments of the clinical trial authorisation, as well as members of the Ethics Committee, shall not have conflicts of interest, are independent of the sponsor, of the clinical trial site and the investigators involved and of persons financing the clinical trial, as well as free of any other undue influence.

In order to guarantee independence and transparency, the Institute shall ensure that persons admitting and assessing the application have no financial or personal interests which could affect their impartiality.

Persons referred to in paragraphs 1 and 2 of this Article shall make an annual declaration of their financial interests.

The Institute States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.

At least one layperson shall participate in the assessment.

Article 180

The holder of the clinical trial authorisation shall inform the Ethics Committee and the Institute of all non-substantial modifications and/or amendments related to the clinical trial.

For substantial modifications, the clinical trial authorisation holder shall submit a request for an opinion from the Ethics Committee and a request for approval to the Institute, which shall be submitted simultaneously.

A substantial modification refers to any change or amendment to any aspect of the clinical trial that is likely to have a significant impact on the safety or rights of the subjects, or the reliability and robustness of the data obtained from the clinical trial.

If the application for approval of substantial modifications is incomplete, the Institute shall notify the applicant within six days of receiving the request and shall set a deadline for addressing the deficiencies, which may not exceed ten days.

The Institute shall issue a confirmation of receipt of a complete application within five days from the date of rectification of the deficiencies referred to in paragraph 4 of this Article.

If the Institute does not notify the applicant within the time limits referred to in paragraphs 4 and 5 of this Article, the application shall be deemed complete.

If the applicant fails to submit additional information within the period referred to in paragraph 4 of this Article, the application shall be deemed to have ceased to be valid.

The Institute shall assess the application for approval of substantial modifications within 38 days from the date of receipt of the complete application.

By way of derogation from paragraph 8 of this Article, if the clinical trial concerns advanced therapy medicinal products or investigational medicinal product(s) obtained through recombinant DNA technology, controlled expression of genes encoding biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells, or by hybridoma and monoclonal antibody methods, the Institute may, for the purpose of expert consultation, extend the deadline for preparing the assessment report by 50 days.

By way of derogation from paragraph 8 of this Article the Institute may extend the assessment period referred to in paragraph 5 by a maximum of 31 days to obtain additional information from the sponsor and evaluate it in accordance with this Law.

In the case referred to in paragraph 10 of this Article, the Institute shall set a deadline of 12 days for the applicant to submit additional information, after which it shall prepare the assessment report within 19 days.

If the applicant fails to submit additional information within the period referred to in paragraph 11 of this Article, the application shall be deemed to have ceased to be valid.

Provisions of paragraphs 4 to 12 of this Article shall apply accordingly to the Ethics Committee's opinion procedure.

Article 181

A clinical trial may be conducted only where all of the following conditions are met:

1) the anticipated benefits to the subjects or to public health justify the foreseeable risks and inconveniences and compliance with this condition is constantly monitored;
2) the subjects or his legally designated representative, have been informed in accordance Article 183 of this Law;
3) the rights to physical and mental integrity, to privacy, and protection of personal data of the subject are safeguarded in accordance with applicable data protection legislation;
4) the clinical trial has been designed to involve as little pain, discomfort, fear and any other foreseeable risk as possible for the subjects and both the risk threshold and the degree of distress are specifically defined in the protocol and constantly monitored;
5) the medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, where appropriate, a qualified dental practitioner;
6) the subject or his legal representative has been provided with contact details of the competent authority from which additional information can be obtained, if necessary; and
7) the subject has not been subjected to any undue influence, including of a financial nature.

The Ethics Committee shall pay particular attention to clinical trials conducted on military personnel, detained persons, and persons institutionalised in social or child protection facilities.

Subjects or their legal representatives are not entitled to financial compensation or other financial incentives, except for reimbursement of expenses and loss of earnings directly associated with their participation in the clinical trial.

Article 182

The processing of personal data in clinical trials of medicinal products is carried out in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

Article 183

Informed consent is given by the subject or their legal representative only after:

1) they have been enabled to understand:
   - the nature, objectives, benefits, implications, risks, and inconveniences of the clinical trial;
   - their rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification;
   - the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial;
   - the possible treatment alternatives, including the follow-up measures if the participation of the subject in the clinical trial is discontinued;
2) the information was provided in a comprehensive, concise, clear, relevant, and understandable manner;
3) the information was delivered through a prior interview with a qualified member of the investigation team;
4) he is given information about the applicable damage compensation system, in accordance with applicable laws;
5) he is given information about EU clinical trial number and how results will be made available, if applicable.

The information referred to in paragraph 1 of this Article shall be available in writing to the subject or his legal representative.

The investigator conducting the discussion shall pay special attention to communicating with vulnerable populations and verify that the subject has understood the information.

Informed consent shall be given in writing, dated and signed by both the investigator referred to in paragraph 1 item 3 of this Article and the subject or legal representative.

If the subject is illiterate, informed consent may be given in an appropriate alternative format and documented via audio or video recording in the presence of at least one impartial witness, who shall also sign the consent.

The subject or their legal representative shall be given a copy of the consent document or recording.

The consent shall be stored in accordance with Good Clinical Practice (GCP) guidelines.

Sufficient time shall be allowed for decision-making about participation.

The subject shall be informed of the summary of trial results, regardless of the outcome, and where possible, once summaries become available.

The sponsor may request, at the time of consent, permission to use the subject's data outside the clinical trial protocol for scientific purposes only.

Use of the subject's data outside the clinical trial protocol for scientific purposes only, shall comply with applicable personal data protection legislation.

Informed consent may be withdrawn at any time by the subject or legal representative.

The subject may withdraw from a trial at any time, irrespective of whether they have suffered harm, and without providing reasons, by withdrawing the given informed consent.

Withdrawal of consent does not affect the activities already being already being conducted or the use of data collected prior to the withdrawal.

Article 184

In the case of incapacitated subjects of giving informed consent, who have not given, or have not refused to give, informed consent before the onset of their incapacity, a clinical trial may only be conducted if, in addition to the requirements of Article 181, the following conditions are met:

1) the informed consent of their legally designated representative has been obtained;
2) the incapacitated subjects have received the information referred to in Article 183 paragraph 1 of this Law in a way that is adequate in view of their capacity to understand it;
3) the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing the information referred to in Article 183 paragraph 1 of this Law to refuse participation in, or to withdraw from, the clinical trial at any time, is respected by the investigator;
4) the clinical trial is essential with respect to incapacitated subjects and data of comparable validity cannot be obtained in clinical trials on persons able to give informed consent, or by other research methods;
5) the clinical trial relates directly to a medical condition from which the subject suffers;
6) there are scientific grounds for expecting that participation in the clinical trial will produce:

- direct benefit for the incapacitated subject outweighing the risks and burdens involved; or
- some benefit for the population represented by the incapacitated subject concerned when the clinical trial relates directly to the life-threatening or debilitating medical condition from which the subject suffers and such trial will pose only minimal risk to, and will impose minimal burden on, the incapacitated subject concerned in comparison with the standard treatment of the incapacitated subject's condition.

Incapacitated subjects shall be involved in the consent process to the extent possible.

Article 185

Clinical trials involving minors may be conducted only if, in addition to the requirements of Article 181, the following conditions are met:

1) the informed consent of their legally designated representative has been obtained;
2) the minors been have received the information referred to in Article 183 paragraph 1 in a way adapted to their age and mental maturity and from investigators or members of the investigating team who are trained or experienced in working with children;
3) the investigator respects the explicit wish of the minor, capable of understanding the information referred to in Article 183 paragraph 1 of this Article, to refuse participation in, or to withdraw from, the clinical trial at any time;
4) the clinical trial is intended to investigate treatments for a medical condition that only occurs in minors or the clinical trial is essential with respect to minors to validate data obtained in clinical trials on persons able to give informed consent or by other research methods;
5) the clinical trial either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;
6) there are scientific grounds for expecting that participation in the clinical trial will produce:
   - a direct benefit for the minor concerned outweighing the risks and burdens involved; or
   - some benefit for the population represented by the minor concerned and such a clinical trial will pose only minimal risk to, and will impose minimal burden on, the minor concerned in comparison with the standard treatment of the minor's condition.

The minor shall take part in the informed consent procedure in a way adapted to his or her age and mental maturity.

If the minor reaches the age of majority during the clinical trial, his express informed consent shall be obtained before that subject can continue to participate in the clinical trial.

Article 186

A clinical trial involving pregnant or breastfeeding women may be conducted only if, in addition to the conditions laid down in Article 181 of this Law, the following conditions are met:

1) the clinical trial has the potential to produce a direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, outweighing the risks and burdens involved;
2) if such clinical trial has no direct benefit for the pregnant or breastfeeding woman concerned, or her embryo, foetus or child after birth, it can be conducted only if::
   - a clinical trial of comparable effectiveness cannot be carried out on women who are not pregnant or breastfeeding;
   - the clinical trial contributes to the attainment of results capable of benefitting pregnant or breastfeeding women or other women in relation to reproduction or other embryos, foetuses or children;
   - the clinical trial poses a minimal risk to, and imposes a minimal burden on, the pregnant or breastfeeding woman concerned, her embryo, foetus or child after birth;
3) where research is undertaken on breastfeeding women, particular care is taken to avoid any adverse impact on the health of the child.

Article 187

Exceptionally, informed consent to participate in a clinical trial may be obtained, and information on the clinical trial may be given, after the decision to include the subject in the clinical trial, provided that this decision is taken at the time of the first intervention on the subject, in accordance with the protocol for that clinical trial and that all of the following conditions are fulfilled:

1) due to the urgency of the situation, caused by a sudden life-threatening or other sudden serious medical condition, the subject is unable to provide prior informed consent and to receive prior information on the clinical trial;
2) there are scientific grounds to expect that participation of the subject in the clinical trial will have the potential to produce a direct clinically relevant benefit for the subject resulting in a measurable health-related improvement alleviating the suffering and/or improving the health of the subject, or in the diagnosis of its condition;
3) it is not possible within the therapeutic window to supply all prior information to and obtain prior informed consent from his or her legally designated representative;
4) the investigator certifies that he or she is not aware of any objections to participate in the clinical trial previously expressed by the subject;
5) the clinical trial relates directly to the subject's medical condition because of which it is not possible within the therapeutic window to obtain prior informed consent from the subject or from his or her legally designated representative and to supply prior information, and the clinical trial is of such a nature that it may be conducted exclusively in emergency situations;
6) the clinical trial poses a minimal risk to, and imposes a minimal burden on, the subject in comparison with the standard treatment of the subject's condition.

If the subject is included in a clinical trial under the provisions of paragraph 1 of this Article, to continue participation, informed consent shall be obtained and the following steps taken:

1) regarding incapacitated subjects and minors, the informed consent shall be sought by the investigator from his or her legally designated representative without undue

delay and the information referred to in 183 paragraph 1 shall be given as soon as possible to the subject and to his or her legally designated representative;

2) regarding other subjects, the informed consent shall be sought by the investigator without undue delay from the subject or his or her legally designated representative, whichever is sooner and the information referred to in Article 183 paragraph 1 shall be given as soon as possible to the subject or his or her legally designated representative, whichever is sooner.

If, in the case referred to in paragraph 2, item 2, where informed consent has been obtained from the legally designated representative, informed consent to continue the participation in the clinical trial shall be obtained from the subject as soon as he is capable of giving informed consent.

If the subject or his legal representative does not give consent, he or she shall be informed of the right to object to the use of data obtained from the clinical trial.

Article 188

The sponsor or their representative shall notify the Institute of the following:

1) the start of the clinical trial, within 15 days from the initiation date in Montenegro;
2) the first visit of the first subject, within 15 days from the date of the first subject's first visit in Montenegro;
3) the completion of subject recruitment, within 15 days from the last subject’s enrolment.

In case recruitment is resumed, the procedure from paragraph 1 item 1 of this Article shall apply.

Article 189

The sponsor or their representative shall notify the Institute of:

1) the end of the clinical trial in Montenegro, within 15 days from the completion date;
2) the completion of the clinical trial in all countries where the trial was conducted, within 15 days from the end date in the last country.

Regardless of the outcome of the clinical trial, the sponsor or representative shall submit to the Institute a summary of the clinical trial results and a summary understandable to a layperson within one year from the end of the clinical trial in all participating countries.

By way of derogation from paragraph 2 of this Article, where justified scientific reasons in the clinical trial protocol prevent submission of the summary within one year, the summary shall be submitted as soon as possible.

In the case referred to in paragraph 3 of this Article, the clinical trial protocol shall specify when the results will be submitted, with justification.

If the clinical trial was conducted for the purpose of obtaining a marketing authorisation, the applicant shall, within 30 days from the date of granting or withdrawal of the application, submit to the Institute the summary of the results and the clinical study report.

The sponsor or representative shall notify the Institute of:

1) temporary halt of the clinical trial in any country where clinical trial is conducted for reasons of a change of the risk-benefit balance, within 15 days from the temporary halt, along with the reasons for such action;
2) resumption of the temporarily halt clinical trial from item1 of this paragraph, within 15 days from temporary halt in each participating country, along with the reasons for such action.

If temporarily halt clinical trial referred to in paragraph 6 item 1 of this Article is not resumed within two years, the end of that period or the date of the sponsor's decision not to resume the trial, whichever occurs earlier, shall be considered the trial end date.

In the case of premature termination, the date of termination shall be deemed the end date of the trial.

If the early termination is due to reasons unrelated to the risk-benefit balance, the sponsor or representative shall notify the Institute of the reasons for the action and, where appropriate, subject follow-up measures.

If the clinical trial protocol includes an interim analysis date before completion, and results are available, the summary of those results shall be submitted to the Institute within one year of the interim analysis.

Article 190

The sponsor or their representative shall notify the Institute, without undue delay, and no later than 15 days from the date of temporary suspension or premature termination of the clinical trial, if such actions are taken due to a change in the risk-benefit balance, accompanied by justification and subject follow-up measures.

The resumption of a clinical trial after such suspension referred to in paragraph 1 of this Article shall be considered a substantial modification in accordance with this Law.

Article 191

The sponsor may, by written agreement, delegate certain or all of their duties to another legal or natural person, institution, or organization, however, such delegation does not release the sponsor from their responsibilities, in particular regarding the safety of subjects and the reliability and robustness of the data generated in the clinical trial.

Article 192

The investigator shall:

1) document adverse events or laboratory abnormalities identified in the protocol as critical to the safety evaluation and report them to the sponsor in accordance with the reporting requirements and within the periods specified in the protocol;
2) record all adverse events, and document all adverse events, unless the protocol provides differently, and report to the sponsor or their representative all serious adverse events

occurring to subjects treated by him in the clinical trial, unless the protocol provides differently;

3) report serious adverse events to the sponsor without undue delay but not later than within 24 hours of obtaining knowledge of the events, unless, for certain serious adverse events, the protocol provides that no immediate reporting is required. Where relevant, the investigator shall send a follow-up report to the sponsor to allow the sponsor to assess whether the serious adverse event has an impact on the risk-benefit balance of the clinical trial;
4) notify the sponsor or their representative, of a serious adverse event with a suspected causal relationship to the investigational medicinal product that occurs after the end of the clinical trial in a subject treated by him or her, the investigator shall, without undue delay, report the serious adverse event to the sponsor.

The sponsor or their representative shall keep detailed records of all adverse events reported by the investigator.

Article 193

The sponsor or their representative shall report to the Institute all relevant information on suspected unexpected serious adverse reactions, including:

1) all suspected unexpected serious adverse reactions to investigational medicinal products occurring in that clinical trial, irrespective of whether the suspected unexpected serious adverse reaction has occurred at a clinical trial site in Montenegro, the European Union, or a third country;
2) all suspected unexpected serious adverse reactions related to the same active substance, regardless of pharmaceutical form and strength or indication investigated, in investigational medicinal products used in the clinical trial, occurring in a clinical trial performed exclusively outside of Montenegro, if that clinical trial is sponsored:
   - by that sponsor, or
   - by another sponsor who is either part of the same parent company as the sponsor of the clinical trial, or who develops a medicinal product jointly, on the basis of a formal agreement, with the sponsor of the clinical trial. For this purpose, provision of the investigational medicinal product or information to a future potential marketing authorisation holder on safety matters shall not be considered a joint development;

3) all suspected unexpected serious adverse reactions to investigational medicinal products occurring in any of the subjects of the clinical trial, which are identified by or come to the attention of the sponsor after the end of the clinical trial.

The time-limit for reporting suspected unexpected serious adverse reactions to the Institute by the sponsor or its representative, taking into account the seriousness of the adverse reactions in question is as follows:

1) in the case of fatal or life-threatening suspected unexpected serious adverse reactions, as soon as possible and in any event not later than seven days after the sponsor became aware of the reaction;
2) in the case of non-fatal or non-life-threatening suspected unexpected serious adverse reactions, not later than 15 days after the sponsor became aware of the reaction;

3) in the case of a suspected unexpected serious adverse reaction which was initially considered to be non-fatal or non-life threatening but which turns out to be fatal or life-threatening, as soon as possible and in any event not later than seven days after the sponsor became aware of the reaction being fatal or life-threatening.

To ensure timely reporting, the sponsor or representative may submit an initial incomplete report, followed by a complete report in accordance with this Law.

Article 194

The sponsor, or their representative, shall submit to the Institute an annual safety report for each investigational medicinal product, excluding placebos, used in a clinical trial sponsored by them.

In the case of a clinical trial involving the use of more than one investigational medicinal product, the sponsor or representative may, if provided for in the protocol, submit a single safety report on all investigational medicinal products used in that clinical trial.

The annual safety report referred to in paragraphs 1 and 2 of this Article shall include only aggregated and anonymised data.

The obligation to submit the annual safety report referred to in paragraphs 1 and 2 of this Article covers the reporting period starts with the first authorisation of a clinical trial and ends with the end of the last clinical trial.

If the clinical trial is conducted in multiple countries, the reporting period shall begin with the date of authorisation in the country where the trial first starts, and end with the last trial completion date in the country where the trial ends last.

The Institute may involve the Ethics Committee in the assessment of information from Article 193 and from paragraph 1 of this Article, where necessary.

Safety reporting for auxiliary medicinal products used in the clinical trial shall be conducted in accordance with this Law's provisions on recording, reporting, and evaluation of pharmacovigilance data.

Article 195

The sponsor, or their representative, and the investigator are obliged to ensure that the clinical trial is conducted in accordance with the clinical trial protocol and the principles of Good Clinical Practice (GCP) of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

During the preparation of the clinical trial protocol, the sponsor, representative, and investigator shall apply quality standards and GCP guidelines accordingly.

Article 196

In order to verify that the rights, safety and well-being of subjects are protected, that the reported data are reliable and robust, and that the conduct of the clinical trial is in

compliance with the requirements of this Law, the sponsor, or their representative, shall adequately monitor the conduct of a clinical trial.

The extent and nature of the monitoring shall be determined by the sponsor or representative based on the basis of an assessment that takes into consideration all characteristics of the clinical trial, including the following characteristics:

1) whether the clinical trial is considered low-intervention;
2) the objective and methodology of the clinical trial;
3) the degree of deviation of the intervention from normal clinical practice.

Article 197

The sponsor, or their representative, shall notify the Institute of any serious breach of the provisions of this Law or of the clinical trial protocol applicable at the time of the breach, without undue delay, but no later than seven days from the date they became aware of the breach.

A serious breach under paragraph 1 of this Article means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial.

The sponsor or their representative shall also notify the Institute of any unexpected events which affect the risk-benefit balance of the clinical trial, but are not suspected unexpected serious adverse reactions as referred to in Article 193 of this Law, without undue delay, but no later than 15 days from the date the sponsor became aware of the event.

The sponsor shall submit to the Institute all inspection reports of third country authorities concerning the clinical trial. When requested by the Institute, the sponsor shall submit a translation of the report or of its summary in Montenegrin language.

Where an unexpected event is likely to seriously affect the risk-benefit balance, the sponsor or their representative and the investigator shall take appropriate urgent safety measures to protect the subjects.

The sponsor shall notify the Member States concerned of the event referred to in paragraph 5 of this Article and the measures taken; that notification shall be made without undue delay but no later than seven days from the date the measures have been taken.

Article 198

The provisions of Articles 174, 175 and 180 and Articles 188 to 197 and Article 202 of this Law do not exclude the criminal and civil liability of the sponsor or its representative, the investigator and other persons to whom the investigator has delegated certain tasks.

Article 199

If the Institute, based on justified reasons, determines that the conditions prescribed by this Law are no longer fulfilled, it may:

1) suspend the clinical trial;
2) require the sponsor to modify any aspect of the clinical trial;
3) revoke the clinical trial authorisation.

In the cases referred to in paragraph 1 of this Article, the Institute shall first obtain the opinion of the sponsor, their representative, and/or the investigator, unless urgency precludes this.

The opinion under paragraph 2 of this Article shall be submitted by the sponsor, their representative, or the investigator within seven days of receiving the request.

The sponsor or their representative shall inform the Institute of such measures taken under paragraph 1 of this Article in each country where the clinical trial is conducted, within seven days from the date of the decision.

Article 200

The Institute shall carry out an inspection to verify compliance with the conduct of the clinical trial in accordance with this Law and the most recent version of European Union regulations relating to clinical trial inspections.

The inspection referred to in paragraph 1 of this Article shall include a review of documentation, premises, records, quality assurance mechanisms, and all other resources which the Institute considers to be related to the clinical trial and which may be located at the trial site, at the premises of the sponsor and/or contract trial organization, or at other institutions where the Institute considers it necessary to conduct it.

The inspection from paragraph 1 of this article is carried out by the Institute as follows:

1) at the trial site;
2) in laboratories performing analyses for the clinical trial;
3) at the manufacturing site of the investigational medicinal product;
4) on the sponsor's location or that of contracted parties.

The Institute may accept an inspection report conducted in accordance with GCP guidelines by an EU Member State or a third country where the clinical trial requirements are equivalent to those in the European Union.

Before the inspection referred to in paragraph 1 of this Article begins, the Institute shall inform the applicant for clinical trial authorisation and the investigator.

After the inspection, the Institute shall prepare a report and deliver it to the trial site and the sponsor.

The Institute may exempt non-commercial sponsors from paying fee for the inspection referred to in paragraph 1 of this Article.

Article 201

The application for a non-interventional study shall be submitted to the Institute by the sponsor of the non-interventional study, or their representative.

A non-interventional study is conducted under the following conditions:

1) the medicinal product(s) are prescribed in accordance with their marketing authorisation;
2) the prescription of the product is independent of the decision to include the patient in the study;
3) no additional diagnostic or monitoring procedures are applied; instead, epidemiological methods are used to analyse collected data.

The Institute shall, within 60 days of receiving a complete application, issue a certificate of registration for the non-interventional study.

Non-interventional studies may also be initiated at the request of the Ministry or the Institute.

Article 202

The detailed conditions for conducting clinical trials, the content of the application for clinical trial authorisation, the accompanying documentation, and the content of the clinical trial summary results, as well as the conditions for conducting non-interventional studies, the application content, and related documentation, as well as documentation for the approval or substantial amendments of the clinical trial authorisation shall be prescribed by the Institute, with the approval of the Ministry.

IX. MEDICINAL PRODUCTS PRICING AND CONSUMPTION

Article 203

A medicinal product for which a marketing authorisation has been granted, or import approval has been issued in accordance with Article 29 of this Law, and which is subject to prescription, may be placed on the market only if a maximum wholesale price has been determined in accordance with this Law.

The adjustment of the maximum wholesale prices of medicinal products referred to in paragraph 1 of this Article shall be carried out at least once per year, and more frequently if necessary.

By way of derogation from paragraph 1 of this Article, the Government may adopt a decision to freeze the prices of all or a specific group of medicinal products.

In the case referred to in paragraph 3 of this Article, the Government shall conduct supervision at least once a year in order to determine whether macroeconomic conditions

justify the continuation of the price freeze and shall announce price increases or decreases, if any, within 90 days from the date of commencement of supervision.

Exceptionally, the authorisation holder may submit a request for exemption from the price freeze referred to in paragraph 3 of this Article, with an appropriate statement of the reasons for submitting the request.

The Government shall adopt a reasoned decision on the request referred to in paragraph 5 of this Article and submit it to the applicant within 90 days from the date of submission of the request.

If the information attached to the request referred to in paragraph 5 of this Article is not adequate or is incomplete, the Government shall notify the applicant to supplement it and shall adopt a final decision within 90 days from the date of receipt of additional information.

If the request referred to in paragraph 5 of this Article is approved, the Government shall issue a statement on the approved price increase without delay.

Time-limits referred to in paragraphs 6 and 7 may be extended once, for 60 days, if the number of requests is exceptionally large, of which the applicant shall be notified before the expiry of the original time-limit.

The criteria for determining maximum wholesale prices of medicinal products referred to in paragraph 1 of this Article shall be prescribed by the Government.

Article 204

The marketing authorisation holder, or the wholesaler who submitted a request for import in accordance with Article 29 of this Law, is obliged to submit to the Institute a request for determination of the wholesale price of the medicinal product within 30 days from the date of issuance of the authorisation or import approval, proposing the price of the product.

The Institute shall decide on the request referred to in paragraph 1 of this Article within 90 days of receiving a complete application.

If the application referred to in paragraph 1 of this Article is incomplete, the Institute shall immediately inform the applicant and set a deadline for rectification, which may not exceed 30 days.

The time required for the applicant to submit the requested data is not included in the time period under paragraph 1 of this Article, from the date the Institute requests additional information until the date the applicant submits them.

If the Institute does not issue a decision within the time period specified in paragraph 2 of this Article, the applicant may place the product on the market at the proposed price.

The Institute shall publish and update the list of determined maximum wholesale prices of medicinal products on its website.

The determined maximum wholesale price shall be valid from the date of determination.

The Institute shall submit to the European Commission, at least once a year, the list of products with maximum wholesale prices established for the relevant period.

Article 205

Wholesalers and pharmacies shall submit to the Institute a report on the total value of sales of all medicinal products, as well as on the sales volume of each individual product (by package size) in Montenegro, by 1 May of the current year for the previous calendar year.

The report referred to in paragraph 1 of this Article shall be considered a business secret.

The Institute shall process the data from the report referred to in paragraph 1 and publish on its website aggregate data on total sales of medicinal products in Montenegro.

The report template referred to in paragraph 1 shall be published on the Institute's website.

The Ministry may, as needed and in cooperation with the Institute and the Health Insurance Fund of Montenegro, determine measures for rational use of medicinal products.

X ADVERTISING OF THE MEDICINAL PRODUCTS FOR HUMAN USE

Article 206

Advertising of medicinal products shall mean any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

1) the advertising of medicinal products to the general public;
2) advertising of medicinal products to persons authorised to prescribe or dispense medicinal products;
3) visits by medical sales representatives to persons qualified to prescribe medicinal products;
4) supply of free samples of medicinal products;
5) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal;
6) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;
7) sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, especially covering travel and accommodation costs;

The provisions of this Law concerning advertising shall not apply to:

1) labelling and the accompanying package leaflets,

2) correspondence, possibly accompanied by material of a non- promotional nature, needed to answer a specific question about a particular medicinal product,
3) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims,
4) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.

Advertising of a medicinal product that does not have a marketing authorisation or is not registered under this Law is prohibited.

Provision of scientific information about a product undergoing authorisation in Montenegro at scientific or professional meetings attended by persons authorised to prescribe or dispense medicinal products, shall not be considered advertising, if only the common name is used and the manufacturer is not mentioned.

Advertising may also be conducted as co-promotion by the marketing authorisation holder and one or more legal or natural persons designated by them.

Article 207

All statements made in a medicinal product advertising shall be consistent with the summary of product characteristics.

Advertising shall promote the rational use of the medicine, through objective presentation and without exaggeration of its properties.

Advertising may not mislead the public.

Advertising of a registered homeopathic medicinal product shall only include the information appearing on its labelling, in accordance with this Law.

Article 208

It is prohibited to advertise medicinal products to the general public that:

1) are available on medical prescription only under this Law;
2) contain psychotropic substances or narcotic by international convention, such as the United Nations Conventions of 1961 and 1971
3) are reimbursed from compulsory health insurance funds.

By way of derogation paragraph 1 of this Article, vaccination campaigns conducted by the manufacturer or its representative, which are approved by the Ministry, may be advertised to the general public.

Medicinal products may be advertised to the general public if their composition and intended use have been approved for use without a medical consultation, diagnosis, or prescription, with advice from a pharmacist if necessary.

Distribution of medicinal products to the general public for promotional purposes is strictly prohibited.

Article 209

Advertising of a medicinal product to the general public shall:

1) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;
2) include the following minimum information:
   — the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance,
   — the information necessary for correct use of the medicinal product,
   — an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

By way of derogation paragraph 1 of this Article, advertising of a medicinal product to the general public may include only the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark if it is intended solely as a reminder.

Article 210

Advertising of medicinal products to the general public may not:

1) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
2) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;
3) suggests that the health of the subject can be enhanced by taking the medicine;
4) suggests that the health of the subject could be affected by not taking the medicine, except in approved vaccination campaigns;
5) is directed exclusively or principally targeted at children;
6) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
7) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
8) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
9) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
10) refers, in improper, alarming or misleading terms, to claims of recovery;
11) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

Article 211

Advertising of a medicinal product to persons authorised to prescribe or dispense medicinal products shall include:

1) essential information compatible with the summary of product characteristics;
2) a statement indicating whether the product is subject to medical prescription or can be supplied without a prescription.

The advertising referred to in paragraph 1 of this Article may also include information on the retail price of the medicinal product or the conditions for reimbursement by compulsory health insurance.

The advertising from paragraph 1 of this Article may consist solely of the name of the medicinal product, its INN (if available), or its trademark, if intended solely as a reminder.

Article 212

In addition to the information referred to in Article 211 paragraph 1 of this Article, promotional material intended for persons authorised to prescribe or dispense medicinal products shall also include the date on which it was drawn up or last revised.

All information contained in the promotional material shall be accurate, up-to-date, verifiable and sufficiently complete to enable persons authorised to prescribe or dispense medicinal products to form their own opinion of the therapeutic value of the medicinal product concerned

Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the promotional material shall be faithfully reproduced and the precise sources indicated.

Article 213

A medical sales representative (hereinafter: medical representative) shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicinal products which they promote.

During each visit to persons authorised to prescribe or dispense medicinal products, medical representative shall provide or have available for them, summaries of the product characteristics of each medicinal product they present together, including price information and details regarding reimbursement from compulsory health insurance, where applicable.

Medical sales representatives shall transmit to the scientific service responsible for providing information about the medicinal products placed on the market by the marketing authorisation holder, particularly information regarding adverse reactions reported to them by the persons they visit.

Article 214

Where medicinal products are being promoted to persons qualified to prescribe or dispense them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

By way of derogation from paragraph 1 of this Article, at events organised exclusively for professional or scientific purposes, hospitality may be provided directly or indirectly, provided they are explicitly limited to the main purpose of the event and do not involve individuals who are not healthcare professionals.

Hospitality related to participation in sales events shall be limited to healthcare professionals and may not deviate from the event's main purpose.

Persons qualified to prescribe and dispense medicinal products are prohibited from requesting or accepting incentives that are banned under paragraphs 1 and 3 of this Article.

The provisions of paragraphs 1, 3, and 4 may not affect the implementation of pricing practices or commercial policies regarding prices, margins, or discounts in accordance with applicable legislation.

Article 215

Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

1) the number of samples for each medicinal product each year on prescription shall be limited in accordance with this Law;
2) any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent authorised prescriber;
3) those supplying samples shall maintain an adequate system of control and accountability;
4) each medicinal product sample shall be no larger than the smallest presentation on the market;
5) each sample shall be marked 'free medical sample — not for sale' or shall show some other wording having the same meaning;
6) each sample shall be accompanied by a copy of the summary of product characteristics;
7) no samples of medicinal products containing psychotropic or narcotic substances, as defined under special legislation, may not be distributed.

Article 216

The marketing authorisation holder is obliged to:

1) establish a scientific service in charge of information about the medicinal products which he places on the market;
2) keep available for, or communicate to the Institute, upon request, a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;
3) ensure that advertising of medicinal products is in compliance with this Law;
4) verify that medical sales representatives employed by his undertaking have been adequately trained and fulfil the obligations imposed upon them by Article 213 paragraph 1 and 3 of this Law;

5) supply the authorities or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities;
6) ensure unrestricted implementation of inspection oversight in relation to advertising, in accordance with the law;
7) ensure that decisions of competent inspectorates or other authorities are implemented without delay and in full.

Article 217

The detailed conditions and methods for advertising medicinal products shall be prescribed by the Ministry.

XI. MARKETING AUTHORISATION FOR VETERINARY MEDICINAL PRODUCTS

1. Obligation of Marketing Authorisation for Veterinary Medicinal Products

Article 218

A veterinary medicinal product shall be placed on the market in Montenegro only if a marketing authorisation has been issued by the Institute, in accordance with this Law.

A medicinal product authorised by the European Commission may also be placed on the market in Montenegro.

A homeopathic veterinary medicinal product may be placed on the market if it has been registered or authorised in accordance with this Law.

Article 219

By way of derogation from Article 218 and Article 299 paragraph 1 of this Law, where necessary to protect animal or public health, the use of veterinary medicinal products without a marketing authorisation may be permitted.

In the case referred to in paragraph 1 of this Article, only veterinary medicinal product authorised in a Member State of the European Union may be used.

In the situation referred to in paragraph 1 of this Article, the Institute shall grant approval for the procurement or importation of veterinary medicinal products without a marketing authorisation.

The Institute shall assess the completeness of the application for the issuance of approval for the procurement or import of veterinary medicinal products that do not have a marketing authorization within 30 days from the date of receipt of the application.

If the application for the issuance of approval for the procurement or import of veterinary medicinal products that do not have a marketing authorization is incomplete, the Institute shall notify the applicant thereof and set a deadline for elimination of deficiencies, which shall not exceed 30 days.

By way of derogation from paragraph 5 of this Article, in justified cases and upon the applicant's request, the Institute may extend the deadline for elimination of deficiencies.

In the event of an epizootic, natural disaster or other emergency situation, the Government shall undertake measures to ensure the supply of veterinary medicinal products

and may establish different procedures and conditions for approval of procurement or import than those laid down in this Law.

More detailed conditions for approval of procurement or import of veterinary medicinal products referred to in paragraph 1 of this Article shall be laid down by the Institute with the approval of the state administration body competent for veterinary affairs.

2. Application for a Marketing Authorisation for a Veterinary Medicinal Product

Article 220

The application for marketing authorisation of a veterinary medicinal product shall be submitted to the Institute, which grants a marketing authorisation valid only in Montenegro.

The applicant referred to in paragraph 1 of this Article may be a natural or legal person established in Montenegro.

The applicant referred to in paragraph 1 of this Article shall have a person responsible for obtaining the marketing authorisation for a veterinary medicinal product and for variations, with whom they have a full-time employment contract.

The applicant referred to in paragraph 1 of this Article shall also have a person responsible for pharmacovigilance.

The person responsible for pharmacovigilance may be employed or otherwise engaged by the marketing authorisation holder.

The qualified person responsible for pharmacovigilance shall hold a degree in veterinary medicine and reside in the territory of Montenegro, i.e. European Union.

By way of exception from paragraph 6 of this Article, the qualified person responsible for pharmacovigilance may also be a person without a degree in veterinary medicine, provided that they have permanent and continuous assistance from a veterinarian.

The applicant for marketing authorisation for a veterinary medicinal product shall be responsible for the accuracy of the data submitted in the documentation for the issuance of the authorisation.

Article 221

The application for a marketing authorisation for a veterinary medicinal product shall be accompanied by:

1) The name and address of the applicant's registered office, the manufacturer or importer of the finished veterinary medicinal product, the manufacturer of active substances, as well as the name and address of the locations where different stages of production, importation, quality control and batch release are carried out (manufacturer flow chart) for Montenegro;

2) Information related to the identification of the veterinary medicinal product;

3) Information on manufacturing and pharmacovigilance;

4) Information on the veterinary medicinal product and other data relevant for the granting of the marketing authorisation for a veterinary medicinal product;

5) Technical documentation required to demonstrate the quality, safety and efficacy of the veterinary medicinal product;

6) Summary of the PSMF.

The Institute shall not assess whether intellectual or industrial property rights are infringed during the marketing authorisation procedure.

Detailed procedures for submission, content of the application and required documentation for the granting of a marketing authorisation for a veterinary medicinal product

shall be prescribed by the Institute, with the approval of the state administration body competent for veterinary affairs.

Article 222

By way of derogation from Article 221 paragraph 1 item 5 of this Law, it shall not be necessary to submit documentation on safety and efficacy for generic veterinary medicinal products, provided that the following conditions are met:

1) bioavailability studies have demonstrated bioequivalence of a generic veterinary medicinal product with the reference veterinary medicinal product or justification is provided as to why such studies have not been conducted;

2) the requirements for the technical documentation of a generic veterinary medicinal product set out in accordance with this Law are fulfilled;

3) the applicant demonstrates that the application concerns a generic veterinary medicinal product of a reference veterinary medicinal product whose data protection period, as referred to in Articles 242 and 243 of this Law, has expired or is due to expire within less than two years.

Where the active substance of a generic veterinary medicinal product consists of salts, esters, ethers, isomers or mixtures of isomers, complexes or derivatives that differ from those used in the reference veterinary medicinal product, the active substance shall be considered the same, unless it differs significantly in respect of properties with regard to safety or efficacy; and where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.

Immediate-release oral pharmaceutical forms of a generic veterinary medicinal product shall be considered as the same pharmaceutical form.

The summary of product characteristics of the generic veterinary medicinal product shall be essentially similar to that of the reference veterinary medicinal product, except for indications or pharmaceutical forms of the reference product which are still covered by patent rights at the time when the marketing authorisation for the generic veterinary medicinal product is granted.

Conducting the necessary tests and studies with a view to applying for a marketing authorisation in accordance with this Article shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for veterinary medicinal products and medicinal products for human use.

Article 223

By way of derogation from Article 222 paragraph 1 of this Law, appropriate pre-clinical or clinical trials shall be submitted if the veterinary medicinal product does not meet all characteristics of a generic veterinary medicinal product for any of the following reasons:

1) there are changes in the active substance or substances, indications for use, strength, pharmaceutical form or route of administration compared to the reference veterinary medicinal product;

2) bioavailability studies cannot be used to demonstrate bioequivalence with the reference veterinary medicinal product; or

3) there are differences in raw materials or manufacturing processes of a biological veterinary medicinal product compared to the reference biological product.

Pre-clinical or clinical trials for a hybrid veterinary medicinal product may be conducted using batches of the reference veterinary medicinal product authorised in an EU Member State or a third country.

The applicant shall demonstrate that the reference veterinary medicinal product has been authorised in a third country in accordance with requirements equivalent to those in the European Union for the reference veterinary medicinal product, and that the products are so highly similar that they can substitute each other in clinical trials.

Article 224

By way of derogation from Article 221 paragraph 1 item 5 of this Law, in the case of veterinary medicinal products containing active substances used in the composition of authorised veterinary medicinal products, the applicant shall not be required to submit safety and efficacy data relating to each individual active substance.

Article 225

By way of derogation from Article 221 paragraph 1 item 5 of this Law, an applicant submitting application based on informed consent shall not be required to submit technical documentation on quality, safety and efficacy if they, in the form of a letter of access, demonstrates that they have permission to use such documentation submitted for already authorised veterinary medicinal product.

Article 226

By way of derogation from Article 221 paragraph 1 item 5 of this Law, the applicant whose application is based on bibliographic data shall not be required to provide documentation on safety and efficacy if they can demonstrate that the active substances of the veterinary medicinal product have been in well-established veterinary use in the European Union for at least ten years, as well as recognized efficacy and an acceptable level of safety (bibliographic application).

In the case referred to in paragraph 1 of this Article, the applicant shall satisfy the requirements prescribed in Article 221 paragraph 3 of this Law.

Article 227

By way of derogation from Article 221 paragraph 1 item 5 of this Law, the applicant for a limited market authorisation shall not be required to provide the comprehensive safety or efficacy documentation required in accordance with this Law, provided that all of the following conditions are met:

1) the benefit of the availability of the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;

2) the applicant provides evidence that the veterinary medicinal product is intended for a limited market.

Where a veterinary medicinal product has been granted a marketing authorisation in accordance with paragraph 1 of this Article, the summary of product characteristics shall clearly state that only a limited assessment of safety or efficacy was conducted due to the lack of complete data on safety or efficacy.

Article 228

By way of derogation from Article 221 paragraph 1 item 5 of this Law, in exceptional circumstances related to animal or public health, an applicant may submit an application which

does not meet all requirements, if the benefit of the immediate availability on the market of the veterinary medicinal product concerned to the animal or public health outweighs the risk inherent in the fact that certain quality, safety or efficacy documentation has not been provided.

In the case referred to in paragraph 1 of this Article, the applicant shall demonstrate that for objective and verifiable reasons can not submit documentation required in accordance with this Law.

Where a veterinary medicinal product has been granted marketing authorisation in accordance with paragraph 1 of this Article, the summary of product characteristics shall clearly state that only a limited assessment of quality, safety or efficacy has been conducted due to the lack of comprehensive data on quality, safety or efficacy.

3. Application for the Registration of a Homeopathic Veterinary Medicinal Product

Article 229

Homeopathic veterinary medicinal products that meet the conditions set out in paragraph 3 of this article shall be registered in accordance with Article 230.

Homeopathic veterinary medicinal products that do not meet the conditions set out in paragraph 3 of this article shall be subject to Article 218 paragraph 1.

A homeopathic veterinary medicinal product shall be registered under a simplified procedure if:

1) it is administered by a route described in the European Pharmacopoeia or the pharmacopoeia of a Member State of the European Union;

2) it has a sufficient degree of dilution to guarantee the safety of the medicinal product, and does not contain more than one part per 10,000 parts of the mother tincture;

3) no therapeutic indications are stated on the packaging or in any other information.

The provisions of Articles 5, 39, 84 and 219, Article 220 paragraph 1 and 8, Article 221 paragraphs 1 and 3, Articles 222 to 228, Article 231, Article 233 to 236, Article 238 paragraphs 2 to 6 and paragraphs 8 to 12, Articles 239 to 248, Article 250, Articles 252 to 254, Articles 263, 265, 274, 276, 299, 300 and 302, Articles 304 to 307 and Article 316 of this Law, shall not apply to homeopathic veterinary medicinal products which are registered in accordance with paragraph 1 of this Article, unless otherwise provided by this Law.

Article 230

The following shall be submitted with the application for the registration of a homeopathic veterinary medicinal product:

1) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the route of administration, pharmaceutical form and degree of dilution to be registered;

2) documentation describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens;

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

4) a manufacturing authorisation for the product;

5) a copy of the registration document for the same homeopathic veterinary medicinal product in the Member States of the European Union;

6) the text to appear on the package leaflet, and the outer and immediate inner packaging for the medicinal product subject to registration;

7) data on the stability of the product.

In the case of homeopathic veterinary medicinal products intended for food-producing animal species, the active substances shall be allowed in accordance with Regulation (EC) No 470/2009 on Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin and acts adopted based on that Regulation.

An application for registration may cover a series of homeopathic veterinary medicinal products of the same pharmaceutical form and derived from the same homeopathic stock or stocks.

The Institute may determine the conditions under which a registered homeopathic veterinary medicinal product may be made available

The Institute shall register a homeopathic veterinary medicinal product within 90 days from the date of receipt of a complete application.

An application for the registration of a homeopathic veterinary medicinal product may be submitted by a natural or legal person established in Montenegro.

The applicant may also be a natural or legal person established in the European Union.

A registration holder of a homeopathic veterinary medicinal product shall have the same obligations as marketing authorisation holder for a veterinary medicinal product.

Homeopathic veterinary medicinal products registered under the simplified procedure shall be entered into the Register of Homeopathic Veterinary Medicinal Products, which is maintained electronically by the Institute.

More detailed conditions and the manner of registration in the Register of Homeopathic Veterinary Medicinal Products shall be prescribed by the Institute, with the approval of the state administration body responsible for veterinary affairs.

4. Marketing Authorisation for a Veterinary Medicinal Product

Article 231

The Institute shall decide on the granting marketing authorisation for a veterinary medicinal product within 210 days from the date of receipt of a valid application.

Within 15 days of receipt of the application, the Institute shall notify the applicant as to whether all the information and documentation required in accordance with Article 221 have been submitted and whether the application is valid.

If the application for granting marketing authorisation is not valid, the Institute shall notify the applicant thereof and shall set a deadline for submitting the missing information and documentation

By way of derogation from paragraph 3 of this Article, in justified cases and upon the request of the applicant, the Institute may extend the deadline for rectifying the deficiencies.

In the course of evaluating the application for the granting of a marketing authorisation, the Institute shall inform the applicant that documentation submitted in support of the application is insufficient and request that the applicant provide additional information within a deadline not exceeding 180 days.

In the case that, during the assessment of the application in accordance with paragraph 3 and paragraph 5 of this Article, the Institute requests the applicant to provide additional information, the time limit referred to in paragraph 1 of this Article shall be suspended until the additional information has been provided.

When reviewing an application for granting marketing authorisation for a veterinary medicinal product, the Institute shall:

1) verify whether the data and documentation submitted are in accordance with Article 221 of this Law;

2) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided;

3) prepare a conclusion on the benefit-risk balance for the veterinary medicinal product.

After reviewing the application for granting marketing authorisation for a veterinary medicinal product as referred to in paragraph 7 of this Article, the Institute shall prepare an assessment report containing the information in accordance with the paragraph 9 of this Article and make it publicly available, after deleting any commercially confidential information.

The report referred to in paragraph 8 of this Article, in case of a positive assessment of the documentation for the veterinary medicinal product, shall contain:

1) a summary of product characteristics for the veterinary medicinal product containing the information laid down in this Law ;

2) any restriction or condition relating the supply or for the safe and effective use, including the classification of the veterinary medicinal product in accordance with Article 229;

3) the text of the labelling and the package leaflet containing the information laid down in this Law

In the case of a unfavourable assessment of the documentation for the veterinary medicinal product, the report referred to in paragraph 8 of this Article shall also contain the justification for such conclusions.

An applicant may withdraw the application for marketing authorisation at any time before the decision referred to in paragraph 1 of this Article has been issued.

If the application is withdrawn after the assessment of the application referred to in paragraph 7 of this Article has been completed, the applicant shall communicate to the Institute the reasons for doing so.

In the case referred to in paragraph 12 of this Article, the Institute shall publish the report referred to in paragraph 8 of this Article on its website, if prepared, without disclosing information that constitutes a business secret.

Article 232

If an application for the granting of a marketing authorisation is submitted for a veterinary medicinal product for which a marketing authorisation has already been granted in the European Union under the CP, MRP or DCP, the applicant may request the granting of a marketing authorisation under the accelerated assessment procedure.

In the case referred to in paragraph 1 of this Article, the Institute shall grant the marketing authorisation within 150 days from the date of receipt of a complete application.

Along with the application for the granting of a marketing authorisation referred to in paragraph 1 of this Article, the documentation referred to in Article 221 of this Law and appropriate declarations by the responsible person of the applicant regarding the identity of the submitted documentation with the documentation on the basis of which the marketing authorisation was granted in the CP, MRP or DCP shall be submitted.

If the application for the granting of a marketing authorisation under the accelerated procedure is not complete, the Institute shall notify the applicant thereof and shall set a deadline for the rectification of the deficiencies.

By way of derogation from paragraph 4 of this Article, in justified cases, upon the request of the applicant, the Institute may extend the deadline for the rectification of the deficiencies by an additional 30 days.

The period referred to in paragraph 2 of this Article shall not include the time necessary for the applicant to provide the Institute with the requested data, i.e. the period from the day the Institute requests additional data from the applicant until the day such data are submitted.

Article 233

In the case of submission of an application referred to in Article 228 of this Law, the Institute may grant a marketing authorisation for veterinary medicinal product under exceptional circumstances and may require the marketing authorisation holder to fulfil one or more of the following requirements:

1) to introduce conditions or restrictions, particularly with regard to the safety of the veterinary medicinal product;
2) to notify the Institute of any adverse event related to the use of the veterinary medicinal product;
3) to conduct a post- authorisation studies.

Article 234

In the procedure for granting a marketing authorisation for veterinary medicinal product, the Institute may require the applicant to submit to the Institute's laboratory or another authorised laboratory samples necessary in order to:

1) test the veterinary medicinal product, its starting materials, intermediate products or other constituent materials, in order to ensure that the control methods employed by the manufacturer, as described in the product documentation, meet the required conditions;
2) in the case of veterinary medicinal products intended for food-producing animals , verify whether the analytical detection method proposed for residue testing is satisfactory and suitable for detecting the presence of residues, particularly at levels exceeding the maximum residue level of the pharmacologically active substance established by the European Commission in accordance with Regulation (EC) No 470/2009, and for the performance of official controls of animals and products of animal origin in accordance with Regulation (EU) 2017/625.

In the case referred to in paragraph 1 of this article, the time limits laid down in Articles 231 paragraph 1 and 232 paragraph 2 of this law shall be suspended until the samples have been provided.

Article 235

The verification of compliance with the conditions in the procedure for granting a marketing authorisation for a veterinary medicinal product, when the manufacturer of the veterinary medicinal product does not have a registered seat in Montenegro, shall be subject to the provisions of Articles 39 and 84 of this Law, mutatis mutandis.

Article 236

A marketing authorisation for a veterinary medicinal product intended for one or more food-producing animals species shall be granted only if the product contains pharmacologically active substances included in the list of active substances that are not allowed in accordance with Regulation (EC) No 470/2009, as well as acts adopted on the basis of that Regulation for the respective target animal species.

For the treatment of animals from the equine family that are not intended for human consumption, in accordance with Regulation (EU) 2016/429 of the European Parliament and

of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ("Animal Health Law") and with regulations adopted on the basis of that Regulation, the Institute may grant a marketing authorisation for a veterinary medicinal product that contains active substances which are not included in the list referred to in paragraph 1 of this Article.

Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of separate legal act on the deliberate release into the environment of genetically modified organisms, in addition to the information, technical documentation and summary listed in paragraph 1 of Article 221 of this Law, it is also necessary to submit:

1) a copy of the written consent of the competent authority for the deliberate release into the environment of the genetically modified organisms for research and development purposes;

2) the complete technical file;

3) the environmental risk assessment in accordance with the principles; and

4) the results of any investigations performed for the purposes of research or development.

For the granting of a marketing authorisation for a veterinary medicinal product that contains or consists of genetically modified organisms, it is also necessary to submit a marketing authorisation issued by the European Commission.

Article 237

In the procedure for granting a marketing authorisation for a veterinary medicinal product, Institute shall , classify the following veterinary medicinal products as subject to veterinary prescription:

1) veterinary medicinal products which contain narcotic drugs or psychotropic substances, or substances frequently used in the illicit manufacture of such drugs or substances, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, the United Nations Convention on Psychotropic Substances of 1971, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, or by European Union legislation on drug precursors;

2) veterinary medicinal products for food-producing animals ;

3) antimicrobial veterinary medicinal products;

4) veterinary medicinal products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures;

5) veterinary medicinal products used for the euthanasia of animals;

6) veterinary medicinal products containing an active substance authorised in the European Union for less than five years;

7) immunological veterinary medicinal products;

8) veterinary medicinal products containing active substances with hormonal or thyreostatic action or β – agonists, except those prohibited by a specific regulation governing veterinary medicinal products containing certain substances with hormonal or thyreostatic effects and β-agonists in livestock production.

The Institute may also determine that a veterinary medicinal product shall be subject to veterinary prescription if the veterinary medicinal product is classified as a narcotic drug in accordance with the separate law or where special precautions are contained in the summary of product characteristics of that medicinal product.

By way of derogation from paragraph 1 of this Article, the Institute may, except for veterinary medicinal products referred to in paragraph 1 points 1, 3, 5 and 8 of this Article, classify a veterinary medicinal product as not subject to veterinary prescription, provided that:

1) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products;

2) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated or to other animals, to the person administering it, or to the environment;

3) the summary of product characteristics of the veterinary medicinal product does not contain warnings about potential serious adverse events deriving from correct use of the medicinal product;

4) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting;

5) the summary of product characteristics does not refer to contraindications related to the use of the product concerned in combination with other veterinary medicinal products commonly used without prescription;

6) there is no risk to public health as regards residues in food obtained from treated animals, even where the veterinary medicinal product is used incorrectly;

7) there is no risk to public or animal health as regards the development of resistance to substances, even if the veterinary medicinal product containing those substances is used incorrectly.

In the process of classification of veterinary medicinal products, the Institute shall take into account the EMA guidelines.

A officinal veterinary medicinal products when intended for food-producing animals shall be subject to a veterinary prescription.

The manner of prescribing and dispensing, as well as the content and format of the veterinary prescription, shall be prescribed by the state administration body competent for veterinary affairs.

8) medicinal product;

9) there is no risk to public or animal health due to the development of resistance to substances, even if the veterinary medicinal product containing such substances is incorrectly used.

In the process of classification of veterinary medicinal products, the Institute shall take into account the EMA guidelines.

A officinal veterinary medicinal products intended for food-producing animals shall be dispensed only on veterinary prescription.

The manner of prescribing and dispensing, as well as the content and format of the veterinary prescription, shall be prescribed by the state administration body competent for veterinary affairs.

Article 238

The marketing authorisation for a veterinary medicinal product shall be issued for an unlimited period of time.

The marketing authorisation for a veterinary medicinal product for a limited market shall be issued for a period of five years.

Before the expiry of the validity period referred to in paragraph 2 of this Article, the marketing authorisation for a limited market shall be re- examined on the basis of an application from the holder of that marketing authorisation holder for re-assessment, which shall include an updated benefit-risk assessment.

A holder of a marketing authorisation for a limited market shall submit an application for re- examination to the Institute no later than six months before the expiry of the period referred to in paragraph 2 of this Article, along with evidence of compliance with the conditions laid down in Article 227 of this Law.

The marketing authorisation for a limited market shall remain valid until the Institute issues a decision on the request referred to in paragraph 3 of this Article.

On the basis of the assessment, the Institute may extend the marketing authorisation for a limited market for an additional five years if the benefit-risk balance remains positive.

The Institute may grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised for a limited market, provided that the holder of the marketing authorisation submits complete data on safety or efficacy in accordance with this Law.

By way of derogation from paragraph 1 of this Article, a marketing authorisation in exceptional circumstances shall be issued for a period of 12 months.

A marketing authorisation in exceptional circumstances may be extended on the basis of an application from the marketing authorisation holder to the Institute no later than three months before the expiry of the validity period referred to in paragraph 8 of this Article, and relate to a re- examination of the benefit-risk balance.

Along with the request referred to in paragraph 9 of this Article, the marketing authorisation holder shall submit an updated benefit-risk assessment, including data demonstrating that special circumstances related to animal or public health still exist.

The marketing authorisation under exceptional circumstances shall remain valid until the Institute issues a decision on the request referred to in paragraph 9 of this Article.

If the benefit-risk balance remains positive, the Institute may extend the validity of the marketing authorisation under exceptional circumstances for another year.

If the marketing authorisation holder for veterinary medicinal product, along with the request referred to in paragraph 9 of this Article, submits complete data on quality, safety, and efficacy in accordance with this Law, the Institute may grant a marketing authorisation for a veterinary medicinal product for an unlimited period of time.

Article 239

The marketing authorisation for a veterinary medicinal product shall include the approved Summary of Product Characteristics, labelling, and package leaflet.

The Summary of Product Characteristics, labelling, and package leaflet for a veterinary medicinal product shall be written in the Montenegrin language.

By way of derogation from paragraph 2 of this Article, the labelling of a veterinary medicinal product may be labelled in one or more other languages.

In the case of issues concerning the availability of the product, and in order to protect animals' health, the Institute may, upon request of the marketing authorisation holder for a specific batch and quantity of the product, approve that the package leaflet is not provided in the Montenegrin language, in whole or in part.

The labelling and package leaflet of a veterinary medicinal product shall be consistent with the approved Summary of Product Characteristics.

The detailed content of the marketing authorisation for a veterinary medicinal product, the content of the Summary of Product Characteristics, the content and method of labelling of the veterinary medicinal product, the list of abbreviations and pictograms, the rules on the size of small immediate packaging units, as well as the content of the package leaflet for the veterinary medicinal product, shall be prescribed by the Institute, with the approval of the state administration body competent for veterinary affairs.

Article 240

The Institute may require the marketing authorisation holder for an antimicrobial veterinary medicinal product to conduct post- authorisation studies in order to ensure that the benefit-risk balance, with regard to the potential development of antimicrobial resistance, remains positive.

Article 241

The Institute shall issue a decision refusing the application for the marketing authorisation of a veterinary medicinal product duly justified and including the reasons for refusal, if it determines that:

1) the documentation submitted with the application does not comply with the requirements laid down in this Law;
2) the benefit-risk balance of the veterinary medicinal product is not positive;
3) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product;
4) the veterinary medicinal product is an antimicrobial veterinary medicinal product presented for use as a growth promoter or to increase yield from treated animals;
5) the proposed withdrawal period is not sufficiently long to ensure food safety, or is insufficiently substantiated;
6) the risk for public health case of development of antimicrobial resistance or antiparasitic resistance outweighs the benefits of the veterinary medicinal product to animal health;
7) the applicant has not provided sufficient evidence of efficacy as regards the target species;
8) the qualitative and quantitative composition of the veterinary medicinal product does not correspond to the data provided in the submitted documentation;
9) the risk to public health or animal health or to the environment is not sufficiently addressed; or
10) the active substance in the veterinary medicinal product meets the criteria for being considered persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, and the veterinary medicinal product is intended for use in food-producing animals, unless it is demonstrated that the active substance is essential for the prevention or control of a serious risk to animal health.

The application for a marketing authorisation of an antimicrobial veterinary medicinal product shall be refused if the antimicrobial substance is reserved for the treatment of certain infections in humans.

The prohibition on the use of antimicrobial substances or groups of antimicrobial substances reserved for treatment of certain infections in humans, in accordance with Commission Implementing Regulation (EU) 2022/1255 on the designation of antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans in order to preserve their effectiveness in human medicine and support the fight against antimicrobial resistance, shall be prescribed by the state administration body competent for veterinary affairs.

Article 242

The period of protection for the technical documentation required to demonstrate the quality, safety, and efficacy of a veterinary medicinal product shall be:

1) ten years for veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs, and cats;

2) 14 years for antimicrobial veterinary medicinal products for cattle, sheep for meat production, pigs, chickens, dogs and cats, containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised in Montenegro or the European Union on the date of submission of the application;

3) 18 years for veterinary medicinal products for bees;

4) 14 years for veterinary medicinal products for animal species other than those referred to in points 1 and 3 of this paragraph.

The period of protection referred to in paragraph 1 of this Article shall apply from the date of issuance of the marketing authorisation for the veterinary medicinal product in accordance with this Law.

Article 243

Where the first marketing authorisation for a veterinary medicinal product is granted for more than one animal species referred to in Article 242 paragraph 1 item 1 or 2 of this Law, or where an extension of the marketing authorisation to another animal species referred to in Article 242 paragraph 1 item 1 or 2 is approved by way of a variation, the period of the protection referred to in Article 242 shall be extended by one year for each additional target species, provided that the variation application has been submitted at least three years before the expiry of the protection period laid down in Article 242 paragraph 1 items 1 or 2 of this Law.

Where the first marketing authorisation for a veterinary medicinal product is granted for more than one animal species referred to in Article 242 paragraph 1 item 4 of this Law, or where an extension of the marketing authorisation to another animal species not referred to in Article 242 paragraph 1 item 1 is approved by way of a variation, the protection period referred to in Article 242 shall be extended by four years, provided that the variation application has been submitted at least three years before the expiry of the protection period laid down in Article 242 paragraph 1 item 4 of this Law.

The period of the protection of technical documentation of the first marketing authorisation established by Article 242 and prolonged by any additional period of protection due to a variation or a new marketing authorisation belonging to the same marketing authorisation, shall not exceed 18 years.

Where an applicant for a marketing authorisation or a variation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of maximum residue limits, together with safety and residue tests and pre-clinical and clinical studies during the application procedure, other applicants shall not refer to results of such studies for five years from the date of granting of the marketing authorisation for which they were carried out.

The prohibition on using those results referred to in paragraph 4 of this Article shall not apply where other applicant has obtained a letter of access to those studies.

The results of relevant pre-clinical or clinical studies shall benefit from four-year data protection period if the variation approved includes a change to the pharmaceutical form, administration route or dosage of the veterinary medicinal product, for which the Institute has concluded that it is demonstrated:

1) a reduction in antimicrobial or antiparasitic resistance; or

2) an improvement in the benefit-risk balance of the veterinary medicinal product.

The prohibition on using of data referred to in paragraph 6 of this Article shall not apply where another applicant has obtained a letter of access to those studies.

Article 244

In addition to the obligations laid down by regulations governing the protection of animals used for scientific research purposes, another applicant for a marketing authorisation for a veterinary medicinal product or for a variation thereof shall not refer to the technical documentation required to demonstrate the quality, safety, and efficacy of the veterinary medicinal product and submitted for the purpose of obtaining the first marketing authorisation or variation, unless:

1) the protection period referred to in Articles 242 and 243 of this Law has elapsed, or is due to elapse in less than two years; or

2) the applicant has obtained written agreement regarding that documentation in the form of a letter of access.

The protection of the technical documentation referred to in paragraph 1 of this Article shall also apply to medicinal products whose authorisation has expired.

A marketing authorisation for a veterinary medicinal product or a variation differing from the marketing authorisation previously granted in Montenegro to the same marketing authorisation holder with regard to target species, strength, pharmaceutical form, administration route or presentations shall be regarded as the same marketing authorisation as the authorisation previously granted to the same marketing authorisation holder, for the purpose of applying the provisions on the protection of technical documentation.

Article 245

The marketing authorisation holder for a veterinary medicinal product shall be responsible for the marketing of its veterinary medicinal products in accordance with this Law.

The designation of a representative or agent shall not relieve the manufacturer and/or the marketing authorisation holder of responsibility for the product.

The marketing authorisation holder shall:

1) within the limits of its responsibilities, ensure appropriate and continued supplies of its veterinary medicinal products;

2) after a marketing authorisation for the veterinary medicinal product has been granted, monitor the latest scientific and technical progress in respect of the methods of manufacture and quality control, and introduce the necessary changes to ensure that the product is manufactured and its quality tested in accordance with generally accepted scientific methods;

3) continuously inform the Institute of any new findings relevant to the assessment of the quality, safety, and efficacy of the veterinary medicinal product on the market;

4) after the marketing authorisation is granted, ensure that the summary of product characteristics (SmPC), package leaflet, and labelling are kept up to date with current scientific knowledge;

5) notify the Institute in writing of the date the veterinary medicinal product is placed on the market, within 15 days of doing so, for each product for which a marketing authorisation has been issued;

6) on the request of the Institute, provide or enable the Institute to take sufficient quantities of samples to enable quality control of the veterinary medicinal product;

7) on the request of the Institute, provide the technical expertise necessary to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal product in the Institute's laboratory;

8) on the request of the Institute, within the time limit set in that request, provide data confirming that the benefit-risk balance remains positive;

9) without delay, notify the Institute of any restriction or prohibition imposed by competent authorities or bodies of other countries where the product is marketed, or submit new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned, including from the outcome of the signal management process carried out in accordance with this Law;

10) submit to the Administration a report on the annual volume of sales of veterinary medicinal products in Montenegro, at least once a year.

The report referred to in paragraph 3 item 10 of this Article shall constitute a business secret.

The Administration shall process the data from the report referred to in paragraph 3 item10 of this Article and publish data on the total sales of veterinary medicinal products in Montenegro on its website.

The marketing authorisation holder for the veterinary medicinal product may not place on the market generic veterinary medicinal product and the hybrid veterinary medicinal product until the period of protection of technical documentation for the reference veterinary medicinal product, as set out in Articles 242 and 243 of this law, has elapsed.

When the marketing authorisation holder decides to cease the marketing of the medicinal product they shall notify the Institute and the Administration at least 60 days prior to the discontinuation, except in cases of urgent withdrawal procedures or other exceptional circumstances.

In the case referred to in paragraph 7 of this Article, the marketing authorisation holder shall inform the Institute and the Administration of the reasons for ceasing the supply of the product.

If, for any reason, the marketing authorisation holder ceases to be the holder of the authorisation has not been transferred in accordance with this Law, they shall immediately notify the Institute or the Administration, as well as all legal entities engaged in wholesale distribution of that product in Montenegro.

In the case referred to in paragraph 9 of this Article, the marketing authorisation holder shall take all necessary measures to withdraw the product from the market within 30 days from the date of cessation of authorisation holder status.

If the marketing authorisation holder fails to comply with paragraph 10 of this Article, the state administration body responsible for veterinary affairs shall adopt a decision on the procedure regarding that product.

For a veterinary medicinal product that is on the market in Montenegro, and for which a marketing authorisation has not been granted, the obligations referred to in paragraph 3, item 11 of this Article shall be assumed by the wholesale distributor that has been granted the import authorisation.

The Administration shall publish the template of the report referred to in paragraph 3 item11 of this Article on its website.

5. Variation, Transfer and Cessation of the Marketing Authorisation for a Veterinary Medicinal Product

Article 246

A variation of marketing authorisation for a veterinary medicinal product means a change to the marketing authorisation from Article 218, which is issued in accordance with Article 231 paragraphs 7, 9, 10 and 11 of this Law.

Depending on the need to assess the quality, safety and efficacy of the veterinary medicinal product, the Institute shall classify variations to the marketing authorisation for a

veterinary medicinal product as variations requiring assessment, and variations not requiring assessment.

The Institute shall establish a list of variations not requiring assessment.

The classification of variations not requiring assessment shall be carried out in relation to the following criteria:

1) the need for a scientific assessment of changes in order to determine the risk to public or animal health or to the environment;

2) whether changes have an impact on the quality, safety or efficacy of the veterinary medicine;

3) whether changes imply no more than a minor alteration to the summary of product characteristics;

4) whether changes are of an administrative nature.

The marketing authorisation holder for a veterinary medicinal product shall:

1) notify the Institute of the variation of the marketing authorisation for a veterinary medicinal product when an assessment as referred to in paragraph 2 of this Article is not required;

2) submit an application to the Institute for approval of the variation of the marketing authorisation for a veterinary medicinal product when an assessment as referred to in paragraph 2 of this Article is required.

The Institute shall lay down more detailed conditions, classification, procedures and required documentation for variations to a marketing authorisation for a veterinary medicinal product, with a approval of the state administration body responsible for veterinary affairs

Article 247

The marketing authorisation holder for a veterinary medicinal product shall notify the Institute of a variation not requiring assessment, as referred to in Article 246 paragraph 1 of this Law, within 12 months from the date of implementation of such variation.

The Institute shall accept or reject the variation referred to in paragraph 1 of this Article within 30 days of notification and, where necessary, amend the marketing authorisation and record the variation in the database and inform the marketing authorisation holder of the veterinary medicinal product thereof.

Article 248

In the case of a variation requiring assessment pursuant to Article 246 paragraph 2 of this Law, the marketing authorisation holder for a veterinary medicinal product shall submit an application for the approval of the variation to the Institute.

The Institute shall, within 15 days, acknowledge receipt of a valid application referred to in paragraph 1 of this Article.

If the application is incomplete, the Institute, as applicable, shall require the marketing authorisation holder to provide the missing information and documentation within a reasonable time limit.

The Institute shall assess the application and prepare an assessment report on the variation within 60 days following the receipt of a valid application.

If, due to the complexity of the case, additional time is needed to assess the application, the Institute may extend the period referred to in paragraph 4 of this Article to 90 days and shall inform the marketing authorisation holder accordingly.

Within the period referred to in paragraph 4 of this article, the Institute may request the marketing authorisation holder to submit additional information, specifying a deadline for their submission.

In the case referred to in paragraph 5 of this Article, the procedure shall be suspended until the supplementary information is provided.

The Institute shall decide on the variation referred to in paragraph 1 of this Article within 30 days from the date the assessment report on the variation is issued. Within the same period, the Institute shall either amend the marketing authorisation in accordance with the assessment report, or reject the variation, and in case of rejection shall inform the marketing authorisation holder of the reasons for such decision.

The marketing authorisation holder for a veterinary medicinal product may implement the variation referred to in paragraph 1 of this Article only after the variation has been approved by the Institute.

The marketing authorisation holder shall place the veterinary medicinal product on the market in accordance with the approved variation no later than 12 months from the date the decision approving the variation was delivered by the Institute.

By way of derogation from paragraph 10 of this Article, for the purpose of protecting public health or animal health or for other justified reasons, the Institute may determine a different deadline for the implementation of the approved variation.

The marketing authorisation holder shall, upon request of the Institute and without delay, submit all information related to the implementation of the variation.

Article 249

The provisions of this Law relating to the transfer of the marketing authorisation for a medicinal product for human use shall apply mutatis mutandis to the transfer of the marketing authorisation for a veterinary medicinal product.

Article 250

The marketing authorization for a veterinary medicinal product shall cease to be valid either at the request of the marketing authorization holder or following a decision to suspend or revoke the authorization.

The Institute shall issue a decision to suspend or revoke the marketing authorisation for a veterinary medicinal product, or request the marketing authorisation holder to submit an application for a variation, if the benefit-risk balance of the veterinary medicinal product is no longer positive or is insufficient to ensure food safety.

The Institute shall revoke the marketing authorisation for a veterinary medicinal product if the marketing authorisation holder ceases to meet the requirements laid down in Article 220 of this Law concerning the location of the marketing authorisation holder.

The Institute may suspend or revoke the marketing authorisation for a veterinary medicinal product or request the marketing authorisation holder to submit an application for a variation if it establishes that the holder:

1) fails to fulfil the obligations referred to in Article 245 of this Law;
2) does not meet the requirements laid down in Article 303 of this Law;
3) has not established a pharmacovigilance system or fails to comply with pharmacovigilance obligations under this Law;
4) the qualified person responsible for pharmacovigilance does not comply with the obligations under this Law.

A veterinary medicinal product for which the marketing authorisation has expired may remain on the market until its expiry date, but not longer than 18 months from the date of expiry

of the marketing authorisation, provided that the expiry of the marketing authorisation is not due to reasons related to the quality, safety, or efficacy of the product.

A veterinary medicinal product for which the marketing authorisation has expired may no longer be manufactured or imported as of the date of expiry of the marketing authorisation. The Institute shall make public, on its website, the decisions to grant, refuse, suspend, revoke or amend by way of a variation marketing authorisations for veterinary medicinal products, as well as the summaries of product characteristics and package leaflets of authorised veterinary medicinal products.

The detailed procedure for the suspension and revocation of marketing authorisations for veterinary medicinal products shall be prescribed by the Institute, with the approval of the state administration authority competent for veterinary affairs.

Article 251

In the event of a risk to public health, animal health or the environment that requires urgent action, the state administration authority competent for veterinary affairs, the Institute, or the Administration may impose temporary safety restrictions on the marketing authorisation holder for a veterinary medicinal product and other persons having obligations under this Law. Those measures may include:

1) restriction of the supply of the veterinary medicinal product;
2) restriction of the use of the veterinary medicinal product;
3) suspension of the marketing authorisation for the veterinary medicinal product.

The Institute shall notify other Member States of the European Union, the European Commission, or the EMA of the measures referred to in paragraph 1 of this Article at the latest on the following working day.

Where applicable, the marketing authorisation holder for the veterinary medicinal product shall be required to submit an application for approval of a variation.

6. Data Collection and Summary of product characteristics for a veterinary medicinal product

Article 252

The Administration shall collect relevant and comparable data on the volume of sales and use of antimicrobial medicinal products used in animals, to enable in particular the direct or indirect evaluation of the use of such products in food-producing animals at the farm level.

The Administration shall draw up an annual data quality management plan concerning the volume of sales and use of antimicrobial medicinal products and shall appoint a person responsible for data management (hereinafter: national contact point).

Legal entities authorised, in accordance with the law governing veterinary activities, other legal entities from Article 284, paragraph 2, to perform veterinary practice shall be required to submit to the Administration, by 1 March of the current year, data on the use of antimicrobial medicinal products used in the previous year.

The entities referred to in paragraph 3 of this Article shall regularly enter data on the use of antimicrobial medicinal products into the Veterinary Information System (hereinafter: VIS), which is maintained by the Administration in accordance with a specific law.

Legal entities engaged, in accordance with the law, in wholesale and retail distribution of veterinary medicinal products shall submit to the Administration, by 1 March of the current year, data on the volume of sales of antimicrobial medicinal products in the previous year.

The entities referred to in paragraph 5 of this Article shall, upon request of the Administration, enter data on the volume of sales of antimicrobial medicinal products into VIS.

The Administration shall collect relevant and comparable data on the volume of sales and use of antimicrobial medicinal products in animals, for the purpose of directly or indirectly assessing the use of such products in food-producing animals at the farm level.

With the derogation of paragraph 7 of this article, the types of antimicrobial medicinal product for which data on the volume of sales and use in animals are collected do not include data on the volume of sales of antimicrobial medicinal product to other wholesalers of veterinary medicinal product.

The type of antimicrobial medicinal product for which data on the volume of sale and use in animals is collected, the quality of the data collected and submitted for the purpose of determining the volume and application of those products, format of the data and the method of collecting and submitting data on the volume of sale and use, prescribed by the state administration body responsible for veterinary affairs.

Legal entities from paragraphs 3 and 5 of this article submit data on the use and sale of antimicrobial drugs on the form prescribed by the Administration and which is available on the Administration s website.

Article 253

The Institute shall take measures to inform and advise small and medium-sized enterprises on compliance with the requirements laid down in this Law.

Article 254

The summary of product characteristics of a veterinary medicinal product shall be harmonised for:

1) A reference veterinary medicinal product in Montenegro for which a marketing authorisation has been granted based on a complete dossier demonstrating quality, safety and efficacy, and which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference product in the Member States of the European Union;

2) A generic and hybrid veterinary medicinal product.

The holder of the marketing authorisation for a reference veterinary medicinal product in Montenegro, referred to in paragraph 1 item 1 of this Article, shall submit to the Institute, within six months after the completion of the harmonisation procedure of SmPCs for reference veterinary medicinal products in the European Union (*listed on the website of the Heads of Medicines Agencies – HMA* – in the European Economic Area), an application for a variation in order to harmonise the SmPC of the veterinary medicinal product in Montenegro with the harmonised text of the SmPC in the European Union.

The holder of the marketing authorisation for a generic veterinary medicinal product shall, within eight months after the completion of the harmonisation procedure of SmPCs for reference veterinary medicinal products in the European Union, submit to the Institute an application for a variation in order to harmonise the SmPC with the SmPC of the reference veterinary medicinal product in the European Union in the following parts:

1) Target animal species;
2) Clinical particulars;
3) Withdrawal period.

By way of derogation from paragraph 3 of this Article, if the authorisation for the hybrid veterinary medicinal product is supported by additional pre-clinical or clinical studies, the SmPC shall not be harmonised.

The holder of the marketing authorisation for a generic or hybrid veterinary medicinal product shall ensure that the SmPC is essentially similar to that of the reference veterinary medicinal product.

XII. PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS

Article 255

The Institute and the marketing authorisation holder for a veterinary medicinal product shall set up and maintain a pharmacovigilance system to carry out pharmacovigilance tasks with respect to the safety and efficacy of authorised veterinary medicinal products, in order to ensure the continuous assessment of the benefit-risk balance.

The Institute and the marketing authorisation holder for a veterinary medicinal product shall take the necessary measures to enable and encourage reporting of suspected adverse events, including:

1) any unfavourable and unintended reaction in an animal following the administration of a veterinary medicinal product;

2) any observation of a lack of efficacy of a veterinary medicinal product following its administration to an animal, whether or not in accordance with the summary of product characteristics;

3) any environmental incident observed following the administration of a veterinary medicinal product to an animal;

4) any noxious reaction in humans exposed to a veterinary medicinal product;

5) any finding of a pharmacologically active substance or residue marker in a product of animal origin exceeding the maximum levels of residues established in accordance with Regulation (EC) No 470/2009 and Regulation (EC) No 726/2004 of the European Parliament and of the Council, after the set withdrawal period has been respected;

6) any suspected transmission of an infectious agent via a veterinary medicinal product;

7) any unfavourable and unintended reaction in an animal to a medicinal product for human use.

Article 256

The Institute shall enter into the European Union pharmacovigilance database, by electronic means, all reports of suspected adverse events that occurred within the territory of Montenegro, within 30 days from the date of receipt of the suspected adverse event report.

The marketing authorisation holder for a veterinary medicinal product shall record in the database referred to in paragraph 1 of this Article any suspected adverse event which has been reported to them or published in scientific literature in relation to their authorised veterinary medicinal products, without delay and no later than within 30 days of receipt of the suspected adverse event report.

The Institute may require the marketing authorisation holder for a veterinary medicinal product to collect specific pharmacovigilance data, in addition to the data referred to in Article 255 paragraph 2 of this Law, and to carry out post-marketing surveillance studies, stating in detail the reasons for the request and setting an appropriate time limit.

Article 257

The marketing authorisation holder for a veterinary medicinal product shall:

1) establish and maintain a pharmacovigilance system for collecting, collating and evaluating information on the suspected adverse events concerning their authorised veterinary medicinal products;

2) have in place PSMF describing in detail the pharmacovigilance system with respect to its authorised veterinary medicinal products, to conduct regular pharmacovigilance system audits, and in cooperation with the manufacturer, to record key findings in the local pharmacovigilance system and the PSMF, and to ensure appropriate corrective actions are planned and implemented based on those findings;

3) ensure the constant and continuous availability of a person responsible for pharmacovigilance in Montenegro;

4) monitor pharmacovigilance data and continuously evaluate benefit-risk assessments of the veterinary medicinal product for which it holds a marketing authorisation, and take appropriate measures as necessary;

5) comply with the Good Pharmacovigilance Practice (GVP) guidelines for veterinary medicinal products;

6) where necessary, based on the assessment of the pharmacovigilance data, submit to the Institute, without delay, an application for approval of.a variation.

The person responsible for pharmacovigilance shall be responsible for the establishment and maintenance of the pharmacovigilance system.

The marketing authorisation holder for veterinary medicinal product shall designate one or more persons responsible for pharmacovigilance.

The person responsible for pharmacovigilance may also be responsible for establishing and maintaining the pharmacovigilance system in the European Union, or the marketing authorisation holder for veterinary medicinal product may appoint a separate person responsible for pharmacovigilance within the EU.

Only one person responsible for pharmacovigilance may be appointed per PSMF.

Marketing authorisation holder may outsource certain pharmacovigilance tasks to a third party who meets the same requirements as the person responsible for pharmacovigilance, and the obligations of a third party shall be specified in detail in the contract and included in the PSMF.

In the case referred to in paragraph 6 of this Article, the marketing authorisation holder for a veterinary medicinal product shall not be released from responsibility for the accuracy and completeness of the PSMF.

The marketing authorisation holder for a veterinary medicinal product shall not disclose information on pharmacovigilance related to a veterinary medicinal product to the scientific or general public without prior notification of the Institute.

The marketing authorisation holder shall ensure that any pharmacovigilance information disseminated about a specific product is presented objectively and does not mislead the scientific or general public.

Upon request from the Institute, the marketing authorisation holder shall provide a copy of the records or any other required part of the PSMF within seven days from the date of receipt of the request.

The marketing authorisation holder shall notify the Institute of a variation relating to any change in the information in the PSMF summary.

When the pharmacovigilance system described in the PSMF is formally terminated, the marketing authorisation holder shall retain the PSMF in electronic form for a further five years.

The Institute shall prescribe the method of data collection, reporting and monitoring of adverse events, good pharmacovigilance practices, and the format and content of the PSMF summary for veterinary medicinal products with the approval of the competent authority of the state administration responsible for veterinary matters.

Article 258

In addition to the obligations laid down in Article 257 of this Law, the marketing authorisation holder for a veterinary medicinal product shall:

1) maintain a record of all suspected adverse events that have occurred within the territory of Montenegro;

2) monitor and collect all information that may affect the assessment of the benefit-risk balance of the medicinal product and submit it to the Institute without delay, as promptly as possible;

3) until the European Union pharmacovigilance database submission functionality is operational, notify the Institute without delay, and no later than 30 days from the date of receipt, of any suspected adverse event that occurred within the territory of Montenegro;

4) until the European Union pharmacovigilance database submission functionality is operational, establish a procedure for obtaining accurate and verifiable data for the scientific assessment of suspected adverse event reports referred to in item 3 of this paragraph, and collect additional case information and submit it to the Institute;

5) until the European Union pharmacovigilance database submission functionality is operational, upon request of the Institute, submit reported cases of suspected adverse events that occurred in the territory of a Member State of the European Union or a third country, within 15 days from the date of receipt of the request;

6) maintain a record of all suspected adverse events occurring in the territory of a Member State of the European Union or a third country.

For a veterinary medicinal product placed on the market in Montenegro without a marketing authorisation, the obligations referred to in paragraph 1 items 2, 3 and 4 of this Article shall be assumed by the wholesaler authorised for import.

The marketing authorisation holder for a veterinary medicinal product shall ensure that the data from the record referred to in paragraph 1 item1 of this Article is available at a single location within the European Union.

The marketing authorisation holder for a veterinary medicinal product may not refuse to consider suspected adverse event reports received electronically or by any other appropriate means from veterinary professionals.

Article 259

The qualified person responsible for pharmacovigilance shall be responsible for:

1) elaborating and maintaining the local pharmacovigilance system and the PSMF in cooperation with the manufacturer, and submitting them to the Institute upon request;

2) allocating reference numbers to the PSMF and communicating that reference number to the pharmacovigilance database for each product;

3) establishing and maintaining a system which ensures that all suspected adverse events which are brought to the attention of the marketing authorisation holder are collected and recorded;

4) compiling suspected adverse event reports referred to in Article 256 paragraph 2 of this Law, assessing them, and submitting them to the Institute;

5) ensuring that any request from the Institute for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly;

6) providing the Institute with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies;

7) applying the signal management process and ensuring the conditions for fulfilling the obligations laid down in Article 257 paragraph 1 item 4 of this Law;

8) monitoring the pharmacovigilance system and ensuring that, if needed, an appropriate preventive or corrective action plan is prepared and implemented, and, if necessary, ensuring an update of the PSMF;

9) ensuring that all personnel of the marketing authorisation holder involved in pharmacovigilance activities receive continuous training;

10) notifying the Institute of any regulatory action taken in the European Union, until access to the European Union pharmacovigilance database is established, and in third countries, related to pharmacovigilance data, within 21 days from the date of receipt of the information.

The person responsible for pharmacovigilance shall be the contact person of the marketing authorisation holder for veterinary medicinal products in case of inspections related to pharmacovigilance.

Article 260

Within the pharmacovigilance system, the Institute shall:

1) maintain records of all reports of suspected adverse events related to the use of veterinary medicinal products that have occurred in Montenegro and have been reported by healthcare professionals or veterinary personnel;

2) lay down the necessary procedures for assessing the results and outcomes of the signal management process and the suspected adverse events reported to it, consider risk management options, and take appropriate measures in accordance with the law, such as temporary safety restriction measures, instructing the marketing authorisation holder to submit a variation application, issuing a decision on suspension, revocation or variation of the marketing authorisation for a veterinary medicinal product, or prohibition of placing on the market;

3) impose specific requirements on veterinarians and healthcare professionals regarding the reporting of suspected adverse events, in cooperation with relevant associations, if necessary;

4) ensure that the professional and, where necessary, the general public is promptly informed about adverse events related to the use of veterinary medicinal products by publishing information on the Institute's website and, if necessary, by other means, with prior or simultaneous notification of the marketing authorisation holder;

5) make available on its website information on different ways of reporting suspected adverse events and other problems related to veterinary medicinal products;

6) forward to the marketing authorisation holder any report of a suspected adverse event related to the use of a veterinary medicinal product submitted to the Institute, within 15 days from the date of receipt of the report;

7) control the pharmacovigilance system of the marketing authorisation holder with regard to the implementation of Good Pharmacovigilance Practice in accordance with this Law;

8) take measures to ensure that effective, proportionate, and dissuasive penalties are imposed on marketing authorisation holders for veterinary medicinal products who fail to comply with their pharmacovigilance obligations under this Law.

Marketing authorisation holders for veterinary medicinal products, or wholesalers authorised for import, as well as veterinary personnel and healthcare professionals, shall participate in the monitoring of reported suspected adverse events occurring in the territory of Montenegro.

The Institute may request the marketing authorisation holder for a veterinary medicinal product to submit a copy of the Pharmacovigilance System Master File (PSMF).

The Institute shall carry out inspections on the compliance of the pharmacovigilance system of the marketing authorisation holder with EU guidelines in accordance with this Law.

Where the control referred to in paragraph 4 of this Article establishes that the marketing authorisation holder does not meet the requirements of Good Pharmacovigilance Practice, the Institute shall inform other EU Member States, EMA, and the European Commission.

The Institute shall ensure regular audits of the PSMF if it is located in Montenegro.

Article 261

Veterinary personnel and healthcare professionals, the marketing authorisation holder for a veterinary medicinal product, and the entity engaged in the wholesale distribution of veterinary medicinal products shall immediately notify the Institute of any suspected adverse events referred to in Article 255 of this Law.

Veterinary personnel and healthcare professionals shall report any suspected adverse event to the marketing authorisation holder for the veterinary medicinal product.

For a product that does not have a marketing authorisation for veterinary use, suspected adverse events shall be reported to the wholesale distributor responsible for placing the product on the market.

Veterinary personnel and healthcare professionals may report suspected adverse events directly to the Institute or through the marketing authorisation holder or the wholesale distributor.

Article 262

The marketing authorisation holder for a veterinary medicinal product shall, where necessary, carry out a signal management process, taking into account sales data and other relevant pharmacovigilance data which may reasonably be expected to be aware and which may be useful in the signal management process, including scientific information gathered from scientific literature reviews.

Where the outcome of the signal management process identifies a change to the benefit-risk balance or a new risk, marketing authorisation holders shall notify it without delay and no later than within 30 days to the Institute and, if necessary, submit an application for a variation.

The marketing authorisation holder for a veterinary medicinal product shall, at least once a year, record and submit to the Institute all results and outcomes of the signal management process, including the conclusion on the benefit-risk balance and, where applicable, references to the relevant scientific literature.

Article 263

A marketing authorisation holder to whom the Institute has granted a marketing authorisation for a veterinary medicinal product and who also holds an authorisation issued in a Member State of the European Union shall inform the Institute if an arbitration procedure in the European Union has been initiated in relation to that veterinary medicinal product.

The Institute and the marketing authorisation holder shall take the necessary measures to align the marketing authorisation with the decision adopted in the arbitration procedure referred to in paragraph 1 of this Article.

For the purpose of implementing the decision referred to in paragraph 2 of this Article, the Institute may request the marketing authorisation holder to submit an application for a variation and may set a deadline for submitting the application.

Article 264

The Institute may engage experts in the field of medicinal products to perform specific professional tasks related to the supervision of pharmacovigilance activities, if such tasks require special expertise.

XIII. CLINICAL TRIALS OF VETERINARY MEDICINAL PRODUCTS

Article 265

A clinical trial of a veterinary medicinal product may be conducted by a legal entity that has obtained a clinical trial authorisation issued by the Institute.

The authorisation referred to in paragraph 1 of this Article shall be issued on condition that the food-producing animals used in the clinical trial, or their products, do not enter the food chain, unless the Institute has established an appropriate withdrawal period.

Clinical trial of a veterinary medicinal product can only be carried out in cases where the foreseeable risks and suffering of animals are estimated to be lower than the expected benefit for the experimental animals and for the animals for which the medicine is intended, which is decided by the Institute.

The application for conducting a clinical trial of a veterinary medicinal product shall be submitted by the sponsor of the clinical trial or the sponsor's representative with a registered office in Montenegro.

The applicant referred to in paragraph 4 of this Article may also be a natural or legal person with a headquarters in the European Union.

The Institute shall decide on the application referred to in paragraph 4 of this Article within 60 days from the date of receipt of a complete application.

The period referred to in paragraph 6 of this Article shall not include the time required for the applicant to provide the requested data to the Institute, i.e. the time from the day the Institute requests additional data from the applicant to the day such data is submitted.

The clinical trial of a veterinary medicinal product shall be conducted in accordance with the Good Clinical Practice Guidelines of the *International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products* (VICH), which are published on the websites of the Institute and the state administration authority competent for veterinary affairs.

Data stemming from clinical trials shall be submitted with the application for the granting of a marketing authorisation for a veterinary medicinal product as part of the technical documentation referred to in Article 221 paragraph 1 item 5 of this Law.

Data stemming from clinical trials conducted outside of Montenegro and the European Union may be taken into account when assessing an application for a marketing authorisation for a veterinary medicinal product only if the trials were designed, implemented, and reported in accordance with the guidelines referred to in paragraph 8 of this Article.

The Institute may suspend or revoke the approval for clinical testing of a veterinary medicinal product if the fulfilment of the conditions under which the authorisation was issued cease to be fulfilled.

The detailed conditions for conducting clinical trials, the content of the application referred to in paragraph 4 of this Article, the accompanying documentation, as well as the manner of conducting clinical trials of veterinary medicinal products, shall be prescribed by the state administration authority competent for veterinary affairs.

XIV. MANUFACTURE, IMPORT AND EXPORT OF VETERINARY MEDICINAL PRODUCTS

Article 266

The manufacture of a veterinary medicinal product may be carried out by a legal or natural person to whom the Institute has issued a manufacturing authorisation for a veterinary medicinal product in accordance with this Law.

A manufacturing authorisation for a veterinary medicinal product shall be granted for:

1) the manufacture of veterinary medicinal products, even if intended only for export;

2) to engage in any part of the process of manufacturing a veterinary medicinal product or the manufacture of the finished veterinary medicinal product, including processing, assembling, packaging and repackaging, labelling and relabelling, storage, sterilisation, testing, or release for supply within the manufacturing process; or

3) the import of veterinary medicinal products from third countries.

By way of derogation from paragraph 2 of this Article, a manufacturing authorisation for a veterinary medicinal product shall not be required for preparation, dividing up, changes in packaging or presentation of the medicinal product if such activities are carried out solely for retail in accordance with this Law.

In the case referred to in paragraph 3 of this Article, each issued quantity of a veterinary medicinal product shall be accompanied by a package leaflet and clearly indicate the batch number and expiry date of the medicinal product.

Article 267

An application for a manufacturing authorisation for a veterinary medicinal product shall be submitted to the Institute.

The following documents shall be submitted with the application referred to in paragraph 1 of this Article:

1) a list of veterinary medicinal products to be manufactured or imported;

2) the name and headquarters of the applicant;

3) the pharmaceutical forms which are to be manufactured or imported;

4) the location of the veterinary medicinal product manufacturing site;

5) a statement confirming that the applicant fulfils the conditions applicable to the holder of a manufacturing authorisation for a veterinary medicinal product and employs a person responsible for manufacturing and batch release of the veterinary medicinal product;

6) other information relevant for obtaining the manufacturing authorisation for a veterinary medicinal product.

The applicant for a manufacturing authorisation for a veterinary medicinal product shall also submit evidence demonstrating compliance with the conditions referred to in paragraph 2 of this Article.

Article 268

The Institute shall decide on the issuance of a manufacturing authorisation for a veterinary medicinal product within 90 days from the date of receipt of a complete application.

If the application for a manufacturing authorisation for a veterinary medicinal product is incomplete, the Institute shall notify the applicant in writing and set a deadline for rectifying the deficiencies.

The Institute may request the applicant to provide additional information concerning the data referred to in Article 267 of this Law and regarding the person responsible for manufacturing and batch release of the veterinary medicinal product.

In the cases referred to in paragraphs 2 and 3 of this Article, the time required for the applicant to submit the requested data to the Institute, i.e. the period from the day the Institute requests the additional data until the day of submission, shall not be counted within the time limit referred to in paragraph 1 of this Article.

The Institute shall issue the manufacturing authorisation for a veterinary medicinal product after verifying compliance with the conditions through an inspection procedure in accordance with the law.

The manufacturing authorisation for veterinary medicinal products shall be issued for specific products, manufacturing sites, and pharmaceutical forms listed in the application for the manufacturing authorisation.

The manufacturing authorisation for a veterinary medicinal product may be issued subject to conditions requiring the applicant to undertake specific measures or implement special procedures within a defined deadline.

In the case referred to in paragraph 7 of this Article, the manufacturer shall fulfil the conditions within the set deadline and inform the Institute accordingly.

If the manufacturer fails to meet the conditions referred to in paragraph 7 of this Article, the Institute may suspend or revoke the manufacturing authorisation for the veterinary medicinal product.

The manufacturing authorisation for a veterinary medicinal product containing narcotic substances shall be issued in accordance with this Law and specific legislation.

The manufacturing authorisation shall be issued on a standardised template established by European Union and EMA instruments and shall be published on the Institute's website in both Montenegrin and English.

Article 269

The holder of a manufacturing authorisation is responsible for the quality, safety, and efficacy of the veterinary medicinal product it manufactures.

Responsibility for the quality, safety, and efficacy of a veterinary medicinal product also lies with the manufacturer releasing the batch, as well as the marketing authorisation holder.

The holder of a manufacturing authorisation for a veterinary medicinal product shall be required to:

1) Have suitable premises, technical equipment, and testing capabilities for the activities specified in the manufacturing authorisation;

2) Have at its disposal the services of at least one person responsible for manufacturing and batch release of the veterinary medicinal product, and ensure that this person performs their duties in accordance with this Law;

3) Enable the person responsible for manufacturing and batch release to carry out their duties, in particular by providing access to the necessary documentation and premises, as well as the required technical and testing equipment;

4) Notify the Institute in writing at least 30 days in advance of any intended replacement of the person responsible for manufacturing and batch release of the veterinary medicinal product; if the replacement is unforeseen, the Institute shall be informed without delay;

5) Appoint persons responsible for manufacturing and quality control, who shall be independent of one another;

6) Ensure the Institute has access to its premises at all times;

7) Maintain records of all veterinary medicinal products it supplies in accordance with this Law and retain samples of each batch;

8) Supply veterinary medicinal products only to wholesale distributors of veterinary medicinal products;

9) Notify the Institute and the marketing authorisation holder in writing and without delay if it becomes aware that any products covered by the manufacturing authorisation are falsified or suspected of being falsified, regardless of whether they were distributed legally or illegally, including unauthorised internet sales;

10) Comply with Good Manufacturing Practice (GMP) for veterinary medicinal products and use as starting materials only active substances manufactured and placed on the

market in accordance with GMP for active substances and Good Distribution Practice (GDP) for active substances;

11) Ensure that the manufacturer, wholesaler, or importer from whom it sources active substances holds a manufacturing or distribution authorisation issued by the competent authority of the EU Member State where they are established;

12) Perform risk-based controls on manufacturers, wholesalers, and importers from whom it procures active substances.

The manufacturer shall, at the request of the Institute, or the Administration submit a report on the manufacturing of the veterinary medicinal product, stock levels, as well as the volume of sales for each individual medicinal product (per packaging unit) in Montenegro.

The report referred to in paragraph 4 of this Article shall be considered a business secret.

The Institute shall process the data referred to in paragraph 4 of this Article and shall publish the data on the total sales of veterinary medicinal products in Montenegro on its website.

The manufacturer of a veterinary medicinal product, or the holder of the manufacturing authorisation for a veterinary medicinal product, shall be obliged to ensure the continuous supply of the market with veterinary medicinal products in accordance with the manufacturing authorisation.

Article 270

The holder of a manufacturing authorisation shall have permanently at its disposal the services of at least one qualified person of the veterinary medicinal product.

The qualified person referred to in paragraph 1 of this Article shall hold a university degree in pharmacy, human medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, or biology.

The qualified person referred to in paragraph 1 of this Article shall have acquired at least two years of practical experience, in one or more authorised manufacturing undertakings, in the activities of quality assurance of medicinal products, qualitative analysis of medicinal products, quantitative analysis of active substances and the checks necessary to ensure the quality of veterinary medicinal products.

The required period of practical experience referred to in paragraph 3 of this Article may be reduced by one year where the university course lasts for at least five years and by one and a half years where the university course lasts for at least six years.

If the holder of a manufacturing authorisation is a natural person who meets the requirements laid down in paragraph 2 of this Article, that person may also perform the duties of the qualified person responsible for batch release.

The Institute may establish appropriate administrative procedures to verify that the qualified person referred to in paragraph 1 fulfils the requirements laid down in paragraphs 2 and 3 of this Article.

Person referred to in paragraph 1 of this Article shall ensure that:

1) Each batch of the veterinary medicinal product manufactured in Montenegro has been produced and subjected to quality control in accordance with this Law and the issued marketing authorisation; Qualified person shall draw up a control report to that effect;

2) If the veterinary medicinal product is imported from a third country, full qualitative and quantitative analysis of at least all active substances, and all other necessary tests to ensure the quality of the medicinal product in accordance with the marketing authorisation, have been performed and that the batch manufactured is in compliance with good manufacturing practice.

The qualified person referred to in paragraph 1 shall keep records in respect of each released production batch.

Records referred to in paragraph 8 of this Article shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for one year after the date of expiry of the batch or at least five years from recording, whichever is longer.

The provision of paragraph 7 shall also apply where a veterinary medicinal product manufactured in Montenegro is exported and subsequently re-imported into Montenegro.

In the case of a medicinal product imported from a third country that has concluded appropriate agreements with Montenegro ensuring that the manufacturer applies Good Manufacturing Practice standards at least equivalent to those set out in Article 279 paragraph 1 item 2 of this Law, and where quality control under paragraph 7 item 1 of this Article is carried out in the exporting country, the qualified person may prepare a quality control report as referred to in paragraph 7 item 1 of this Article without conducting necessary, unless Institute decides otherwise.

Article 271

If the holder of a manufacturing authorisation requests a modification and/or supplementation of the information referred to in Article 267 paragraph 2 of this Law, they shall submit to the Institute a request for the modification or supplementation of the manufacturing authorisation for veterinary medicinal products.

The request referred to in paragraph 1 of this Article shall contain a description of the requested modification and/or supplementation.

The Institute shall decide on the request referred to in paragraph 1 of this Article within 30 days from the date of receipt of a complete request.

By way of exception to paragraph 3 of this Article, in justified cases, or where there is a need for an inspection, the decision-making period of the Institute may be extended to up to 90 days.

If the request referred to in paragraph 1 of this Article is incomplete, the Institute shall inform the applicant accordingly and set a deadline for the rectification of the deficiencies.

The time period referred to in paragraphs 3 and 4 of this Article does not include the time required for the applicant to provide the requested data to the Institute, i.e. the period from the day the Institute requests additional data from the applicant to the day of their submission.

If the approved change requires an amendment to the data from the manufacturing authorisation, the Institute shall issue a new manufacturing authorisation for the veterinary medicinal product and update the Register of manufacturers of medicinal products.

If the approved information change does not require an amendment to the data from the manufacturing authorisation, the Institute shall approve the change by means of a written notification.

Article 272

In the event of non-compliance with the requirements laid down in this Law, the Institute shall, without prejudice to any other appropriate measures under national law, take one or more of the following measures:

1) suspend the manufacture of veterinary medicinal products;

2) suspend imports of veterinary medicinal products from third countries;

3) suspend or revoke the manufacturing authorisation for one or more pharmaceutical forms;

4) suspend or revoke the manufacturing authorisation for one or more activities in one or more manufacturing sites.

The manufacturing authorisation for a veterinary medicinal product shall also cease to be valid either at the request of the holder of the manufacturing authorisation or following a decision of the Institute to revoke the authorisation.

The Institute may suspend or revoke the manufacturing authorisation or suspend or revoke the authorisation for a veterinary medicinal product if the manufacturer:

1) does not carry out the manufacturing in accordance with the manufacturing authorisation, or no longer meets the conditions prescribed by this Law;

2) fails to fulfil, within the prescribed period, the obligations established on the day of issuance or after the issuance of the manufacturing authorisation;

3) fails to submit a request for the issuance of a GMP certificate in accordance with this Law;

4) in other justified cases in accordance with the law.

The Institute may also temporarily suspend the manufacture or import of veterinary medicinal products from third countries, or suspend or revoke the manufacturing authorisation for a group of medicinal products or for all medicinal products in the event of non-compliance with Article 268 paragraphs 5 to 8, Article 269, and Article 270 paragraphs 4 to 8 of this Law.

By the adoption of the decision referred to in paragraphs 2 to 4 of this Article, the manufacturing authorisation or marketing authorisation for a veterinary medicinal product shall cease to be valid for the period specified in the decision or permanently.

Article 273

The detailed conditions, the content of the request and accompanying documentation for the issuance of a manufacturing authorisation for veterinary medicinal products, as well as the content of the manufacturing authorisation, shall be prescribed by the Institute, with the approval of the state administration body responsible for veterinary affairs.

Article 274

A legal or natural person with headquarters or residence in Montenegro that is engaged in the manufacturing, import, or distribution of active substances used as starting materials in veterinary medicinal products shall register their activity with the Institute and shall comply with good manufacturing practice or good distribution practice.

The provisions of Article 105 of this Law shall apply mutatis mutandis to the registration procedure and the maintenance of the register referred to in paragraph 1 of this Article.

The conditions for the manufacturing, import, and distribution of active substances referred to in paragraph 1 of this Article shall be prescribed by the Institute, with the approval of the state administration authority responsible for veterinary affairs.

Article 275

The manufacturing, import, and distribution of active substances for veterinary medicinal products, including active substances intended for export, shall comply with the Good Manufacturing Practice (GMP) guidelines and the Good Distribution Practice (GDP) guidelines for active substances for veterinary medicinal products.

The provisions of Articles 106 to109 of this Law shall apply mutatis mutandis to the conformity control referred to in paragraph 1 of this Article, the issuance of GMP certificates for each site of manufacture, quality control, and batch release, as well as to extraordinary inspections of compliance.

Article 276

At the request of the manufacturer, exporter, or the competent authority of the importing country, the Institute shall issue a Certificate of Pharmaceutical Product (CPP) confirming that:

1) the manufacturer holds a manufacturing authorisation for a veterinary medicinal product;

2) the manufacturer holds a GMP certificate; or
3) the veterinary medicinal product is authorised in Montenegro.

Article 277

The holder of the manufacturing authorisation for a veterinary medicinal product shall keep records for all veterinary medicinal products supplied, including:

1) the date of the transaction;
2) the name of the veterinary medicinal product and, where applicable, the marketing authorisation number, as well as, as appropriate, the pharmaceutical form and strength;
3) the quantity supplied;
4) the name and address or headquarters of the recipient;
5) the batch number of the veterinary medicinal product;
6) the expiry date.

The holder of the marketing authorisation for a veterinary medicinal product shall make the records referred to in paragraph 1 of this Article available to the competent authorities for the purposes of inspection for one year after the expiry date of the batch or for at least five years from the date of recording, whichever is longer.

Article 278

The Institute shall enter the data on issued manufacturing authorisations for veterinary medicinal products into the Register of manufacturers.

Upon request of the manufacturer or other legal or natural persons with a legitimate legal interest, the Institute shall issue a certificate containing publicly available data recorded in the Register of manufacturers.

Article 279

The Institute shall publish the following on its website:

1) data on registered manufacturers, importers, and distributors of active substances used in the manufacture of veterinary medicinal products;
2) regularly updated GMP guidelines and GDP guidelines for active substances for veterinary medicinal products, as well as formal risk assessment guidelines in accordance with applicable European Union guidelines;
3) data on issued, suspended, or revoked manufacturing authorisations for veterinary medicinal products;
4) data on issued, suspended, or revoked GMP certificates for veterinary medicinal products;
5) data on GDP certificates for active substances for veterinary medicinal products.

The data referred to in paragraph 1 points 1, 3, and 4 of this Article shall be entered by the Institute into the EudraGMDP database.

In the event of non-compliance by importers, manufacturers or distributors of active substances with the requirements laid down in this Law, the Institute shall temporarily or definitively remove those importers, manufacturers or distributors from relevant Registers.

Article 280

The provisions of this Law relating to the manufacture of veterinary medicinal products shall apply mutatis mutandis to the import of veterinary medicinal products from third countries.

XV. WHOLESALE DISTRIBUTION AND RETAIL OF VETERINARY MEDICINAL PRODUCTS

Article 281

The distribution of veterinary medicinal products shall be carried out as wholesale and retail distribution.

Wholesale distribution of veterinary medicinal products includes procuring, holding, supplying or exporting of veterinary medicinal products weather for profit or not , apart from supply of veterinary medicinal products to end users.

By way of derogation from paragraph 2 of this article, the supply of small quantities of veterinary medicinal products, which covers up to ten unit packages per veterinary medicinal products, between holders of an authorization for retail of veterinary medicinal products, is not considered wholesale, provided that it is carried out no more than once a month, of which the responsible person keeps records.

Wholesale distribution of veterinary medicinal products may be carried out by:

1) legal or natural persons established in Montenegro that hold a wholesale distribution authorization for veterinary medicinal products issued in accordance with this Law (hereinafter: wholesale distributor of veterinary medicinal products);

2) manufacturers of veterinary medicinal products established in Montenegro, for medicinal products from their own manufacturing portfolio;

3) legal and natural persons established in the European Union, holding a wholesale distribution authorization for veterinary medicinal products issued in an EU Member State and having notified the Administration of the commencement of their activity in Montenegro.

Only veterinary medicinal products for which a marketing authorization has been issued or which have been registered in accordance with this Law, as well as those referred to in Article 219 of this Law, may be placed on the wholesale market in Montenegro.

Wholesale distribution of veterinary medicinal products also includes distribution of veterinary medicinal products received as donations or humanitarian aid.

Retail distribution of veterinary medicinal products shall be carried out in accordance with this Law.

The procedure for reporting wholesale trade in veterinary medicinal products in Montenegro for the persons referred to in paragraph 4 item 3 of this Article is prescribed by the state administration body responsible for veterinary affairs.

Article 282

Wholesale distribution of veterinary medicinal products shall be prohibited for:

1) any veterinary medicinal product for which a marketing authorization has not been issued, or for which no approval for procurement or import has been granted in accordance with this Law;

2) any product manufactured by an entity that does not hold a manufacturing authorization of veterinary medicinal product;

3) any product not labelled in accordance with this Law, unless otherwise provided by this Law;

4) any product lacking the appropriate quality documentation as required by this Law;

5) any product whose expiry date has passed or for which a quality defect has been identified such that the risk outweighs the benefit, in accordance with this Law;

6) any falsified product;

7) any product sold via sale at distance.

It shall be prohibited to supply or sell a veterinary medicinal product for the treatment of animals outside of a pharmacy or a legal entity authorized, in accordance with the law

governing veterinary activities, to conduct retail distribution of veterinary medicinal products, unless otherwise regulated by the law governing animal health protection.

The provisions of Article 145 of this Law shall apply mutatis mutandis to a quality defect of a veterinary medicinal product.

Wholesale immediately suspends the distribution of all veterinary medicinal products that they determine or suspect to be falsified and act according to instructions from the competent authorities, in accordance with this law.

Wholesale shall have an established procedure for dealing with falsified medicinal products.

The incident is recorded with all original details and investigated;

All suspected counterfeit veterinary medicinal products found in the supply chain are immediately separated physically or electronically, stored in a separate area from all other veterinary medicinal products and appropriately labelled. All dealings with such products are documented and records are kept.

The wholesaler shall inform the competent authorities about all withdrawals, and if the veterinary medicinal product is exported, the clients from the exporting country or the competent authorities of that country are also informed about the withdrawal.

In the event of withdrawal of a veterinary medicinal product, the wholesaler shall inform, with the appropriate degree of urgency and clear instructions, all customers to whom the product was sold.

Article 283

The wholesale distributor of veterinary medicinal products is obliged to carry out wholesale in accordance with the authorisation and the good distribution practice of veterinary medicinal products (hereinafter: GDP).

The wholesale distributor may otsource certain tasks of the distribution to another wholesale distributor.

By way of derogation from paragraph 2 of this article, wholesale distributor from paragraph 1 of this article may also entrust the transport of veterinary medicinal products to a legal or physical person that is not a wholesaler of veterinary medicinal products, and which is registered for carrying out transport, in accordance with the law and meets the requirements of the GDP.

Detailed manner and conditions for implementing good distribution practice measures for veterinary medicinal products applied by holders of a manufacturing authorisation for veterinary medicinal products, that carry out wholesale distribution of veterinary medicinal products, for medicinal products from their manufacturing range and wholesale, including those who have headquarters or operate within special customs regimes, e.g. free zones or customs warehouses, shall be prescribed by the state administration body competent for veterinary affairs.

Article 284

A wholesale distributor of veterinary medicinal products shall supply veterinary medicinal products only to other wholesale distributors of veterinary medicinal products and to legal entities holding an authorization for the retail distribution of veterinary medicinal products.

By way of derogation from paragraph 1 of this Article, a wholesale distributor of veterinary medicinal products may supply veterinary medicinal products to legal entities performing veterinary activities in accordance with the regulation governing veterinary practice, scientific and educational institutions authorized to conduct animal experiments in accordance with the regulation governing the protection of animal welfare and manufacturers

of medicated feed for animals who hold an approval issued in accordance with the regulation governing animal feed safety.

The wholesale distributor is obliged to ensure the continuous supply of legal entities from paragraphs 1 and 2 of this article with veterinary medicinal products, in order to ensure the needs of animal health in Montenegro.

The wholesale distributor is obliged to, at the request of legal entities from paragraphs 1 and 2, supply the veterinary medicinal product as soon as possible, so that it does not endanger the life and health of animals and people.

The wholesale distributor, as well as the marketing authorisation holder, are obliged, in accordance with this law, to provide the necessary supplies of veterinary medicinal products in order to continuously supply the market, i.e. to start procurement, import and provide a certificate of quality control in a timely manner, so that there is no interruption in the supply of veterinary medicinal products to the market.

Article 285

A wholesale distributor of veterinary medicinal products shall:

1) verify that the received veterinary medicinal products are not falsified;

2) have in place an emergency plan for the recall of a veterinary medicinal product from the market, based on a decision by the Administration or the Institute, or in cooperation with the manufacturer or the marketing authorisation holder of the product concerned;

3) ensure that the Administration, for the purpose of inspection in accordance with this Law, is granted access to the required records for a period of five years;

4) provide access to premises, installations and equipment for the purpose of inspection in accordance with this Law;

5) ensure compliance with Good Distribution Practice (GDP);

6) maintain a quality management system that defines responsibilities, procedures and risk management measures relating to its activities.

A wholesale distributor of veterinary medicinal products shall obtain veterinary medicinal products only from a holder of a manufacturing authorization for veterinary medicinal products or from other holders of a wholesale distribution of veterinary medicinal products, aligned with GDP.

Article 286

The wholesale distribution shall have, at least one person responsible for the wholesale distribution of veterinary medicinal products and the implementation of GDP.

The person referred to in paragraph 1 of this article shall hold a degree in veterinary medicine or pharmacy and shall be employed full-time.

Article 287

A wholesale distributor of veterinary medicinal products shall keep detailed records of each transaction of veterinary medicinal products, including:

1) date of the transaction;

2) name of the veterinary medicinal product, including, as appropriate, pharmaceutical form and strength;

3) batch/lot number;

4) expiry date of the veterinary medicinal product;

5) quantity of received or supplied veterinary medicinal product, stating pack size and number of packs;

6) name and permanent address or registered place of business of the supplier in the event of purchase or of the recipient in the event of sale.

A wholesale distributor of veterinary medicinal products shall carry out a detailed audit of the stock at least once a year and compare incoming and outgoing of veterinary medicinal products recorded with veterinary medicinal products currently held in stock, and records of discrepancies shall be retained for at least five years and made available to the competent authorities.

The wholesale distributor of veterinary medicinal products shall submit to the Administration, by 1 March of the current year, data on the wholesale distribution of veterinary medicinal products for the previous year, on the form prescribed by the Administration and published on the Administration s website.

Article 288

The person referred to in Article 281, paragraph 4 of this law may not start the wholesale distribution of veterinary medicinal products before obtaining an authorisation for the wholesale distribution of veterinary medicinal products.

The application for issuing an authorisation from paragraph 1 of this article is submitted to the Administration for each location.

In the application from paragraph 2 of this article, a wholesale distribution of veterinary medicinal products shall state the data on the groups of veterinary medicinal products for which it is requesting a marketing authorisation.

Along with the application from paragraph 2 of this article, the applicant is obliged to submit the following:

1) name and address of the legal entity, proof of professional background and employment contract with the person responsible for wholesale distribution of veterinary medicinal products;

2) lease agreement or proof of ownership (real estate deed) of business premises that ensures proper storage, keeping and wholesale distribution of veterinary medicinal products;

3) emergency action plan for the withdrawal or recall of the veterinary medicine product from the market by the decision of the Institute or the Administration in cooperation with the marketing authorisation holder for the withdrawn veterinary medicine;

4) list of equipment and technical data on the equipment,

5) proof of the established record keeping system;

6) quality system description, quality manual or other appropriate document and list of standard operating procedures;

7) proof of the paid fees for the procedure in accordance with a special law;

8) a layout of the facility with shown rooms and spaces used for the wholesale distribution of veterinary medicinal products, including the equipment shown on the layout.

The Administration shall decide on the application from paragraph 2 of this article within 90 days from the date of receipt of the complete application at the latest.

In the event that the application from paragraph 2 of this article is not complete, the Administration informs the applicant about this in writing and sets a deadline for eliminating the deficiencies.

After submitting the complete application from paragraph 2 of this article, the Administration forms a wholesale review committee (hereinafter: the committee), in order to determine the fulfilment of the requirements established by this law.

After verifying the fulfilment of the prescribed conditions and at least one inspection of the wholesale distributor in terms of space, equipment, personnel and appropriate documentation and systems established by the wholesale distributor, the committee draws up a report with a proposal for issuing a conditional authorisations for a maximum period of two months.

The Administration, based on the proposal from paragraph 8 of this article, issues a conditional authorisation for the wholesale distribution of veterinary medicinal products and enters the wholesale distributor in the Register referred to in Article 289 of this law.

Before the expiration of the deadline referred to in paragraph 8 of this article, the committee shall conduct a subsequent inspection of the wholesale distributor during the performance of wholesale activities, in order to determine and verify the fulfilment of other conditions established by this law.

When the direct inspection from paragraph 8 of this Article establishes that the prescribed conditions in terms of space, equipment, personnel and appropriate documentation and the established system have not been met, the commission draws up minutes with a proposal to reject the request, on the basis of which the Administration makes a decision on rejection.

If the subsequent inspection from paragraph 10 of this article determines that the conditions prescribed by this law have been met, the Administration issues a authorisation for the wholesale distribution of veterinary medicinal products, based on the committee proposal.

If a subsequent inspection establishes that the conditions laid down by this Law are not fulfilled, the Administration shall issue a decision revoking the conditional wholesale distribution authorisation for veterinary medicinal products and removing the wholesale distributor from the register referred to in Article 289 of this Law.

Detailed requirements for wholesale distribution of veterinary medicinal products, the content and format of the application for the wholesale distribution authorisation of veterinary medicinal products, the content of the wholesale authorisation, conditions that shall be met by persons who sell veterinary medicinal products containing drugs or psychotropic substances and accompanying documentation are prescribed by the state administration body responsible for veterinary affairs.

Article 289

The Register of granted, suspended and revoked authorisations for the wholesale distribution of veterinary medicinal products (hereinafter: Register of wholesale distributors of veterinary medicinal products) is established and maintained by the Administration.

The Administration enters data from the Register of wholesale distributors of veterinary medicinal products into the EudraGMDP database.

At the request of wholesale distributor and other legal or natural persons who have a justified legal interest, the Administration issues a certificate on the data kept Register of wholesale distributors of veterinary medicinal products.

The wholesale of wholesale distributor is obliged to notify the Administration of temporary or permanent interruption of the supply of veterinary medicinal products at least two months before the interruption, except in case of urgent withdrawal or in case of force majeure, of which it informs the Administration without delay.

The content, form and manner of keeping the register referred to in paragraph 1 of this article shall be prescribed by the state administration body responsible for veterinary affairs.

Article 290

The wholesale distributor is obliged to, in the event of a change in the terms of the authorization, notify the Administration in writing within 15 days from the date of the change and submit a request for a change or supplement to the authorization.

In the event that the request from paragraph 1 of this article is not complete, the Administration informs the applicant about this in writing and sets a deadline for eliminating the deficiencies.

The Administration decides on the request from paragraph 1 of this article within 30 days from the date of receipt of the complete request.

Detailed conditions for supplementing or changing the wholesale authorisation are prescribed by the state administration body responsible for veterinary affairs.

Article 291

The authorization for wholesale distribution of veterinary medicinal products ceases to be valid at the request of the wholesale distributor or upon revoke by the Administration.

The administration can suspend or revoke the wholesale distribution authorization of veterinary medicinal products if the wholesale distributor:

1) does not carry out wholesale distribution in accordance with the granted authorization, i.e. if it does not submit a request for change or amendment of the authorization in accordance with this law;

2) ceases to meet the requirements for wholesale distribution in accordance with this law;

3) fails to eliminate non-compliances in the work identified by the Administration or the veterinary inspector in accordance with this law within a certain period of time;

4) does not fulfil the obligation to continuously supply the market with medicinal products for which it has been granted a wholesale authorization;

5) carries out wholesale distribution of falsified medicine or fails to notify the competent authorities under Article 145 of this law for a medicinal product suspected of being falsified or found to be falsified.

If the Administration revokes the permit for wholesale distribution, it informs the customs authority about this.

In the event that the Administration assesses that the wholesale distribution, which was granted a wholesale authorization by another EU member state, has ceased to meet the conditions on the basis of which the authorisation was issued, it shall notify the European Commission and that member state thereof without delay.

Article 292

In addition to the requirements laid down by this Law, person engaged in the wholesale distribution of veterinary medicinal products containing narcotic drugs and psychotropic substances shall comply with specific requirements in accordance with a special law.

Article 293

Retail of veterinary medicinal products can be carried out by legal entities based in Montenegro that have an authorisation for the retail of veterinary medicinal products issued in accordance with this law (hereinafter: veterinary pharmacy).

In addition to veterinary pharmacies, the retail of veterinary medicinal products can also be carried out by legal entities that, in accordance with the law regulating veterinary activity, can engage in retail trade, if they have an authorization for the retail trade of veterinary medicinal products issued in accordance with this law.

Article 294

The application for the issuance of an authorization for the retail of veterinary medicinal products, for each individual location, is submitted to the Administration before starting the activity.

The application from paragraph 1 of this article shall be accompanied by appropriate documentation in terms of space, personnel, equipment and procedures for the retail of veterinary medicinal products.

The veterinary pharmacy and persons referred to in Article 293 paragraph 2 of this law shall have a person responsible for the retail of veterinary medicinal products who has graduated from the veterinary faculty.

Veterinary pharmacy and persons referred to in Article 293, paragraph 2 of this law, who manufacture extemporaneously prepared veterinary medicinal products, shall also have a pharmacist.

Veterinarians and veterinary technicians may perform work in the veterinary pharmacy and the person referred to in Article 293 paragraph 2 of this law.

The Administration issues an authorisation for the retail of veterinary medicinal products within 30 days from the date of receipt of a complete application.

The Administration shall verify the fulfilment of the conditions prescribed by this law within three months from the date of issuance of the permit for retail of veterinary medicinal products.

The Administration enters data on issued authorisations for the retail of veterinary medicinal products in the Register and publishes them on the Administration's website.

The detailed manner of submission and the content of the request from paragraph 1 of this article and accompanying documentation, the detailed requirements regarding space, personnel and equipment, as well as the content and method of keeping the register from paragraph 8 of this article shall be prescribed by the state administration body responsible for veterinary affairs.

Article 295

Veterinary pharmacy and entities referred to in Article 293, paragraph 2 shall keep records of the marketing of veterinary medicinal products issued on veterinary prescription, which shall in particular include:

1) date of the retail transaction;

2) name of the veterinary medicinal product, including, as applicable, pharmaceutical form and strength;

3) batch number;

4) data on the quantity received or dispensed;

5) name and address of the wholesale distributor in the event of purchase, or of the recipient in the event of sale;

6) full name and contact details of the prescribing veterinarian and, where appropriate, a copy of the veterinary prescription;

7) marketing authorisation number of the veterinary medicinal product.

Veterinary pharmacies and the entities referred to in Article 293 paragraph 2 of this Law shall be required to keep records on the retail distribution of veterinary medicinal products not subject to veterinary prescription.

Veterinary pharmacies and the entities referred to in Article 293 paragraph 2 of this Law shall carry out, at least once a year, a detailed audit of the stock and compare the incoming and outgoing veterinary medicinal products recorded with veterinary medicinal products currently held in stock. Records of any discrepancies shall be kept for a minimum of five years and made available to the competent authorities upon request.

Veterinary medicinal products subject to veterinary prescription may only be sold to persons of legal age.

Veterinary pharmacies and the entities referred to in Article 293 paragraph 2 of this Law shall notify the Administration of any changes related to the retail distribution authorisation for veterinary medicinal products within 15 days from the date such change occurs.

Article 296

Veterinary pharmacies and the entities referred to in Article 293 paragraph 2 of this Law shall be removed from the register referred to in Article 294 paragraph 8 of this Law:

1) at the request of the holder of the retail distribution authorisation for veterinary medicinal products;

2) upon the proposal of the veterinary inspector, where the inspection establishes that the veterinary pharmacy or the entity referred to in Article 293 paragraph 2 of this Law does not meet the prescribed requirements or has not carried out the authorised activity for more than one year.

Article 297

A veterinary pharmacy, i.e. a person referred to in Article 289, paragraph 2 of this law, may offer veterinary medicinal products not subject to a veterinary prescription for sale at distance, with prior notification to the Administration.

The Administration shall enter into the register referred to in Article 294 paragraph 8 of this Law the data on veterinary pharmacies and the entities referred to in Article 293 paragraph 2 of this Law that engage in sale at distance of veterinary medicinal products, including their addresses and websites.

The Administration publishes on its website:

1) information on the regulations governing the offering of veterinary medicinal products for sale at distance, including information on the fact that there may be differences in the classification of veterinary medicinal products between the member states of the European Union;

2) information on the common logo;

3) list of veterinary pharmacies, i.e. persons referred to in Article 293, paragraph 2,

permitted to offer veterinary medicinal products not subject to veterinary prescription for sale at distance.

4) link to the EMA website.

Veterinary pharmacies and legal entities referred to in Article 293 paragraph 2 of this law are obliged to publish at least the following on the website they use for the purpose of distance retail:

1) contact details of the Administration;

2) a hyperlink to the website of the Administration, where data on sale at distance are published;

3) common logo, which is clearly displayed on every page of the website where veterinary medicinal products are offered for sale at distance;

4) a hyperlink to the Register from article 294, paragraph 8 of this law.

The detailed conditions for the design of the common logo and method of using the common logo are prescribed by the state administration body responsible for veterinary affairs.

Article 298

A veterinarian may prescribe a veterinary prescription in paper or electronically only after a clinical examination or other appropriate assessment of the health status of the animal or group of animals.

In the case referred to in paragraph 1 of this Article, the quantity of the prescribed veterinary medicinal product shall be limited to the amount necessary for the treatment of that animal or group of animals from the same owner.

A veterinary prescription for an antimicrobial medicinal product for metaphylaxis may only be issued after a diagnosis of the infectious disease by a veterinarian.

Upon request of the competent authority, the veterinarian shall justify a veterinary prescription for an antimicrobial medicinal product, in particular in the case of metaphylaxis or prophylaxis.

As regards antimicrobial medicinal products for metaphylaxis or prophylaxis, they shall be prescribed only for a limited duration to cover the period of risk.

A veterinary prescription for an antimicrobial medicinal product and a veterinary medicinal product containing narcotic drugs or psychotropic substances and substances from which narcotic drugs can be obtained is valid for five days from the day of issue, and for all other veterinary drugs, the prescription is valid for 30 days from the day of the prescription.

A veterinarian may use a veterinary medicinal product subject to veterinary prescription without a prescription if providing direct animal health care services or for the preparation of medicated feed, in which case the veterinarian shall maintain appropriate records.

Veterinary prescriptions issued in another European Union Member State shall also be valid in Montenegro.

The Administration shall publish the veterinary prescription template on its website.

Veterinary medicinal products containing narcotic drugs and psychotropic substances shall be dispensed using a special prescription form published by the Administration on its website.

The content and format of the veterinary prescription referred to in paragraphs 9 and 10 of this Article, the manner of keeping and storing records of issued veterinary prescriptions, as well as the content, manner of keeping and storing the records referred to in paragraph 7 of this Article, shall be prescribed by the state administration body responsible for veterinary affairs.

Article 299

A veterinary medicinal product shall be used in accordance with the conditions laid down in the marketing authorisation for the veterinary medicinal product, and in the case of a veterinary medicinal product referred to in Article 219 of this Law, in accordance with the instructions for the veterinary medicinal product.

The use of veterinary medicinal products for the prevention and control of diseases shall be carried out in accordance with the legislation governing animal health protection.

Inactivated immunological veterinary medicinal product referred to in Article 2 paragraph 3 item 2 of this Law shall only be used in exceptional circumstances, in accordance with a veterinary prescription, and only if no immunological veterinary medicinal product is authorised for the target animal species and the indication.

More detailed conditions for the use of veterinary medicinal products, a list of veterinary medicinal products that may only be administered by a veterinarian, as well as detailed measures to ensure the efficient and safe administration of veterinary medicinal products for oral administration, except for medicated animal feed, through other means, such as mixing drinking water with the veterinary medicinal product or manually mixing the veterinary medicinal product in the animal feed that the animal keeper gives to food-producing animals, shall be prescribed by the state administration body competent for veterinary affairs.

Article 300

The use of antimicrobial medicinal products is prohibited:

1) routinely nor used to compensate for poor hygiene, inadequate animal husbandry, lack of animal care, or poor farm management practices;

2) for the purpose of promoting nor to increase yield in animals;

3) for prophylaxis, other than in exceptional cases, for administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe, and the use of antibiotics for

prophylaxis shall be limited to administration to an individual animal only, under the condition of this point;

4) for metaphylaxis, except where the risk of spread of infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available.

The state administration body responsible for veterinary affairs can by Order additionally limit or prohibit the use of certain antimicrobial medicinal products if it is justified and in order to implement the national policy for reducing antimicrobial resistance.

The Administration shall issue guidelines on the alternatives referred to in paragraph 1 item 4 of this Article and shall actively support the development and implementation of guidance that contributes to the understanding of the risks associated with metaphylaxis and the criteria for initiating metaphylaxis.

Medicinal products which contain antimicrobial substances that are reserved for human use, in accordance with Article 24 points 2 and 3, may not be administered pursuant to Articles 304, 305, and 306 of this Law.

The list of medicinal products that shall not be used contrary to the terms of the marketing authorisation. and medicinal products that shall not be used under certain conditions contrary to the terms of the marketing authorization in accordance with Articles 304, 305 and 306 of this Law, established by the European Commission, shall be published by the competent authority for veterinary affairs in the "Official Gazette of Montenegro".

The state administration body for veterinary affaires shall inform EC on restrictions or prohibitions from paragraph 2 from this article.

Article 301

Owners or keepers of food-producing animals shall keep records of medicinal products administered to animals and, where applicable, a copy of the veterinary prescription.

The record referred to in paragraph 1 of this Article shall include:

1) the date of the first administration of the medicinal product to the animal;

2) the name of the medicinal product;

3) the quantity of the medicinal product administered;

4) the name and address of the supplier;

5) evidence of acquisition of the medicinal products used;

6) identification of the animal or group of animals treated;

7) name, surname, and contact details of the veterinarian who prescribed, dispensed, or administered the medicinal product, if applicable;

8) the withdrawal period, even if it is zero;

9) the duration of treatment.

If the information required under paragraph 1 of this Article is already available on the copy of the veterinary prescription, in the farm register, or in the single lifetime identification document for equidae in accordance with this Law, it does not need to be recorded separately.

The record referred to in paragraph 1 of this Article shall be kept for 5 years and made available to the competent inspection authority upon request.

The detailed method of record-keeping and the template for the record referred to in paragraph 1 of this Article, as well as the detailed content and manner of keeping the single lifetime identification document for equidae, shall be prescribed by the state administration body competent for veterinary affairs.

Article 302

The state administration body competent for veterinary affairs may prohibit the manufacture, importation, distribution, possession, sale, supply, or use of immunological veterinary medicinal products on the entire territory or part of the territory of Montenegro if:

1) the use of the medicinal product may interfere with the implementation of a national programme for the diagnosis, control, or eradication of animal diseases;

2) the use of the medicinal product may cause difficulties in certifying the absence of disease in live animals or contamination of foodstuffs or other products obtained from treated animals;

3) the strains of disease agents of the against to which the product provides immunity are not predominantly present throughout the entire territory or part of the territory of Montenegro, in terms of geographical distribution.

By way of derogation from Article 299 paragraph 1 of this Law, and in the absence of a veterinary medicinal product authorised by the Institute or a competent authority of a European Union Member State, in the event of an outbreak of an animal disease established by a special regulation governing animal health protection, the Institute, in cooperation with the Administration, may authorise the use of an immunological veterinary medicinal product that does not have a marketing authorisation.

By way of derogation from Article 299 paragraph 1 of this Law, where a marketing authorisation has been granted for an immunological veterinary medicinal product but that product is no longer available in Montenegro or in any EU Member State, and the disease is not established by a special regulation on animal health protection, the Institute, in cooperation with the Administration, may authorise the use of an unauthorised immunological veterinary medicinal product on a case-by-case basis.

The Administration shall, without delay, inform the European Commission of any actions taken pursuant to paragraphs 1, 2, and 3 of this Article, including details of the conditions imposed for the implementation of those provisions.

Where an animal is to be exported and is subject to specific binding health requirements in the country of destination, the Institute, in cooperation with the Administration, may authorise the use of an immunological veterinary medicinal product that does not have a marketing authorisation, exclusively for that animal, provided its use is permitted in the destination country.

Article 303

A veterinarian who is resident in a Member State of the European Union and provides animal health services in Montenegro may possess and administer a veterinary medicinal product that has not been authorised by the Institute to an animal or group of animals under his/her care, in the quantity not exceeding the amount required for treatment prescribed by the veterinarian, provided that:

1) a marketing authorisation for the veterinary medicinal product has been granted by the competent authority of the EU Member State in which the veterinarian resides or by the European Commission;

2) the veterinary medicinal product is transported by the veterinarian in its original packaging;

3) the veterinarian acts in accordance with the guidelines on good veterinary practice;

4) the veterinarian determines the withdrawal period stated on the labelling or package leaflet of the veterinary medicinal product;

5) the veterinarian does not retail any veterinary medicinal product to an owner or keeper of the animals treated in Montenegro.

The provisions of paragraph 1 of this Article shall not apply to immunological veterinary medicinal products, except in the case of toxins and sera.

Article 304

Where there is no authorised veterinary medicinal product in Montenegro, or a product referred to in Article 219 of this Law, for a specific indication in a non-food-producing animal species, a veterinarian may, under his/her own responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned using:

1) a veterinary medicinal product authorised by the Institute or by the competent authority of an EU Member State for use in the same or another animal species for the same or for another indication;

2) if no veterinary medicinal product as referred to in item 1 is available, a medicinal product for human use authorised by the Institute or by the competent authority of an EU Member State;

3) if neither of the products referred to in points 1 and 2 is available, an appropriate extemporaneously prepared veterinary medicinal product (magistral or officinal formula) prepared according to a veterinary prescription.

Except in the case of immunological veterinary medicinal products, where none of the options referred to in paragraph 1 is available, the veterinarian may, under his/her own responsibility and in particular to avoid unacceptable suffering, treat animals not intended for food production using a veterinary medicinal product authorised in a third country for the same species and indication.

The medicinal products referred to in paragraphs 1 and 2 of this Article may also be used for the treatment of equidae not intended for human consumption, provided that the unique lifelong identification document indicates that the animal is not intended for slaughter for human consumption.

The provisions of paragraphs 1, 2 and 3 of this Article shall also apply where a veterinary medicinal product authorised by the Institute is temporarily unavailable on the market.

Article 305

Where there is no authorised veterinary medicinal product in Montenegro, or a product referred to in Article 219 of this Law, for an indication concerning a food-producing terrestrial animal species, a veterinarian may, under his/her own responsibility and in particular to avoid causing unacceptable suffering to animals, treat such animals using:

1) a veterinary medicinal product authorised by the Institute or by the competent authority of a Member State of the European Union for use in the same or in another food-producing terrestrial animal species for the same or for another indication;

2) if there is no product under item 1 of this paragraph, a veterinary medicinal product authorised by the Institute or by the competent authority of a Member State of the European Union for use in non-food-producing animal species for the same indication;

3) if there is no veterinary medicinal product under points 1 and 2 of this, a medicinal product for human use authorised by the Institute or by the competent authority of a Member State of the European Union;

4) if there is no medicinal product under points 1, 2 and 3 of this paragraph, an appropriate extemporaneously prepared veterinary medicinal product (magistral or officinal formula) prepared according to a veterinary prescription.

Except as regards immunological veterinary medicinal products, where there is no medicinal product under paragraph 1 of this Article, the veterinarian may, under his/her own responsibility and in particular to avoid causing unacceptable suffering, treat food-producing terrestrial animals with a veterinary medicinal product authorised in a third country for the same species and the same indication.

The pharmacologically active substances contained in the medicinal product used under paragraphs 1 and 2 of this Article shall be authorised in accordance with Regulation (EC) No 470/2009 and of the Council and Regulation (EC) No 726/2004.

The provisions 1, 2, 3 of this Article shall also apply where a veterinary medicinal product authorised by the Institute is temporarily unavailable on the market.

Article 306

Where there is no veterinary medicinal product authorised by the Institute, or a product referred to in Article 219 of this Law for an indication concerning a food-producing aquatic species, the veterinarian may, under his/her own responsibility and in particular to avoid causing unacceptable suffering to animals, treat such animals using:

1) a veterinary medicinal product authorised by the Institute or by the competent authority of a Member State of the European Union for use in the same or another food-producing aquatic species, for the same or for another indication;

2) if there is no veterinary medicinal product referred to in item 1 of this paragraph, a veterinary medicinal product authorised by the Institute or by the competent authority of a Member State of the European Union for use in food-producing terrestrial species, containing a substance present in the list referred to in paragraph 3 of this Article;

3) if there is no veterinary medicinal product referred to in points 1 and 2 of this paragraph, a medicinal product for human use authorised by the Institute or by the competent authority of a Member State of the European Union, provided it contains a substance included on the list referred to in paragraph 3 of this Article; or

4) if there is no product referred to in points 1, 2 and 3 of this paragraph, an appropriate extemporaneously prepared veterinary medicinal product (magistral or officinal formula) prepared according to a veterinary prescription.

By way of derogation from paragraph 1 points 2 and 3 of this Article, and until the list referred to in paragraph 3 of this Article is established, the veterinarian may, under his/her own responsibility and in particular to avoid causing unacceptable suffering to animals, treat aquatic food-producing animal species on a particular holding:

1) with a veterinary medicinal product authorised by the Institute or by the competent authority of a Member State of the European Union for use in food-producing terrestrial animal species;

2) if there is no veterinary medicinal product referred to in item 1 of this paragraph, with a medicinal product for human use authorised by the Institute or by the competent authority of a Member State of the European Union.

The list of substances used in veterinary medicinal products authorised for use in food-producing terrestrial animals, or substances contained in medicinal products for human use authorised in accordance with this Law, that may be used in food-producing aquatic species pursuant to paragraph 1 of this Article, as established by the European Commission, shall be published by the competent authority for veterinary affairs in the "Official Gazette of Montenegro."

Except as regards immunological veterinary medicinal products, where there is no product referred to in paragraphs 1 and 2 of this Article available, a veterinarian may, under his/her own responsibility and in particular to avoid causing unacceptable suffering to animals, treat food-producing aquatic species with a veterinary medicinal product authorised in a third country for the same species and the same indication.

The pharmacologically active substances contained in the medicinal products used in accordance with paragraphs 1, 2 and 4 of this Article shall be permitted in accordance with Regulation (EC) No 470/2009 and Regulation (EC) No 726/2004.

The provisions from 1 to 5 of this Article shall also apply where a veterinary medicinal product authorised by the Institute is temporarily unavailable on the market.

Article 307

Where no withdrawal period is specified in the summary of product characteristics (SmPC) of a medicinal product used in accordance with Articles 305 and 306 for the relevant animal species, the veterinarian shall determine the withdrawal period based on the following criteria:

1) For meat and offal from food-producing mammals and poultry and farmed game birds the withdrawal period may not be shorter than:

- the longest withdrawal period provided in the summary of the product characteristics for meat and offal multiplied by a factor of 1.5;
- 28 days if the medicinal product is not authorised for use in food-producing animals;
- one day, if the medicinal product has a zero withdrawal period and is used in a different taxonomic family than that the target species authorised.

2) For milk from animals producing milk for human consumption the withdrawal period may not be shorter than:

- the longest withdrawal period for milk provided in the summary of the product characteristics for any animal species multiplied by a factor of 1.5;
- seven days if the medicinal product is not authorised for use in animals producing milk for human consumption;
- one day if the medicinal product has a zero withdrawal period.

3) For eggs from animals producing of eggs for human consumption:

- the withdrawal period may not be shorter than the longest withdrawal period for eggs provided in the summary of the product characteristics for any animal species multiplied by a factor of 1.5;
- ten days if the product is not authorised for use in animals producing eggs for human consumption.

4) For aquatic species producing meat for human consumption the withdrawal period may not be shorter than:

- the longest withdrawal period for any aquatic species indicated in the summary of the product characteristics multiplied by a factor of 1.5 and expressed in degree-days;
- if the medicinal product is authorised for food-producing terrestrial animal species , the longest withdrawal period specified in the summary of product characteristics for any of the food-producing animal species multiplied by a factor of 50 and expressed as degree-days, but not exceeding 500 degree-days;
- 500 degree-days if the medicinal product is not authorised for use in food-producing animals;
- 25 degree-days if the longest withdrawal period for any animal species is zero.

If the calculation of the withdrawal period under item 1 indent 1, item 2 indent 1, item 3 indent 1 and item 4 indents 1 and 2 of this Article results in a fraction of a day, the withdrawal period shall be rounded to the nearest whole day.

For bees, the veterinarian shall determine an appropriate withdrawal period by assessing the specific situation of the individual beehive or beehives on a case-by-case basis, taking into account the risk of residues in honey or any other foodstuffs harvested from the beehives intended for human consumption.

A list of substances essential for the treatment of equidae or which provide additional clinical benefit compared to other treatment options available for equine species, for which the withdrawal period is six months, shall be established by the competent authority for veterinary affairs.

Article 308

Provisions of Article 300 of this Law relating to the use of antimicrobial medicinal products for the purpose of promoting growth or increasing yield in animals, and the provisions of Article 241 paragraph 3 of this Law concerning the prohibition of the use in animals of antimicrobial substances or groups of antimicrobial substances reserved exclusively for the treatment of certain infections in humans, shall apply, as appropriate, also to animals imported into Montenegro.

Detailed requirements regarding the use of antimicrobial medicinal products in animals imported into Montenegro shall be laid down by the state administration authority responsible for veterinary affairs.

Article 309

In the event of a risk to public health, animal health or the environment, the Institute or the competent authority for veterinary affairs shall prohibit the supply of a veterinary medicinal product, and shall prohibit the marketing authorisation holder or the supplier to cease the supply or recall of the veterinary medicinal product from the market where it has established that:

1) the benefit-risk balance of the veterinary medicinal product is no longer positive;

2) the qualitative or quantitative composition of the veterinary medicinal product is not as stated in the summary of product characteristics;

3) the recommended withdrawal period is insufficient to ensure the food safety;

4) the quality control has not been carried out; or

5) the incorrect labelling might lead to a serious risk to animal health or public health.

The prohibition on supply and the recall from the market referred to in paragraph 1 of this Article may be restricted solely to the contested production batch or batches of the veterinary medicinal product concerned.

Article 310

Veterinary medicinal products with an expired shelf-life, or in which there is an inaccuracy in terms of its prescribed quality and other medicinal products prohibited for marketing or recalled from the market can not be on the market or in use.

Veterinary medicinal products shall be disposed in accordance with the documentation of the manufacturer based on which the authorisation for the medicinal product is issued and in accordance with the law governing waste management.

XVI. ADVERTISING OF VETERINARY MEDICINAL PRODUCTS

Article 311

Advertising of a veterinary medicinal product means the making of a representation in any form in connection with veterinary medicinal products in order to promote the supply, distribution, sale, prescription or use of veterinary medicinal products and comprising also the supply of samples and sponsorships.

Advertising of a veterinary medicinal product shall:

1) make it clear that it aims at promoting the supply, sale, prescription, distribution, or use of the veterinary medicinal product;

2) not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide;

3) comply with the summary of product characteristics of the veterinary medicinal product;

4) not include information which could be misleading or lead to incorrect use of the veterinary medicinal product;

5) encourage the responsible use of the veterinary medicinal product, by presenting the product objectively and without exaggerating its properties.

It is prohibited to advertise a veterinary medicinal product that has not been granted a marketing authorisation or that is not authorised for marketing, or for which the marketing authorisation has been revoked in accordance with this Law.

It is prohibited to advertise a veterinary medicinal product for which the marketing authorisation has been suspended, during the period of that suspension.

A veterinary medicinal product shall not be distributed for promotional purposes, except for small quantities of samples.

Samples referred to in paragraph 5 of this Article shall be labelled with the statement "free sample – not for sale" or words of equivalent meaning and shall only be given directly to veterinarians during sponsored events or by sales representatives during their visits.

Antimicrobial veterinary medicinal products shall not be distributedfor promotional purposes, either as samples or in any other presentation.

Article 312

The advertising of a veterinary medicinal product that is subject to veterinary prescription shall be allowed only when made exclusively to veterinarians.

By way of derogation from paragraph 1 of this Article, advertising of a veterinary medicinal product subject to veterinary prescription is permitted to professional keepers of animals provided that:

1) it is limited to immunological veterinary medicinal products;

2) it includes an explicit invitation to professional keepers of animals to consult the veterinarian about the immunological veterinary medicinal product.

By way of derogation from paragraphs 1 and 2 of this Article, it is prohibited to advertise inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link.

Article 313

Where veterinary medicinal products are being promoted to persons qualified to prescribe or dispense them, no gifts, pecuniary advantages or benefit in kind may be supplied, offered, or promised to them, unless they are inexpensive and relevant to the practice of prescription or supply of medicinal products.

Persons qualified to prescribe or dispense veterinary medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 of this Article.

Paragraph 1 shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes, whereby such hospitality shall always be strictly limited to the main objectives of the event.

Paragraphs 1, 2 and 3 shall not affect existing measures or trade practice relating to prices, margins and discounts.

Article 314

Detailed conditions and manner of advertising veterinary medicinal products shall be prescribed by the state administration authority responsible for veterinary affairs.

XVII. QUALITY CONTROL OF VETERINARY MEDICINAL PRODUCTS

Article 315

The marketing authorisation holder for a veterinary medicinal product shall have at its disposal the results of quality control carried out on the veterinary medicinal product or on the constituents and intermediate products of the manufacturing process, in accordance with the methods laid down in the marketing authorisation.

If the Institute concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take measures in relation to the marketing authorisation holder and the manufacturer.

The Institute shall notify the competent authorities of the Member States of the European Union in which the veterinary medicinal product is authorised, or the EMA if the veterinary medicinal product was authorised under the centralised procedure, about the measures referred to in paragraph 2 of this Article.

Article 316

For the purposes of Article 315 paragraph 1 of this Law, the Institute may require the holder of a marketing authorisation for immunological veterinary medicinal product to submit copies of all control reports signed by the qualified person referred to in Article 270 of this Law.

The holder of a marketing authorisation for immunological veterinary medicinal product shall ensure that an adequate number of representative samples of each batch of the veterinary medicinal product is held in stock at least up to the expiry date and provide samples promptly to the Institute on request.

The Institute may require the holder of a marketing authorisation for an immunological veterinary medicinal product to submit a sample of the batch of the bulk or finished product before placing it on the market for control in an OMCL, if necessary for reasons of the protection of human and animal health.

The marketing authorisation holder shall, upon request by the Institute, immediately submit the samples referred to in paragraph 2 of this Article, along with the control reports referred to in paragraph 1, for control testing.

The Institute shall notify the Member States of the European Union in which the marketing authorisation for the immunological veterinary medicinal product is authorised, as well as the EDQM, of its intention to conduct laboratory quality control of the batch of the immunological veterinary medicinal product.

The laboratory quality control of the submitted sample shall include all tests carried out by the manufacturer on the finished immunological veterinary medicinal product, in accordance with the specifications set out in the dossier for marketing authorisation.

By way of derogation from paragraph 6 of this Article, the tests may be restricted to justified tests agreed between Member States of the European Union and, if necessary, the EDQM.

For immunological veterinary medicinal products authorised under the centralised procedure, the tests referred to in paragraph 6 may be reduced to justified tests subject to EMA's approval.

The Institute shall recognise the test results of immunological veterinary medicinal products conducted in a Member State of the European Union.

The laboratory quality control referred to in paragraph 6 shall be completed within 60 days of the receipt of the sample and the control report, unless a longer period is required to perform the tests, in which case the European Commission shall be notified.

The Institute shall inform the Member States of the European Union in which the marketing authorisation for the immunological veterinary medicinal product has been issued, the EDQM, the marketing authorisation holder, and, where necessary, the manufacturer of the results of the tests referred to in paragraph 6.

The Institute shall verify whether the manufacturing process used in the production of immunological veterinary medicinal products has been validated and whether batch-to-batch consistency of the produced batches is ensured.

Article 317

Other matters relating to the quality control of veterinary medicinal products shall be governed mutatis mutandis by the provisions of this Law applicable to the quality control of medicinal products for human use.

XVIII. INSTITUTE FOR MEDICINES AND MEDICAL DEVICES

Article 318

The Institute is established by the Government.

Article 315

In exercising public authority in the field of medicinal products and medical devices, the Institute perform tasks acts, in accordance with the principles of legality, objectivity and transparency.

The Institute is functionally independent from other state bodies and all legal and natural persons carrying out the manufacture, production, marketing and testing of medicinal products and medical devices, as well as drugs and precursors, and their associated activities.

In cooperation with the faculties of medical, natural and technical-technological sciences the Institute develops and exchanges expert knowledge in order to improve quality and education, participates in carrying out scientific research in the field of medical sciences and interdisciplinary research and scientific work in the field of medicinal products and medical devices and other related fields.

The Institute is a teaching base for the faculties of medical and other sciences, for scientific fields within its competences, based on a contract, in accordance with the Law.

Article 320

The Institute shall carry out the following affairs:

1) issue marketing authorisation, decide on variation, renewal, transfer, suspension and revocation of marketing authorisation;

2) register traditional herbal and homeopathic medicinal products;

3) issue clinical trial authorisations, decide on amendments, conducts control of clinical trials and record non-interventional studies;

4) establish and organize the system of pharmacovigilance with the purpose of monitoring safety of medicinal products on the market and detecting changes in relation to risk-benefit ratio of their use;

5) issue manufacturing authorisations;

6) issue wholesale authorisations for medicinal products for human use;

7) assess compliance with GMP, GDP, GVP and GCP guidelines;

8) issue CPP;

9) grant approval for the import of medicinal products for which marketing authorization is not issued in accordance with this Law;

10) issues authorisation for the procurement of a veterinary medicinal product for which a marketing authorisation has not been granted in accordance with this Law

11) issue authorisations for narcotics and precursors in accordance with special laws;

12) grant approval for import and export of immunological medicinal products and medicinal products from the blood and plasma, as well as approval for export of these medicinal products or which marketing authorization is not issued;

13) conduct quality control, as well as control of the supply chain for the purpose of detecting falsified and substandard medicinal products in the legal supply chain;

14) set maximum prices of medicinal products in accordance with this Law;

15) give expert opinion on the classification of a product into a medicinal product or a group of medicinal products and other expert opinions and expert advice within its competences;

16) inform expert and general public about medicinal products, organize professional and educational gatherings and prepare and publish professional publications within its competences;

17) carry out inspections in the area of manufacture and wholesale of human and veterinary medicinal products, pharmacovigilance and clinical trials;

18) collect and process data on the consumption of human medicinal products;

19) cooperate with international entities and national regulatory bodies in the field of medicinal products and medical devices;

20) make connections with international information networks about medicinal products and with the regulatory bodies responsible for medicinal products and medical devices and their associations;

21) adopts secondary legislation within its competencies for the implementation of this Law with the approval of the Ministry;

22) keep registers in accordance with this Law and issue certificates regarding the data contained therein;

23) classify medicinal products in accordance of this Law;

24) carry out activities in the field of medical devices in accordance with a special Law;

25) carry out educational and scientific research activities in cooperation with faculties of health orientation in the field of medicinal products and medical devices and other related areas of interdisciplinary research;

26) exchange data and information on veterinary medicinal products with the competent state administration body for veterinary medicinal products which are important for the performance of tasks within the scope of competence of these authorities;

27) shall take the necessary measures to ensure cooperation with customs authorities;

28) perform other duties in accordance with the Law and the Statute.

Article 321

Managing bodies of the Institute are the Steering board and General Manager.

Members of the Steering Board and the General Manager may not perform in their own name and for their own account, as well as on behalf and for the account of other natural or legal person, the activities of manufacturing, wholesale and testing of medicinal products, nor may have other personal interests (property, shares, membership in management or contractual relations) with persons engaged in these activities, on which they shall sign the statement.

Persons referred to in paragraph 2 of this Article may not participate in the preparation of documentation submitted along with the applications which the Institute decides upon in accordance with the Law.

Persons referred to in paragraph 2 of this Article may not be persons exercising rights under regulations governing pension and disability insurance.

Article 322

The governing body of the Institute is the Steering Board.

The Steering Board shall have a chairperson and four members appointed and dismissed by the Government from among professionals in the field of health, veterinary medicine and environmental protection.

One Steering Board member shall be the employees' representative proposed by the Institute.

Chairperson and members of the Steering Board shall be appointed for a four-year period and may be reappointed once.

Article 323

The Steering Board shall:

1) define the business policy and strategic objectives of the Institute;

2) adopt the Statute, the Act on internal organisation and jobs scheme, the Code of conduct and other general acts of the Institute;

3) issue secondary legislation for the implementation of this Law within the competences of the Institute;

4) adopt the Activity plan and Financial plan for each calendar year;

5) adopt the Annual activity report and financial and final accounts for each calendar year and submit it to the Government for information;

6) decide on the choice of an external auditor of annual financial statements of the Institute;

7) make investment decisions in accordance with the Statute of the Institute;

8) submit the Activity report to the Government at least once a year;

9) adopt the Rules of procedure;

10) perform other activities determined by the Law and Statute of the Institute.

The Steering Board is accountable to the Government for its work and the work of the Institute.

Article 324

The term of office of the Chairperson or a Steering Board Member shall terminate:

1) upon the expiry of the term for which they were appointed;

2) by submitting a written resignation;

3) by dismissal.

The Chairperson or a Steering Board Member shall be dismissed if:

1) they are convicted and sentenced to an unconditional prison term;

2) they are convicted of a criminal offence rendering then unfit to perform their duties;

3) they act contrary to the Law, the Statute, or general acts of the Institute;

4) they carry out activities for which they were appointed in an unprofessional or negligent manner;

5) it is established that upon appointment as Chairperson of a member they provided false information or omitted data on circumstances important to their appointment.

Article 325

The General Manager shall represent the Institute.

The General Manager shall be appointed and dismissed by the Steering Board based on the public competition.

The General Manager shall be appointed for a five-year period and may be reappointed.

General Manager of the Institute shall be a person with at least VII1 level of qualifications and at least five years of experience in expert and managerial positions in the

area of medicinal products and/or medical devices legislation and whose Development Strategy of the Institute is accepted by the Steering Board.

General Manager may not be a person who, at least three years before applying for the position, was employed in the manufacture, marketing and clinical trials of medicinal products and medical devices at other legal persons, person who participated in preparation of the documentation to be submitted with the application for obtaining marketing authorisation for a medicinal product registration of medical devices, and other activities in the field of medicinal products and medical devices legislation.

General Manager is accountable to the Steering Board for his/her work.

Article 326

The General Manager shall:

1) organise and manage the work of the Institute;

2) be responsible for the legality, efficiency and economical effectiveness of the Institute;

3) be responsible for the implementation of strategies, working programs and plans of the Institute;

4) pass decisions, i.e., administrative acts within the competences of the Institute, which are not the responsibility of the Steering Board of the Institute;

5) act upon the decisions of the Steering Board;

6) make decisions on the rights of the employees in accordance with the Law.

Article 327

General Manager's term of office shall terminate upon the expiry of the period for which he/she was appointed upon submission of a written resignation to the Steering Board or upon dismissal.

General Manager of the Institute may be dismissed before the expiry of the period for which he/she was appointed, if:

1) he/she fails to perform the function of General Manager in accordance with the Law, the Statute and other general acts of the Institute;

2) fails to implement decisions and conclusions of the Steering Board.

The decision on the dismissal of the General Manager shall be made by the Steering Board.

An administrative dispute may be initiated against the decision referred to in paragraph 3 of this Article.

Article 328

The Institute may establish advisory bodies (hereinafter: committees), for giving opinions in accordance with this Law.

Members of the committees may be permanent, as well as members of commissions upon invitation.

Committee members may not perform in their own name and for their own account, as well as on behalf and for the account of the other natural or legal person, the activities of manufacturing, wholesale and testing of medicinal products, nor may have other personal interests (property, shares, membership in management or contractual relations), with persons engaged in these activities, on which they shall annually sign the statement.

Committee members may not participate in the preparation of documentation submitted along with the applications which the Institute decides upon in accordance with the Law.

The Institute shall dismiss a member of the committee who acts contrary to paragraph 3 and 4 of this Article, as well as in the case that he/she fails to perform entrusted tasks, or performs them negligently.

Costs of the work of experts and committee members shall be provided from the Institute's funds.

The Institute shall publish on its website Rules of procedure of Committees, including agendas and minutes of meetings and decisions made on meetings.

Work of committees shall in more detail be regulated by the Rules of procedure.

Article 329

The Institute shall establish a list of experts for the purpose of giving opinion in accordance with this Law.

Experts referred to in paragraph 1 of this Article shall be selected from among distinguished experts in the field of medicinal products and shall fulfil the criteria from Article 328, paragraphs 3 and 4 of this Law.

Experts referred to in paragraph 1 of this Article may not perform in their own name and for their own account, as well as on behalf and for the account of the other natural or legal person, the activities of manufacturing, wholesale and testing of medicinal products, nor may have other personal interests (property, shares, membership in management or contractual relations), with persons engaged in these activities, on which they shall annually sign the statement

The Institute shall remove from the List an expert who acts contrary to paragraph 2 of this Article, as well as in the case that he/she fails to perform entrusted tasks, or performs them negligently.

Working costs of experts from paragraph 1 of this Article shall be provided by the funds of the Institute.

Article 330

Employees of the Institute, members of the managing and advisory bodies of the Institute, persons from the list of experts, as well as employees of the Ministry, state administration body responsible for veterinary matters shall treat as classified all the data in the documentation attached to the application for marketing authorisation as well as in other procedures before the Institute, particularly if:

1) data are confidential, and/or which as a whole or in a precise form and set of its components are not generally known or easily available to persons usually dealing with such kind of information;

2) data have a commercial value due to their confidentiality, during the period of confidentiality;

3) data for which an applicant for a medicinal product marketing authorisation, under the circumstances, takes reasonable measures to keep them confidential.

Persons referred to in Paragraph 1 of this Article shall also keep as a business secret all the data in the documentation submitted along with the application for the issuance of marketing authorisation, variations or a renewal that refer to undisclosed tests (examinations) of medicinal products using new chemical solutions, or whose generation requires considerable effort.

For the purpose of controlling unfair competition, employees and persons referred to in Paragraph 1 of this Article shall not disclose the information from the documentation submitted during the procedure of obtaining a marketing authorisation, as well as in other procedures before the Institute, except with the consent of the applicant for a marketing authorisation, or the applicant in other procedures before the Institute, as well as with the exception of the data

available to the expert and general public with the purpose of providing information on a medicinal product that is necessary for their use or handling, or required for the protection of health of humans.

In case of violation of the obligation referred to in paragraphs 1, 2, and 3 of this Article, the regulations in relation to the protection of business secrets shall apply.

Regulations on the protection of intellectual property shall apply to the protection of the data referred to in paragraph 2 of this Article.

Documentation referred to in paragraph 1 of this Article shall be kept permanently in electronic form.

Persons from paragraph 1 of this Article shall have no financial or other interests in the pharmaceutical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests in accordance with EMA recommendations.

The Institute shall make publicly accessible its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.

Article 331

Funds for the work of the Institute are provided from its own revenues generated from fees established for performing activities in the field of medicinal products and medical devices in accordance with the law, as well as from other sources in accordance with the law.

The Institute shall use the funds referred to in paragraph 1 of this Article to perform activities within its competences in accordance with the Law.

The Institute shall independently manage the funds referred to in paragraph 1 of this Article in accordance with the Law.

Article 332

In procedures before the Institute the applicant shall pay the fee, unless otherwise provided by this Law.

The Institute shall not charge the fee referred to in paragraph 1 of this Article for medicinal products with orphan designation and medicinal products provided as donations and humanitarian aid.

Payment method and the amount of fees referred to in paragraph 1 of this Article shall be set by the Institute.

Article 333

Employees of the Institute shall perform their duties and tasks in accordance with the Law, the Statute, the Act on internal organisation and job scheme and other general acts of the Institute.

General labour regulations shall apply to employees of the Institute in terms of rights, obligations and responsibilities.

The provisions of the Law regulating the administrative procedure shall apply to the procedures carried out by the Institute, unless otherwise provided by this Law.

An administrative dispute may be initiated against decisions of the Institute.

Article 334

General acts of the Institute are the Statute, rulebooks, the Act on internal organisation and job scheme and other general acts.

The Statute is a fundamental general act of the Institute.

The Statute of the Institute shall regulate in more detail the headquarters of the Institute, activities of the Institute, its internal organization, the tasks of the Institute's bodies, conditions

and procedure for appointing a General Manager, tasks and work of committees, as well as other issues of importance for the work of the Institute.

XIX. SUPERVISION

Article 335

Supervision over the implementation of this Law and regulations adopted pursuant to this Law, in accordance with their jurisdiction, shall be carried out by the Ministry and the state administration body responsible for veterinary matters affairs and the Institute.

Article 336

Control shall be conducted by competent inspectors in the area of medicinal products, as follows:

1) pharmaceutical inspector in relation to the manufacture of human and veterinary medicinal products, wholesale of medicinal products for human use, clinical trials of medicinal products, as well as application of guidelines of GMP, GDP, GVP and GCP guidelines as well as the application of GMP and GDP guidelines for active substances for human and veterinary medicinal products in accordance with this the Law and the law governing inspection supervision;

2) health inspector, in relation to medicinal products for human use in the retail sale of medicinal products and in the use of medicinal products in health institutions, advertising of medicinal products for human use, labelling of medicinal products for human use and the expiry date provided on the packaging and pharmacovigilance in health institutions, in accordance with this Law and the laws regulating inspection supervision, health inspection, health care, health insurance and pharmacy activities;

3) veterinary inspector, in relation to the wholesale and retail sale of veterinary medicinal products, application of GDP guidelines, the use of medicinal products in veterinary institutions, advertising of veterinary medicinal products, labelling of veterinary medicinal products and the expiry date provided on the packaging, prohibition of placing on the market, or suspension of marketing or withdrawal from the market of veterinary medicinal products that do not meet prescribed quality, safety and efficacy standards, in accordance with this Law and the laws regulating inspection supervision and veterinary medicine;

4) market inspector in relation to prices of medicinal products in the wholesale and the retail sale of medicinal products, in accordance with this Law and laws governing inspection supervision and internal trade.

Article 337

Within the control, the pharmaceutical inspector shall, in addition to obligations and authorities prescribed by the Law on inspection supervision, have the authority and obligations to:

1) review general and individual acts, records, contracts and other documents relating to the manufacture of human and veterinary medicinal products, wholesale of human medicinal products, testing and quality control of medicinal products, system of pharmacovigilance, as well as the documentation relating to the application of GMP, GDP, GVP and GCP guidelines;

2) carry out an immediate insight into the implementation of GMP and GDP guidelines, as well as into standard and operational procedures in these areas;

3) perform immediate insight into the implementation of GVP guidelines by the marketing authorization holder and other persons engaged by it to perform pharmacovigilance activities;

4) perform immediate insight into the implementation of GCP guidelines;

5) hear and take statements from responsible and interested parties;

6) inspect business premises, facilities, installations, devices, equipment;

7) examine raw materials, active substances, excipients, intermediates, medicinal products, labelling of medicinal products;

8) take samples of the medicinal product and raw materials for the purpose of quality control, as well as request the submission of evidence on the quality control of the medicinal product and/or the composition of the medicinal product and intermediate products in accordance with the approved processes in the procedure for the issuance of the marketing authorisation;

9) take copies of documents whereby stating it in the Record;

10) examine personal documents of employees for the purpose of identification;

11) take photographs, or records information about a person, area, object, accessory, medicinal products, etc. for the purpose of gathering evidence;

12) ask for data from official records and other databases relating to persons if they are necessary for the carrying out the inspection supervision;

13) conduct inspection supervision at the premises of the marketing authorisation holder, brokers and all laboratories contracted by the manufacturer.

Article 338

Within the supervision, health inspector, in addition to obligations and authorities prescribed by the law on inspection supervision, has the authority and obligations to:

1) controls retail an medicinal products use in healthcare institutions;

2) check the advertising of medicinal products for human use;

3) take copies of documents whereby stating it in the Record;

4) ask for data from official records and other databases relating to persons if they are necessary for the carrying out the inspection supervision;

5) examine personal documents of employees for the purpose of identification;

6) take photographs, or videos of the information about a person, area, object, accessory, medicinal products, etc. for the purpose of gathering evidence.

Article 339

Within the supervision, veterinary inspector, in addition to obligations and authorities prescribed by the law on inspection supervision and the law on veterinary medicine, has the authority and obligations to:

1) review general and individual acts, records, contracts and other documentation related to wholesale and retail sale of veterinary medicinal products as well as documentation related to the application of the GDP guidelines;

2) perform an immediate insight to the implementation of GDP guidelines;

3) take copies of documents whereby stating it in the Record;

4) examine personal documents of employees for the purpose of identification;

5) hear and take statements from responsible and interested parties;

6) inspect business premises, facilities, installations, devices, equipment and checks compliance with prescribed conditions for the wholesale and retail sale of veterinary medicinal products;

7) ask for data from official records and other databases relating to persons if they are necessary for the carrying out the inspection supervision;

8) monitor and control advertising of veterinary medicinal products;

9) take samples of veterinary medicinal products for the purpose of quality control;

10) prohibit advertising of a product to which medical indications are attributed, and it is not a veterinary medicinal product within the meaning of this Law, as well as the advertising of a medicinal product that misleads the expert and general public whether published or in preparation;

11) prohibit marketing and use of a veterinary medicinal product for which a marketing authorisation has not been issued by the Institute, or the European Commission, or which has not been granted a purchase or import approval issued by the Institute, in accordance with this Law;

12) prohibit marketing and use of a homeopathic veterinary medicinal product that has not been registered, or for which a marketing authorisation has not been issued in accordance with this Law

13) prohibit marketing of a product which is determined to contain an active substance or a substance similar to the active one, and it is not a veterinary medicinal product within the meaning of this Law;

14) take photographs or videos of data on a person, space, object, accessories, medicinal products and other, for the purpose of collecting evidence;

15) control dispensing and use of veterinary medicinal products by veterinarians, or control the record-keeping of animal owners or keepers

16) perform other examinations in accordance with this Law and other regulations, according to the indicated needs.

Article 340

Within the supervision, a market inspector, in addition to obligations and authorities prescribed by the law on inspection supervision, has the authority and obligations to:

1) review general and individual acts, records, contracts and other documentation related to the prices of medicinal products on the market;

2) take copies of documents whereby stating it in the Record;

3) examine personal documents of employees for the purpose of identification;

4) ask for data from official records and other databases relating to prices of medicinal products if they are necessary for the carrying out the inspection supervision

Article 341

In addition to administrative measures and actions determined by the law governing inspection supervision, the pharmaceutical inspector shall, when he/she determines non-compliance with the requirements established by this law and the law on inspection supervision, has the authority and obligation to:

1) order performance of activities in accordance with the conditions prescribed by this Law and the law on inspection supervision;

2) order elimination of identified irregularities and deficiencies within a specified period;

3) prohibit implementation of actions that are contrary to this Law;

4) temporarily prohibit the work of a legal and natural person if they are engaged in testing, production, marketing, brokering, quality control of a medicinal product without the approval or authorisation of the Institute;

5) prohibit legal and natural persons from manufacturing medicinal products, wholesale of medicinal products or batches of medicinal product, laboratory testing of medicinal products and chemicals if they do not harmonize operations, eliminate deficiencies within the deadline or if there is a critical non-compliance with the GMP and GDP guidelines;

6) suspend marketing of the medicinal product in wholesale, i.e. its batch that does not meet the conditions prescribed by this Law;

7) order withdrawal of a medicinal product or its batch from wholesale distribution, in cases prescribed by this Law;

8) prohibit work and submit a proposal to the Institute for revoking the authorisation to perform the activity in question;

9) order the marketing authorisation holder to remove from the position the qualified person if that person does not meet conditions prescribed by this Law.

Article 342

In addition to administrative measures and actions determined by the law governing inspection supervision, the health inspector, when he determines non-compliance with the requirements established by this Law and other regulations, has the authority and obligation to do the following:

1) prohibit wholesale of a falsified medicinal product;

2) prohibit retail sale of a medicinal product the shelf-life of which has expired;

3) the use of medicinal products that are improperly stored or handled;

4) prohibit use of a homeopathic medicinal product that has not been authorised in accordance with this Law

5) temporarily prohibit production of galenic medicinal products and laboratory testing of medicinal products and chemicals if the business is not harmonized or the identified deficiencies are not eliminated within the deadline;

6) prohibit advertising of a product to which medical indications are attributed, and it is not a medicinal product within the meaning of this Law, as well as advertising of a medicinal product that misleads the expert and general public whether it has been published or is being prepared, as well as every advertising that is not in accordance with this Law;

7) prohibit marketing of a product that is determined to contain an active substance or a substance similar to an active substance, but is not a medicinal product within the meaning of this Law;

8) suspend retail sale of the medicinal product, i.e. its batches, if they do not meet requirements in accordance with this Law;

9) order withdrawal of a medicinal product from retail sale, or its batches, if they do not meet the requirements in accordance with this Law;

10) order destruction of a defective medicinal product in accordance with this Law;

11) order undertaking of other measures in accordance with the Law.

Measures referred to in paragraph 1, item 6 of this Article shall be taken without delay, with temporary or permanent effect.

In order to prevent further consequences of misleading advertising, which is prohibited by a final decision, the health inspector may publish that decision in whole or in part, or in a form he/she deems appropriate, or publish a statement correcting the advertising.

Article 343

In addition to administrative measures and actions determined by the law governing inspection supervision, the veterinary inspector, when he determines non-compliance with the requirements established by this Law, and other regulations, has the authority and obligation to:

1) order performance of activities in accordance with the conditions prescribed by this Law and the law on inspection supervision;

2) order elimination of identified irregularities and deficiencies within a specified period;

3) prohibit implementation of actions that are contrary to this Law;

4) temporarily prohibit the work of a legal and natural person, if they are engaged in the marketing of medicinal products without approval;

5) prohibit legal entities and natural persons wholesale of veterinary medicinal products, i.e. batches of medicinal products, if they do not harmonize their operations, eliminate deficiencies within the deadline, i.e. if there is a critical non-compliance with the Guidelines for Good distribution practice;

6) suspend wholesale of a veterinary medicinal product or its batch, that does not meet the conditions prescribed by this Law;

7) order withdrawal of a veterinary medicinal product or its batches from wholesale in cases prescribed by this Law;

8) prohibit marketing of falsified medicinal products;

9) prohibit retail sale marketing of a veterinary medicinal product the shelf-life of which has expired;

10) prohibit the use of veterinary medicinal products that are improperly stored or handled, i.e. that is used in the manner that is contrary to the Law;

11) prohibit advertising of a product to which medical indications are attributed, and it is not a veterinary medicinal product within the meaning of this Law, as well as the advertising of a medicinal product that misleads the expert and general public whether published or in preparation;

12) suspend retail sale of veterinary medicinal product, i.e. its batch which do not correspond to the conditions prescribed by this Law;

13) order withdrawal of a veterinary medicinal product or its batch from retail sale in cases prescribed by this Law;

14) order destruction of a defective veterinary medicinal product and a falsified medicinal product in accordance with this Law;

15) order undertaking of other measures for which he/she is authorized by another law.

Article 344

In addition to administrative measures and actions determined by the law governing inspection supervision, the market inspector, when he/she determines non-compliance with the requirements established by this law, and other regulations, has the authority and obligation to:

1) seize illegally acquired property gain in the case when the legal person that carries out the wholesale of medicinal products, or the retail sale of medicinal products, has stated higher prices of medicinal products than the set prices;

2) order undertaking other measures for which he/she is authorized by another law.

Article 345

Legal and natural persons whose work is subject to supervision shall enable the inspector to have smooth access and conduct supervision in accordance with this Law, regardless of whether it is an announced or unannounced supervision, as well as to make available to him/her a sufficient number of samples of medicinal products for analysis free of charge, or to provide him/her with all necessary data at their disposal .

The inspector shall control the fulfilment of requirements for medicinal products by repeated inspections and, if necessary, unannounced inspections, by requesting the control laboratory to examine samples, as well as control the business premises of the authorisation holder.

The inspector may also control the facility of the manufacturer of active substances, which are used as starting substances for medicinal products, unannounced, whenever he/she considers that there is probable cause to question the observance of the provisions of this Law.

The costs of taking samples of medicinal products shall be borne by the marketing authorisation holder, i.e. a person that registered a medicinal product, manufacturer, wholesaler, health institution and veterinary organisations.

Article 346

The Institute, in cooperation with the EMA, shall ensure compliance with the provisions of this Law through the conduct of inspections, which may be unannounced, and when possible, through the request that Official Medicines Control Laboratory (OMCL) or another authorised laboratory conducts sample testing.

The Institute shall exchange information with EMA on completed and planned inspections.

The Institute and EMA shall also cooperate in coordinating inspections in third countries.

Inspections shall include, but not be limited to the following:

1) repeated inspections of manufacturers located in Montenegro, EU Member States, or third countries, as well as in wholesalers;

2) establishment of a supervisory system by the Institute, ensuring that inspections are carried out with adequate frequency based on risk at the premises of manufacturers, importers, and wholesalers of active substances located in Montenegro, with their effective monitoring; where there is reason to reckon that the provisions of this Law are not being observed, including non-compliance with GMP or GDP guidelines, the Institute may conduct inspections of:

- manufacturers and suppliers of active substances located in third countries,
- manufacturers and importers of excipients;

3) inspections referred to in items 1 and 2 may also be carried out, at the request of an EU Member State, the European Commission, or EMA, within the EU or in third countries;

4) inspections may also be conducted at the premises of marketing authorisation holders and brokers;

5) upon explicit request from the manufacturer, the Institute may conduct inspections of starting materials;

6) inspections shall be carried out by pharmaceutical inspectors authorised to:

- inspect manufacturing and business premises of medicinal product manufacturers, manufacturers of active and excipient substances, and laboratories engaged by the manufacturer for quality control,

- take samples, including those for independent testing in an OMCL or other authorised laboratory,

- review all documents relevant to the inspection, while observing the limitations in EU Member States concerning manufacturing method descriptions (in force since 21 May 1975),

- inspect premises, records, documents, and the PSMF of the marketing authorization holder and any third party contracted to carry out pharmacovigilance activities;

7) inspections carried out in accordance with GMP and GDP guidelines.

The Institute shall take all necessary measures to ensure that manufacturing processes for immunological medicinal products are properly authorised and result in products of consistent quality.

After conducted inspection referred to in paragraph 1 of this Article, the pharmaceutical inspector shall prepare an Inspection record in the official premises of the Institute within 7 days from completed inspection, to be signed in the official premises of the Institute.

Following the inspection, the Institute shall issue a report on whether the inspected party complies with GMP and GDP guidelines, where applicable, and whether the marketing

authorization holder complies with the pharmacovigilance requirements defined in this Law and with GVP guidelines.

The report from paragraph 7 shall be delivered to the inspected party by the Institute.

Prior to the report's adoption, the Institute shall give the inspected party the opportunity to submit comments to it.

The Institute shall issue a GMP or GDP certificate within 90 days from the date of the inspection within the meaning of this Article, provided the inspected party was found to comply with the applicable guidelines.

If the inspection is conducted for the purpose of issuing a certificate for European Pharmacopoeia monographs, the Institute shall issue the relevant certificate.

If the inspection findings referred to in paragraph 4, item 6, indents 1, 2 and 3 of this Article or the outcome of an inspection of a distributor of medicinal products or active substances or a manufacturer of excipients indicate that the inspected party does not comply defined requirements and/or GMP or GDP guidelines, such information shall be entered into the EU database.

If the inspection referred to in paragraph 4 item 6 indent 4 of this Article shows that the marketing authorization holder is not compliant with its pharmacovigilance system as described in the PSMF or the provisions of this Law related to pharmacovigilance, the Institute shall issue a warning and allow the marketing authorization holder to submit comments.

In the case referred to in paragraph 13 of this Article, the Institute shall inform other EU Member States, EMA, and the European Commission.

Where appropriate, the Institute shall take the necessary measures to ensure that a marketing authorisation holder is subject to effective, proportionate and dissuasive penalties.

XX. PENAL PROVISIONS

Article 347

For a misdemeanor, a legal person shall be fined from 5.000 euros to 20.000 euros if it:

1) fails to place a medicinal product on the market in accordance with the renewed authorisation within 12 months from the date of renewal of the marketing authorisation (Article 77 paragraph 5);
2) fails to submit the PSUR upon request of the Institute, without delay or at least every six months from the date of issuance or renewal of a conditional marketing authorisation (Article 78 paragraph 6);
3) dispenses or sells a medicinal product contrary to the dispensing mode as specified in the marketing authorisation (Article 85 paragraph 9);
4) manufactures a medicinal product for which a marketing authorisation has not been granted (Article 91 paragraph 1 item 1);
5) manufactures a medicinal product without holding a manufacturing authorisation (Article 91 paragraph 1 item 2);
6) manufactures a medicinal product not in compliance with the manufacturing authorisation (Article 91 paragraph 1 item 3);
7) manufactures a medicinal product without adequate quality control documentation (Article 91 paragraph 1 item 4);
8) manufactures a falsified medicinal product (Article 91 paragraph 1 item 5);
9) does not have a qualified person (Article 96 paragraph 3 item 1);
10) does not have a person responsible for the manufacture and does not have a person for quality control that meet the requirements for the manufacture and quality control in accordance with this Law (Article 96 paragraph 3 item 2);

11) holds medicinal products which have not been granted a marketing authorisation in accordance with this Law (Article 96 paragraph 3 item 3);
12) fails to notify the Institute in advance of all changes it intends to implement in relation to the manufacturing conditions referred to in Article 92 of this Law, or fails to immediately notify in case of unexpected change of qualified person (Article 96 paragraph 3 item 4);
13) fails to provide the Institute or the competent authority of an interested EU Member State access to premises at any time (Article 96 paragraph 3 item 5);
14) fails to enable the qualified person to perform duties independently and fails to provide necessary resources (Article 96 paragraph 3 item 6);
15) uses active substances in manufacturing that are not produced in compliance with GMP guidelines for active substances (Article 96 paragraph 1 item 7 indent 1);
16) does not use active substances in the manufacturing process that have been distributed in accordance with the GDP guidelines for active substances (Article 96 paragraph 3 item 7 indent 2);
17) manufacturing and distribution sites are not controlled, which is performed by the marketing authorization holder on his own or in his behalf is done by another person with whom the contact is not concluded (Article 94 paragraph 1 item 7 indent 3);
18) fails to immediately inform the Institute and the marketing authorisation holder if it becomes aware of, or suspects, falsification of medicinal products, regardless of legal or illegal distribution, including forbidden internet sale (Article 96 paragraph 3 item 8);
19) fails to verify that manufacturers, importers and wholesalers of active substances are registered with the Institute or competent authority of the EU Member State in which they are established (Article 96 paragraph 3 item 9);
20) fails to verify the authenticity and quality of active and excipient substances (Article 96 paragraph 3 item 10);
21) fails to ensure that manufacturing is carried out in accordance with the manufacturing authorisation, GMP and GDP guidelines (Article 97 paragraph 1 item 1);
22) fails to ensure that the manufacturing process of the authorised product is in line with the documentation approved during the marketing authorisation procedure (Article 97 paragraph 1 item 2);
23) fails to regularly review its manufacturing methods in relation to the progress of science and technology (Article 97, paragraph 1, item 3)
24) fails to establish and implement an effective pharmaceutical quality assurance system, including active participation of management and personnel across different departments (Article 97 paragraph 1 item 4);
25) fails to demonstrate that a medicinal product imported from third countries is manufactured in accordance with standards equivalent to EU GMP and by manufacturers holding the necessary authorisations (Article 97 paragraph 2);
26) does not employ at least one full time employed qualified person that is constantly available (Article 98 paragraph 1);
27) employs a person for batch release that does not have the required academic degree in pharmacy, medicine, chemistry, pharmaceutical chemistry and technology, or biology, and lacks relevant practical experience (Article 98 paragraph 2);
28) fails to promptly notify the Institute of any change to the manufacturing site, quality control site, batch release site, person responsible for batch release, person responsible for manufacturing or quality control, or significant changes to premises and equipment (Article 100 paragraph 1);

29) fails to investigate and document, and promptly inform the Institute of any deviation in manufacturing, or other circumstances raising concern about the quality, safety or efficacy of the medicinal product (Article 100 paragraph 2);
30) carries out wholesale of a medicinal product that does not have a marketing authorisation or import approval (Article 115 paragraph 1 item 1);
31) carries out wholesale of a medicinal product manufactured by an unauthorised manufacturer (Article 115 paragraph 1 item 2);
32) carries out wholesale without holding a wholesale authorisation issued in accordance with this Law (Article 115 paragraph 1 item 3);
33) carries out wholesale of a medicinal product that is not labelled in accordance with this Law (Article 115 paragraph 1 item 4);
34) carries out wholesale of a medicinal product with an expired shelf-life or with a quality defect presenting a greater risk than benefit (Article 115 paragraph 1 item 5);
35) carries out wholesale of a falsified medicinal product (Article 115 paragraph 1 item 6);
36) fails to carry out wholesale of medicinal product in accordance with a wholesale authorisation and GDP guidelines (Article 116 paragraph 1);
37) procures medicinal products from persons without a wholesale authorisation or from manufacturers (Article 119 paragraph 1 item 2);
38) supplies medicinal products to entities that do not hold a wholesale distribution authorisation or are not authorised to dispense medicinal products in accordance with special law (Article 119 paragraph 1 item 3);
39) fails to verify, including through checking safety features on outer packaging, that received medicinal products are not falsified, as well as in another manner in accordance with this Law (Article 119 paragraph 1 item 4);
40) does not have a recall plan for medicinal products upon decision of the Institute or in cooperation with the manufacturer or marketing authorisation holder (Article 119 paragraph 1 item 5);
41) fails to ensure compliance with GDP guidelines (Article 119 paragraph 1 item 8);
42) fails to maintain a quality management system defining responsibilities, procedures, and risk management measures related to its activities (Article 119 paragraph 1 item 9);
43) fails to immediately inform the Institute, health inspectorate, and, where applicable, the marketing authorisation holder about any falsified medicinal product that has been offered or supplied, or any suspicion thereof (Article 119 paragraph 1 item 10);
44) procures medicinal products from another wholesaler without verifying that the wholesaler operates in compliance with GDP guidelines, including checking whether the wholesaler holds a wholesale distribution authorisation (Article 119 paragraph 2);
45) procures medicinal products from a manufacturer or importer without verifying that a manufacturer or importer in question holds a manufacturing authorisation (Article 119 paragraph 3);
46) for each delivery of a medicinal product fails to provide a document indicating: the date of delivery; the name and pharmaceutical form of the product; the quantity supplied; the name and address of the supplier and sender; and the batch number, at least for medicinal products bearing safety features, in accordance with this Law (Article 124 paragraph 1);
47) fails to submit to the Institute the application for amendment to the authorisation in case of the change of conditions from the wholesale authorisation (Article 129 paragraph 1);
48) fails to operate a pharmacovigilance system through which it performs scientific evaluation of all information, assesses options for risk minimisation and prevention, and undertakes appropriate measures (Article 152 paragraph 1 item 1);

49) fails to conduct regular checks of the pharmacovigilance system and to record the findings of it in the PSMF, and based on these findings, fails to prepare and implement appropriate corrective measure (Article 152 paragraph 1 item 2);
50) fails to maintain and, upon request of the Institute, fails to make available the PSMF as part of the pharmacovigilance system (Article 153 paragraph 1 item 3);
51) fails to implement RMS for each medicinal product within its pharmacovigilance system (Article 153 paragraph 1 item 4);
52) fails to monitor the outcome of risk minimisation measures outlined in the RMP or imposed as conditions in a conditional marketing authorisation, marketing authorisation under exceptional circumstances, or marketing authorisation with obligations, in accordance with this Law (Article 153 paragraph 1 item 5);
53) fails to update the RMS and monitor pharmacovigilance data to identify new risks, changes to known risks, or any change in the benefit-risk balance of the medicinal product (Article 153 paragraph 1 item 6);
54) fails to maintain records of all suspected adverse reactions occurring in Montenegro, whether reported spontaneously by patients or healthcare professionals, or observed during post-authorisation studies (Article 156 paragraph 1 item 1);
55) fails to monitor and collect all information that may affect the assessment of the benefit-risk balance of a medicinal product, and fails to submit such information to the Institute without delay and as soon as possible (Article 156 paragraph 1 item 2);
56) fails to submit PSUR in electronic format to the Institute and the EMA that contains summaries of data important for the assessment of risks and benefits of use of the medicinal product, including results of all studies taking into account that they can potentially impact the marketing authorisation (Article 159 paragraph 1 item 1);
57) fails to submit PSUR in electronic format to the Institute and the EMA that contains summaries of scientific evaluation of the benefit-risk balance, based on all available data, including data obtained from clinical trials involving unapproved indications and populations (Article 159 paragraph 1 item 2);
58) fails to notify the Ethics Committee and the Institute of all non-substantial amendments related to a clinical trial (Article 180 paragraph 1);
59) fails to submit a request for an opinion from the Ethics Committee and an application for approval of substantial amendments to the Institute, simultaneously submitted to the Institute (Article 180 paragraph 2);
60) fails to ensure that the clinical trial is conducted in accordance with the clinical trial protocol and the GCP guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (Article 195 paragraph 1)
61) fails to notify the Institute of serious breach of the provisions of this Law or the clinical trial protocol applicable at the time of the breach, without undue delay, and no later than seven days after becoming aware of the breach (Article 197, paragraph 1)
62) fails to submit a request to the Institute for setting wholesale prices of medicinal products, within 30 days from the date of issuing the authorisation, or approval for import, in accordance with this Law, proposing the price of the medicinal product (Article 204, paragraph 1);
63) fails to submit a report to the Institute by 1 May of the current year for the previous year, on the total value of all medicinal products sold, as well as the volume of sales for each individual product per packaging) in Montenegro (Article 205 paragraph 1);
64) advertises a medicinal product for which no marketing authorization has been granted or which is not registered in accordance with this law (Article 206, paragraph 3);

65) advertises a medicinal product to the general public while giving the impression that a medical examination or surgical intervention is unnecessary, especially through diagnosis determination or suggesting treatment methods via mail, i.e. without visiting a doctor (Article 210, paragraph 1, item 1);
66) advertises a medicinal product to the general public and suggests that the effects of taking the medicinal product are guaranteed, that adverse reactions or minimized non-existing, or that the medicinal product in question has the same or better effect than another medicine or treatment (Article 210, paragraph 1, item 2);
67) advertises a medicinal product to the general public suggesting that the health of the user can be improved by taking the medicinal product in question (Article 202, paragraph 1, item 3;
68) advertises a medicinal product to the general public suggesting that not taking the medicinal product in question may worsen the health of the user, except in vaccination campaigns conducted by the manufacturer or their representative, previously approved by the Ministry (Article 210, paragraph 1, item 4);
69) carries out advertising of a medicinal product that is primarily or exclusively directed at children (Article 210, paragraph 1, item 5);
70) advertises a medicinal product that includes recommendations from scientists, healthcare professionals, or individuals whose popularity may encourage consumption of the medicinal product (Article210, paragraph 1, item 6);
71) advertises a medicinal product suggesting that the product is a food, cosmetic, or other consumer product (Article 210, paragraph 1, item 7);
72) advertises a medicinal product suggesting that the product is safe and effective due to its natural origin (Article 210, paragraph 1, item 8);
73) advertises a medicinal product whereby describing or detailing the history of a disease in a manner that could lead to incorrect self-diagnosis (Article 210, paragraph 1, item 9);
74) advertises a medicinal product in an inappropriate, disturbing, or misleading manner by claiming that recovery will occur (Article 210, paragraph 1, item 10);
75) advertises a medicinal product using inappropriate, disturbing, or misleading terminology, or visual depictions of changes in the human body caused by disease, injury, or the effect of a medicinal product on the human body or its parts (Article 210, paragraph 1, item 10);
76) within its capacities fails to ensure continuous supply of veterinary medicinal products in accordance with the wholesale authorisation or the marketing authorisation for the veterinary medicinal product (Article 245, paragraph 3, item 1);
77) fails to continuously inform the Institute of any new findings related to the quality, safety, and efficacy assessment of a veterinary medicinal product placed on the market (Article 245, paragraph 3, item 1);
78) after granting a marketing authorisation for a veterinary medicinal product, fails to ensure that the summary of product characteristics, the package leaflet, and labelling are kept up to date in line with the latest scientific knowledge (Article 237, paragraph 3, item 4);
79) places a generic veterinary medicinal product or a hybrid veterinary medicinal product on the market before the expiry of the data protection period for the reference veterinary medicinal product referred to in Articles 242 and 243 of this Law (Article 245, paragraph 6);
80) fails to immediately notify the Institute, or the Administration, as well as all legal persons that carry out the wholesale distribution of medicinal products in Montenegro, of the cessation of the status of authorisation holder for the medicinal product in

question, and the transfer of the marketing authorisation for the medicinal product has not been carried out (Article 245 paragraph 9);

81) fails to place the veterinary medicinal product on the market in accordance with the approved variation for that product within 12 months from the date of receipt of the Institute's decision approving the variation (Article 248, paragraph 10);
82) fails to establish and maintain a pharmacovigilance system for the collection, compilation and evaluation of data on suspected adverse reactions for veterinary medicinal products for which it holds a marketing authorisation (Article 257, paragraph 1, item 1);
83) does not have a PSMF detailing the pharmacovigilance system for veterinary medicinal products for which it is the marketing authorisation holder, or fails to perform regular checks of the pharmacovigilance system, both in the local system and in the PSMF, in cooperation with the manufacturer, fails to document the main findings of the check, and based on them, fails to ensure the preparation and implementation of appropriate corrective measures (Article 257, paragraph 1, item 2);
84) fails to follow pharmacovigilance data and to conduct regular assessments of the benefit-risk balance of a veterinary medicinal product for which a marketing authorisation has been granted, and does not take appropriate measures when necessary (Article 257, paragraph 1, item 4);
85) fails to comply with the Guidelines on Good Pharmacovigilance Practice for veterinary medicinal products (Article 257, paragraph 1, item 5);
86) at the request of the Institute, fails to submit a copy of the records or other requested part of the PSMF within 7 days from the date of receipt of the request (Article 257 paragraph 10)
87) fails to report to the Institute a variation of any change in data in the PSMF summary (Article 257, paragraph 11)
88) fails to notify the Institute and the marketing authorisation holder in writing, without delay, upon becoming aware that medicinal products covered by a manufacturing authorisation are falsified or suspected of being falsified, regardless of whether they have been distributed legally or illegally, including forbidden internet sale (Article 269, paragraph 3, item 9);
89) fails to comply with Good Manufacturing Practice (GMP) for veterinary medicinal products and does not use as starting materials only active substances manufactured and placed on the market in accordance with GMP for active substances and Good Distribution Practice (GDP) for active substances (Article 269, paragraph 3, item 10);
90) carries out manufacturing, import, or distribution of active substances for veterinary medicinal products, including active substances intended for export, that are not compliant with GMP guidelines or GDP guidelines for active substances for veterinary use (Article 275, paragraph 1);
91) fails to record, for each veterinary medicinal product supplied, the following data: date of the transaction; name of the veterinary medicinal product and, where applicable, the marketing authorisation number; pharmaceutical form and strength, where appropriate; quantity supplied; name and address or headquarters of the recipient; batch number; and shelf life (Article 277, paragraph 1);
92) fails to make records referred to in Article 277, paragraph 1 available to the competent authorities for inspection purposes for one year after the expiry date of the batch, or for at least five years from the date of recording, whichever period is longer (Article 277, paragraph 2);

93) carries out wholesale of a veterinary medicinal product for which no marketing authorisation has been granted or no approval for procurement or import has been issued in accordance with this Law (Article 282, paragraph 1, item 1);
94) carries out wholesale of a veterinary medicinal product manufactured by a person that does not possess a manufacturing authorisation (Article 282, paragraph 1, item 2);
95) carries out wholesale of a veterinary medicinal product that is not labelled in accordance with this Law, unless otherwise provided by this Law (Article 282, paragraph 1, item 3);
96) carries out wholesale of a veterinary medicinal product that lacks appropriate quality documentation in accordance with this Law (Article 282, paragraph 1, item 4);
97) carries out wholesale of a veterinary medicinal product with an expired shelf-life or which has been determined to have a quality defect such that the risk outweighs the benefit of its use, in accordance with this Law (Article 282, paragraph 1, item 5);
98) carries out wholesale of a falsified veterinary medicinal product (Article 282 paragraph 1 item 6);
99) sells veterinary medicinal product via sale at distance (Article 282 paragraph 1 item 7);
100) carries out wholesale of veterinary medicinal products in the manner that is not in line with the wholesale authorisation and Good Distribution Practice guidelines for veterinary medicinal products (Article 283, paragraph 1);
101) does not keep detailed records of wholesale transactions of veterinary medicinal products, including: transaction date, name of the veterinary medicinal product, including, where applicable, pharmaceutical form and strength, batch/lot number, expiry date, quantity received or supplied, including packaging size and number, name and permanent address or headquarters of the supplier in case of purchase, or the recipient in case of sale (Article 287, paragraph 1);
102) fails to conduct at least once per year a detailed inventory audit comparing recorded incoming and outgoing quantities with the actual stock, or fails to retain records of discrepancies for at least five years and make them available to the competent authorities (Article 287, paragraph 2);
103) fails to submit wholesale data for veterinary medicinal products to the Administration by 1 March for the previous calendar year (Article 287, paragraph 3);
104) commences wholesale distribution of veterinary medicinal products without a wholesale distribution authorisation (Article 288, paragraph 2);
105) in the event of a change in the conditions specified in the wholesale distribution authorisation for veterinary medicinal products, fails to notify the Administration in writing within 15 days from the date of the change and fails to submit a request for the amendment or supplementation of the authorisation (Article 290, paragraph 1);
106) advertises a veterinary medicinal product that has not been granted marketing authorisation, or for which the authorisation has been revoked, in accordance with this Law (Article 311, paragraph 3);
107) advertises a veterinary medicinal product for which the marketing authorisation has been suspended, during the suspension period (Article 311, paragraph 4);
108) does not have results of quality control testing for the veterinary medicinal product, its ingredients, or intermediates in the manufacturing process, in accordance with methods specified in the marketing authorisation (Article 315, paragraph 1).

For the misdemeanor referred to in paragraph 1 of this Article, the responsible person within the legal person shall also be fined in the amount of EUR 1,000 to EUR 2,000.

For the misdemeanour referred to in paragraph 1, items 1 to 108 of this Article, a natural person/entrepreneur shall be fined in the amount of EUR 5,000 to EUR 6,000.

In addition to the fine for the misdemeanor referred to in paragraph 1 of this Article, a protective measure prohibiting the performance of the activity for a period of six months may also be imposed.

Article 348

For a misdemeanour, a legal person shall be fined from 3,000 EUR to 20,000 EUR if:

1) the medicinal product placed on the market is not labelled in accordance with this law (Article 70, paragraph 1);
2) the information on the outer and inner packaging of the medicinal product and in the package leaflet is not easily readable, understandable, and indelible (Article 70, paragraph 2);
3) the name of the medicinal product and its strength, if the product comes in more than one strength, are not indicated in Braille on the packaging (Article 70, paragraph 4);
4) the medicinal product issued on prescription, except for radiopharmaceuticals, does not have on its packaging a security feature allowing wholesale and retail distributors of medicinal products to verify the authenticity of the medicinal product and identify each individual package (Article 71, paragraph 1);
5) safety features specified in Article 34, paragraph 10 of this Law are removed or covered completely or partially, unless the prescribed conditions are met (Article 72, paragraph 1);
6) the package leaflet is not in line with the approved summary of product characteristics and is not written in the Montenegrin language (Article 73, paragraph 1);
7) it fails to provide the Institute with a report on the manufacturing of medicinal products, stocks, and sales volumes for each individual medicinal product (per packaging) in Montenegro, upon request (Article 100, paragraph 4);
8) it fails to continuously supply the market with medicinal products in accordance with the manufacturing authorisation(Article 100, paragraph 6);
9) it fails to keep records, either in paper form (invoices for procurement or sale) or electronic form, of every transaction for received, delivered, or brokered medicinal products, containing at least the following data: date, name of the medicinal product, quantity received, delivered, or brokered, name and address of the supplier or recipient, if applicable, and the batch number of the medicinal product, at least for medicinal products with security features in accordance with this law (Article 119, paragraph 6);
10) it fails to ensure the delivery of the medicinal product to healthcare institutions at the earliest possible time, upon their request, depending on the availability of the product and in accordance with their responsibilities (Article 122, paragraph 2);
11) it fails to keep records of all batches, quantities, and distributors of the medicinal product placed on the market in Montenegro, regardless of whether it is a distributor of the medicinal product in question or not (Article 122, paragraph 5);
12) it fails to enable the Institute to take the necessary samples of medicinal products for laboratory testing (Article 141, paragraph 1);
13) within the pharmacovigilance system, it fails to ensure that the person responsible for pharmacovigilance referred to in Article 33, paragraphs 5, 6 and 7 of this Law is permanently and continuously available (Article 153, paragraph 1, item 1)
14) it fails to notify the Institute prior to or simultaneously with the public release of pharmacovigilance information regarding the medicinal product (Article 155, paragraph 1);

15) it fails to ensure that the information referred to in Article 155, paragraph 1 of this law is presented objectively and does not mislead (Article 155, paragraph 2);
16) it fails to keep records of all suspected adverse reactions to the medicinal product in Montenegro, reported spontaneously by patients or healthcare professionals, or observed during post-authorisation studies (Article 156, paragraph 1, item 1);
17) fails to monitor and collect all information that may affect the assessment of the benefit-risk balance of the medicinal product, and fails to submit such information to the Institute without delay and as soon as possible (Article 156, paragraph 1, item 2);
18) until the functionality for submission to the European Union pharmacovigilance is established, it fails to forward to the Institute each received report of a suspected serious adverse reaction occurring in the territory of Montenegro within 15 days of receipt (Article 156, paragraph 1, item 3);
19) until the functionality for submission to the European Union pharmacovigilance is established, fails to submit to the Institute any received report of a suspected non-serious adverse reaction occurring in the territory of Montenegro within 90 days of receipt (Article 156, paragraph 1, item 4);
20) it fails to establish a procedure for obtaining accurate and verifiable data for scientific evaluation of the suspected adverse reaction reports referred to items 3 and 4 of this paragraph, and fails to collect additional case information and submit it to the Institute, until the functionality for submission to the EudraVigilance database is established (Article 156, paragraph 1, item 5);
21) until the functionality for submission to the EudraVigilance database is established, it fails to submit to the Institute, upon request, the reported cases of suspected serious and unexpected adverse reactions that occurred in the territory of the European Union or a third country, within 15 days from the date of receipt of the request (Article 156, paragraph 1, item 6);
22) it fails to keep records of all suspected adverse reactions to the medicinal product occurring in the territory of the European Union or a third country (Article 156, paragraph 1, item 7);
23) it refuses to review suspected adverse reaction reports received electronically or by any other appropriate means from patients or healthcare professionals (Article 156, paragraph 5);
24) it fails to provide in electronic form the Institute and EMA with a PSUR containing all sales volume data and all prescribing data held by the marketing authorization holder, including an estimate of the population exposed to the medicinal product (Article 159, paragraph 1, item 3);
25) it conducts non-interventional PASS in a way that promotes the use of the medicinal product (Article 164, paragraph 4);
26) it commences clinical trials before obtaining the clinical trial authorization issued by the Institute (Article 170, paragraph 3);
27) it fails to notify the Institute about the commencement of clinical trials within 15 days from the start of the clinical trial in Montenegro (Article 188, paragraph 1, item 1);
28) it fails to notify the Institute about the first visit of the first subject within 15 days from the first subject's visit in Montenegro (Article 188, paragraph 1, item 2);
29) it fails to notify the Institute about the completion of recruitment of subjects for the clinical trial within 15 days from the completion of recruitment (Article 188, paragraph 1, item 3);
30) it fails to notify the Institute about the completion of the clinical trial in Montenegro within 15 days from its completion (Article 189, paragraph 1, item 1);

31) it fails to notify the Institute about the completion of the clinical trial in all countries where the clinical trial is conducted, within 15 days from the completion of the clinical trial in the last country (Article 189, paragraph 1, item 2);
32) regardless of the outcome, it fails to provide the Institute with a summary of the clinical trial results and a summary written in a way that is understandable to the general public within one year from the completion of the clinical trial in all countries (Article 189, paragraph 2);
33) it fails to notify the Institute of the temporary suspension of a clinical trial in all countries where the clinical trial is conducted, for reasons not affecting the benefit-risk balance, within 15 days from the date of the suspension in those countries, including a justification (Article 189, paragraph 6, item 1);
34) it fails to maintain detailed records of all adverse events reported by the investigator (Article 198, paragraph 2);
35) it fails to report to the Institute all relevant information concerning a suspected unexpected serious adverse reaction (Article 193, paragraph 1);
36) it fails to notify the Institute about any unexpected events that affect the benefit-risk balance of the clinical trial but are not suspected of being serious adverse events as defined in Article 186 of this law, without unnecessary delay, and no later than 15 days from the date the sponsor becomes aware of the event (Article 197, paragraph 3)
37) it places a medicinal product for which an authorization for a medicinal product or a marketing authorization has been issued under Article 29 of this law, that is subject to prescription, on the market without determining the maximum wholesale price in accordance with this law (Article 203, paragraph 1)
38) it engages in advertising of medicinal products that are subject to prescription, in accordance with this law to the general public (Article 208, paragraph 1, item 1)
39) it engages in advertising of medicinal products containing psychotropic substances or drugs established by an international convention, such as the United Nations Single Convention on Narcotic drugs of 1961 and the Convention of 1971 (Article 208, paragraph 1, item 2)
40) it engages in advertising of medicinal products that are provided through mandatory health insurance funds (Article 208, paragraph 1, item 3)
41) it distributes medicinal products to the general public for promotional purposes (Article 208 paragraph 4)
42) it fails to establish a scientific service responsible for providing information about medicinal products placed on the market (Article 216, paragraph 1, item 1)
43) it fails to make available or provide to the Institute, upon request, copies of all advertisements along with a statement identifying the target audience, the method of publication, and the date of first publication (Article 216, paragraph 1, item 2)
44) it fails to ensure that the advertising of medicinal products complies with this Law (Article 216, paragraph 1, item 3)
45) it fails to ensure that the sales representatives employed by the entity are adequately trained and fulfil the obligations prescribed by Article 213 paragraphs 1 and 3 of this Law (Article 216, paragraph 1, item 4)
46) it fails to ensure uninterrupted inspection oversight regarding advertising in accordance with the law (Article 216, paragraph 1, item 6)
47) it fails to ensure that decisions by relevant inspections and other authorities are implemented promptly and fully (Article 216, paragraph 1, item 7)
48) by March 1 of the current year, fails to provide the Administration with data on the use of antimicrobial medicinal products used in the previous year (Article 252 paragraph 3)

49) it fails to regularly enter data on the use of antimicrobial medicinal products in the Veterinary Information System, which is managed by the Administration in accordance with a special law (Article 252 paragraph 4)
50) until March 1 of the current year, fails to provide the Administration with data on the volume of sales of antimicrobial medicinal products in the previous year on the form prescribed by the Administration (Article 252 paragraph 5)
51) it forwards the information on pharmacovigilance for a veterinary medicinal product to the professional and general public without prior notification to the Institute (Article 257, paragraph 8)
52) it fails to ensure that all information provided on the pharmacovigilance of a particular medicinal product is presented objectively and does not mislead the professional and general public (Article 257, paragraph 9)
53) it fails to keep records of the retail supply of veterinary medicinal products issued on veterinary prescription, which shall in particular include: the date of supply; the name of the veterinary medicinal product, including, where applicable, the pharmaceutical form and strength; batch number; quantity received or supplied; name and registered address of the veterinary wholesale distributor (in case of purchase) or of the recipient (in case of sale); name, surname, and contact details of the veterinarian who issued the prescription, and, where required, a copy of the prescription; and the marketing authorisation number of the veterinary medicinal product (Article 295, paragraph 1)
54) it fails to keep records of marketing of non-prescription veterinary medicinal products (Article 295, paragraph 2)
55) it fails to conduct at least one detailed annual stock audit, comparing stock entries and exits with current inventory levels of veterinary medicinal products, and fails to retain records of discrepancies for a minimum of five years and make them available to the competent authorities upon request (Article 295, paragraph 3)
56) it supplies veterinary medicinal products subject to veterinary prescription to persons who are not of legal age (Article 295, paragraph 4)
57) it fails to notify the Administration of any change in the authorisation for the retail distribution of veterinary medicinal products within 15 days from the date of the change (Article 295, paragraph 5)

For misdemeanour under paragraph 1 of this Article the responsible person in the legal person shall be fined from 500 EUR to 2,000 EUR.

For the misdemeanour referred to in paragraph 1, items 1 to 57 of this Article, a natural person/entrepreneur shall be fined in an amount ranging from EUR 3,000 to EUR 6,000.

Along with the fine for the misdemeanour under paragraph 1 of this Article, a protective measure of prohibition of activity may be imposed for a period of up to six months.

Article 349

A fine ranging from 1,000 euros to 2,000 euros will be imposed to a natural person if:

1) they fail to ensure that every batch of a medicinal product manufactured in Montenegro has undergone quality control in compliance with this Law and the marketing authorization (Article 99, paragraph 1, item 1);
2) where the medicinal product is imported from a third country, regardless of whether it was manufactured in the EU, and full qualitative and quantitative quality control of all active substances, as well as all other tests or controls necessary to ensure the quality of the medicinal product in accordance with the marketing authorisation, has not been

performed for each manufactured batch in Montenegro (Article 99, paragraph 1, item 2);

3) they fail to notify the Institute in writing about any suspicions of adverse reactions of a medicinal product, particularly when it comes to serious and unexpected adverse reactions, and for vaccines intended for human use, to notify the Institute for Public Health of Montenegro (Article 168, paragraph 1);
4) they fail to report to the Institute any suspicion of serious adverse reactions within 30 days of becoming aware of the event, and to provide additional information if necessary (Article 168, paragraph 2);
5) they fail to notify the Institute immediately in writing or by phone (followed by a written report) in the case of serious adverse reactions resulting in death (Article 168, paragraph 3);
6) when reporting adverse reactions for a biological medicinal product, they fail to provide the name of the medicinal product and its batch number, if available (Article 168, paragraph 4);
7) they, as employees of the Institute responsible for evaluating clinical trial authorization requests or substantial amendments to the clinical trial authorisation, as well as members of the Ethics Committee are in a conflict of interest, and are not independent of the sponsor, the clinical trial site and the investigators involved in the clinical trial and are exposed to any inappropriate influence (Article 179, paragraph 1) (Article 173);
8) they fail to record adverse events or deviations in laboratory analyses that are specified in the clinical trial protocol as critical for safety assessment and to report them to the sponsor in accordance with the reporting requirements and deadlines set by the protocol (Article 192, paragraph 1, item 1);
9) they fail to record all adverse events, unless otherwise provided by the clinical trial protocol, and fail to report to the sponsor or their representative all serious adverse events occurring in subjects treated by the investigator during the clinical trial, unless otherwise provided by the clinical trial protocol (Article 192, paragraph 1, item 2);
10) they fail to notify the sponsor or their representative without undue delay, and no later than 24 hours after becoming aware of a serious adverse event, unless the clinical trial protocol specifies that urgent reporting is not required for certain adverse events; and, if required, the investigator fails to provide the sponsor or their representative with a follow-up report, thereby preventing the sponsor from assessing whether the serious adverse event impacts the benefit-risk balance of the clinical trial (Article 193, paragraph 1, item 3);
11) they fail to notify the sponsor or their representative without undue delay upon becoming aware of a serious adverse event possibly related to the investigational medicinal product, which occurred after the clinical trial ended in a subject previously treated by the investigator (Article 194, paragraph 1, item 4);
12) they fail to update the local pharmacovigilance system and the PSMF in cooperation with the manufacturer, and fails to submit them to the Institute upon request (Article 259, paragraph 1, item 1);
13) they fail to assign PSMF reference numbers and submit the reference number in question to the pharmacovigilance database for each veterinary medicinal product (Article 259 paragraph 1 item 2)
14) they fail to establish and maintain a system ensuring the collection and aggregation of all information about suspected adverse events of which the marketing authorisation holder for veterinary medicinal products has been informed (Article 259, paragraph 1, item 2);

15) they fail to aggregate suspected adverse event reports pursuant to Article 256, paragraph 2 of this Act, perform their evaluation, and report them to the Institute (Article 259, paragraph 1, item 4);
16) they fail to ensure the complete and timely provision of additional information relevant for the benefit-risk assessment of the veterinary medicinal product, upon the Institute's request (Article 259, paragraph 1, item 5);
17) they fail to provide the Institute with other information necessary for detecting changes in the benefit-risk balance of the veterinary medicinal product, including post-marketing studies (Article 259, paragraph 1, item 6);
18) they fail to implement the signal management process and fail to ensure and establish conditions necessary to comply with the obligations under Article 259, paragraph 1, item 4 of this Law (Article 259, paragraph 1, item 7);
19) they fail to monitor the pharmacovigilance system and to ensure, if necessary, preparation and implementation of appropriate preventive or corrective action plans and, if required, updates to the PSMF (Article 259, paragraph 1, item 8);
20) they fail to ensure that all employees of the marketing authorisation holder for veterinary medicinal products involved in pharmacovigilance activities receive continuous training (Article 259, paragraph 1, item 9);
21) they fail to notify the Institute of any regulatory measure taken in the European Union, until access to the European Union pharmacovigilance database is established, and in third countries, and is related to pharmacovigilance data, within 21 days from the date of receipt of the information (Article 259, paragraph 1, item 10)
22) they fail to report any suspicion of adverse events referred to Article 255 of this Law immediately to the Institute (Article 261 paragraph 1);
23) they fail to report any suspicion of adverse events for a veterinary medicinal product to the marketing authorization holder (Article 261, paragraph 2);
24) they fail to ensure that every batch of the medicinal product produced in Montenegro is manufactured and subjected to quality control in accordance with this Law, as well as in accordance with the issued marketing authorisation (Article 2270, paragraph 7, item 1);
25) this fail to ensure that, if the medicinal product is imported from a third country, a full qualitative and quantitative quality control of all active substances, as well as all other tests or controls necessary to guarantee the quality of the medicinal product in accordance with the marketing authorisation, are carried out for every batch produced in Montenegro (Article 270, paragraph 7, item 2);
26) a veterinarian, upon request of the competent authority, fails to provide justification for prescribing a veterinary prescription for an antimicrobial medicinal product, especially in cases of metaphylaxis or prophylaxis (Article 298, paragraph 4);
27) the owner or keeper of food-producing animals fails to keep records regarding the medicinal products administered to animals, including the date of the first administration, the medicinal product name, quantity administered, name and address of the supplier, proof of acquisition of the product, identification of the treated animals or group of animals, details of the veterinarian who prescribed or administered the product, the withdrawal period (including a zero-day withdrawal period), and the treatment duration (Article 301 paragraphs 1 and 2).

XXI. TRANSITIONAL AND FINAL PROVISIONS

Article 350

Regulations for the implementation of this Law shall be adopted within 12 months from the date of entry into force of this Law.

Until the adoption of the regulations referred to in paragraph 1 of this Article, the regulations that were in force until the date of entry into force of this Law shall apply, provided that they are not contrary to this Law.

Article 351

Manufacturers with headquarters in Montenegro, wholesalers, importers, and holders of marketing authorizations for medicinal products are required to align their operations with the provisions of this Law and the regulations issued for its implementation no later than 24 months from the date of application of this Law.

Article 352

Certificates of compliance issued by the Institute in accordance with the law in force until the date of entry into force of this law shall be valid until the expiry of the period for which they were issued.

Article 353

The marketing authorization for a medicinal product issued in accordance with the regulations in effect prior to the entry into force of this Law shall remain valid until the expiration of the period indicated in the authorization decision issued by the Institute.

Marketing authorisation holder for a veterinary medicinal product which was authorised in accordance with the regulations in force until the date of entry into force of this Law shall be obliged to align the medicinal product authorisation, with regard to information on the veterinary medicinal product, with the provisions of Article 299, paragraph 4 of this Law, no later than 9 May 2029.

Article 354

Procedures before the Institute and the Administration initiated until the date of entry into force of this Law shall be completed in accordance with the regulations under which they were initiated.

Article 355

Veterinary medicinal products that are labelled and have a package leaflet approved in accordance with the regulations in force until the date of entry into force of this Law shall be brought into line with the provisions of this Law no later than 29 January 2027.

Article 356

The provision of Article 2, paragraph 3, item 2, regarding obligations related to certificates of Good Manufacturing Practice for inactivated immunological veterinary medicinal products that are produced from pathogens and antigens obtained from animals, or from animals within an epidemiological unit, and are used for the treatment of that animal or animals within the same epidemiological unit, or for the treatment of animals in a unit with confirmed epidemiological connection, shall start to apply from the date of application of the GMP guidelines for veterinary medicinal products referred to in Article 279, paragraph 1, item 2 of this Law.

Article 252, paragraph 4 shall apply for a period of one year from the date of entry into force of this Law.

Article 357

The provisions of Article 29; Article 33 paragraph 2; Article 34 paragraph 5; Article 115 paragraph 1 item 7; Article 124 paragraph 3; Article 137 paragraph 4; Article 144 paragraph 3;, Article 231 paragraph 4; Article 247 paragraphs 1 and 2 in the part of the application for a variation within 12 months;, Article 248; Article 254; Article 257; Article 263; Article 282 paragraph 1 item 7; and Art. 115 paragraph 1, 156 paragraph 3, 203 paragraph 1, 204 paragraph 1, Articles 219, 245 paragraph 12, 258 paragraph 2, 260 paragraph 2 and 320 paragraph 1 item 9 in the part relating to "approval for import" and Article 320 paragraph 1 item 12 of this Law shall apply until the date of accession of Montenegro to the European Union.

Article 358

The provisions of Article 3, paragraph 3; Article 28, paragraph 2; Article 30; Article 31; Article 33, paragraph 3; Article 43, paragraph 2; Article 45, paragraph 8; Article 47; Article 48, paragraph 2 in the part "European Commission"; Article 50, paragraph 2; Article 55; Article 60, paragraph 3; Article 61, paragraph 1, item 1 in the part relating to the PRAC; Article 62, paragraph 2; Articles 71-72; Article 85, paragraph 7; Articles 87 - 89; Article 90, paragraph 4, item 2; Article 97, paragraph 2; Article 99, paragraph 1, item 2, paragraphs 2, 3 and 4; Article 106, paragraph 7; Article 111, paragraph 2; Article 113; Article 114, paragraph 5; Article 115, paragraphs 2, 3 in the part relating to the EU; Article 116 paragraph 2 in the part of imports from a third country and paragraphs 5 and 6; Article 119 paragraph 1 item 4, paragraph 3 in the part "importer" and paragraph 4; Article 121; Article 123; Article 124 paragraph 1 item 5 in the part "at least for medicinal products bearing safety features", paragraph 2; Article 125; Article 130 paragraphs 4,5 and 6; Article 132; Article 134 paragraph 2; Article 135 paragraph 2; Article 136 paragraphs 1, 4 and 5; Article 140 paragraphs 1-6; Article 147 paragraph 3; Article 149 paragraph 2 items 1 and 3; Article 150 paragraphs 1 and 2; Article 151; Article 153 paragraph 1 item 2, paragraph 3; Article 155 paragraph 3, 4 and 5; Article 156 paragraph 1 item 7, paragraph 4; Article 157; Article 159 in the part relating to EMA; Article 161 paragraphs 3 and 4; Article 162; Article 163; Article 165; Article 167 paragraph 2; Article 176 paragraph 1 item 5; Article 196 paragraph 8; Article 210 paragraph 2; Article 211 paragraph 2; Article 212 paragraph 3; Article 214 paragraphs 5 and 6; Article 218 paragraph 2; Article 219 paragraph 2; 220 paragraph 6 in the part relating to residence in the European Union; Article 230 paragraph 7; Article 251 paragraph 2; Article 256 paragraphs 1 and 2; Article 258 paragraph 1 item 6 and paragraph 3; Article 259 paragraph 1 item 2; Article 260 paragraph 5; Article 265 paragraph 5; Article 266 paragraph 2 item 3; Article 270 paragraph 7 item 2; Article 279 paragraph 2; Article 280; Article 281 paragraph 4 item 3; 285 paragraph 2 in the part relating to the importer possessing manufacturing authorisation; Article 289 paragraph 2; Article 291 paragraph 4; Article 297; Article 298 paragraph 8; Article 300 paragraph 6; Article 302 paragraph 4; Article 303; Article 315 paragraph 3; Article 316 paragraphs 3, 5, 6, 7, 8, 10 and 11; Article 320, paragraph 1, item 9 in the part relating to "marketing authorisation" and item 10 and Article 346, paragraph 1, in the part "cooperation with the EMA", paragraphs 2, 3, paragraph 4, item 1 in the part "European Union Member States", item 3, item 4 in the part "premises of brokers" and item 6, indent 3, paragraphs 11, 12 and 14; this Law shall apply from the date of accession of Montenegro to the European Union.

Article 359

On the date of entry into force of this Law, the Law on Medicinal Products ("Official Gazette of Montenegro", No. 80/20, 84/24 and 35/25), as well as the provisions of Article 94, paragraphs 1, 2, 4, 5 and 6; Article 141, items 18 and 19; Article 162, paragraph 1, items 15)-17) and Article 162a, paragraph 1, item 9 of the Law on veterinary matters ("Official Gazette of Montenegro", No. 30/12, 48/15, 57/15, 52/16, 43/18, 84/24 and 92/25) shall cease to be valid.

Article 360

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

* This Law transposes the following documents:
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
Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC