LAW ON MEDICINES

I GENERAL PROVISIONS

Article 1

This law shall regulate the conditions for the manufacturing, marketing and testing of medicinal products for human use and veterinary use, measures for providing quality, safety and efficacy of medicinal products, competence of bodies in the field of medicinal products, as well as other relevant issues for performing these activities.

The provisions of this Law shall apply on medicinal products intended for placing on the market, which are manufactured industrially or by a manufacturing process involving an industrial process.

If, according to its definition and characteristics, a product can at the same time be considered as a medicinal product and another product to which the provisions of other regulations may apply, the provisions of this Law shall apply.

Article 2

The provisions of this Law shall not apply to the following:

1) magistral formulas;
2) galenic products, with the exclusion of the quality control provisions;
3) medicinal products intended for research and development;
4) intermediate products intended for further processing by an authorised manufacturer,
5) whole blood, plasma or blood cells of human origin, except for plasma which is prepared by a method involving an industrial process;
6) radionuclides in a sealed radiation source;
7) advanced therapy medicinal products prepared exclusively on a non-routine basis;
8) medicated feedingstuffs;
9) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from one or more animals from the holding and used for the treatment of animals in that holding and at the same locality; and
10) additives in animal feedingstuffs.

Article 3

Manufacturing and marketing of medicinal products are public service obligations.

Manufacturing, marketing, testing and control of medicinal products may be performed by legal persons that meet the requirements prescribed by this Law and the regulations adopted for implementing of this Law.

In Montenegro on the market and in use can be a medicinal product that has a marketing authorisation (hereinafter: marketing authorisation).

In Montenegro on the market and in use can be a medicinal product that has a marketing authorisation issued by the European Commission, in accordance with this Law.

Article 4

It is prohibited to manufacture and market following medicinal products:

1) for which marketing authorisation or the approval for the procurement or import is not issued;
2) which are manufactured by the legal entity that does not have manufacturing authorisation;
3) which are not labelled in accordance with the provisions of this Law;
4) whose shelf life labelled on the package is expired;

5) for which deficiency regarding its prescribed quality is determined;
6) which are falsified;

which are intended for the treatment of animals used for human consumption and which are made of substances that cannot be used for the manufacture of medicinal products for veterinary use (hereinafter: veterinary medicinal product).

The state administration authority competent for veterinary affairs may prohibit the manufacture or marketing and use of an immunological veterinary medicinal product for the eradication or suppression of animal diseases, if it is determined:

1) the administration of an immunological veterinary medicinal product on animals will interfere with the implementation of national programs for the diagnosis, suppression and eradication of animal diseases or would cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or in other products obtained from treated animals;
2) the disease for which the immunological veterinary medicinal product is intended is largely absent from the territory in question;

In case referred to in paragraph 2 of this article, the state authority competent for veterinary affairs shall inform the Institute for medicinal products and medical devices (hereinafter: the Institute) and the European Commission.

It is prohibited to dispense and sell medicinal products outside pharmacies and contrary to the mode of dispensing of medicinal products.

Notwithstanding paragraph 4 of this Article, a doctor of veterinary medicine, or a graduated veterinarian (hereinafter: a veterinarian) may dispense a medicinal product necessary for treating animals under his supervision, in accordance with the Law.

Article 5

Notwithstanding Article 3 of this Law, the Institute may approve procurement or import of a medicinal product that do not have a marketing authorisation in the case of:

1) medicinal products intended for research purposes including veterinary medicinal products used to obtain the results referred to in Article 47 paragraph 1 item 4) of this Law**;**
2) medically justified need to protect health, in case of an epidemic, epizootic, natural disasters or other emergencies;
3) in case of a treatment of individual patient or a group of patients, with a medicinal product that was, by taking personal responsibility, prescribed by a medical doctor or dental medicine doctor who conducts the treatment;
4) in case of a treatment of individual animal or group of animals with a medicinal product prescribed by a veterinarian who conducts the treatment;
5) medicinal products for compassionate use.

In cases of paragraph 1 item 2) of this article, marketing authorisation holders, manufacturers and healthcare professionals are not responsible for any possible damage resulting from the use of an unauthorised medicinal product or from the off-label use of authorised medicinal product when such use is recommended, or required by the ministry competent for health (hereinafter: the Ministry).

Provisions of paragraph 2 of this Article are not applicable to liability of the marketing authorisation holders and manufacturers for medicinal product quality deficiencies.

Article 6

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

Article 7

Terms used in this Law shall have the following meaning:

1) **active substance** shall mean any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;
2) **safety of the medicinal product** shall mean an acceptable ratio between efficacy and adverse effects of medicinal products;
3) **bioequivalence** assumes that two medicinal products that are pharmaceutical equivalents or pharmaceutical alternatives have a similar bioavailability after administration of the same molar dose to such an extent that can be expected the same effect, including efficacy and safety of the administration;
4) **bioavailability** shall mean the speed and degree of availability of the active substance from the medicinal product, determined from the relationship between concentration-time in the systemic circulation or excreted material;
5) **Investigator's brochure** shall mean a compilation of the clinical and non-clinical data on the investigational medicinal product which are relevant to the study of the product or products in human subjects;
6) **Centralised procedure** shall mean the procedure for granting marketing authorisation for medicinal products by the European Medicines Agency;
7) **Decentralized procedure** for marketing authorisation shall mean the marketing authorisations procedure initiated simultaneously in the reference state and in other Member States concerned which are involved in the same process. It is mandatory for medicinal products, for which centralized procedure or mutual recognition procedure for granting marketing authorisation is not conducted, which have not yet obtained the marketing authorisation for in the European Union and which will be marketed in more than one Member State of the European Union.
8) **Good pharmacy practice** shall mean a quality assurance system, which refers to the organization, implementation, expert supervision and quality control in the pharmacy activities, providing quality of services provided for the patient at the pharmacy;
9) **Good clinical practice** shall mean a set of internationally recognised ethical and scientific requirements and quality assurance system which are used in designing, conducting, recording and reporting on clinical trials involving human subjects;
10) **Good manufacturing practice** shall mean the part of the quality assurance system which ensures that medicinal products are consistently and permanently produced and controlled in accordance with the relevant quality standards which are in line with their intended purpose;
11) **Good laboratory control practice** shall mean the part of the Good Manufacturing Practice ensuring quality in the process of the quality control of medicinal products;
12) **Good laboratory practice** shall mean a quality assurance system governing organizational processes and conditions conducting pre-clinical trials regarding safety for human administration and the environment, its control, manner of reporting and documentation, in accordance with regulation governing chemicals;
13) **Good distribution practice** shall mean a quality assurance system that relates to organizing, carrying out and expert supervision of the distribution of medicinal products, from manufacturer to end user;
14) **Good pharmacovigilance practice** shall mean guidelines of quality assurance in planning, organization and implementation of procedures related to collecting, processing and evaluating safety data on medicinal product with the aim of protecting

the health of the population and animals (EudraLex - Volume 9 - Pharmacovigilance guidelines);

15) **efficacy of the medicinal product** shall mean the ability of the medicinal product proven by clinical trials conducted in accordance with this Law
16) **The Ethics Committee for clinical trials** (hereinafter: the Ethics Committee) shall mean an independent body consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection by among other things expressing an opinion on the trial protocol, the suitability of investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consents;
17) **The European Medicines Agency** (hereinafter: EMA) shall mean an agency of the European Union established by Regulation No 726/2004/EC;
18) **falsified medicinal product** shall mean 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, its 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;

19) **pharmaceutical equivalents** shall mean finished medicinal products containing the same active substance in the same amount and in the same pharmaceutical form and the same route of administration, and correspond to the same or comparable standards;
20) **pharmaceutical alternatives** shall mean medicinal products containing the same active substance, but in the form of another salt, ester or alike or in other pharmaceutical form or in different strength;
21) **pharmaceutical form** shall mean form of the medicinal product suitable for the administration (tablets, capsules, ointments, solution for injection, premix etc.)
22) **pharmacopoeia** is a collection of prescribed norms and standards for the substances and manufacturing of medicinal product by which is determined their identification, characteristics, quality, method of preparation and analysis;
23) **pharmacological and toxicological (pre-clinical) medicinal product testing's** shall mean testing which determines pharmacodynamic, pharmacokinetic and toxicological properties of the medicinal product**;**
24) **pharmacovigilance** shall mean the system of activities related to collection, identification, evaluation, understanding, prevention and response to adverse reactions to medicinal products, as well as other problems relating to their use;
25) **formal assessment of the documentation** shall mean procedure of determining whether the documentation submitted to obtain the relevant authorisations contain all the required parts in accordance with this Law and regulations adopted to implement this Law;
26) **generic medicinal product** shall mean a medicinal product which has the same qualitative and quantitative composition of active substances 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. 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 various salts, esters or derivatives of an authorized active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form;

27) **Pharmacovigilance system master file** (hereinafter: PSMF) shall mean a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorized medicinal products;
28) **finished medicinal product** shall mean medicinal product that is manufactured industrially, or within an industrial process with the intention of placing onto the market;
29) **informed consent** shall mean decision, which must be written, dated and signed, to take a part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented;
30) **international non-proprietary name (generic name) of the medicinal product** shall mean an international non-proprietary name (INN) recommended by the World Health Organization or, if one does not exist, the usual common name;
31) **subject** shall mean an individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control;
32) **Post-authorisation safety study** (hereinafter: PASS) shall mean any study relating to an authorised medicinal product conducted with the aim of identifying, characterizing or quantifying a safety hazard, confirming the safety profile of the medicinal product or of measuring the effectiveness of risk management measures;
33) **investigator in clinical trial (hereinafter: investigator)** shall mean a doctor or person with a faculty of health orientation and proper expert qualifications for clinical trials who is directly involved and responsible for the care of patients, i.e. persons or animals subject to clinical trial and for their treatment and also responsible for the conduct of a clinical trial. If a trial is conducted by a team of individuals at a trial site the principal investigator is the responsible person;
34) **strength of the medicinal product** shall mean the content of the active substance expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form;
35) **withdrawal period** shall mean the period necessary between the last administration of the veterinary medicinal product to animals, under prescribed conditions of use and in accordance with the provisions of this Law, until the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues of pharmacological active substances in quantities in excess of the maximum residue limits in European Union;
36) **clinical trial** shall mean any investigation in human subjects which is intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s), and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal products with the object of ascertaining its (their) safety and/or efficacy. This includes clinical trials conducted in either one site or multiple sites, whether in one or more states;
37) **inspection of clinical trials** shall mean the act by the Institute of conducting an official review of documents, facilities, records, quality assurance arrangements and any other resources related to clinical trials and that may be located at the site of the trial, at the sponsor‘s and/or contract research organization’s facilities or in other establishment;

38) **quality of medicinal product** shall mean characteristic which can be determined by examining the quality of all ingredients of the medicinal product and represents acceptable physical, chemical, biological, pharmaceutical-technological and other characteristics of the medicinal product, in accordance with the requirements from the marketing authorisation;
39) **investigational medicinal product** shall mean a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorized form or when used for an unauthorized indications or when used to gain further information about the authorized form;
40) **list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products** (draft Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products) shall mean list prepared by the Committee for Herbal Medicinal Products (HMPC) at the EMA containing data on indications, strength, posology, route of administration and other data necessary for the safe use of herbal substances in traditional herbal medicinal products;
41) **European Union reference dates list** (hereinafter: EURD list) shall mean the list of active substances and combinations of active substances with determined dates and frequency of submitting PSUR, as well as with category for medicinal product for which PSUR needs, or does not need to be submitted, in accordance with CHMP (Committee for Medicinal Products for Human Use) and CMDh (Co-ordination group for Mutual recognition and Decentralized procedures – human), following the consultations with PRAC (Pharmacovigilance Risk Assessment Committee) of the EMA).
42) **medicinal products containing narcotics** shall mean medicinal products of specific qualitative and quantitative composition in certain pharmaceutical form which are used in medical, veterinary, educational, laboratory and scientific purposes in accordance with special laws;
43) **magistral formula** shall mean any medicinal product prepared in a pharmacy laboratory for an individual patient, in accordance with a medical prescription from pharmaceutical reference books or pharmacopoeia;
44) **medicated feedingstuffs** shall mean any mixture of a veterinary medicinal product or products and feed which is ready prepared for placing on the market and intended to be fed to animals without further processing, because of its curative or preventive properties or other properties as a medicinal product covered by Article 28 of this Law;
45) **medical error** shall mean an unintended error in prescription, dispensing or administration of a medicinal product by a healthcare professional or patient;
46) **intermediate product (or semi-product)** shall mean any product that has undergone a partial processing and is used as raw material in the successive step of a medicinal product manufacture;
47) **the Community Herbal Monograph** of the European Union shall mean monograph brought by the HMPC which contains a summary of the pharmaceutical, clinical and pharmacological characteristics of certain herbal medicine;
48) **multi-centre clinical trial** shall mean a clinical trial conducted according to a single protocol at more than one site and therefore by more than one investigator, whether or not the sites are located in the same or different state;
49) **name of a medicinal product** shall mean the name which may be either new, generic or scientific name. A trademark, or the name of the manufacturer, or the marketing authorisation holder shall be added to generic, or scientific name, while the new name shall differ from generic and shall not be misleading;

50) **non-interventional trial of a medicinal product** shall mean a study where the medicinal product(s) is(are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of patients to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicinal product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to patients and epidemiological methods shall be used for the analysis of collected data;
51) non-commercial clinical trials shall mean clinical trials conducted by investigators without the participation of the pharmaceutical industry;
52) **off-label use of a medicinal product** shall mean the use that is not compliant with the approved summary of product characteristics**;**
53) **off-label use of a veterinary medicinal product** shall mean the use of a medicinal product that is not in accordance with the approved summary of the product characteristics, including misuse and abuse of medicinal product;
54) **unexpected adverse reaction** shall mean an adverse reaction, the nature, severity, or outcome of which is not consistent with the Summary of Product Characteristics or the investigator‘s brochure for medicinal products in clinical trials;
55) **adverse event** shall mean unwanted experience created in the period of medicinal product administration for which the cause-effect relationship with medicinal product use does not have to be proven and represents any unwanted and unintended sign (e.g. an abnormal laboratory finding), symptom or disease, the timely associated with medicinal product administration;
56) **adverse event in a clinical trial** shall mean any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have to prove a causal relationship with this treatment;
57) **adverse reaction to a medicinal product s**hall mean a response to a medicinal product which is noxious and unintended;
58) **adverse reaction to investigational medicinal product** shall mean all untoward and unintended responses to an investigational medicinal product related to any dose administered;
59) **adverse reaction to a veterinary medicinal product** shall mean harmful and unintended reaction which occurs at doses normally used in animals for the prophylaxis, diagnosis, treatment of disease, or to restore, correct or modify physiological function;
60) **adverse reaction to the veterinary medicinal production in humans** shall mean noxious unintended reaction which occurs in humans being following the exposure to the veterinary medicinal product;
61) **marketing authorisation holder** shall mean any natural or legal person established in the European Union that is in possession of a marketing authorisation issued by Institute or the European Commission and that is responsible for placing medicinal products on the market;
62) **quality assurance** shall mean continuous process by which the quality is introduced in all stages of manufacturing, including a documented tracking system of all ingredients and individual manufacturing process, i.e. quality control which includes all controls in relation to the quality of medicinal product - in the manufacturing process (at the beginning and during the process), on the finished product (product batches) and on samples taken from the market (control after placing on the market);
63) **labelling of medicinal products** shall mean information on the immediate or outer packaging;

64) **Official Control Authority Batch Release Certificate** (hereinafter: OCABR) shall mean a certificate verifying that a batch of an immunological medicinal product or product from human blood or plasma has been tested in an official laboratory in accordance with OCABR guidelines;
65) **risk-benefit balance** shall mean an evaluation of positive therapeutic effects of the medicinal product in relation to the risks as defined in item 82 of this Article;
66) **original medicinal product** shall mean a medicinal product that was the first to get the authorisation for the medicinal product in the world based on the complete documentation on the quality, safety and efficacy in accordance with the valid requirements;
67) **serious adverse reaction** shall mean an adverse reaction which results in death, is life-threatening, requires inpatient hospitalization or prolongation of hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect;
68) **serious adverse reaction/serious adverse event in a clinical trial** shall mean any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;
69) **serious adverse reaction to a veterinary medicinal product** shall mean any adverse reaction which results in death, is life-threatening, can cause incapacitation, congenital anomalies, or result in permanent or prolonged symptoms in the animals treated;
70) **Periodic safety update report** (hereinafter: PSUR) shall mean the report on safety of a medicinal product which contains all available information on safety of a medicinal product and which is submitted to the Institute by the marketing authorisation holder after the issuance of marketing authorisation.
71) **Risk Management Plan (hereinafter: RMP)** shall mean a detailed description of the Risk Management System;
72) **misuse of medicinal product** shall mean an unintended, inappropriate use of a medicinal product that is not compliant with the approved documents on a medicinal product;
73) **starting substance** i.e. raw materials for pharmaceutical use shall mean any substance (active and excipient) used in the manufacturing of the medicinal product, or for the making of galenic medicinal product**;**
74) **excipient** shall mean any constituent of a of a medicinal product other than the active substance or packaging material;
75) **mutual recognition procedure (hereinafter MRP)** shall mean the procedure for issuing marketing authorisation which, upon obtaining approval in the reference member state, commences simultaneously in the reference member state and other member states involved in the same procedure and which is mandatory for those medicinal products that are not subject to the centralized procedure and which will be marketed in more than one European Union member state;
76) **representative of the marketing authorisation holder** shall mean a natural or a legal person designated by the marketing authorisation holder as to represent him in Montenegro;
77) **pre-mix for medicated feedingstuffs** shall mean a veterinary medicinal product that is manufactured in a way to serve solely for the manufacturing of medicated feed;
78) **manufacturer of a medicinal product** shall mean a legal person holding the manufacturing authorisation issued by the competent authority;

79) **protocol of a clinical trial** shall mean a document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments;
80) **reference medicinal product** shall mean a medicinal product that is authorized for marketing in European Union based on the complete documentation on the quality, safety and efficacy of medicinal product administration;
81) **residues of pharmacologically active substances** shall mean all pharmacologically active substances, expressed in u mg/kg or μg/kg per weight of fresh sample, whether they are active substances, excipients, or the degradation product and their metabolites which remain in food obtained from animals;
82) **risk related to use of a medicinal product** shall mean any risk relating to the quality, safety or efficacy of a medicinal product as regards patient health or public health, or animal health, as well as any risk of undesirable effects on the environment;
83) **compassionate use** shall mean administering a medicinal product containing a new active substance which belongs to the significant therapeutic-scientific-technical innovation and which is in the process of obtaining marketing authorisation in the countries of the European Union or in the process of clinical trial in the EU for the purposes of obtaining marketing authorisation, which is intended for patients with a serious disease that cannot be treated satisfactorily with medicinal products that already have the marketing authorisation in Montenegro or the European Union or the countries of the European Economic Area (hereinafter: EEA), or in countries having a mutual recognition agreement with the EU countries (hereinafter: EUMRA)**.**
84) **Summary of the Product Characteristics** shall mean a summary of expert information on a medicinal product which has been approved through the marketing authorisation procedure and which is intended for healthcare professionals;
85) **certificate for the purpose for export of medicinal product** shall mean a document issued by competent authority of the country of the manufacturer issued in accordance with the recommendations of the World Health Organization;
86) **Pharmacovigilance system** shall mean a system used by the marketing authorisation holder and the Institute, to fulfil the pharmacovigilance tasks and responsibilities in accordance with this Law and rulebook for the implementation of this Law to monitor the safety of authorised medicinal products and detect any change to their risk-benefit ratio;
87) **Risk Management System** (hereinafter: RMS) shall mean a set of pharmacovigilance activities and interventions designed to identify, characterize, prevent or minimize risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;
88) **Guidelines for Good Manufacturing Practice** shall mean guidelines for the system of quality assurance related to the organization of medicinal product manufacturing, quality control of medicinal product and carrying out of supervision. Guidelines for Good manufacturing practice for active substances are the part of the Guidelines of Good Manufacturing Practice
89) **outer packaging** shall mean the packaging into which is placed the immediate packaging;
90) **clinical trial sponsor** shall mean an individual, company, institution or organisation which takes responsibility for the initiation, conducting and/or financing of a clinical trial;

91) **expert public** shall mean healthcare professionals and veterinarians, pharmacists and other professionals involved in the manufacturing and wholesale of medicinal product, as well as in organization of compulsory health insurance;
92) **post-marketing surveillance studies** shall mean pharmacoepidemiological study or clinical trials, in accordance with the terms of the marketing authorisation for a veterinary medicinal product, conducted with the aim of identifying and investigating a safety hazard relating to an authorized veterinary medicinal product;
93) **substandard medicinal products** shall mean medicinal products that fail to meet either their quality standards or their specifications, or both;
94) **essentially similar medicinal products** shall mean medicinal products that have the same qualitative and quantitative composition of active substance in the same pharmaceutical form or different forms of oral immediate release (tablets and capsules), with proven bioavailability/bioequivalence, if necessary, with a medicinal product that is used for comparison until it is scientifically proven significant difference in terms of safety and efficacy of the medicinal product**;**
95) **immediate packaging** shall mean the container or other form of packaging immediately in contact with the medicinal product;
96) **package leaflet** shall mean a leaflet containing information for the user, which accompanies the medicinal product;
97) **sample of the medicinal product** shall mean the quantity of the medicinal product necessary for pharmaceutical testing;
98) **countries that have the same or similar requirements for issuance of marketing authorisation** for a medicinal product are countries having their regulations in compliance with the standards of the European Union and the countries that are members of the International Conference on Harmonization of technical requirements for issuance of marketing authorisation.
99) **abuse of medicinal products** shall mean persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects;
100) **food-producing animal** means any animal that cultivate, hold, slaughter or collect for the production of food for human consumption.

II COMPETENCES

Article 8

Government of Montenegro (hereinafter: Government) shall:
1) establish criteria for determining maximum-prices of medicinal products used for human use that are marketed in Montenegro and that are on the Reimbursement list;
2) take measures for the medicinal products providing in cases of emergencies and may provide a different method, procedure and conditions for approving the procurement of a medicinal product, issuing marketing authorisation, clinical trial, manufacturing, marketing, quality control and, labelling, pharmacovigilance and advertising of medicinal products, from the requirements prescribed by this Law;
3) perform other duties in accordance with this Law.

Article 9

The Ministry shall:
1) establish a national pharmacopoeia, and the magistral formulas;
2) pass rulebooks and other acts for the implementation of this Law;

3) establish measures for the rational use of medicinal products;
4) propose criteria for setting prices of medicinal products from article 8 paragraph 1 item 1) of this Law;
5) suggest to the Government taking measures referred to in Article 8 paragraph 1 item 2) of this Law;
6) perform other duties in accordance with this Law.

In accordance with this Law, the state authority responsible for veterinary matters shall:
1) pass regulations and other acts for the implementation of this Law;
2) suggest to the Government taking measures referred to in Article 8 paragraph 1 item 2) of this Law;
3) perform other duties in accordance with the Law.

Authority responsible for veterinary matters shall issue wholesale and retail sale authorisations for veterinary medicinal products and perform inspection supervision:
1) over holders of wholesale authorisation for veterinary medicinal products;
2) of retail sale of veterinary medicinal products and use of medicinal products in veterinary institutions;
3) of medicinal products advertising;
4) of medicinal products labelling and expiry date on the packaging;
5) of prohibition of marketing, i.e., order of marketing suspension or recall from the market of veterinary medicinal products that do not fulfill quality, safety and efficacy standards and conditions prescribed with this Law and rulebooks for the implementation of this Law.

State authority competent for inspection affairs shall perform inspection supervision:
1) of retail sale of medicinal products;
2) medicinal products advertising;
3) of medicinal products labelling and expiry date on the packaging;
4) use of medicinal product in health care institution;
5) pharmacovigilance in health care institution;
6) medicinal products pricing in retail and wholesale.

Article 10

The Institute shall perform activities regarding the evaluation of quality, safety and efficacy of products considered as medicinal products and other similar activities in the field of medicinal products.

Article 11

The Institute is established by the Government.

The Institute is a legal person with rights, obligations and responsibilities determined by the Law and the Statute of the Institute.

Article 12

Authorities of the Institute are: Steering Board and the General Manager.

The president and members of the Steering Board and the General Manager cannot perform in their own name and for its own account, as well as on behalf and for account of the other natural or legal entity, the activities of manufacturing, marketing and testing of medicinal products and medical devices nor can 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.

Article 13

Authority governing the Institute is the Steering Board.

The Steering Committee is consisted of the president and four members who are appointed and released by the Government.

President and members of the Steering Board are appointed among professionals in the field of health, veterinary medicine and environmental protection and one member is a representative of the employees proposed by the Institute.

Steering Board members shall be appointed for the four-year period and may be reappointed.

Article 14

Steering Board shall perform the following tasks:

1) define the business policy of the Institute;
2) adopt statute of the Institute, act on internal organisation and systematisation and other general acts;
3) adopt financial plan and final account;
4) decide on the choice of an auditor;
5) adopt the report on business operating;
6) bring the working program of the Institute;
7) make investment decisions;
8) adopt a code of conduct for employees of the Institute;
9) take measures to ensure the quality, safety and efficacy of medicinal products;
10) submit at least once a year a work report to the Government;
11) make in second instance decisions on the employees' rights of the Institute;
12) adopt the Rules of procedure regarding its work; and
13) 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 15

The Institute is presented and represented by the General Manager.

General Manager is appointed and released by the Steering Committee based on the public contest.

General Manager shall be appointed for the five-year period and may be re-elected.

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 medical devices legislation and whose development strategy is accepted by the Steering Board and the Expert-Scientific Board.

General Manager cannot be a person who was employed at least for three years in the manufacture, marketing and clinical trials of medicinal products and medical devices at other legal entities, person who participated in preparation of the documentation to be submitted with the application for obtaining marketing authorisation for a medicinal product and entering into the register 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 work.

Article 16

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 working programs and plans of the Institute;

4) pass the decisions, i.e., administrative acts within the competence 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 17

General Manager of the Institute may be released of his duties before the expiry of his term, if:

1) the function of General Manager is not done in accordance with the law, statute and other general acts of the Institute;
2) does not act upon the decisions and conclusions of the Steering Board;
3) submits the request for dismissal in writing.

Article 18

The Institute shall form the Expert-scientific Committee that consists of at least five employees of the Institute with specialized and scientific titles from the Institute's activities.

Expert-scientific Committee shall:

1) propose and give opinions on the development strategy of the Institute and propose expert basis for the program of work and development of the Institute;
2) propose and give opinions on issues of expert work of the Institute;
3) give an opinion on the programs of all forms of expert and scientific training for the need of the Institute;
4) adopt a program for scientific-research and development activities;
5) analyse, evaluate and adopt reports on the implementation of programs and projects;
6) perform other duties in accordance with law and the statute of the Institute.

The Institute statute shall define the manner of electing of members of the Committee from paragraph 1 of this Article.

Article 19

The Institute, in cooperation with the faculties of health, natural and technological-technical orientations, develops and exchanges expert knowledge in order to raise quality and education, participates in the implementation of scientific research in the field of medical sciences and interdisciplinary research and scientific work in the field of medicinal products and medical devices and in other related areas.

The Institute is a teaching base of the faculties of health orientation, for scientific areas of its activity, based on a contract, in accordance with the law.

Article 20

General acts of the Institute are the following: statute and other general acts.

Statute of the Institute shall regulate the basis of internal organization, activities and the work of advisory bodies, Expert-scientific Committee, detailed manner of electing members of Expert-scientific Committee and the termination of the mandate, transparency and other issues relevant to the work of the Institute.

Article 21

Employees of the Institute shall carry out tasks in accordance with the act on internal organization and systematization.

In terms of rights, obligations and responsibilities of employees of the Institute, labour regulations shall be applied.

Article 22

The Institute shall:

1) issue marketing authorisation;
2) issue manufacturing and wholesale authorisations for medicinal products for human use;
3) issue an approval for clinical trials of medicinal products, amendments of the approval, perform control of conducting and monitor the safety of the investigational medicinal product;
4) record non-interventional clinical trials;
5) establish and organize a system of pharmacovigilance in order to monitor safety of medicinal products on the market and detect any changes in relation to risk-benefit ratio of their use;
6) issue certificates on Good Manufacturing Practice and Good clinical practice and other certificates in accordance with this Law;
7) issue certificates for the purpose of export in accordance with recommendations of WHO;
8) issue a consent for import of unauthorised medicinal products in accordance with the Article 5of this Law**;**
9) issue authorisations for narcotic drugs and psychotropic substances in accordance with the legislation regulating this areas;
10) issue approval for import and export of immunological medicinal products and medicinal products from the blood and plasma;
11) conduct quality control in accordance with the law;
12) participate in international standardization in the field of medicinal products;
13) perform collecting and processing of data on marketing and consumption of medicinal products;
14) keep the registers stipulated by this Law;
15) conduct inspection surveillance on conducting this Law;
16) perform activities of information and education on medicinal products, organise professional and educational conferences and provide information of importance for the conducting measures of rational use of medicinal products;
17) carry out the cooperation with international entities and national regulatory bodies in the field of medicinal products;
18) participate in the harmonisation of regulations in the field of medicinal products with regulations of the European Union and regulations and guidelines of international institutions;
19) issue expert opinions on the classification of the products into the medicinal product or group of medicinal products as well as other expert opinion within its jurisdiction;
20) carry out activities related to disposal and destruction of waste for its own purposes;
21) establish maximum prices of medicinal products used in human medicine, in accordance with criteria established by the Government;
22) perform activities in the field of medical devices in accordance with special law;
23) perform educational, scientific and research work in cooperation with the faculties of health orientation in the field of medicinal products and medical devices and other related fields of interdisciplinary research; and
24) perform other duties in accordance with the law.

The Institute shall perform activities referred to in paragraph 1 items 1-11, 13-16 and 18-22 of this Article as activities within transferred jurisdiction.

Article 23

Funding for the Institute is provided from its own resources, i.e., from the fees established for performing activities referred to in Article 22 paragraph 1 items 1-11 and 14, 16, 19, 21 and 22 of this Law, as well as from other resources in accordance with the law.

The funds referred to in paragraph 1 of this Article shall be used by the Institute to fulfill its competencies in accordance with this Law.

For medicinal products that are used to treat rare diseases in humans ("Orphan" medicinal products), to treat rare diseases in less abundant animal species ("MUMS") and medicinal products from the humanitarian aid, the Institute does not charge fees referred to in paragraph 1 of this Article.

Article 24

The applicant shall cover costs incurred in performing of the activities referred to in the Article 22 paragraph 1 of this Law, unless otherwise provided by this Law.

Manner of payment of fees as well as the amount of fees referred to in paragraph 1 of this Article, which correspond to the actual costs of performed activities shall be determined by the Institute.

The Steering Board of the Institute shall give consent to the act referred to in paragraph 2 of this Article.

Article 25

For professional assistance in performing certain tasks within the jurisdictions of the Institute, the Institute may establish a list of experts (hereinafter: Commissions) and use the professional services of institutions that have necessary expert and scientific knowledge in the field of medicinal products.

Commission members referred to in paragraph 1 of this Article may be permanent and members by invitation for specific types of medicinal products.

The mandate of the permanent members of the commission is four years and they can be re-elected.

The more detailed manner of work of the Commissions is regulated by the Rules of procedure.

Activities costs for experts and Commission members referred to in paragraph 1 of this Article shall be provided by the Institute's fund and are paid in accordance with the Institute's decision.

On its website the Institute publishes Rules of procedure of Steering Board and Commissions referred to in paragraph 1 of this article, including agendas for its meetings and minutes of its meetings, accompanied by decisions taken and information about voting.

Article 26

Employees in the Institute, members of bodies and commissions of the Institute, as well as engaged experts from the list of experts cannot perform in their own name and for its own account, as well as on behalf and for account of the other natural or legal entity, the activities of manufacturing, marketing and testing of medicinal product nor can have other personal or financial interests (property, shares, membership in management or contractual relations), within persons engaged in these activities, on which they will sign the annual declaration.

Persons referred to in paragraph 1 of this Article cannot participate in preparation of documentation submitted with the application referred to in the Article 22 paragraph 1 of this Law.

The Institute will dismiss the expert from the list of experts and commission member who acts contrary to paragraph 1 and 2 of this article, as well as in the in the case of non-performance or negligent performance of entrusted tasks.

Article 27

Persons referred to in Article 26, paragraph 1 of this Law, as well as employees of the Ministry, competent state authority for veterinary affairs, competent authority responsible for veterinary affairs and competent authority for the inspection affairs are obliged to keep confidential all data from the documentation submitted with the application for issuing medicinal product marketing authorisation , as well as in other procedures in accordance with this Law, especially if:

1) data are confidential, and which are not well known or not readily available to persons who normally deal with this type of information;
2) data have commercial value because of its confidentiality and for the duration of confidentiality;
3) data for which applicant for medicinal product marketing authorisation , amendment or renewal of the authorisation is taking, under the circumstances, measures to keep them confidential.

The persons referred to in paragraph 1 of this Article, keep confidential data from documentation for obtaining the medicinal product marketing authorisation, amendment or renewal of authorisation, related to undisclosed tests (trials) of pharmaceutical products which use new chemical compounds or whose creation requires considerable effort.

In order to combat unfair competition, employees and persons referred to in paragraph 1 of this Article shall not disclose information from the documentation submitted in the procedure for obtaining the medicinal product marketing authorisation , as well as in other proceedings.

The data referred to in paragraph 1 of this Article can be made public in the case of approval of the medicinal product marketing authorisation applicant and in other procedures in accordance with this Law, as well as in the case of a needed for providing information on the medicinal product to the professional and general public that are necessary for the use or handling, as well as protection of human and animals health.

The documentation accompanying the marketing authorisation application is the property of the manufacturer, and represents the confidential data.

In the event of a breach of the obligation referred to in paragraphs 1 to 4 of this Article, the regulations governing the confidentiality of data shall apply.

III MEDICINAL PRODUCTS

Article 28

Medicinal product is any substance or combination of substances presented as having properties for treating or preventing disease in human beings or animals and any substance or combination of substances which may be used in or administered to human beings or animals, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis.

Substance referred to in paragraph 1 of this Article is any substance, irrespective of origin, which may be:

1) human (e.g. human blood and human blood products);
2) animal (e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products);
3) vegetable (e.g. micro-organisms, plants, parts of plants, secretions, extracts);

4) chemical (e.g. elements, naturally occurring chemical materials and chemical products obtained by a chemical change or synthesis).

Article 29

Biological medicinal product shall mean a medicinal product whose active substance is a biological substance that is produced or secreted from a biological source, and whose total characteristics and quality are determined by physical-chemical-biological testing, together with corresponding data on the manufacturing process and control of the manufacturing process (immunological medicinal products, medicinal products derived from human blood and plasma, advanced therapy medicinal products, etc.).

Article 30

Immunological medicinal products shall mean any medicinal product consisting of vaccines, toxins, serums or allergen products:.

Vaccines, toxins, serums shall include:

1) agents used to produce active immunity (such as cholera vaccine, BCG, polio 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 Tests, brucellin, etc.);
3) agents used to produce passive immunity (such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin).

Allergen product shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.

Immunological medicinal product intended for use in veterinary medicine shall mean any medicinal product administered to animals in order to produce their active or passive immunity, or to diagnose the state of their immunity.

Article 31

Advanced therapy medicinal products shall mean any of the following medicinal products for human use: a gene therapy medicinal product, somatic cell therapy medicinal product and tissue engineering medicinal product, intended for human use.

Gene therapy medicinal product shall mean a biological medicinal product which has the following characteristics:

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.

Somatic cell therapy medicinal product shall mean a biological medicinal product which has the following characteristics:

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.

Tissue engineered medicinal product shall mean a medicinal 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 a human tissue.

Medicinal products referred to in paragraph 4 of this Article may contain cells or tissues of human or animal origin, or both. The cells or tissues may be viable or non-viable. It may also contain additional substances, such as cellular products, bio-molecules, biomaterials, chemical substances, scaffolds or matrices.

Into the group of medicinal products referred to in paragraph 4 of this Article are not included products containing or consisting exclusively of non-viable human or animal cells and/or tissues, which do not contain any viable cells or tissues and which do not act principally by pharmacological, immunological or metabolic action.

Medicines referred to in paragraph 1 of this Article may also be prepared on a non-routine basis according to special requirements for use in the hospital, under the expert supervision of a medical doctor, based on a prescription for an individual patient in Montenegro.

The Ministry shall prescribe the conditions regarding premises, personnel and equipment, the content of the application and the procedure for obtaining an approval for non-routine production, as well as other necessary conditions for the preparation and use of drugs referred to in paragraph 7 of this Article.

Article 32

Medicinal product derived from human blood or human plasma shall mean medicinal products based on blood constituents which are prepared industrially by public or private establishments, such medicinal products including, in particular, albumin, coagulating factors and immunoglobulins of human origin.

Blood and its components intended for transfusion shall not be considered as medicinal product in terms of this Law.

Article 33

Radiopharmaceuticals are: radiopharmaceutical medicinal products, radionuclide generators, radiopharmaceutical kits and radionuclide precursors.

Radiopharmaceutical shall mean any medicinal product, which when ready for use, contains one or more radionuclides (radioactive isotopes), included for a medicinal purpose.

Radionuclide generator shall mean any system incorporating a fixed parent radionuclide from which is produced daughter radionuclide which is to be obtained by elution or by any other method and is used in a radiopharmaceutical.

Radiopharmaceutical kit shall mean any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration.

Radionuclide precursor shall mean any other radionuclide produced for the radio-labelling of another substance prior to administration.

Article 34

Herbal medicinal product shall mean any medicinal product exclusively containing as active ingredients one or more herbal substances or one or more such herbal preparations, or one or more such herbal substances in combination with one or more herbal preparations.

Herbal substances shall mean whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, dried form, but sometimes fresh and certain exudates that have not been subjected to a specific treatment.

Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

Herbal preparations shall mean preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, pressing, fractionation, purification, concentration or fermentation.

Herbal preparations include comminuted or powdered herbal substances, tinctures, extracts, essential oils, pressed juices and processed exudates.

Article 35

Traditional herbal medicinal product is a medicinal product, which is based on scientific principles, and it is a result of tradition or other traditional therapeutic approaches.

Medicinal product referred to in paragraph 1 of this Article is a medicinal product that fulfils the following conditions:

1) has indications that are specific to traditional herbal medicinal products that are in their composition and purpose designed for use without medical supervision for the purpose of diagnosis or issuing a prescription or to follow the course of treatment;
2) they are exclusively intended for administration in accordance with a specified strength and posology;
3) they are intended for external or oral use and/or for inhalation;
4) its period of traditional use has passed, or at least 30 years of use prior to the date of the submission of the application for issuing the marketing authorisation, including at least 15 years within the European Union;
5) there are sufficient data on the traditional use of medicinal product, 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 whose therapeutic safety is well documented, it can be considered a traditional herbal medicinal product, if the effect of these vitamins or minerals is just a support in relation to the effect of active herbal ingredients in terms of declared indication (or indications).

A traditional herbal medicinal product that meets the requirements referred to in paragraphs 2 and 3 of this Article shall be entered into the Registry of traditional herbal medicinal products.

Application for entering into the Registry of traditional herbal medicinal products shall be submitted in accordance with the Article 63 of this Law if following conditions are met:

1) European Union monography on herbal medicine has been adopted by the HMPC; or
2) herbal medicinal product consists of herbal substances, their preparations or combinations for use in traditional herbal medicines, which are on the List of Herbal Substances.

Article 36

Application for entering into the Registry of traditional herbal medicinal products shall be submitted by natural or legal person established that fulfill the conditions set out in Article 44 paragraph 2 of this Law.

Application for entering into the Registry of traditional herbal medicinal products shall be submitted by natural or legal person established in the established in the European Union.

The Institute may refuse the application for entering the medicinal product into the Registry referred to in paragraph 1 of this Article, if the requirements referred to in Article 35 paragraphs 2 and 3 of this Law are not met or if:

1) qualitative, or quantitative composition of the medicinal product does not match the declared composition;

2) indications are not in accordance with the requirements referred to in Article 35 paragraph 2 of this Article;
3) medicinal product could be harmful under normal conditions of use;
4) data on traditional use are insufficient, especially if the pharmacological effect of the medicinal product or its effectiveness are not entirely convincing on the basis of long-term use and experience;
5) quality of the medicinal product is not satisfactorily proven from the pharmaceutical aspect.

In the case of refusal of the application referred to in paragraph 3 of this Article, the Institute shall notify the European Commission and the competent authorities of the other Member States of the European Union that requests it, of that decision and the reasons for the refusal.

The Institute shall not enter a certain traditional herbal medicinal product in the Registry of traditional herbal medicinal products if it assesses that medicinal product meets the requirements for issuing marketing authorisation in accordance with this Law and regulations adopted to implement this Law.

In case referred to in paragraph 5 of this Article an application shall be submitted to the Institute for issuing the marketing authorisation for the medicinal product.

Article 37

Homeopathic medicinal product is any medicinal product prepared from substances called the homeopathic stocks in accordance with a homeopathic manufacturing procedure, described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in member states of the European Union.

A homeopathic medicinal product may contain a number of principles.

Homeopathic medicinal product and homeopathic veterinary medicinal product without therapeutic indications in a pharmaceutical form that does not pose a risk to the patient shall be entered in the Register of homeopathic medicinal products if they meet the following conditions:

1) they are administered orally or externally;
2) no specific therapeutic indications appears on the labelling of the medicinal product or in any information relating thereto;
3) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription;
4) there is sufficient degree of dilution to guarantee safety of the homeopathic veterinary medicinal product; in particular, homeopathic veterinary medicinal product shall not contain more than one part per 10000 mother tincture;
5) if the homeopathic veterinary medicinal product is administered by a route described in the European Pharmacopoeia, or the pharmacopoeia of the Member State of the European Union.

If the European Commission, based on new scientific evidence, changes the conditions referred to in paragraph 3, item 3 of this Article for homeopathic medicinal products or items 2 and 4 of this Article for homeopathic veterinary medicinal products, the Institute may decide on the medicinal product in line with the decision of the European Commission.

The Institute shall not enter a certain homeopathic medicinal product in the Registry of homeopathic medicinal products, if it assesses that the medicinal product meets the requirements for issuing marketing authorisation for the medicinal product in accordance with this Law and regulations adopted to implement this Law.

In the case referred to in paragraph 5 of this Article the applicant for issuing the marketing authorisation for the medicinal product may submit the application to the Institute.

Article 38

The provisions of this Law shall apply to traditional herbal medicinal products and homeopathic medicinal products relating to the placement of a medicinal product on the market, manufacture, classification, advertising, marketing, labelling, importation, quality control, pharmacovigilance, suspension of marketing and withdrawal from the market and supervision and penalties, except this Law provided otherwise.

The detailed conditions and manner of entry in the Registry of traditional herbal medicinal products and Registry of homeopathic medicinal products as well as issuing the marketing authorisation for traditional herbal and homeopathic medicinal products, manufacture, marketing, control, pharmacovigilance, labelling and advertising of these medicinal products is regulated by the Ministry.

Article 39

For the treatment of the appropriate animal species only veterinary medicinal product which obtained marketing authorisation referred to in Article 3 and consent referred to in Article 5 of this Law can be used, which is intended for the treatment or prevention of diseases, the correction or modification of physiological function, or achievement of other medically justified objectives in a particular animal species.

If for treatment of certain animal species there is no authorised veterinary medicinal product referred to in paragraph 1 of this Article, the authorized veterinarian may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animal concerned with a product intended for other animal species, or for other condition in the same animal species if such product obtained authorisation or the consent referred to in Article 5 of this Law.

If for treatment of certain animal species there is no veterinary medicinal product referred to in paragraphs 1 and 2 of this Article, for certain animal species a medicinal product intended for use in human medicine can be used, if such medicinal product obtained the marketing authorisation or the consent referred to in Article 5 of this Law.

If for treatment of certain animal species there is no medicinal product referred to in paragraphs 1, 2 and 3 of this Article, for the treatment of certain animal species an appropriate galenic or magistral medicinal product can be used.

Products referred to in paragraphs 2, 3 and 4 of this article, also apply to the treatment of the equidae which are not intended for human consumption, in accordance with the separate legal act regulates identification and registration of equide.

Article 40

If medicinal products referred to in Article 39 paragraphs 2, 3 and 4 are used in food-producing animals, such products must as active substance contain exclusively pharmacologically active substances referred to in the Article 56 of this Law, and a veterinarian shall specify the appropriate withdrawal period.

In the case referred to in paragraph 1 of this Article the veterinarian shall keep adequate records and make it available to the authority responsible for veterinary inspection, for a period of at least five years.

For products referred to in paragraph 1 of this Article withdrawal period shall be specified which cannot be shorter than:

1) seven days for eggs,
2) seven days for milk,

3) 28 days for meat, including fat and offal of poultry and mammals,
4) 500 degrees-days for fish meat.

Withdrawal period referred to in paragraph 3 of this Article, shall be updated in line with the Regulation EU 2019/06 of the European Parliament and European Council.

For homeopathic medicinal products containing active principles referred to in the Article 56 of this Law, and for which maximum residue level is not required, the withdrawal period referred to in paragraph 3 of this Article shall be reduced to zero.

Notwithstanding paragraph 1 of this Article, substances for the specific disease conditions, treatment needs or zootechnical purposes can be used in equidae intended for human consumption in case where no medicinal product authorised for equidae, or referred to in paragraph 1 of this Article would yield equally satisfactory results in terms of successfully treating the animal, avoiding unnecessary suffering for the animal, or ensuring the safety of those treating the animal.

For medicinal products referred to in paragraph 6 of this Article, the withdrawal period cannot be less than six months.

Substances referred to in paragraph 6 of this Article are included in the List of substances essential for the treatment of equidae and substances that make additional clinical benefit compared to other available treatment options of equidae determined in Regulation 1950/2006/EC.

The records referred to in paragraph 2 of this Article shall contain: date of examination of the animals, datails of the animal owner, number of animals treated, diagnoses, medicinal products prescribed, doses administered, duration of treatment and the withdrawal periods recommended.

Regulations referred to in paragraph 4 and 8 of this Article, translated to Montenegrin language, shall be published on Ministry, Institute and state authority competent for veterinary affairs website.

Article 41

Galenic medicinal product is a medicinal product made based on the applicable pharmacopoeia, valid magistral formula or standard formulations of professional pharmaceutical manuals and in line with guidelines on Good galenic laboratory practice.

Galenic medicinal product can be prepared in a galenic laboratory of the pharmacy performing the activity as a health institution at the primary health care level in small quantities, up to 300 ready-made individual packages by the batch.

Galenic medicinal product prepared in galenic laboratory is intended for sale or procurement of pharmacies or other health institutions.

Galenic medicinal product prepared in galenic laboratory of the pharmacy is intended for issuing, sale or use and administration for patients of that pharmacy, or pharmacy which is part of other health care facility that performs activities on the primary health care level, as well as in appropriate veterinary institution with which the pharmacy in whose galenic laboratory a galenical medicinal product is made concluded a contract on delivery of certain quantities of that galenic medicinal product.

Galenic medicinal product which is exclusively used in veterinary institution, shall be prepared in a galenic laboratory of veterinary institution in the amount up to 100 ready-made individual packages per day.

Active substances with a withdrawal period cannot be used for the preparation of galenic and the magistral medicinal products for use in veterinary care for the treatment of food producing animals or food production for human consumption.

Preparation of galenic medicinal products in quantities prescribed in paragraphs 2 and 5 of this Article shall not be considered manufacture in terms of this Law.

Article 42

Galenic medicinal product can be prepared in a galenic laboratory of health care institution which performs health care activities at the secondary and tertiary health care level (hereinafter: galenic laboratory of hospital pharmacy) in the quantity required for providing health care of the patients of that health care institution.

Notwithstanding paragraph 1 of this Article, on the basis of a contract for the delivery of a certain quantity of galenic medicine, other health care institutions may be supplied at the secondary or tertiary level of health care for the needs of patients of those institutions, with the consent of the Ministry.

If the pharmacy referred to in Article 41, paragraph 2 of this Law supplies other health care institutions, i.e. veterinary institutions, on the basis of a contract in accordance with this Law, for the needs of patients, i.e. users of that health care institution, i.e. veterinary institution, such supply shall be considered retail sale in accordance with this Law.

Preparation of the galenic medicinal products in the galenic laboratory of hospital pharmacy is not considered manufacture in terms of this Law.

Galenic medicinal product referred to in paragraph 1 of this Article cannot be found in wholesale distribution, or in retail sale distribution.

Each batch of galenic medicinal product must have a certificate of analysis issued by a laboratory which meets the requirements for performing quality control.

Requirements in terms of premises, equipment and personnel, as well as other necessary conditions for the preparation of galenic medicinal products in galenic laboratory of the pharmacy, in galenic laboratory of hospital pharmacy, or galenic laboratory of veterinary facilities is regulated by the Ministry or the state authority competent for veterinary matters.

Article 43

List of galenic medicinal products used in human medicine is established by the Ministry, and list of galenic medicinal products used in veterinary care is established by the state authority responsible for veterinary matters.

Guidelines of Good practice in the preparation of galenic medicinal products is published on the website of the Ministry.

IV MARKETING AUTHORISATION FOR A MEDICINAL PRODUCT

Article 44

Application for marketing authorisation for a medicinal product shall be submitted to the Institute.

An applicant referred to in paragraph 1 may be:

1) manufacturer seated in Montenegro, or its representative or agent that is seated in Montenegro;
2) for medicinal product's manufacturer, who is not seated in Montenegro, its representative or its agent, who is seated in Montenegro;
3) representative of a foreign legal entity who is not the manufacturer of that medicinal product, but is a marketing authorisation holder in the European Union countries, and who is seated in Montenegro

An application for the marketing authorisation may be submitted by a natural or a legal person established in the European Union.

The applicant referred to in paragraph 2 of this Article must have responsible person for marketing authorisation, amendments and renewal of marketing authorisation and responsible person for pharmacovigilance with full time working contract concluded**.**

The person responsible for pharmacovigilance of medicinal products for human use must have a degree in pharmacy, medicine or dentistry, and person for pharmacovigilance of veterinary medicinal products shall have a degree in faculty of pharmacy, or veterinary faculty and must be available for 24 hours and have residence in Montenegro.

The applicant referred to in paragraph 2 of this Article is obliged to, through the contract with a manufacturer, or marketing authorisation holder on whose behalf the application for issuing the authorisation for the medicinal product is submitted, determine the liability insurance against any damage caused by the use of the medicinal product in Montenegro.

The marketing authorisation holder shall be responsible for placing the medicinal product on the market and for its marketing in accordance with this Law.

The designation of a representative or an agent referred to in paragraph 2 shall not relieve the manufacturer and/or marketing authorisation holder of the responsibility for a medicinal product.

Article 45

Marketing authorisation shall be also issued for radionuclide generators, radiopharmaceutical kits, radiopharmaceuticals, radionuclide precursors and industrially prepared radiopharmaceuticals.

Marketing authorisation shall not be required for a radiopharmaceutical prepared for use from authorized radionuclide generators, radionuclide kits or radionuclide precursors in accordance with the manufacturer's instructions and are used exclusively in an approved health care facility in accordance with special regulations.

Marketing authorisation shall also be issued for industrially prepared advanced therapy medicinal products.

For a medicinal product referred to in paragraph 3 of this Article, an application for a marketing authorisation may be submitted, after the issuance of the marketing authorisation by the European Commission in accordance with Regulation 1394/2007/EC.

The regulations referred to in paragraph 4 of this Article, translated into the Montenegrin language, shall be published on the website of the Ministry and the Institute.

Article 46

Application for marketing authorisation shall be accompanied by the following:

1) name and permanent address of the applicant and manufacturer, where applicable;
2) name of the medicinal product;
3) qualitative and quantitative particulars of all the constituents of the medicinal product, including the reference to its international non-proprietary name (INN), where an INN for the medicinal product exists, or a reference to the relevant chemical name, or other common name;
4) assessment of the risks that the medicinal product may have on the environment (effect of the medicinal product to the environment is estimated for each individual case and specific methods for its restriction are provided)/evaluation of the potential environmental risks posed by the medicinal product (this impact shall be assessed and, 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 storage of the medicinal product, its administration to patients and for the disposal of waste products,

together with an indication of potential risks presented by the medicinal product for the environment;

9) description of the 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 principles and guidelines of good manufacturing practice by conducting audits, which shall contain a reference to the 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 (physico-chemical, biological and/or microbiological) tests,
- pre-clinical (toxicological and pharmacological) tests,
- clinical trials;

12) summary of the pharmacovigilance system of the applicant that shall contain the following parts:
- proof that the applicant has at his disposal a qualified person responsible for pharmacovigilance
- a statement signed by the applicant to the effect that the applicant has the necessary means to fulfill the tasks and responsibilities stipulated in the provisions of this Law relating to pharmacovigilance,
- a reference to the location where the pharmacovigilance system master file for the medicinal product (PSMF) is kept;

13) the risk management plan (RMP) describing the risk management system which the applicant will introduce for the medicinal product concerned, together with the summary thereof;
14) a statement to the effect that clinical trials carried out outside the European Union comply with the ethical requirements laid down in the EU regulations on clinical trials;
15) a summary of the product characteristics, a mock-up of the outer and of the immediate packaging of the medicinal product, together with a package leaflet;
16) a document showing that the manufacturer is authorised in his own country to produce medicinal products (manufacturing authorisation);
17) copies of:
- any authorisation, obtained in another EU Member State or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with the list of those EU Member States in which an application for authorisation is being assessed,
- the summary of the product characteristics proposed by the applicant in the authorisation procedure currently underway in the EU Member States or the one(s) last approved by competent authorities of other EU Member States, the package leaflet proposed in the authorisation procedure currently underway in the EU Member States or the mock-ups of last approved one(s) by competent authorities of other EU Member States,
- details of any decision(s) to refuse authorisation, whether in any EU Member State or a third country, and the reasons for such a decision;

18) a copy of the decision on the designation of the medicinal products for rare and serious diseases from European Commission and a copy of the EMA opinion.

The risk management system referred to in paragraph 1 item 13 of this Article shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data (post-market data).

The information shall be updated in the RMP, where applicable.

Together with the documents and particulars concerning the results of the pharmaceutical and pre-clinical tests and the clinical trials referred in paragraph 1 item 11 of this Article, applicant shall submit detailed expert summaries on these parts of documentation.

Expert summaries referred to in paragraph 4 of this Article, must be drawn up and signed by experts with the necessary professional qualifications, which shall be set out in a curriculum vitae.

In addition to the data and the documents referred to in paragraph 1 of this Article, an application for issuance of the marketing authorisation for a medicinal product containing radionuclide generator shall also contain the following:

- a general description of the system together with a detailed description of the components of the system which may affect the composition or quality of the daughter radionuclide preparation; and
- qualitative and quantitative particulars of the eluate, or the sublimate.

For issuance of the marketing authorisation for similar biological medicinal product, in addition to the documentation referred to in paragraph 1 of this Article, it is necessary to submit the approval form EMA obtained via centralised procedure.

Within the procedure of the issuance of marketing authorisation, the Institute shall not assess whether there is an infringement of the intellectual or industrial property rights.

Article 47

Application for obtaining marketing authorisation for veterinary medicinal product shall, in addition to the documentation referred to in the Article 46 paragraph 1 items 1, 2, 3, 5, 6, 9, 15, 16 and 17 of this Law be also accompanied by:

1) dosage for the various species of animal for which the medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;
2) reasons for any precautionary and safety measures to be taken relating to storage of medicinal product, its administration to an animal, as well as disposing of waste, with an indication of the potential risks that the medicinal product might pose to the environment, to human and animal health and to plants;
3) withdrawal period, for veterinary medicinal product intended for food-producing species;
4) results of:
- pharmaceutical (physico-chemical, biological or microbiological) tests,
- safety tests and residue tests,
- pre-clinical and clinical trials,
- tests assessing the potential risks posed by the medicinal product for the environment;
5) detailed description of the pharmacovigilance system and, where appropriate, risk management system provided by the applicant.

The documents and particulars concerning the testing results referred in paragraph 1 item 4 of this Article shall be accompanied by detailed expert summaries, with a justification of the use of relevant scientific data from the literature in accordance with the Article 52 of this Law, signed by experts of appropriate professional qualification, with the expert's curriculum vitae.

Notwithstanding paragraph 1 item 4 of this Article, the applicant shall not submit the results of certain trials of immunological veterinary medicinal products on the target species, with a justification for not carrying out this trials and especially if such trials are opposite to European Union provisions in this area.

Article 48

Global marketing authorisation shall mean that after the authorisation for the reference medicinal product being issued for the first time in Montenegro or European Union countries, every new authorisation for the medicinal product based on amendments in terms of the strength

of the medicinal product, pharmaceutical form, route of administration, packaging, and for veterinary medicinal products and all additional animal species, as well as all amendments and applications for extension of the marketing authorisation, shall be considered as part of the same global marketing authorisation.

Applicant referred to in Articles 46 and 47 of this Law shall not be required to provide the results of non-clinical tests and of clinical trials, i.e. safety and residue results, if he can demonstrate that the application is submitted for a generic medicinal product of a reference medicinal product, which is, or has been authorised in Montenegro, EU Member State or based on the centralised marketing authorisation procedure, for not less than eight years since the issuance of the global marketing authorisation for the reference medicinal product.

Bioavailability studies need not be submitted by the applicant from paragraph 2 of this article, if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the guidelines of the European Commission and of the EMA for bioequivalence studies.

The marketing authorisation holder shall not place on the market the generic medicinal product referred to in paragraph 2 of this Article until 10 years have elapsed from the initial authorisation of the reference product.

The 10-year period referred to in paragraph 4 of this Article may be extended for one year for a medicinal product for human use, if during the first eight years of the 10-year protection period 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 protection periods referred to in paragraphs 2, 4 and 5 of this Article for the purpose of marketing authorisation application and generic medicinal product placing on market shall be calculated as of the date of the initial authorisation within the global marketing authorisation.

In case referred to in paragraph 2 of this Article, the applicant for marketing authorisation shall indicate the EU Member State in which the reference medicinal product is or has been authorized, as well as the date of the initial authorisation.

In case where the reference medicinal product reffered to in paragraph 2 of this Article is or has been authorized for marketing in Montenegro, on request of the competent authority of the EU Member State, the Institute shall within a 30 days submit a confirmation showing that the reference medicinal product either is or has been authorized in Montenegro, accompanied by the data on the full composition of the reference medicinal product and, if required, other information from the relevant documentation.

Article 49

For veterinary medicinal products used to treat bees, fish and other less abundant species (MUMS), the period referred to in Article 48 paragraph 4 of this Law shall be extended to three years cumulatively, if necessary.

If the new authorisation is issued for the use of reference medicinal products on another food-producing species, for a period of five years from the date of issuing marketing authorisation for that medicinal product, the period referred to in Article 48 paragraph 4 of this Law shall be extended for another year (cumulatively), and a maximum of three years if used for the treatment of four animal species or more animal species whose products are used for human food.

Article 50

In cases where the medicinal product does not fall within the definition of a generic medicinal product, or where the bioequivalence cannot be demonstrated through bioavailability studies or in case of changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration in regards to reference medicinal product, the marketing

authorisation applicant referred to in Article 48 of this Law shall be required to provide the results of the appropriate non-clinical tests and clinical trials and safety residue tests and and preclinical tests and clinical trials for veterinary medicinal products**.**

Article 51

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 differences relating to raw materials, or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, the applicant referred to in Article 48 of this Law shall be required to provide the results of appropriate non-clinical tests or clinical trials to the application for marketing authorisation.

The content of supplementary data and the scope of studies referred to in paragraph 1 of this Article are laid down in the Guidelines of the European Commission and the EMA for medicinal product biologically similar medicinal product.

The applicant referred to in paragraph 1 of this Article shall not be required to submit results of other tests from the reference medicinal product‘s dossier.

Article 52

Applicant referred to in Article 48 of this Law shall not be required to provide the results of pre-clinical tests or clinical trials, i.e. safety and residue results and non-clinical tests and clinical trials results for veterinary medicinal products, if he can demonstrate that the active substance(s) of the medicinal product(s) have been in well-established medicinal use in the European Union for at least ten years, with recognized efficacy and an acceptable level of safety (bibliographic application).

In the event referred to in paragraph 1 of this Article, the applicant shall be required to replace the results of non-clinical tests or clinical trials by detailed information from appropriate scientific literature.

Experts referred to in article 46 paragraph 5 of this Law shall justify any use made of scientific literature referred to in paragraph 2 of this Article.

Assessment reports published by EMA, following the evaluation of an application for the establishment of maximum residue level can be appropriately used as literature, particularly for the safety tests.

If the applicant referred to in paragraph 1 of this Article uses scientific data from the literature for the purpose of obtaining the marketing authorisation for the medicinal product for food producing species, as well as new research on the residue tests for the purpose of obtaining the marketing authorisation for the medicinal product for other food producing species, protection period of the data on conducted research is three years after the issuance of the authorisation for the medicinal product.

Article 53

In case of medicinal products containing a new combination of active substances not hitherto used for therapeutic purposes, but only as individual substances in the composition of medicinal products authorised in the EU, the applicant referred to in Articles 46 and 47 of this Law shall be required to provide the results of new pre-clinical tests or new clinical trials relating to that combination, but he shall not have to provide scientific data or results of pre-clinical tests or of clinical trials relating to each individual active substance.

For veterinary medicinal products, in addition to the results referred to in paragraph 1 of this Article, the applicant for a marketing authorisation shall submit the results of safety testing and residue testing.

Article 54

Marketing authorisation holder may allow another applicant to use the pharmaceutical, pre-clinical and clinical documentation of a medicinal product, and pharmaceutical, safety and residue documentation as well as preclinical and clinical documentation for veterinary medicinal products, based on which the authorisation was granted, with a view to submitting new applications for obtaining marketing authorisation for other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.

Article 55

Protection period referred to in the Article 48 of this Law shall also apply to the reference medicinal products in accordance with Articles 52, 53 and 54 of this Law.

In cases where an application is made for a new indication for a well-established active substance referred to in the Article 52 of this Law, a period of one year protection may be granted to the applicant, relating exclusively to that new indication, provided that significant pre-clinical and clinical studies were carried out to demonstrate the efficacy of the relevant active substance in relation to the new indication.

Article 56

Marketing authorisation for veterinary medicinal product intended for food-producing species, shall be issued only if the medicinal product contains pharmacologically active substances determined by the list of allowed substances in accordance with Commission Regulation 37/2010 on pharmacologically active substances and their classification in relation to the maximum permitted amounts of residues in food of animal origin, establishing maximum residue level in the European Union.

Marketing authorisation holder, i.e. the Institute shall take the necessary measures to amend or revoke marketing authorisation if it is necessary in accordance with amendments of the regulation referred to in paragraph 1 of this Article within 60 days of the publication of the amendment.

Notwithstanding paragraph 1 of this Article, veterinary medicinal product containing pharmacologically active substances which are not on the List referred to in paragraph 1 of this Article may be authorised for certain equidae which are not intended for human consumption in accordance with the separate legal act regulates identification and registration of equide.

Veterinary medicinal product referred to in paragraph 3 of this Article cannot contain pharmacologically active substances which are forbidden by the list of prohibited substances referred to in paragraph 1 and must be intended for conditions for which there is no authorised veterinary medicinal products and intended for treatment of equidae.

The regulations referred to in paragraph 1 of this Article, translated into the Montenegrin language, shall be published on the website of the Ministry, the Institute and the state competent authority for veterinary affairs.

Article 57

During the authorisation procedure, the Institute may examine the medicinal product, its starting materials and, its intermediate products or other constituent materials and analytical methods including analytical methods for detection of residues for testing in its own or other authorized laboratory, in order to ensure that the control methods employed by the manufacturer and described in the product dossier accompanying the application are satisfactory.

At the request of the Institute an applicant for marketing authorisation is obliged to provide samples of a medicinal product and/or prescribed reference or working standards required for pharmaceutical testing.

Within the process of issuing marketing authorisation, the Institute may require other data important for obtaining marketing authorisation, under the condition that the applicants for marketing authorisation are not brought into the position of inequality.

In the procedure of issuing the marketing authorisation for the medicinal product, the Institute may exceptionally request supervision over the manufacturing of medicinal product, for which the application for obtaining marketing authorisation, amendment or renewal of the authorisation is submitted.

In the course of authorisation, the Institute shall determine whether the manufacturers and the importers of medicinal products from the third countries carry out manufacture in compliance with particulars pursuant to Article 46 paragraph 1 item 5 of this Law, and/or carry out controls according to methods described in the particulars in accordance with Article 46 paragraph 1 item 9 of this Law.

Where manufacturers or importers referred to in paragraph 5 of this Article, in justifiable cases have certain stages of a product manufacture and/or of the control carried out by other legal or natural persons, the Institute shall determine whether those legal or natural persons comply with manufacturing conditions laid down in Article 46 paragraph 1 item 5 of this Law, and/or carry out controls in accordance with the methods referred to in Article 46 paragraph 1 item 9 of this Law.

Article 58

During the authorisation procedure, the Institute shall draw up assessment reports on the medicinal product dossiers accompanied by opinion about the results of the pharmaceutical, pre-clinical tests and the clinical trials, on RMP and pharmacovigilance system and for veterinary medicinal products with opinion about the results of safety and residue testing.

The Institute shall update the assessment report whenever new information becomes available which is important for the evaluation of the quality, safety and/or efficacy of the medicinal product concerned.

The Institute shall make publicly available on the portal its assessment report on a medicinal product dossier together with the explanation of opinions provided for each indication, except confidential data.

The assessment report referred to in paragraph 3 of this Article shall include summary of product characteristics, conditions of use of the medicinal products and be written in a manner easily comprehensible to the general public.

Article 59

Content of application and required documentation for issuance of the marketing authorisation referred to in articles 31, 46-54 and 65 of this Law shall be prescribed by the Ministry.

Article 60

The Institute is obliged to, within 90 days from the date of receipt of the application referred to in articles 46-54 of this Law, conduct a formal evaluation of the documentation for obtaining the marketing authorisation for the medicinal product regulated by this Law and regulations adopted to implement this Law.

If the application referred to in paragraph 1 of this Article is not complete, the Institute in written form informs the applicant to fulfill the application with requested data within 30 days from the date of receipt of written notice.

In the period referred to in paragraph 1 of this Article the time required for the applicant to submit to the Institute requested additional data (clock stops) is not included.

The Institute shall, not later than 210 days from the date of receipt of a complete formal application, issue the authorisation for the medicinal product, or make a decision on denial of the application for issuing the authorisation for the medicinal product, based on the assessment documentation of the quality, safety and efficacy of the medicinal product, unless this Law provides otherwise.

The period referred to in paragraph 4 of this Article, which can not be longer than 180 days, does not include the time needed to submit additional documentation to the Institute or to provide additional clarifications (clock stops).

Time-limits referred to in paragraphs 1 to 5 of this Article shall be applied also to the procedures of renewal and transfer of the marketing authorisation referred to in articles 71 and 81 of this Law.

Article 61

Marketing authorisation for a medicinal product is issued, as a rule, for a period of five years.

An integral part of the authorisation referred to in paragraph 1 of this Article are summary of product characteristics, package leaflet, as well as approved labelling.

The Institute shall ensure that the data provided in the approved summary of the product characteristics are harmonised with the data accepted during the authorisation procedure.

The Institute shall regularly make publicly available on its website the information relating to the authorised marketing authorisations, summaries of product characteristics, package leaflets and all conditions for obtaining marketing authorisations, with pertaining time-limits, as well as authorisations which ceased to be valid.

The Institute shall immediately submit to EMA information referred to in paragraph 4 of this article as well as information on all decisions on refusing or withdrawing marketing authorisation, cancelling a decision on refusing or withdrawing marketing authorisation, prohibiting supply or withdrawing a product from the market, together with the reasons on which such decisions are based.

Content of marketing authorisation shall be prescribed by the Ministry.

Article 62

Marketing authorisation shall be issued within the accelerated procedure if:

1) a medicinal product used in human medicine is of highest interest for the protection of public health, primarily in relation to therapeutic innovation;
2) a medicinal product that has already obtained the marketing authorisation in the European Union Member States, by the centralized procedure, the procedure of mutual recognition, or by decentralized procedure.

Application for issuing the marketing authorisation for the medicinal product referred to in paragraph 1 of this Article contains documentation regulated by Article 46 and 47 of this Law.

Application for issuing of the authorisation referred to in paragraph 1 item 2 of this Article shall be accompanied by the documentation referred to in Article 46 and 47 of this Law and relevant statements of the responsible person of the applicant in relation to identity of submitted documentation with the documentation based on which marketing authorisation is obtained by centralized procedure, the procedure of mutual recognition or by decentralized procedure.

The authorisation referred to in paragraph 1 of this Article shall be issued not later than 150 days after receipt of formally completed application.

Article 63

The issuance of a marketing authorisation in two or more European Union Member States is carried out by MRP or DCP procedure.

If the Institute during the procedure for issuing marketing authorisation determines that another marketing authorisation application for the same medicinal product is being examined in another Member State, Institute shall issue a decision to suspend the procedure applied for and shall instruct the applicant to initiate the mutual recognition procedure or decentralized procedure for the authorisation of the relevant medicinal product.

Where based on data referred to in Article 46 paragraph 1 item 17 of this Law the Institute determines that at the time of application in Montenegro the medicinal product has already received a marketing authorisation in another EU Member State, the Institute shall issue a decision to suspend the procedure, except if the application is submitted in accordance with the mutual recognition procedure.

More detailed conditions and the content of the documentation for issuance of a marketing authorisation for a medicinal product referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

Article 64

In the marketing authorisation, the Institute may impose the following conditions for marketing authorisation holder:

1) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;
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 those referred to in pharmacovigilance provisions;
4) to comply with any other conditions or restrictions with regard to the safe and effective use of the medicinal product;
5) to ensure the existence of an adequate pharmacovigilance system;
6) to conduct post-authorisation efficacy studies where new findings 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.

In the marketing authorisation the Institute shall lay down deadlines for the fulfillment of conditions listed in paragraph 1 of this Article.

If the marketing authorisation holder fails to comply with conditions from the paragraph 1 of this Article, the Institute shall revoke the marketing authorisation.

Marketing authorisation referred to in paragraph 1 of this Article can be issued for:

1) medicinal products used to treat, prevent or diagnose serious and life threatening diseases;
2) medicinal products used in emergency situations;
3) medicinal products used to treat rare diseases;
4) medicinal products having obtained the conditional marketing authorisation by centralized procedure;
5) other medicinal products of interest for public health.

The Institute may issue a conditional authorisation for the medicinal product referred to in paragraph 1 of this Article with a prior agreement with the applicant to meet conditions and obligations referred to in Article 46 of this Law.

Fulfillment of the conditions referred to in paragraph 2 of this Article shall be checked by the Institute once in 12 months from the date of issuing the conditional authorisation for the medicinal product.

Article 65

Notwithstanding conditions referred to in Articles 46 and 47 of this Law, the Institute can issue the authorisation under special circumstances with prior arrangement with the applicant,

only for the medicinal product of special public interest for the health of human population and animals.

Marketing authorisation referred to in paragraph 1 can be granted only when the applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, for objective and substantiated reasons in accordance with the Article 46 of this Law.

The authorisation referred to in paragraph 1 of this Article shall be issued for a period of 12 months, with the obligation of the applicant to fulfill obligations relating to the safety of the medicinal product and to inform the Institute of any adverse event while using the medicinal product, as well as about taken safety measures.

The Institute, at the request of the applicant for a medicinal product which meets the requirements referred to in paragraphs 1 and 3 of this Article may extend the authorisation under special circumstances, for new 12 months.

Request for re-assessment of meeting the conditions referred to in paragraphs 1, 3 and 4 of this Article is submitted not later than 90 days before the expiry date of the authorisation issued under special circumstances, with data justifying the special public interest for the health of human population and animals, as well as other data prescribed by this Law and regulations adopted to implement this Law.

Article 66

After granting a marketing authorisation for a medicinal product, in justified cases the Institute may request fulfillment of the following conditions from the marketing authorisation holder

1) to conduct a post-authorisation safety study if there are new findings about risks of use of an authorized medicinal product,
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.

Application referred to in the paragraph 1 of this Article shall include the objectives and timeframes for the notification and conducting of the safety and efficacy studies.

Marketing authorisation holder may submit written observation in response to the imposed conditions, within 30 days of receipt of the notification.

The Institute may approve to marketing authorisation holder a deadline not longer than 60 days to submit written observation on fulfillment of conditions referred to in paragraph 1 of this Article.

On the basis of the written observation referred to in paragraph 4 of this Article, the Institute shall either confirm or withdraw request for fulfillment of conditions referred to in paragraph 1 of this Article.

Where the Institute confirms the obligation referred to in paragraph 1 of this Article, it shall pass a decision on amendment of marketing authorisation.

In case referred to in paragraph 6 of this Article, marketing authorisation shall contain conditions imposed on marketing authorisation holder in accordance with Article 64 of this Law.

The marketing authorisation holder shall incorporate the conditions and obligations referred to in Articles 64, 65 and 66 of this Law, in his risk management system.

In case where the same risks as those referred to in paragraph 1 item 1 of this article, apply to more than one medicinal product, after consulting the PRAC, the Institute shall instruct the marketing authorisation holders to conduct mutual post-authorisation safety studies.

The Institute shall inform EMA about authorisations referred to in Article 64, 65 and 66 of this Law.

Article 67

The Institute shall refuse the application for issuing the marketing authorisation if it determines that:

1) benefit-risk ratio is not favourable;
2) medicinal product does not have therapeutic effect, or that therapeutic effect of the medicinal product is not sufficiently proven by the applicant;
3) qualitative and quantitative composition of the medicinal product does not match the data in the submitted documentation;
4) documentation provided with the medicinal product is not in accordance with the conditions regulated by this Law and regulations made under this Law.

The Institute shall refuse the application for issuing the marketing authorisation for veterinary medicinal product if, in addition to conditions referred to in paragraph 1 of this Article, determines that:

1) recommended withdrawal period is not long enough to ensure that food obtained from treated animals does not contain residues which could pose a hazard health to consumers, or is insufficiently substantiated; and
2) veterinary medicinal product is suggested for use that is prohibited in accordance with special law.

Article 68

Marketing authorisation holder is obliged to continuously inform the Institute of any new findings on the assessment of quality, safety and efficacy of medicinal products on the market.

Marketing authorisation holder shall submit the application to the Institute for amendment of the authorisation for the medicinal product (hereinafter: variation), in accordance with this Law.

The Institute is obliged, within 30 days of the date of receipt the application referred to in paragraph 2 of this Article, to perform a formal evaluation of the documentation for approval of variation.

If the application referred to in paragraph 2 of this Article is not complete, the Institute shall notify the applicant in written form to complete the application with additional data within 30 days from the date of submitted written notification.

The Institute brings the decision about the application referred to in paragraph 2 of this Article within 90 days from the date of receipt of the application.

The period referred to in paragraphs 4 and 5 of this Article does not include the time necessary for the applicant to submit to the Institute requested additional information (clock stops).

Marketing authorisation holder is obliged within 12 months from the date of receipt of the decision on the variation approval issued by the Institute, to place the medicinal product on the market in accordance with the approved variation.

If within the deadline from paragraph 5 the Institute does not issue a decision on variations regarding approved package leaflet and/or labelling and which are not related to changes to the summary of product characteristics, the marketing authorisation holder shall put the change into effect.

In case referred to in paragraph 8 of this article, marketing authorisation holder and the manufacturer are legally liable in accordance with the provisions of this Law.

Detailed conditions, the manner and the necessary documentation for amending of the authorisation or for the medicinal product shall be prescribed by the Ministry.

Article 69

After obtaining a marketing authorisation for a medicinal product, the marketing authorisation holder shall be required to:

1) take account of scientific and technical progress for manufacturing and quality control processes and introduce any changes that may be required to enable the medicinal product is manufactured and checked regarding quality by means of generally accepted scientific methods;
2) submit to the Institute any new information which might entail amendments to the data, documents and files of the medicinal product provided in the authorisation procedure or the referral procedure in the European Union;
3) inform the Institute, without delay of any restriction or prohibition imposed by the competent authorities of other states in which the medicinal product is marketed and of any other new information which might influence the risk-benefit ratio of the medicinal product concerned;
4) submit to the Institute both positive and negative results of clinical and other studies in all indications and populations of subjects, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is not covered by the marketing authorisation;
5) ensure that the product information are kept up to date with the current scientific knowledge, including the conclusions of public reports relating to assessment of the medicinal product dossier and recommendations of the EMA made public on its website.

In the case referred to in paragraph 1 of this Article, the Institute may require that the marketing authorisation holder initiates the procedure for variation(s) approval or to amend, ex officio, the authorisation for placing the medicinal product on the market.

In order to enable continuous assessment of the risk-benefit ratio, the Institute may at any time ask the marketing authorisation holder to forward data demonstrating that the risk-benefit ratio of the medicinal product remains favourable, as well as to submit a copy of the PSMF for medicinal products for human use at the latest seven days after receipt of the request.

Article 70

In cases referred to in Article 69 paragraph 1 items 1 to 4 of this Law, the marketing authorisation holder shall submit an application for the variation approval to the Institute where the variation entails amendments to data in the approved medicinal product dossier.

To the application for the variations approval referred to in paragraphs 1of this Article, the marketing authorisation holder shall attach the data and/or documents and/or medicinal product files, as required by the type of variation.

Article 71

Not later than nine months before the marketing authorisation ceases to be valid, marketing authorisation holder is obliged to submit an application for its renewal to the Institute.

Marketing authorisation may be renewed for a further period of next five years based on reassessment of the product‘s risk-benefit ratio.

Article 72

Marketing authorisation holder shall submit the application for renewal of the marketing authorisation to the Institute and shall provide documentation with expert reports on quality, safety and efficacy, including the evaluation of data contained in suspected adverse reactions reports and in the periodic safety update reports submitted in accordance with pharmacovigilance provisions of this Law, as well as information on all variations submitted as well as variations approved/notified since the marketing authorisation was granted until the date of application for its renewal.

Marketing authorisation holder is obliged to place medicinal product on the market within 12 months from the date of obtaining of the decision on renewal of the marketing authorisation.

Marketing authorisation holder is obliged to, 60 days before the expiry of the marketing authorisation, inform the Institute that he will not initiate the procedure for renewal of the marketing authorisation.

The medicinal product, whose marketing authorisation is expired and is not renewed, may be on the market after expiry of the validity date of the marketing authorisation until the expiration of the shelf life of the medicinal product, but not longer than 180 days after the expiry of the validity date of the marketing authorisation.

Article 73

Marketing authorisation holder is obliged to inform in writing the Institute on the date of placing the medicinal product on the market within 15 days from the date of placing the medicinal product on the market for each pharmaceutical form, strength and packaging.

Article 74

If the Institute determines that a medicinal product which obtained the marketing authorisation is safe, based on data on pharmacovigilance for a period of five years from the date of issuance, or renewal of the marketing authorisation, the Institute shall issue the marketing authorisation for an unlimited period.

Notwithstanding paragraph 1 of this Article, the Institute shall not issue the marketing authorisation for an unlimited period due to justified grounds relating to pharmacovigilance, including exposure of an insufficient number of patients to the medicinal product concerned.

In the case referred to in paragraph 2 of this Article, the Institute shall decide on the renewal of the marketing authorisation for five years.

The Institute is obliged to make a decision on revoking the marketing authorisation for an unlimited period if, on the basis of pharmacovigilance data, it determines that the medicine is not safe for life and health of humans and animals.

Article 75

The applicant is responsible for the accuracy of the data in the documentation in the procedures before the Institute.

Article 76

Marketing authorisation shall cease to be valid upon the expiry of the time limit for which it was issued and at the request of the marketing authorisation holder.

The authorisation referred to in paragraph 1 of this Article shall cease to be valid if the following is determined:

1) medicinal product is harmful under prescribed conditions of use, or there is no therapeutic effect, or therapeutic effect of the medicinal product is not sufficiently proven by the applicant;
2) risk-benefit ratio is unfavourable;
3) qualitative and quantitative composition of the medicinal product does not correspond to the data from submitted documentation;
4) manufacture and testing of the medicinal product have not been carried out in accordance with the provisions of this Law;
5) the authorisation is issued based on incomplete or incorrect data, or if the data have not been amended in accordance with this Law;
6) marketing authorisation holder does not meet the approved conditions any longer;
7) medicinal product is not labelled in accordance with the provisions of this Law and the marketing authorisation holder does not comply with the request for correction in labelling;

8) conditions and obligations set in line with the Article 46 paragraph 1 items 5) and 9) and Article 64, 65 and 66 of this Law are not fulfilled;
9) conditions set in line with the article 44 paragraph 1 items 5 and 9 of this Law are not fulfilled;
10) medicinal product is placed on the market contrary to the provisions of this Law.

In cases referred to in paragraph 2 of this Article, the Institute may pass the decision on the termination of the marketing authorisation, temporary cessation of validity, or marketing authorisation amendment and propose to the state competent authority for inspection affairs, or the state authority responsible for veterinary affairs to suspend, or prohibit marketing of the medicinal product in accordance with the law.

Article 77

In addition to provision referred to in Article 76 paragraph 2 of this Law, the Institute may adopt a decision on the temporary revocation of the marketing authorisation or amendment of marketing authorisation for veterinary medicinal product if it finds that:

1) that the risk-benefit ratio of medicinal products, under approved conditions of use, is unfavourable, in particular with regard to animal health and welfare and consumer safety, when the marketing authorisation is issued for zoo-technical use;
2) medicinal product has no therapeutic effect on the animal species for which it is intended;
3) qualitative and quantitative composition of the product is not in accordance with the stated;
4) withdrawal period is not long enough to ensure that food obtained from treated animals does not contain residues which could pose a risk to consumers' health;
5) medicinal product is offered for sale for the use which is prohibited in accordance with the special Law
6) the information in the approved documentation provided with the medicinal product is not accurate;
7) quality control is not conducted;
8) data is not amended in line with the provisions of this Law, or
9) the Institute is not provided with new data in line with the provisions of the article 69 of this Law.

In the case of a particular risk to public and animal health, the Institute shall promptly inform the expert public and, if necessary, general public, on the decision to terminate the validity of the marketing authorisation.

In the case referred to in paragraph 2 of this Article, the Institute shall take the measures referred to in Article 76 paragraph 3 of this Law.

Article 78

Marketing authorisation shall cease to be valid if the Institute or the state competent authority for veterinary matters determines that:

1) medicinal product was not on the market in Montenegro the three years from the date of issuing marketing authorisation;
2) medicinal product was marketed for a certain period in Montenegro after issuing of the marketing authorisation, and after that period, three consecutive years it was not on the market in Montenegro.

Ministry, or the state competent authority for veterinary matters may, in order to protect health of the population and animals, suggest to the Institute not to pass the decision on cessation of the validity of the marketing authorisation in cases referred to in paragraph 1 of this Article.

The provisions referred to in paragraph 1 of this Article shall not be applied to the medicinal products which marketing authorisation holder places on the market exclusively outside the territory of Montenegro.

Article 79

Measures for urgent recall of medicinal product or a batch of medicinal product from the market, suspension or prohibition of marketing of medicinal product shall be taken by the Institute, the state competent authority for veterinary affairs and the state competent authority for inspection affairs, or, if the Institute, determines that:

1) medicinal product is harmful under the prescribed conditions of use;
2) it is unquestionable that the risk-benefit ratio of veterinary medicinal products, under approved conditions of use, is unfavourable, in particular with regard to health and welfare of animals and safety to consumers, when the authorisation issued for veterinary medicinal product for zoo-technical use is in question;
3) medicinal product does not have therapeutic effect, i.e., veterinary medicinal product does not have therapeutic effect on animal species for which it is intended;
4) the risk-benefit ratio is unfavourable in relation to the approved use;
5) qualitative and quantitative composition of the medicinal product is not the one which is stated;
6) recommended withdrawal period is not sufficient to ensure that the food obtained from the treated animals does not contain residues that could pose a health risk to the consumer;
7) quality control is not conducted
8) medicinal product is not manufactured in accordance with the issued manufacturing authorisation;
9) a falsified medicinal product is identified on the market;
10) the shelf life of a medicinal product is expired.

Exceptionally, based on the assessment of the benefit-risk ratio of the medicinal product, the Institute may, until a final decision is made, allow the supply of a withdrawn medicinal product only to patients whose treatment is in progress.

The holder of a marketing authorisation for a medicinal product may take the measures referred to in paragraph 1 of this Article, of which he shall notify the Institute no later than 24 hours from the moment of learning of the existence of reasons for initiating such measures.

Article 80

When a marketing authorisation holder decides to discontinue marketing of a medicinal product or to withdraw it from the market, either temporarily or permanently before the expiry of marketing authorisation or should he decide to apply for the revocation of the marketing authorisation or not to apply for the authorisation renewal, he shall notify the Institute accordingly at least 60 days before the interruption of the market supply with the medicinal product, except in case of an urgent withdrawal procedure or other exceptional circumstances.

In the case referred to in paragraph 1 of this Article, the marketing authorisation holder is required to inform the Institute about the reasons for his decision to discontinue the market supply of the medicinal product concerned and notify Health Insurance Fund of Montenegro on medicinal product prescribed and dispensed from the budget of the Fund.

Information referred to in paragraphs 1 and 2 of this article for veterinary medicinal products, the Institute shall submit to EMA.

Article 81

The marketing authorisation holder may apply for transfer of the authorisation to another holder that complies with the conditions laid down in the Article 44 of this Law.

The Institute within the time-limit referred to in the Article 60 of this Law shall adopt the decision to approve the transfer of the authorisation for the medicinal product to the new marketing authorisation holder, or refuse the application for transfer the authorisation for the medicinal product.

The new marketing authorisation holder is obliged within 12 months from the date of decision adoption referred to in paragraph 2 of this Article, to place on the market the medicinal product in accordance with approved transfer of the marketing authorisation.

The content of the application and required documentation for transfer of the authorisation for the medicinal product is regulated by the Ministry.

Article 82

If the marketing authorisation holder lose the capacity of marketing authorisation holder for any reason before the expiry of marketing authorisation for the medicinal product and transfer of the marketing authorisation was not performed in accordance with this Law, he is obliged to inform, without delay, the Institute i.e. state competent authority veterinary affairs, and all legal persons engaged in wholesale of that medicinal product in Montenegro.

Marketing authorisation holder referred to in paragraph 1 of this Article shall take all necessary measures to recall that medicinal product from the market within 30 days of cessation of the marketing authorisation holder capacity.

If the marketing authorisation holder does not act in accordance with paragraph 1 of this Article, the Ministry i.e. state competent authority for veterinary affairs, shall decide on the further procedure with that medicinal product.

Article 83

In the event of an epidemic, natural disaster or emergency, the Institute may exceptionally authorize procurement i.e. import of a particular type and quantity of medicinal products before the conditions for issuing the marketing authorisation for a medicinal product are met.

In the event of an epizootic diseases, the Institute may authorize procurement i.e. import of a immunological veterinary medicinal products.

The authorisation referred to in paragraph 1 and 2 of this Article shall be issued only for the duration of circumstances referred to in paragraph 1 and 2 of this Article.

The authorisation referred to in paragraph 2 of this article shall be issued by the Institute after state competent authority for veterinary affairs has notified the European Commission thereof.

Article 84

If an animal is imported from or is exported to a third country and is subject to certain binding health procedures, the Institute may, for the animal in question, authorize import of a immunological veterinary medicinal products that does not have marketing authorisation issued by the Institute but is authorized under the legislation of the third country.

Institute and state competent authorities for veterinary affairs shall take measures related to the supervision of import and use of the veterinary immunological medicinal product referred to in paragraph 1 of this article.

Article 85

During the procedure of issuing of marketing authorisation the Institute shall determine the mode of dispensing of medicinal products, i.e. shall perform the classification of medicinal

products to medicinal products subject to medical prescription and medicinal products not subject to medical prescription.

On the basis of new facts, the Institute will review the valid classification of the medicinal product referred to in paragraph 1 of this Article.

If the marketing authorisation holder submits data on pre-clinical or clinical trials, on the basis of which the Institute approves the change of dispensing mode of the medicinal product subject to medical prescription to a medicinal product not subject to medical prescription, the submitted data cannot be used at the request of another marketing authorisation holder to change the dispensing mode of the medicinal product with the same active substance, for a period of one year.

Dispensing i.e. the sale of medicinal products contrary to conditions specified in the marketing authorisation is prohibited unless in cases referred to in the Article 39 and 40 of this Law.

For the person who dispenses or sells the medicinal products contrary to paragraph 1 of this Article the competent chamber shall temporarily recall the working permit in accordance with the law.

Form and content of the prescription, criteria for the classification of medicinal products, manner of prescription and dispensing of medicinal products for human or veterinary use shall be prescribed by the Ministry or state competent authority for veterinary affairs.

Article 86

The person authorised to prescribe the medicinal products in accordance with the law cannot be owner or co-owner of the pharmacy.

V TESTING OF MEDICINAL PRODUCT FOR THE PURPOSE OF PROVIDING DOCUMENTATION IN THE PROCEDURE OF ISSUING OF MEDICINAL PRODUCT MARKETING AUTHORISATION

Article 87

In order to obtain the marketing authorisation, a medicinal product must be subjected to pharmaceutical, pharmacological-toxicological and clinical testing.

The manufacturer shall carry out appropriate tests referred to in paragraph 1 of this Article and provide expert documentation relating to these testing.

The medicinal product can be pharmaceutically, pharmacological-toxicologically and clinically tested after issuing marketing authorisation, as a part of laboratory quality control or to obtain additional data on the medicinal product.

The medicinal product shall be tested in accordance with the guidelines of Good Manufacturing Practice, Good Laboratory Practice and Good clinical practice for human or veterinary medicinal products.

The guidelines referred to in paragraph 4 of this Article shall be published on the website of the Ministry and the Institute, and the guidelines of Good clinical practice for veterinary medicinal products shall be published by the state competent authority for veterinary affairs.

Guidelines referred to in paragraph 4 of this article shall be revised to take account of technical and scientific progress.

Article 88

Pharmaceutical testing of medicinal products shall include chemical-pharmaceutical-biological testing of medicinal product's quality, in accordance with the requirements for issuing marketing authorisation.

Article 89

The procedure of pharmaceutical testing of medicinal products, as described in the documentation for obtaining the marketing authorisation, must comply with contemporary scientific achievements or findings and principles of Good Laboratory Control Practice.

Documentation for carrying out the procedure of pharmaceutical medicinal product testing must include detailed descriptions of testing methods, description of the necessary equipment, reagents and other necessary data, or references to European, national or other recognized pharmacopoeia or other validated methods of analysis, so that pharmaceutical medicinal product testing can be repeated and in order to ensure the comparability of results.

Detailed content of the pharmaceutical medicinal product testing, and documentation referred to in paragraph 2 of this article shall be prescribed by the Ministry.

Article 90

Pharmacological-toxicological testing of medicinal product is the process of determining medicinal product's safety and pharmacological properties of the medicinal product, which is performed in accordance with the requirements for the issuing marketing authorisation.

Article 91

The procedure of pharmacological-toxicological testing of medicinal product, as described in the documentation submitted for issuing of marketing authorisation, must correspond to the level of scientific state of the art and the rules of Good Laboratory Practice.

Documentation for carrying out the procedure of pharmacological-toxicological testing of a medicinal product must contain detailed descriptions of testing methods, so that pharmacological-toxicological testing of the medicinal product can be repeated and in order to ensure the comparability of results.

Pharmacological-toxicological testing of medicinal product must define pharmacodynamic, pharmacokinetic and toxicological properties that were determined on animals that were subjected to testing and must predict the possible effects on humans, i.e. on animals, in case of veterinary medicinal products.

For the veterinary medicinal products the documentation of pharmacological-toxicological testing must include the data on metabolism, kinetics and the excretion of residues, as well as on the routine pharmaceutical method that can be used for determining of residues.

In case referred to in paragraph 4 of this Article the withdrawal period is determined on the basis of maximum residue level referred to in the Article 56 of this Law.

Detailed content of pharmacological-toxicological testing of medicinal products, as well as the documentation referred to in paragraph 2 of this Article shall be prescribed by the Ministry, i.e. the competent authority for veterinary affairs for veterinary medicinal products.

Article 92

Clinical trial of a medicinal product may be conducted by the legal person that was given the approval by the Institute.

Clinical trial is conducted in a health care institution, at the expense and at the request of legal person applying for a clinical trial.

Clinical trial may also be conducted at the request of the Ministry, or the Institute.

Legal person applying for a clinical trial must provide investigational medicinal products free of charge and devices used for their administration, if appropriate.

Article 93

Clinical trial of a medicinal product may be undertaken and carried out only in cases when the rights of the subject to physical and mental integrity are assured as well as foreseeable risks

and inconveniences are estimated to be less than the anticipated benefits for individual subject and other present and future subjects.

Requirements referred to in paragraph 1 of this Article must be assured and permanently monitored during the conduction of the clinical trial.

Compliance with the requirements from the paragraph 2 of this article provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.

Clinical trial referred to in paragraph 1 of this Article can be initiated only upon positive opinion of Ethics Committee, Ministry of Health' s decision and decision issued by the Institute.

The Ethics Committee is formed by the Ministry as a special independent body.

All clinical trials, including bioavailability and bioequivalence studies, shall be designed, conducted and reported in accordance with the principles of Good clinical practice.

The proposal of the opinion referred to in paragraph 4 of this Article, on all clinical trials planned to be conducted in Montenegro, including multicentre clinical trials conducted simultaneously in several healthcare institutions, shall be submitted to the Ministry by the Ethics Committee.

The proposal of the opinion referred to in paragraph 4 of this Article for all clinical trials carried out in more than one Member State of the European Union simultaneously including Montenegro, shall be submitted to the Ministry by the Ethics Committee.

A closer composition, method of work and decision-making of the Ethics shall be prescribed by the Ministry.

Guidelines on the application format and documentation to be submitted for an ethics committee opinion which are harmonised with the Guidelines of the European Commission, shall be published on the website of the Ministry and the Institute.

Article 94

The application for clinical trials shall be submitted by the sponsor of the clinical trial or a representative of the sponsor seated in Montenegro.

An application for clinical trial may be submitted by a natural or a legal person established in the European Union.

The sponsor of the clinical trial or its representative shall have a person responsible for a clinical trial that is permanently available.

The sponsor of the clinical trial may transfer, to another natural or legal person, all or part of its liability by contract, which does not relieve him from the responsibility for clinical trial.

Article 95

Applicant for a clinical trial, including non-commercial clinical trial, may submit the application for clinical trial at the same time to the Ethical Committee and to the Institute.

More detailed conditions, content of the application, documentation required to conduct clinical trial and notification of non-interventional trial shall in more details be prescribed by the Ministry.

Article 96

The Institute shall, within 30 days of receipt of the application for the conduct of clinical trial perform a formal evaluation of the documentation.

The Institute shall issue an approval for clinical trial of medicinal product within 60 days of receipt of complete application with documentation, including positive opinion of the Ethics Committee.

The time needed to submit additional documentation or providing additional explanations at the request of the Institute (clock stops) shall not be included in the period referred to in paragraphs 1 and 2 of this Article.

If the Institute does not issue an approval for clinical trial or a decision on the refusal of the application within the time-limit referred to in paragraphs 1 and 2 of this Article, a clinical trial may commence with the positive opinion of the Ethics Committee.

Notwithstanding paragraph 4 of this Article, a clinical trial may not commence before obtaining the approval of the Institute for clinical trials for: gene therapy, somatic cell therapy, including xenogenic cell therapy and all medicinal products containing genetically modified organisms, as well as biological medicines as defined in article 29 of this Law.

No gene therapy clinical trials can be carried out which result in modifications to the subject's germ line genetic identity.

If the Institute informs the sponsor that there are reasons to refuse the application for clinical trial conducting, the sponsor may modify the content of the application referred to in Article 94 paragraph 1 of this Law, but only once.

If the sponsor does not modify the application in accordance with the notice from the Institute referred to in paragraph 7 of this Article, the application shall deemed to be refused and the clinical trial must not commence.

The deadline for issuing the authorisation under paragraph 2 of this Article may be extended for a maximum of 30 days, or a total up to 90 days, if clinical trials are related to medicinal products for gene therapy or somatic cell therapy or medicinal products that contain genetically modified organisms.

The deadline referred to in paragraph 9 of this article, may be extended by a further 90 days in the case of consultation with domestic or foreign experts and in case of xenogenic cell therapy, there shall be no time limit to the authorisation.

Ethics Committee shall give its opinion proposal within the timelines defined in paragraphs 1, 2, 3, 9 and 10 of this article.

The Ministry shall submit justified opinion of the Ethics Committee referred to in paragraph 11 of this Article to the applicant and the Institute.

On the clinical trials of medicinal products referred to in paragraph 5 of this Article, the provisions of this Law and the law regulating the field of genetically modified organisms shall be applied.

Article 97

Applicant for clinical trial is required to notify the Ethics Committee and the Institute on all administrative and substantial amendments to the clinical trial.

Substantial changes from the paragraph 1 of this Article are those that can significantly affect the safety, i.e. physical and psychological integrity of the trial subjects, or can change the interpretation of scientific documents from the application for the conduct of clinical trial or which are significant for the further course of clinical trial.

In the case referred to in paragraph 2 of this Article, the applicant shall submit a request for an opinion to the Ethics committee and a request for approval of the substantive amendment to the Institute.

Time-limit within which the Ethics Committee and the Institute shall give an opinion on substantial amendments to the clinical trial referred to in paragraph 3 of this Article is 35 days of the date of receipt of the application in due form.

Substantial amendments can be introduced after obtaining a positive opinion of the Ethics Committee and if the Institute raised no grounds for non-acceptance of the application within the time-limit referred to in paragraph 4 of this Article.

If the opinion of the Ethics committee is not positive, or the Institute informs the applicant about the reasons for which the approval cannot be issued, the applicant may change the protocol or withdraw the proposed amendment.

Notwithstanding the time limit referred to in paragraph 4 of this Article, in the case of any new event related to the conduct of a clinical trial or the development of a investigational medicinal product, which could affect the safety of the trials subjects, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against any immediate hazard.

Sponsor shall inform the Ethics Committee and the Institute of those new events and measures referred to in paragraph 7 of this Article, as soon as possible.

Article 98

Institute is obliged to enter the following data on clinical trial into the European (EudraCT) database:

1) submitted applications for clinical trial authorisations;
2) amendments to applications referred to in Article 96 paragraph 7 of this Law;
3) amendments referred to in Article 97 paragraph 2 of this Law;
4) positive opinions given by the Ethics Committee;
5) completion of clinical trials; and
6) completed inspection Good clinical practice guidelines conducting.

In addition to data referred to in paragraph 1 of this Article, the Institute shall also submit other information on clinical trials in response to a reasoned requirement of a Member State, the EMA or the European Commission.

Article 99

Clinical trials of medicinal products shall be conducted only with informed consent of the trial subjects.

Exceptionally, if informed consent is given by the incapacitated subject or a minor, the informed consent must be signed by his legal representative or the guardian, after he had been made aware of the risks and the objectives of the trial.

Exceptionally, if the individual is unable to write, oral consent may be given in the presence of at least one witness that is not an investigating team member, in accordance with the Law.

Persons referred to in paragraphs 1 and 2 of this Article need to have the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the nature, significance, objectives, implications, risks and conditions of the trial.

Persons referred to in paragraphs 1 and 2 of this Article may, at any time, withdraw their informed consent for the participation in the clinical trial.

Prisoners or persons who might be coerced into giving consent to participate in a clinical trial shall not be trial subjects.

Article 100

The principles of medical ethics and compulsory protection of privacy and information about subjects shall be respected in conducting clinical trials, in accordance with the regulations adopt on the basis of this Law and Good clinical practice guidelines.

Clinical trials of medicinal products shall be conducted in the premises of the legal person referred to in Article 92 of this Law, with whom the sponsor, or applicant for the clinical trial has signed the clinical trial agreement.

Total costs of the clinical trial and expenses of the sponsor, i.e. applicant for clinical trial, including expenses of medical and other services incurred by the legal person referred to in

Article 92 of this Law, as well as compensations to investigators and subjects, shall be defined by the agreement referred to in paragraph 2 of this Article.

Compensations to investigators and trial subjects referred to in paragraph 3 of this Article shall be paid by the sponsor, or the applicant for clinical trial to the legal person with whom he has signed the clinical trial agreement.

Before the beginning of a clinical trial, sponsor, or the applicant for clinical trial must be insured against liability for injury, death, or treating of trial subjects, related to the clinical trial.

Article 101

In addition to requirements stipulated in articles 93 to 100 of this Law, clinical trial on minors and incapacitated persons for giving informed consent who have not given or not refused informed consent before the onset of their incapacity, may be undertaken only if following conditions are met:

1) the informed consent of the parents or legal representative has been obtained and this consent represents the presumed will of these persons which may be revoked at any time, without harmful consequences to them;
2) these persons have received information according to its capacity of understanding, from staff with experience with minors and incapacitated subjects, regarding the trial, the risks and the benefits;
3) the investigator, or where appropriate the principal investigator, are considering the explicit wish of these persons who are capable of forming an opinion and assessing this information, to refuse participation or to be withdrawn from the clinical trial at any time;
4) no incentives or financial inducements are given except compensation;
5) direct benefit for the group of patients is obtained from the clinical trial and only where such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods; additionally, such research should either relate directly to a clinical condition from which the minor concerned suffers or be of such a nature that it can only be carried out on minors;
6) that such clinical research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods and relates directly to a life-threatening or debilitating clinical condition from which the incapacitated subject concerned suffers;
7) that clinical trial is conducted following the guidelines from article 93 paragraph 4 of this Law;
8) clinical trials have been designed to minimize pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress have to be specially defined and constantly monitored;
9) the Ethics Committee, with pediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of pediatrics, has endorsed the protocol;
10) the Ethics Committee, with expertise in the relevant disease and the patient population concerned or after taking advice in clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;
11) the interests of the patient always prevail over those of science and society;
12) there are grounds for expecting that administering the medicinal product to be tested will produce a benefit to the patient outweighing the risks or produce no risk at all.

Article 102

Applicant for the clinical trial shall inform the Institute about the course of a clinical trial on a quarterly basis, up to the possibility of accession to EudraCT database of the European Union.

If the clinical trial is terminated before the time specified in the plan of clinical trial, or temporarily suspended, the applicant for the clinical trial shall within 15 days notify the Institute on it, stating detailed explanation of the cause.

Applicant for the clinical trial shall within 90 days from the day of completing clinical trial, inform the Institute on a clinical trial that was completed according to the clinical trial plan.

Within one year from the completion of clinical trials, the applicant for the clinical trial shall submit to the Institute report on completed clinical trials.

Article 103

The application for conducting non-interventional trial shall be submitted by the marketing authorisation holder, or its representative.

The Institute shall, within 30 days of receipt of the application in due form issue an verification of notification of the non-interventional trial.

Non-interventional trial of a medicinal product may begin if the Institute does not issue a verification or does not issue a decision refusing the application within the period referred to in paragraph 2 of this Article.

Content of the application, documentation required for non-interventional study notification shall in more details be determined by the Ministry.

Detailed conditions and the manner of clinical trials of veterinary medicinal products, procedure and documentation required for obtaining approval for clinical trials shall be determined by the Ministry responsible for veterinary matters.

Article 104

In the process of development and manufacture of an investigational medicinal product, while drafting the documentation relating to clinical trials, and in the course of clinical trials, the clinical trial sponsors, applicant for the clinical trial and investigators shall comply with conditions determined by this Law and the regulations adopted based on this Law, as well as with the principles and guidelines of Good manufacturing practice and Good clinical practice.

The applicant for obtaining a manufacturing authorisation or import of an investigational medicinal product must meet the requirements pertaining to obtaining those authorisations in accordance with this Law.

The manufacturer of investigational medicinal products must fulfill the requirements referred to in article 117, paragraphs 1 and 2, as well as the requirements referred to in article 119, paragraphs 4 items 2) and 3) and paragraphs 5, 6 and 7 of this Law.

In the case where the investigational medicinal product which is used as a comparator product in clinical trial is manufactured in a third country and which has a marketing authorisation, but it does not provide documentation confirming that each production batch has been manufactured in accordance with the conditions referred to in article 117 of this Law, the person referred to in article 117, paragraph 2, item 2) of this Law shall ensure that the conditions referred to in article 119, paragraph 4, item 3) of this Law are met for each production batch.

Detailed requirements referred to in paragraphs 1, 2 and 3 of this Article, as well as the manner of verifying the fulfillment of requirements and the content of manufacturing or import authorisation of a medicinal product in a clinical trial shall be prescribed by the Ministry.

Article 105

Healthcare professional participating in a clinical trial as an investigator, shall report all serious adverse reactions to the sponsor, as soon as possible, except those for which such action is not required by the clinical trial protocol, or investigator's brochure.

Additional information for the application referred to in paragraph 1 of this Article, the healthcare professional shall submit in the form of detailed written reports.

The applications referred to in paragraphs 1 and 2 of this Article shall contain a unique identification code assigned to the respondent.

Healthcare professional referred to in paragraph 2 of this Article shall report adverse events that are not serious and/or laboratory abnormalities identified in the protocol as critical to safety evaluations, to the sponsor within the deadlines specified in the trial protocol.

Sponsor shall assess reports referred to in paragraph 1 of this Article and promptly inform all investigators, the Ethics Committee and the Institute on all the information that could cause harm to subjects' health, conducting clinical trials, or suspension of clinical trials.

Sponsor shall keep detailed records of all adverse reactions/adverse events reported by the investigator and assess their seriousness, causality and expectancy.

Sponsor shall not reduce the degree of causality assessed by the investigator. If the sponsor disagrees with the causality assessment made by investigator, the report submitted to the Institute must contain both assessments.

Records referred to in paragraph 6 of this Article, shall be submitted to the Member States in whose territory the clinical trial is being conducted, if they so requested.

Guidelines on the collection, verification and presentation of adverse reactions/events arising from clinical trials, which are harmonized with the Guidelines of the European Commission, shall be published on the website of the Ministry and the Institute.

Article 106

The sponsor or applicant for the clinical trial shall report to the Institute the following adverse reactions manifested on the territory of Montenegro:

1) serious, unexpected adverse reactions occurred during the course of clinical trial;
2) serious, expected adverse reactions occurred in the course of the clinical trials, but with an increased frequency of manifestation (clinically significant);
3) serious danger to patients occurred in the course of the clinical trials of the medicinal product (e.g., lack of efficacy of the medicinal product for patients with life-threatening disease);
4) serious and unexpected adverse reactions occurred after the completion of the clinical trial study and which are reported to the sponsor by the investigator;
5) serious and unexpected adverse reactions to the medicinal product used as a comparator in a clinical trial, on which the marketing authorisation holder in Montenegro is also notified.

Sponsor shall report to the Institute adverse reactions referred to in paragraph 1 of this Article directly if he is seated in Montenegro, or via his representative.

Institute enters data from paragraph 1, item 1), 4) and 5) of this article, in the EMA database (EudraVigilance).

Article 107

Sponsor shall report to the Institute and to the Ethics Committee immediately, or not later than seven days from the day of initial finding (initial report) of serious, unexpected adverse reactions occurred in the course of the clinical trials that are fatal or life-threatening.

Sponsor shall report to the Institute and to the Ethics Committee additional information regarding the reports referred to in paragraph 1 of this Article, not later than eight days after the first, i.e. initial report.

Reports on serious, unexpected adverse reactions that are not fatal in terms of paragraph 1 of this Article and are not life-threatening shall be submitted by the sponsor to the Institute no later than 15 days from the first information on adverse reactions (initial report) and then he shall submit the following report as soon as additional information becomes available.

The sponsor shall also inform all investigators of the adverse reactions referred to in paragraph 1 and 3 of this article.

Reports referred to in paragraph 1 of this Article, shall be submitted to all Member States in whose territories the clinical trial is being conducted.

Article 108

Sponsor, or the applicant for the clinical trial shall submit to the Institute and to the Ethics Committee the following:

1) a list of all suspected serious and unexpected adverse reactions to the medicinal product (hereinafter: SUSAR) in all the countries in which the same clinical trial is conducted, at least once in six months, or more often at the request of the Institute;
2) Safety Update Report of the medicinal product in development, at least once a year, and the final safety report of the investigated medicinal product after the completion of the clinical trial.

Notwithstanding to paragraph 1 of this Article, the individual SUSAR from all the countries in which the same clinical trial is conducted shall be submitted at the request of the Institute.

Sponsor shall provide the Member States in whose territory the clinical trial is being conducted and the Ethics Committee with data referred to in paragraph 1 of this article, once a year.

Article 109

The control of compliance of conduction of clinical trials with the protocol, Good clinical practice guidelines and valid legislation shall be performed by the Institute which takes measures to protect public health.

The Institute shall conduct control of the clinical trials in accordance with the latest updated version of the regulations of the European Union relating to clinical trials.

Institute shall conduct control referred to in paragraph 1 of this Article of the following:

1) on sites where clinical trial is conducted;
2) laboratories where clinical trial analyses are performed;
3) manufacturing site of the investigated medicinal product
4) on the location of sponsors and contractual parties.

The Institute shall control the compliance of clinical trials that are conducted on the territory of Montenegro (before the commencement, in the course and after the completion of the clinical trial) as a part of the procedure for obtaining marketing authorisation, as well as during the marketing authorisation validity period.

Article 110

The Institute can also conduct control at the request of the applicant for clinical trials.

The Institute can accept the control of clinical trials conducted in accordance with the guidelines of Good clinical practice in the European Union Member State, or other state having the same requirements for conducting of clinical trials as Montenegro.

Article 111

Prior to control of clinical trial, the Institute is obliged to inform the applicant and the investigator of the clinical trial on the control of clinical trial of medicinal product.

The Institute shall deliver to the applicant a report on conducted control of clinical trial of medicinal product.

Article 112

Where the Institute has objective grounds for considering that the conditions from the request for authorisation referred to in Article 96 paragraph 2 are no longer met or has information raising doubts about the safety or scientific validity of the clinical trial, it may suspend or prohibit the clinical trial and shall notify the sponsor thereof.

Except in case of imminent risk, if the Institute, based on conducted control, determines that the initiated clinical trial does not have to be urgently suspended, additional information on the conducting of the clinical trial shall be requested from the applicant for the clinical trial.

The applicant for the clinical trial or the investigator is obliged to provide the Institute with all required information within seven days.

In the cases referred to in paragraph 1 of this article, the Institute shall inform the Ethics committee.

In the cases referred to in paragraph 1 of this article, the Institute shall inform the EMA or the European Commission.

Article 113

Where the Institute has objective grounds for considering that the sponsor or the investigator or any other person involved in the conduct of the trial no longer meets the obligations laid down, it shall forthwith inform him thereof, indicating the course of action which he must take and informs the Ethics Committee, without delay.

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

At the request of the EMA or one of the EU Member States, as well as after consultations with the Member States in which clinical trial is carried out, the European Commission may request a new inspection if differences between EU Member States in conducting clinical trial in relation to the requirements of Good clinical practice and the EU directive in this area were established.

Upon receipt of a reasoned request from a Member State of the European Union to the European Commission, regardless of international agreements between the European Union and third countries, the Commission on its own initiative or a Member State may propose that the trial site and/or the sponsor's premises and/or the manufacturer established in a third country undergo an inspection by a qualified inspector from the European Union.

Article 114

Animals and animal products which underwent clinical trials referred to in the Article 87 paragraph 1 of this Law are prohibited to be used for food production. -

Notwithstanding from paragraph 1 of this Article, products of animals may be used if the withdrawal period is specified in accordance with Article 40 of this Law, or sufficient to ensure that prescribed residue levels in food referred to in Article 56 of this Law are not exceeded.

VI MANUFACTURE OF MEDICINAL PRODUCTS

Article 115

Manufacture of medicinal products in Montenegro can be performed only by legal persons that have manufacturing authorisation in accordance with this Law.

Notwithstanding paragraph 1 of this Article, manufacturing authorisation is not required for the preparation, dividing up, repacking of medicinal products, if these procedures are performed in a health institution by a pharmacist who dispenses medicinal product to a patient.

Article 116

Application for manufacturing authorisation shall contain the following:

1) a list of medicinal products and pharmaceutical forms for which the authorisation is required;
2) name and seat of the manufacturer of medicinal products, manufacturing site, site of quality control, as well as site responsible for batch release of medicinal product on the market;
3) a description of the whole, or a part of the manufacturing process, including various processes of dividing up, packaging or presentation for which the authorisation is required;
4) the name of the persons responsible for the manufacture, for quality control and for batch release of medicinal products on the market;
5) information about personnel, equipment and premises, in accordance with the Law and regulations for implementing this Law;
6) information on waste management and environmental protection;
7) other information relevant for obtaining of authorisation, in accordance with this Law.

Article 117

A legal person that manufactures medicinal products must meet the conditions and act in accordance with the manufacturing authorisation issued by the Institute, Good Manufacturing Practice and Good Distribution Practice guidelines.

Legal person referred to in paragraph 1 of this Article shall

1) have the person responsible for the manufacture, who at all stages monitors manufacture preparation, manufacture and storage of medicinal products;
2) have at least one qualified person for the release of every medicinal product batch on the market who should be permanently available
3) given the scope and complexity of manufacture, it must have appropriate personnel consisting of qualified persons in the field of pharmacy, chemistry, biology, biochemistry, biotechnology, chemical technology, medicine, dental medicine, veterinary medicine, or other corresponding professions;
4) have suitable premises and equipment requisite for the manufacture, quality control, storage and distribution of medicinal products,
5) allow the representatives of the competent authority concerned access to manufacturing site/contracted manufacturing sites and documentation at any time;
6) enable the qualified person for batch release of the medicinal product on the market to independently carry out his duties by placing at his disposal all the necessary facilities;
7) use, in the manufacture, only active substances manufactured which are:
   - manufactured in accordance with the Good Manufacturing Practice for active substances,
   - marketed in accordance with Good distribution practice for active substances, and
   - under the supervision of manufacturing and distribution sites of the active substance, carried out by himself or under his responsibility, through legal or natural persons licensed in that area, on the basis of the contract;
8) inform in writing the Institute and the marketing authorisation holder without delay, if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or suspected of being falsified;

9) verify that the manufacturers, importers or distributors from whom he obtains active substances are approved by the competent authority of the state in which they are established;
10) verify the authenticity and quality of the active substances and the excipients;
11) dispose pharmaceutical waste in accordance with a special law regulating waste management; and
12) keep detailed record on all delivered veterinary medicinal products, including the samples, and make it available for inspection to competent authorities for at least 3-year period.

Legal person referred to in paragraph 1 of this Article shall ensure excipients are of appropriate quality for the manufacture of medicinal products, by ascertaining and proofing that in their production the good manufacturing practice is applied.

Quality of excipients is assessed based on a risk assessment that takes into account the requirements of other quality systems, the source and intended use of excipients and previous instances of defects in their quality.

Legal person that manufacture medicinal products derived from blood, radiopharmaceuticals and biotechnological medicinal products must meet specific requirements regarding premises, equipment and personnel.

Detailed requirements referred to in paragraphs 1, 2 and 3 of this Article, as well as the manner of verifying the fulfillment of requirements and the content of manufacturing authorisation shall be prescribed by the Ministry.

Guidelines of Good Manufacturing Practice shall be published on the website of the Ministry and the Institute.

Article 118

A manufacturer of medicinal products who does not have seat in Montenegro is obliged to submit proof of fulfillment of the conditions provided by Good Manufacturing Practice.

Fulfillment of conditions from paragraph 1 of this article shall be assured by submitting a GMP certificate issued by the regulatory body of one of a member state of the EEA, or EUMRA or by verification of the compliance with the GMP requirements by the Institute (hereinafter: GMP certificate)

Exceptionally from paragraph 2 of this Article, the Institute may in relation to the estimated risk of potential nonconformity with the requirements of the Good Manufacturing Practices Guidelines decide on the fulfillment of the conditions referred to in paragraph 1 of this Article and issue a GMP certificate.

Article 119

Person referred to in Article 117 paragraph 2 item 2) of this of this Law shall be graduate of faculty of pharmacy and have practical experience relating to manufacture, i.e. quality control at least for two years at the manufacturer of medicinal products.

Notwithstanding paragraph 1 of this Article, qualified person, may instead of faculty of pharmacy be graduate of other faculties (medicine, veterinary medicine, chemistry, biology...) depending on the type of manufactured medicinal products.

Persons referred to in paragraph 2 of this article are obliged to provide evidence on acquired knowledge in line with standards in EU Member States.

Person referred to in paragraph 1 of this Article shall:

1) ensure that the manufacture and control of each batch of the medicinal product is performed in accordance with the Law and regulations passed for the implementation of this Law, as well as in accordance with the requirements for obtaining marketing authorisation;

2) in the process of batch release of a medicinal products on the market confirm in a register, or other relevant document designated for this purpose, that each batch is manufactured in accordance with Law and regulations passed for the implementation of this Law;

3) for medicinal products coming from third countries, irrespective of whether the product has been manufactured in the EEA, that each manufactured batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation; and

4) for medicinal products intended to be placed on the market of the European union, ensure that the packaging is labelled in accordance with the requirements of article 166 of this Law.

Exceptionally, person referred to in paragraph 1 of this Article, may be relieved of responsibility to secure conditions from paragraph 4 item 3) of this Article, if the medicinal products is coming from third countries, with which appropriate arrangements have been made by the EEA ensuring that the manufacturer of the medicinal product applies standards of Good manufacturing practice equivalent to those laid down by the EEA and to ensure that these controls have been carried out in the exporting country.

The batch of medicinal product which have undergone control in one of the Member State of the European Union accompanied by the control reports signed by the qualified person referred to in paragraph 1 of this Article is exempted from the controls when released on the market in Montenegro.

Register, or other relevant document referred to in paragraph 4 item 2) of this Article must be updated and available to competent authorities for at least five-year period.

Article 120

Manufacture of active substances used as starting materials shall include both total and partial manufacture, import and processes of dividing up, packaging, or presentation prior to its incorporation into a medicinal product.

Processes referred to in paragraph 1 shall be carried out in accordance with Good Manufacturing Practice for active substances.

Legal persons seated in Montenegro that obtained wholesale authorisation (hereinafter: wholesaler), and/or importer carrying out processes that involve dividing up, repackaging or presentation of active substance must meet the requirements of Good Manufacturing Practice for active substances.

Article 121

Legal persons may import active substances under the condition that active substance is manufactured in accordance with the requirements of Good Manufacturing Practice and that written confirmation from competent authority of the exporting third country is enclosed to the delivery of active substance which states that the:

1) active substance is manufactured in accordance with requirements of Good Manufacturing Practice aligned with those laid down by the European Union;
2) Good Manufacturing Practice is under regular, stringent and transparent supervision at the manufacturing site; and
3) exporting country, in the case of established incompliance in supervision, is obliged to inform the European Commission without delay.

Requirements referred to in paragraph 1 of this Article shall not apply if the exporting country is on the list of countries approved by the European Commission.

Notwithstanding paragraph 1 of this Article, with a view of ensuring the availability of medicinal products, the imported active substance does not need to have a written confirmation during the validity of the certificate of Good Manufacturing Practice, i.e., if at the

manufacturing site of the active substance intended for export, supervision was conducted by a Member State of the European Union and if the requirements of Good Manufacturing Practice for the active substance laid down in the European Union have been complied with.

In case referred to in paragraph 3 of this Article, the Institute shall inform the European Commission thereof.

More detailed conditions for import of active substance shall be prescribed by the Ministry.

Article 122

Legal persons seated in Montenegro performing the activities of manufacture, import and distribution of active substances shall enrol in the Register of manufacturers, importers, or wholesalers of active substances.

Application for enrolment in the register referred to in paragraph 1 of this article, shall be submitted to the Institute not later than 60 days before the day of the planned beginning of conducting that activity.

The application referred to in paragraph 2 of this Article shall contain:

1) name and address of the legal person;

2) data on active substances that will be manufactured, imported or distributed;

3) data on the premises and equipment etc.; and

4) other data in accordance with this Law.

In the procedure of the enrolment in the register referred to in paragraph 1 of this article, the Institute may, on the basis of a risk assessment, decide on conducting supervision, of which it shall notify the applicant in writing within 60 days from the day of the receipt of a duly filed application.

In case referred to in paragraph 4 of this article, the applicant must not begin conducting the activities referred to in paragraph 1 of this article.

After the conducted supervision, the Institute shall, within 60 days from the day grant or refuse enrolment in the register referred to in paragraph 1 of this Article, by a decision.

If the Institute does not notify the applicant about the implementation of supervision within the period referred to in paragraph 4 of this Article, the applicant may start the activities referred to in paragraph 1 of this Article.

Legal person referred in paragraph 1 of this Article, shall once a year report to the Institute all amendments to the documentation referred to in paragraph 3 of this Article.

Legal person referred in paragraph 1 of this Article shall submit an application to the Institute for the approval of the amendment of the decision on the enrolment in the Registry, if amendments may affect the quality or the safety of the active substance

The Institute shall within 30 days, from the day of the receipt of a duly filed application, referred to in paragraph 8 of this Article, grant a decision on amendment of the enrolment in the Register.

Data on the register referred to in paragraph 1 of this Article, Institute shall enter into the EMA (EudraGMP) database.

Legal persons referred to in paragraph 1 of this Article shall keep a detailed record about all orders and deliveries of active substances that can be used in the manufacture of veterinary medicines and make it available to the competent authorities for a period of at least three years.

Article 123

Legal person that is involved in collecting, treating or processing blood, its components and derivatives, as the substances for the manufacture of medicinal products from the blood, must

meet specific requirements regarding premises, equipment and personnel, in accordance with the special law.

Manufacturing and purifying processes used in the manufacture of medicinal products derived from human blood or human plasma shall be properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of specific viral contamination.

Legal person referred to in paragraph 1 of this Article is obliged to notify the Institute on the methods used to reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from human blood or human plasma.

Manufacturing processes in the manufacture of immunological medicinal products must be properly validated and the batches of medicinal products must be of uniform quality.

Article 124

The application for obtaining the manufacturing authorisation shall be submitted to the Institute.

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

Period referred to in paragraph 2 of this Article shall not include the time needed for the submission of additional documentation, or providing additional explanations at the request of the Institute (clock stops).

Manufacturing authorisation shall be issued after having made sure of the accuracy of the particulars supplied in the application.

Manufacturing authorisation may be issued for the indefinite period.

Exceptionally, if the requirements referred to in the Article 117 and 118 of this Law are not met, conditional authorisation may be issued with the obligation to carry out certain accurate obligations imposed either when authorisation is issued, or at a later date prescribed after the marketing authorisation is issued.

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

The Institute shall issue a certificate of the Good Manufacturing Practices on the basis of the verification of the fulfillment of conditions within 90 days.

The certificate referred to in paragraph 8 of this Article shall be issued prior to the commencement of the manufacturing, for a period of up to 3 years from the control of fulfillment of conditions and on the request of the manufacturer.

The form and content of the authorisation referred to in paragraph 4, GMP certificate and the report on the compliance with the guidelines of Good Manufacturing Practices shall be issued on a standardized form determined by the acts of the European Union and the EMA and are published on the website of the Ministry and the Institute, in Montenegrin and English.

Article 125

Manufacturing authorisation shall be issued for a specific manufacturing site, i.e. manufacturing facility, pharmaceutical form and specific finished medicinal product.

Manufacturing authorisation shall be issued for the complete procedure, or parts of the procedure of manufacture of medicinal products.

Manufacturing authorisation shall be issued also for:

1) medicinal products intended solely for the export;
2) medicinal products intended for clinical trials; and
3) active substances, excipients and intermediate products.

Article 126

Manufacturer of medicinal products shall be responsible for the quality, safety and efficacy of the medicinal product which is manufactured.

Manufacturer placing a medicinal product on the market, as well as marketing authorisation holder are also responsible for the quality, safety and efficacy of the medicinal product.

Article 127

The medicinal product manufacturer is obliged to submit to the Institute the application for amendment of manufacturing authorisation, if he changes the conditions of the manufacturing authorisation.

The Institute, within 30 days of receipt a complete application, shall issue a decision on amending the manufacturing authorisation based on assessment of data from the application.

Period referred to in paragraph 2 of this Article shall not include the time needed for submission of additional documentation or providing additional explanations at the request of the Institute (clock stops).

Exceptionally, the deadline referred to in paragraph 2 of this Article may be extended to 90 days.

Article 128

Manufacturer is obliged, without delay, to inform the Institute of any major accidents or mistakes in the process of manufacture, sudden replacement of the person referred to in Article 117 paragraph 2 item 2) of this of this Law, as well as other situations for which one can doubt the quality, safety and efficiency of the medicinal product.

In cases referred to in paragraph 1 of this Article, the Institute shall take actions on suspension of manufacturing or marketing of a medicinal product, i.e. actions on prohibition of marketing or recall of the medicinal product from the market in accordance with this Law.

Manufacturer of the medicinal product, i.e., active substance, is obliged to ask the Institute's consent for monitoring of manufacturing site, or the control of compliance with Good manufacturing practice that is announced from another state.

Article 129

Manufacturer of medicinal products is obliged to keep detailed records of all relevant activities of the manufacturing procedure, as set out in the manufacturing authorisation and in accordance with Good Manufacturing Practice.

Article 130

Manufacturing authorisation shall cease to be valid:

1) at the request of the manufacturer;
2) if a manufacturer:

- changes the conditions of the manufacturing authorisation, without submitting an application for amendment of the authorisation,
- no longer comply with the requirements of Article 117 of this Law.

Cessation of validity of the authorisation referred to in paragraph 1 of this Article may be temporary until the fulfillment of conditions for obtaining manufacturing authorisation.

Decision on the cessation of validity of the authorisation referred to in paragraph 1 of this Article shall be passed by the Institute.

Data on the granted manufacturing authorisations, on manufacturing authorisations ceased to be valid and on certificates of compliance with the Good Manufacturing Practice, Institute shall enter into the EMA (EudraGMP) database.

Data referred to in paragraph 4 of this article for veterinary medicinal product shall be forwarded by the Institute to the EMA which enters that information in EMA (EudraGMP) database.

Article 131

Manufacturer may sell medicinal products from his program exclusively to legal persons having manufacturing authorisation, wholesale authorisation, manufacturers of medicated food, pharmacies and other health and veterinary institutions.

The manufacturer can provide medicinal products from his program free of charge in the manner and under conditions regulated by the Ministry.

Manufacturer is obliged to submit regularly the report to the Institute on the total value of the performed sale of medicinal products, as well as the quantity of sale for all individual medicinal products (in packages) in Montenegro.

The report referred to in paragraph 3 of this Article is confidential and the data on total sale in Montenegro processed by the Institute is available to the public.

The content of the report referred to in paragraph 3 of this Article, the period for which is submitted, and the manner of submission of reports shall be prescribed by the Ministry.

Article 132

Manufacturer of medicinal products may import or export medicinal products from its program and also starting materials, raw substances, intermediates, bulk products in accordance with manufacturing authorisation, marketing authorisation, or contract on outsourced manufacture.

At the request of the manufacturer, the exporter or the authorities of an importing third country, the Institute issues certificates for the purpose of export in accordance with recommendations of World Health Organization as well as approved summary of the product characteristics for medicinal products that have marketing authorisation issued by the Institute.

For medicinal products that don't have a marketing authorisation issued by the Institute, for the purpose of issuing the certificate referred to in paragraph 2 of this Article, manufacturer shall provide a declaration explaining why medicinal products have no marketing authorisation.

VII MARKETING OF MEDICINAL PRODUCTS

Article 133

Marketing of medicinal products is performed as the wholesale and the retail sale.

The wholesale shall include all activities consisting of procuring, holding, supplying or exporting medicinal products apart from supplying medicinal products to the public.

Wholesale of medicinal product include also import and export.

Wholesale may be performed by:

1) wholesalers which have the wholesale authorisation issued by the Institute for medicinal products for human use or the competent authority for veterinary affairs for medicinal products for veterinary use; and
2) manufacturers of medicinal products seated in Montenegro for the medicinal product they manufacture.

Marketing of medicinal products referred to in paragraph 1 of this Article may only be performed with medicinal products having marketing authorisation and the medicinal products referred to in Article 5 of this Law.

Wholesale of medicinal products from humanitarian aid shall also be considered the wholesale.

Article 134

Importer is a natural or legal person seated in the European Union, who performs import of medicinal products and possesses the manufacturing authorisation for the parts of manufacture that it performs i.e. import of medicines from third countries.

Imported batches of medicinal product referred to in paragraph 1 of this Article, for which quality control in a Member State of the European Union has been carried out, are not subject to additional quality control, but are placed on the market in Montenegro on the basis of the quality control certificate signed by the responsible person for the batch release of medicinal products from the Member State of the European Union.

Imported batches of medicinal products referred to in paragraph 1 of this Article from the EUMRA are placed on the market in Montenegro on the basis of the certificate of quality control from the exporting country.

Persons referred to in paragraph 1 of this Article shall be obliged to submit a copy of the marketing authorisation for a veterinary medicinal product which they deliver to another Member State.

Article 135

Parallel import of a medicinal products from European Union to Montenegro (hereinafter: parallel import) may be carried out by wholesalers authorised for wholesale of medicinal products and who are not marketing authorisation holders or in any business relationship with the marketing authorisation holder for the concerned medicinal product.

Wholesalers who perform parallel import shall forthwith notify the Institute and the marketing authorisation holder and not later than 15 days prior the parallel import.

Wholesaler referred to in paragraph 2 of this Article shall prior the parallel import notify the marketing authorisation holder and the EMA for any medicinal product which is authorised by EMA via centralised procedure.

Article 136

Brokering of medicinal products shall mean all activities in relation to the sale or purchase of medicinal products for human use, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person.

The broker is a natural or a legal entity seated in Montenegro or the European Union, which holds an authorisation for brokering of medicinal products.

Brokers referred to in paragraph 2 of this Article seated in Montenegro shall submit to the Institute an application for issuing authorisation for brokering.

Application for brokering shall contain the following:

1) name and seat of the broker; and
2) list of medicinal products which the application is submitted for.

The Institute shall grant the authorisation for brokering within 90 days of receipt of a duly filed application.

Brokers referred to in paragraph 2 of this Article shall satisfy the following conditions:

1) have a plan for urgent recall of the medicinal product from the market in line with the Institute's decision or in agreement with the manufacturer or the marketing authorisation holder and keep documents enabling such recall;
2) keep records of orders, deliveries and brokering in a written, electronic or any other form and make it accessible for inspection to competent authorities;
3) operate a quality assurance system which defines processes, responsibilities and risk management;

4) immediately notify the Institute of any falsified medicinal product received or offered or any medicinal products suspected of being falsified;
5) act in accordance with Guidelines of good distribution practice.

The broker referred to in paragraph 2 of this article shall be obliged to enable to the representatives of the competent authority to perform inspection at any time.

The Institute shall keep a register of brokers, with information referred to in paragraph 4 item 1) of this article, which shall be published on the Institute's website.

Article 137

Natural and legal persons seated outside of Montenegro, in a Member State of the European Union, who satisfy the conditions for the wholesale or brokering of medicinal products in the EU Member State where they are established, shall submit the notification about the beginning of their operations on the territory of Montenegro to the Institute which keeps record on it.

Persons referred to in paragraph 1 of this article for the wholesale distribution fulfill the same conditions as wholesalers with a authorisation issued by the Institute, including obligations prescribed by Article 144 of this Law.

Article 138

Wholesalers are obliged to procure medicinal products directly from manufacturers, importers or from other wholesalers who hold the relevant authorisation granted by the competent authority.

Wholesalers may supply medicinal products from its program to other wholesalers, manufacturers of medicated food, pharmacies, as well as other health and veterinary institutions, who have authorisations to perform activities issued by the competent authority.

Wholesaler may provide medicinal products from its program free of charge in the manner and under the conditions prescribed by the Ministry.

Wholesalers and manufacturers can perform export of medicinal products to third countries in which case they shall ensure that medicinal products are supplied to legal persons who are authorized by the competent authority of the importing country concerned.

The persons referred to in paragraph 4 of this article shall, when exporting, attach a document containing the following information: date of export, name of the medicinal product, quantity of the delivered medicinal product, name and address of the supplier and batch number.

Medicines intended for export to third countries do not need to have a marketing authorisation issued by the Institute or in the Member State of the European Union.

If the persons referred to in paragraph 4 of this Article are receiving medicinal products from third countries that are not intended to be placed on the market in the European Union, they shall ensure that the medicinal products are obtained only from persons who are authorised for wholesale by the competent authority of the exporting country concerned.

Article 139

Legal person performing wholesale of medicinal products is obliged to act in accordance with Good Distributing Practice.

Legal person referred to in paragraph 1 of this Article must meet at least the following conditions:

1) must have qualified person for storage and distribution of medicinal products;
2) must have other appropriate personnel;
3) must have suitable premises and equipment so as to ensure proper storage of medicinal products, keeping record and storage documentation on quality of medicinal products, as well as means for safe transport.

4) must enable at any moment to the Institute, i.e. pharmaceutical inspector to inspect fulfillment of conditions and the documentation;
5) have a plan for urgent recall of the medicinal product, in line with the decision of the Institute, competent authority for inspection affairs, or competent authority for veterinary matter, or in agreement with the manufacturer, or the marketing authorisation holder, as well as to keep documents enabling such recall;
6) keep records of orders, deliveries and brokering in a written, electronic or any other form and make it available to the pharmaceutical inspector for a period of five years, which contain at least following information: date, name of the medicinal product, quantity received, supplied or brokered, name and address of the supplier, batch number etc.;
7) keep records of orders and deliveries of veterinary medicinal products in a written, electronic or any other form and make it available for inspection by the competent authorities for a period of at least three years, which must contain at least following information: date, name of the veterinary medicinal product, quantity of received or supplied medicinal product, name and address of the supplier, batch number, expiry date, annual audits on comparing incoming and outgoing medicinal supplies with supplies currently held in stock and any discrepancies being recorded;.
8) operate a quality assurance system which defines processes, responsibilities and risk management for wholesale of medicinal products for human use;
9) make systematic checks to make sure that the medicinal products he receives are not falsified by using safety features on packs in accordance with Article 165 paragraph 2 of this Law;
10) encloses to legal persons referred to in Article 138 paragraph 2 of, a documentation with records from item 6) of this paragraph for every supply of medicinal products.

Legal person referred to in paragraph 1 of this Article shall immediately notify the Institute and marketing authorisation holder of any falsified medicinal product offered or received, as well as any medicinal products suspected of being falsified.

Person responsible for storage and distribution of medicinal products must be graduate of faculty of pharmacy or for the wholesale of veterinary medicinal products faculty of veterinary medicine or faculty of pharmacy.

Wholesale authorisation holder is obliged to conclude the full-time working contract with persons referred to in paragraph 2 item 1) of this Article.

The legal person performing wholesale of medicinal product is obliged to ensure continuous availability of persons referred to in paragraph 2 of this Article.

The legal person referred to in paragraph 1 of this Article must have a copy of the certificate on conducted quality control for each batch of medicinal product he distributes.

Guidelines on Good Distributing Practice for medicinal products for human use shall be published on the website of the Ministry and the Institute.

Detailed requirements referred to in paragraph 2 of this Article, content of the wholesale authorisation and the manner of determining compliance for the wholesale shall be prescribed by the Ministry, i.e. state competent authority for veterinary affairs.

Article 140

The legal person performing wholesale of medicinal products from blood, radiopharmaceutical, and immunological medicinal products, medicinal products containing narcotic and psychotropic substances and precursors must meet specific requirements in terms of premises, equipment and personnel in accordance with a special law and authorisation for medicinal products containing narcotic and psychotropic substances shall be issued in accordance with this Law and special law.

Article 141

Application for obtaining wholesale authorisation for medicinal products for human use shall be submitted to the Institute, and for veterinary medicinal products to the competent authority for veterinary affairs.

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

1) name and seat of the legal person and the place of storage of medicinal products;
2) list of types and groups of medicinal products for which the wholesale authorisation is applied;
3) name of the responsible person under whose supervision the receipt, storage and delivery of medicinal products is performed;
4) evidence of available vehicles for the transport of medicinal products;
5) other information relevant for obtaining of wholesale authorisation in accordance with this Law.

The authorisation for the wholesale of medicinal products may be issued for a particular storage site(s), for a particular type or group of medicinal products as required, based on fulfillment of prescribed conditions.

The authorisation for the wholesale of medicinal products, except for wholesale of medicinal products containing narcotic and psychotropic substances, shall be issued for an indefinite period.

Article 142

The Institute or competent authority for veterinary affairs shall issue wholesale authorisation within 90 days of receipt of a duly filed application referred to in Article 141 paragraph 1 of this Law.

Time-limit referred to in paragraph 1 of this Article shall not include time for submitting additional documentation, or providing additional explanation at the request of the Institute (clock-stop)

The Institute shall issue a certificate of the Good Distribution Practices (hereinafter: GDP certificate) within 90 days based on the verification of the fulfillment of conditions in accordance with this Law.

The certificate referred to in paragraph 3 of this Article shall be issued before commencing wholesale for a period of up to 5 years from the control of fulfillment of conditions and on the request of the wholesaler.

The form and content of the authorisation referred to in paragraph 1 of this Article, GDP certificate and the report on the compliance with the guidelines of Good distribution practice shall be issued on a standardized form determined by the acts of the European Union and the EMA and published on the website of the Ministry and the Institute, in Montenegrin and English..

Data on the wholesale authorisations issued, wholesale authorisations ceased to be valid and on certificates of compliance with the Good distribution practice, Institute shall enter into the EMA (EudraGMP) database.

Article 143

For any amendment to wholesale authorisation the holder of authorisation shall submit to the Institute, i.e. competent authority for veterinary affairs the application for approval of such amendments.

Article 144

Wholesale authorisation holder and marketing authorisation holder are obliged to ensure a continuous supply of medicinal products in accordance with the wholesale authorisation and marketing authorisation.

Wholesale authorisation holder shall supply, health or veterinary institution at their request with medicinal product for which he obtained the wholesale authorisation in the shortest term in a manner that does not endanger life and health of people, i.e. animals.

The holder of authorisation referred to in paragraph 1 of this Article shall provide, in order to ensure continuous supply of market with the medicinal products, the necessary stocks of medicinal products, i.e. timely begin procurement, import and acquiring confirmation of performed quality control in order to avoid interruption in the supply of market with the medicinal products.

The holder of authorisation referred to in paragraph 1 of this Article shall deliver, upon request of the Ministry, i.e. the state competent authority for veterinary affairs, within required time, the other medicinal product which is authorised for marketing in Montenegro, as well as medicinal products specified in Article 5 of this Law.

Marketing authorisation holder is required to conclude contract on the wholesale of medicinal products with all legal persons performing the wholesale of medicinal products, and at the request of the Institute, i.e. competent authority for veterinary affairs, to submit a list of these legal persons.

Article 145

Wholesale authorisation holder is obliged to inform, without delay, the Institute, i.e. competent authority for veterinary affairs of any major accident or incident which could affect the quality of medicinal products or safe handling.

In the cases referred to in paragraph 1 of this Article, competent authority for veterinary affairs may order the suspension or the recall of the medicinal products from the market.

Article 146

Institute, i.e. competent authority for veterinary affairs may adopt a decision on cessation of validity of the wholesale authorisation for medicinal products, if the wholesale authorisation holder:

1) no longer fulfills the conditions for the wholesale of medicinal products based on which the authorisation was issued;
2) changes the conditions of the authorisation without submitting an application for amendments to the wholesale authorisation;
3) within a specified period does not eliminate the deficiencies and irregularities identified by the competent inspection authority;
4) does not fulfill the obligation of continuous supply of market with the medicinal products for which the wholesale authorisation was issued;
5) submits the request for cessation of validity of wholesale authorisation.

Article 147

Legal and natural persons that when carrying out their activities in any way get in the possession a medicinal product (transporter, postal operator, the holder of customs warehouse, etc.) are obliged to act in accordance with the instruction provided on the package of the medicinal product for transport.

Manufacturer, i.e. holder of the wholesale and retail sale authorisation is responsible for the transport and handling of medicinal products on the territory of Montenegro.

Article 148

Retail sale of medicinal products, as a part of health care is performed in the pharmacy.

For the distribution of medicinal products referred to in paragraph 1 of this Article, the person responsible for preparation, handling and dispensing of medicinal products must be a graduate pharmacist.

The retail sale of medicinal products referred to in paragraph 1 of this Article shall be in accordance with the Guidelines of Good pharmacy practice.

Pharmacy cannot dispense or sell medicinal products to other legal and natural persons, except for patients, owners or keepers of animals and health and veterinary institutions.

Requirements in terms of premises, equipment and personnel for performing the retail sale of medicinal products for veterinary use, as well as content of the records shall be prescribed by the state competent authority for veterinary affairs.

Guidelines of Good pharmacy practice shall be published on the website of the Ministry.

Pharmacy may provide medicinal products from its program free of charge in the manner and under the conditions prescribed by the Ministry.

Article 149

Manufacturers, wholesale authorisation holders, pharmacies and veterinary institutions are obliged to keep records on the type and quantity of imported and exported, as well as sold, i.e. dispensed medicinal products for which the marketing authorisation or import authorisation was issued in accordance with Article 5 of this Law.

More detailed conditions for issuing the import authorisation for medicines referred to in Article 5 of this Law shall be prescribed by the Ministry.

Article 150

Wholesale authorisation holders, pharmacies and veterinary institutions are obliged to regularly, at least annually, report to the Institute on total value of performed sale of all medicinal products, as well as the quantity of sale for individual medicinal products (in packages) in Montenegro.

Marketing authorisation holder shall, at the request of the Institute, submit the information referred to in paragraph 1 of this Article, on reasons relating to pharmacovigilance.

The report referred to in paragraph 1 of this Article is confidential and the data on total sale in Montenegro, processed by the Institute, are available to the public.

The form and content of the report referred to in paragraph 1 of this Article, a period for which is submitted and the manner of submission are regulated by the Ministry.

Article 151

The applicant for obtaining the marketing authorisation can import samples of medicinal products, substances and other materials that are required in the procedure of obtaining the marketing authorisation, based on confirmation of the Institute, in accordance with this Law.

The Institute can import the samples of medicinal products and substances that are used as reference substances in the quality control of medicinal products, in accordance with this Law.

Article 152

The person who enters or exits the country can carry a reasonable amount of medicinal products that is necessary for personal usage or for the animal traveling with him, for maximum six months.

Person referred in paragraph 1 of this Article can carry medicinal products containing narcotic and psychotropic substances, in accordance with the special law.

Person referred to in paragraph 1 of this Article must not receive needed medicinal products via the post or delivery service.

Article 153

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.

Medicinal products referred in paragraph 1 of this Article must be destroyed 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.

Article 154

Pharmacies in Montenegro may over the Internet offer for distance selling, in line with a special regulation, medicinal products, which are not subject to medical prescription.

Pharmacies, which offer medicinal products for distance selling over the Internet, shall provide the Ministry with the following data:

1) name and permanent address of the place of activity from where those medicinal products are supplied;
2) starting date of the selling activity;
3) the address of the website used for that purpose and all relevant information necessary to identify that website.

The web page from paragraph 2 of this Article shall contain at least following:

1) the contact details of the Ministry;
2) a hyperlink to the website of the Ministry with data about pharmacies offering distance selling of medicinal products;
3) the common logo of a defined form in the European Union, clearly displayed on every page of the website that relates to the offer for sale of medicinal products at a which contains a hyperlink to the list of pharmacies offering distance selling of medicinal products.

Detailed conditions and manner of Internet offer for distance selling of medicinal products that are issued without prescription are prescribed by Ministry.

VIII QUALITY CONTROL

Article 155

The Institute shall ensure that all medicinal products meet the prescribed quality standards by assessment of the quality documentation, laboratory quality control and control procedure by the Institute, in accordance with the Law.

Laboratory quality control of each medicinal product when necessary, shall be performed in accordance with European, national pharmacopoeia or other recognized pharmacopoeia or other valid methods of analysis.

In order to monitor and detect substandard and falsified medicines, the Institute may also use laboratory quality control methods based on diffraction or fluorescence of x rays and other methods.

The elements of quality of medicinal products shall be determined and documented for each stage of manufacture and marketing in accordance with Good manufacturing practice for all medicinal products.

Article 156

The Institute has the right to carry out the following laboratory quality controls:

1) quality control of medicinal product before its placing on the market:
   - in the procedure of issuing the marketing authorisation for medicinal product,

- of the first batch of medicinal product after issuing the marketing authorisation,
- for the renewal of the authorisation and during the procedure of amendment to the authorisation, if necessary,
- obligatory quality control (re-analysis) of each batch of immunological medicinal products and medicinal products from blood or plasma;

2) quality control of medicinal products on the market:
   - by taking random samples at least once during the validity of marketing authorisation,
   - of each batch of imported medicinal products,
   - by testing the quality of hazardous medicinal products,
   - by solving identified problems;
3) of magistral and galenic medicinal products.

Laboratory quality control is conducted also by checking the methodology, elaboration of standards, i.e. by the development of pharmacopoeia and through international cooperation in order to ensure quality of medicinal products.

Wholesale authorisation holder and/or marketing authorisation holder as well as the manufacturer are obliged to submit at the request of the Institute valid certificates on conducted quality control for each batch of medicinal product and/or active substances and excipients and intermediates in accordance with the requirements from Article 46 paragraph 1 item 9) of this Law.

For the purposes of the control referred to in paragraph 1 item 1) indent 4, the Institute may request the manufacturer to submit a protocol on the manufacture and control of a medicinal product, signed by a person referred to in Article 117 of this Law.

The Institute may conduct the control of the sample of each medicinal product for which finds necessary, in order to ensure adequate quality, provided that the legal persons that are authorized for manufacturing and marketing of medicinal products are not put in to the mutually unequal position.

Article 157

In the case of laboratory quality control referred to in Article 156 paragraph 1 item 1) indent 4 of this Law before placing a batch of immunological medicinal product on the market, in order to protect human and animal health, the Institute shall notify the Member States of the European Union in which immunological medicinal product was approved and the European Directorate for the Quality of Medicines (hereinafter: EDQM).

Laboratory control referred to in paragraph 1 of this Article must include all tests performed by the manufacturer on the finished product, in accordance with the documentation referred to in Article 46 and 47 of this Law.

Exceptionally, the tests referred to in paragraph 2 of this Article may be limited to justified tests, which have been agreed between the Member States and, if necessary, the EDQM.

For immunological veterinary medicinal products authorized by the centralized procedure, the tests referred to in paragraph 2 of this Article may be limited to justified tests after the approval of the EMA.

The Institute shall inform the Member States of the European Union in which the immunological medicinal product is authorized, EDQM, the holder of the marketing authorisation and, if necessary, the manufacturer of the medicinal product of the results of the examination referred to in paragraph 1 of this Article.

If a batch of an immunological medicinal product does not comply with the manufacturer's manufacturing and control protocol or the specifications specified in the marketing authorisation, measures shall be taken in accordance with the law, against the marketing authorisation holder and, if necessary, the medicinal product manufacturer. The Institute shall

inform the Member States of the European Union in which the immunological medicinal product was authorized for the medicinal product of the measures taken.

The Institute recognizes the results of tests of immunological medicinal products conducted in a member state of the European Union.

Article 158

Quality control of medicinal products referred to in Article 156 of this Law shall be carried out by the control laboratory for pharmaceutical medicinal product testing, in accordance with the Guidelines of Good control laboratory practice.

The Institute may establish its own control laboratory, or by contract may entrust the quality control of medicinal products to other laboratory in Montenegro, or national laboratory for quality control of medicinal products of other country.

The content and the manner of pharmaceutical testing of medicinal product, for the purpose of quality control, shall be prescribed by the Ministry.

Article 159

On the results of quality control of medicinal products referred to in Article 156 of this Law, the control laboratory shall submit the report to the Institute.

The Institute is obliged to carry out a quality control of immunological medicinal products and the medicinal products from blood or plasma within 60 days from the day of receiving the sample of the medicinal products.

Results referred to in paragraph 1 of this Article shall be considered confidential, except when the informing the public about the results is in the interest of public health.

Article 160

Legal persons that manufacture and perform marketing of medicinal products must enable to the Institute to take the required number of samples of medicinal products for quality control referred to in Article 156 of this Law.

The costs of taken samples and the control of medicinal products referred to in Article 156 of this Law shall be covered by the applicant for the marketing authorisation, marketing authorisation holder, i.e. wholesale authorisation holder, pharmacy and veterinary institution.

Exceptionally from paragraph 2 of this article, the costs of quality control of medicines from the Article 156 paragraph 1 item 2) indent 1 shall be covered by the Institute or natural or legal person that submitted the request for conducting of quality control to the competent authority for inspection affairs or to the Institute, for the second and each subsequent time during the validity of the marketing authorisation, if it is proved that the quality of medicinal product meets the quality standards.

Article 161

The Institute develops a system which prevents the possibility of medicines suspected of being danger to health, from reaching the patients.

The system referred to in paragraph 1 of this Article enables withdrawal of a medicinal product or a medicinal product batch in accordance with Article 79 of this Law, as well as by the marketing authorisation holder, both during and outside working hours by persons referred to in paragraph 3 of this Article.

Healthcare professionals and veterinary care professionals who come into contact with the medicinal products, or patient-user of medicinal product, natural and legal persons manufacturing and marketing medicinal products, are required to inform the Institute in writing on quality defects of medicinal product for which they found out.

In case of suspected falsified medicinal products, the persons referred to in paragraph 1 of this article shall immediately inform the Institute, competent authority for inspection affairs, i.e. competent authority for veterinary affairs and marketing authorisation holder.

In the case that the medicinal products referred to in paragraph 1 of this Article are already available to patients, the Institute shall issue an urgent public announcement, within 24 hours, containing sufficient information on the quality defect or falsification of the medicinal product as well as the risks of their use.

If it is suspected that the medicinal products referred to in paragraph 1 of this Article present a serious danger to public health, the Institute shall inform all participants referred to in paragraph 3 of this Article.

In the case referred to in paragraph 6 of this Article, the Institute shall rapidly alert all Member States.

IX LABELLING OF MEDICINAL PRODUCTS

Article 162

Any medicinal product that is on the market must be labelled in accordance with the marketing authorisation and must be in accordance with the approved summary of the product characteristics.

Name of the medicinal product for human use on the packaging must be indicated in Braille.

Notwithstanding paragraph 2 of this Article, the name of a medicinal product used in accordance with the marketing authorisation exclusively in a healthcare institution under the control of a healthcare professional, as well as a medicinal product for clinical trial, need not be indicated in Braille.

Article 163

The labelling of the traditional and homeopathic medicinal product must contain the name of the therapeutic school based on which it was approved, and other prescribed labels.

Veterinary medicinal products must be labelled in manner that clearly stated that they are for animal treatment only.

The obligation of labelling refers to the substances and combinations of substances intended for further processing, as well as the galenic medicinal products produced in the pharmacy.

Article 164

Package leaflet is enclosed in the package of medicinal product and must be in accordance with the summary of the product characteristics approved by the Institute.

Package leaflet shall be provided in Montenegrin language and languages that are in official use in Montenegro.

Article 165

Labelling of outer and immediate packaging of medicinal product and the content of package leaflet shall be approved by the Institute.

Medicinal product subject to prescription, with the exception of radiopharmaceuticals, must have a safety feature on the packaging that allows persons who perform wholesale and retail to verify the authenticity of the medicinal product, identify individual packs, as well as a device allowing verification of whether the outer packaging has been tampered with.

Exceptionally, the medicinal product referred to in paragraph 2, does not need to have a safety feature on the packaging, if it is on the list adopted by the European Commission.

Exceptionally, a non-prescription medicinal product must bear the safety feature on the packaging referred to in paragraph 2, if it is on the List adopted by the European Commission, after assessing that there is a risk of falsification.

Article 166

The safety features referred to in Article 165 shall not be removed, neither covered nor fully or partially, unless the manufacturer verifies that the medicinal product concerned is authentic and that it has not been tampered with prior to the partial or complete removal of the safety features.

If the manufacturer replaces safety features referred to in Article 165 of this Law, with the equivalent features in terms of the possibility of authentication, the identification of the individual package and providing evidence of tampering of the medicinal product, that replacement must be carried out without the opening of the immediate packaging.

The replacement of the safety features referred to in paragraph 2 of this Article shall be carried out in accordance with the requirements of the Good Manufacturing Practice and under the supervision of the Institute.

The safety features referred to in paragraph 2 of this Article shall be considered equivalent if they meet the requirements laid down by the delegated acts of the European Commission and are equally effective with regard to the conditions referred to in paragraph 2 of this Article.

Manufacturer referred to in paragraph 1 of this Article shall be responsible for the procedures referred to in paragraph 1 and 2 of this Article.

The content and manner of labelling of the outer and immediate packaging of the medicinal products, content of the package leaflet, as well as types of medicinal products that must contain a safety features are determined in more details by the Ministry, i.e., the state competent authority for veterinary affairs for veterinary medicinal product.

X PHARMACOVIGILANCE

Article 167

The Institute and the marketing authorisation holder shall organize the pharmacovigilance system with the aim of collecting and assessing the information related to safe use of medicinal products and other information that may be relevant for the assessment of the risk-benefit ratio of medicinal products on the market.

The Institute shall through the system of pharmacovigilance evaluate all the data regarding the safe use of a medicinal product, consider options for risk minimization and prevention, and if necessary, take appropriate actions in accordance with this Law.

The pharmacovigilance of veterinary medicinal products is aimed to collecting and evaluating information obtained with regard to suspected adverse reactions to veterinary medicinal products under approved conditions of use on animals and adverse reactions in humans associated with the use of these medicinal products, lack of expected efficacy, off-label use, investigations of the validity of the withdrawal period and on potential environmental issues related to the use of veterinary medicinal product.

Pharmacovigilance system referred to in paragraphs 1 and 3 of this Article shall be organized in accordance with guidelines of the Good practice in pharmacovigilance.

Article 168

Within the pharmacovigilance system referred to in Article 167 paragraph 2 and 3 of this Law, the Institute shall:

1) keep records of all suspected adverse reactions that have been reported in Montenegro, by patients and healthcare and veterinary professionals;
2) take actions to encourage patients and healthcare professionals and veterinary professionals to report suspected adverse reactions to medicinal products, with the involvement of respective associations, if necessary;
3) take all appropriate actions to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;
4) ensure that the expert and when appropriate general public is timely informed on pharmacovigilance of medicinal products through the publication on the website or through other means, if necessary, were information which are personal or commercially confidential omitted, unless disclosure is necessary for the protection of public health;
5) on its website provide information on different manners of medicinal products suspected adverse reactions reporting;
6) cooperate with the marketing authorisation holders in the detection of duplicates of suspected medicinal products adverse reaction reports;
7) for reports submitted by a marketing authorisation holder may involve the marketing authorisation holder in the collecting additional information's for medicinal products adverse reaction reporting occurred in Montenegro;
8) ensure, through the methods for collecting data and where necessary through additional information, that all appropriate actions are taken to identify any biological medicinal product prescribed, dispensed, or sold on the territory of the Montenegro which is the subject of a suspected adverse reaction report, with due regard to the name of the medicinal product and the batch number;
9) submit to marketing authorisation holder any suspected medicinal product adverse reaction report which has been submitted to the Institute by a healthcare professional or patient, within 15 days from the receipt of serious adverse reaction or within 90 days from the receipt of non-serious adverse reactions;
10) inform the marketing authorisation holder of the veterinary medicinal product on suspected serious adverse reaction and adverse reaction in humans in Montenegro immediately, and at latest within 15 days of receiving the report.
11) submit suspected adverse reaction reports occurred in Montenegro in an adverse reactions database of Collaborative Center of the World Health Organization (Uppsala Monitoring Center);
12) perform a regular audit of its pharmacovigilance system and reports the results to the European Commission every two years thereafter.

The management of funds intended for activities connected with pharmacovigilance from article 167 of this Law shall be provided in line with the Article 23 of this Law and under the permanent control of the Institute in order to guarantee independence in the performance of those pharmacovigilance activities.

Provisions from paragraph 2 shall not preclude the possibility of charging fees for performing those activities to marketing authorisation holders.

Article 169

Within the pharmacovigilance system referred to in Article 167 paragraph 2 of this Law, the Institute shall:

1) submit electronically to the EudraVigilance database all medicinal product serious suspected adverse reactions that occur in the Montenegro within 15 days from the receipt of this information;

2) submit electronically to the EudraVigilance database all medicinal product non-serious suspected adverse reactions that occur in Montenegro within 90 days from the receipt of this information;
3) cooperate with EMA and marketing authorisation holders in the detection of duplicates of medicinal product suspected adverse reaction reports;
4) ensure that reports of medicinal product suspected adverse reactions arising from an error associated with the use of a medicinal product that are reported to the Institute, are made available to the EudraVigilance database.

Information collected within the system referred to in article 167 paragraph 3 of this Law, for veterinary medicinal products, Institute communicates to other Member States of the European Union and EMA.

Information from paragraph 2 of this article, related to serious adverse reactions and human adverse reactions of veterinary medicinal product, Institute submits electronically to the EudraVigilance Veterinary database, within 15 calendar days from the receipt of the information.

Marketing authorisation holders shall access those reports through the EudraVigilance database.

Article 170

The Institute shall set up and maintain a national medicines website which shall be linked to the European medicines website of the EMA.

By means of the website from paragraph 1 of this Article, the Institute shall make publicly available the following data and documents:

1) public assessment reports, together with a summary thereof,
2) summaries of product characteristics and package leaflets,
3) summaries of risk management plans,
4) list of medicinal products subject to an additional post-authorisation follow-up,
5) information on the different ways of reporting suspected adverse reactions to medicinal products by healthcare professionals and patients and forms, including the web-based structured forms.

Article 171

Marketing authorisation holder shall:

1) establish the system of pharmacovigilance in order to fulfill pharmacovigilance tasks in accordance with the law;
2) through the system of pharmacovigilance evaluate all safety information, consider options for risk minimization and prevention and take appropriate action in accordance with this Law;
3) conduct regular audit of the pharmacovigilance system and place a note concerning the main findings of the audit in the pharmacovigilance system master file (PSMF) and based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented.

Data referred to in paragraph 1 item 3 of this Article may, once the corrective actions have been fully implemented, be removed.

Article 172

As part of the pharmacovigilance system referred to in Article 167 of this Law, the marketing authorisation holder shall:

1) have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance in the Montenegro ;

2) maintain PSMF in cooperation with the manufacturer and make it available at Institute's request;
3) conduct RMS for every medicinal product;
4) monitor the outcome of risk minimisation measures which are contained in the RMP or which are laid down as conditions pursuant to Article 64 of this Law;
5) update the risk management system and monitor pharmacovigilance data to determine whether there are new risks, or whether risks have changed, or whether there are changes to the benefit-risk ratio of medicinal products.

Article 173

Marketing authorisation holders that obtained marketing authorisations before 21 July 2012 shall not be required to operate a risk management system for each authorised medicinal product pursuant to Article 172 paragraph 1 item 3) of this Law.

Notwithstanding paragraph 1 of this Article, the Institute may stipulate that the marketing authorisation holder is to operate RMS if there are concerns about the risks affecting the risk-benefit ratio of an authorised medicinal product.

Pursuant to paragraph 2 of this Article, the Institute shall oblige the marketing authorisation holder to submit a detailed description of the RMS which he intends to introduce for the medicinal product concerned.

The Institute may impose fulfillment of obligations referred to in paragraphs 2 and 3 of this Article in duly justified cases, with written notification and timeframe for submission of the detailed description of the RMS.

On a request of marketing authorisation holder, the Institute shall provide marketing authorisation holder with an opportunity to present written observations to the obligation from paragraphs 2 and 3 of this Article, within 30 days of receipt of the written notification from the Institute.

In case referred in paragraph 6 of this Article, the Institute shall make decision on marketing authorisation variations accordingly to include the measures in accordance with Article 64 paragraph 1 item 1) of this Law.

Article 174

Marketing authorisation holder is obliged to:

1) keep records of all suspected adverse reactions to the medicinal product which manifested in Montenegro, reported spontaneously by the patient or healthcare professional or occurring in the context of a post-authorisation study;
2) monitor and collect all information that may affect the assessment of the risk-benefit ratio of the medicinal product and to submit it to the Institute, without delay, in the shortest possible time;
3) forward each received notification on the serious adverse reaction to the medicinal product manifested in the territory of Montenegro to the Institute, not later than 15 days from the receipt of this information;
4) inform the Institute on non-serious suspected adverse reactions that occur in Montenegro within 90 days following the day on which the marketing authorisation holder received this information;
5) establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports referred to in paragraphs 3 and 4 of this Article and also collect follow-up information on these reports;
6) report all serious and unexpected adverse reactions occurred in the EU or, a third country, at the request of the Institute not later than 15 days from the receipt of this information.

7) cooperate with the Institute in the detection of duplicates of suspected adverse reaction reports.

For an unauthorised medicinal product, obligations referred to in paragraph 1 of this Article shall be overtaken by the wholesale authorisation holder.

Article 175

Marketing authorisation holders shall submit electronically to the EudraVigilance database all suspicions to:

1) all non-serious suspected adverse reactions that occur in Montenegro within 90 days from the receipt of this information;
2) all serious suspected adverse reactions that occur in the Montenegro within 15 days from the receipt of this information;
3) all non-serious suspected adverse reactions that occur in the Member States of the European union, within 90 days from the receipt of this information;
4) all serious suspected adverse reactions that occur in the Member States of the European union within 15 days from the receipt of this information;
5) all serious suspected adverse reactions that occur in the third countries within 15 days from the receipt of this information;

Marketing authorisation holder shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports referred to in paragraph 1 of this Article and shall collect follow-up information on these reports and submit the updates to the EudraVigilance database.

Marketing authorisation holder shall cooperate with the Institute and the EMA in the detection of duplicates of suspected adverse reaction reports.

Article 176

Marketing authorisation holder shall not forward to the expert and general public the pharmacovigilance information affecting the use of medicinal product, without prior notice to the Institute.

Marketing authorisation holder is obliged to ensure that all information provided on pharmacovigilance of particular medicinal product must be shown objectively and not to mislead the expert and general public.

Marketing authorisation holder shall be required to inform EMA and the European Commission about the information referred to in paragraph 1 of this Article, before the public announcement is made.

The Institute shall notify other Member States, EMA and the European Commission, not later than 24 hours prior to the public announcement relating to pharmacovigilance information, except in the case of the need for urgent public announcement due to protection of public health.

In cooperation with EMA, the Institute will publish announcement regarding the safety of the active substances that are contained in the medicinal products, which are authorized in Montenegro and in one of the member states of the European Union.

Any information referred to in paragraphs 4 and 5 of this Article, which are personal or commercially confidential, shall be omitted, unless disclosure is necessary for the protection of public health.

Article 177

For all medicinal product that obtained marketing authorisation, summary of product characteristics and package leaflet shall include the text inviting healthcare professionals and patients to report adverse reactions to medicinal products.

Article 178

The Institute shall on its portal make available the list of medicinal product subject to additional monitoring published by EMA.

The Institute may decide further monitoring of medicinal product authorised for marketing in Montenegro and that are not on the list published by EMA.

Medicinal products referred to in paragraphs 1 and 2 of this Article shall be labelled by an inverted full black triangle followed by an explanation in the summary of product characteristics and package leaflet.

Article 179

Healthcare professional is obliged to:

1) notify the Institute in writing about any medicinal product suspected adverse reaction, in particular about serious and unexpected adverse reactions, while in the case of vaccines they shall also notify the Institute of Public Health of Montenegro.
2) report serious adverse reactions to the Institute within 30 days after their knowledge, and later if necessary by filing subsequent reports.
3) reported to the Institute suspicion to serious adverse reactions with a fatal outcome shall without delay, in writing, or by phone following the subsequent written notification.

Article 180

The patient may report any suspected adverse reaction to medicinal products and vaccines to the Institute or the marketing authorisation holder, while for the incapacitated subject or a minor suspected adverse reaction may be reported by parent, legal representative, or guardian.

Article 181

Marketing authorisation holder shall submit PSUR to the Institute containing:

1) a summary of data relevant to the benefit and risk of the medicinal product, including the results of all studies with consideration of their potential impact on the marketing authorisation of the medicinal product;
2) a scientific assessment of the risk-benefit ratio of the medicinal product, including data from clinical trials in unauthorized 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 relating to the volume of prescription, including the assessment of the population exposed to the medicinal product.

Notwithstanding paragraph 1 of this Article the marketing authorisation holders for authorisations issued for generic, bibliographic applications, entry in the Register of traditional herbal medicines and the Register of homeopathic medicines shall submit PSUR to the Institute in the following cases:

1) where such obligation has been laid down in accordance with Article 64 or Article 66 of this Law;
2) based on the request by the Institute regarding the concerns relating to pharmacovigilance data, or due to lack of PSUR relating to particular active substance.

Article 182

The Institute shall specify the frequency for submission of PSUR if the PSUR submission period is not prescribed for the active substance by the EURD list.

The dates of submission of PSUR according to the specified frequency shall be calculated from the date of the issuing marketing authorisation.

For authorisation which were issued before 21 July 2012 and for which the frequency and dates of submission of PSUR are not laid down with marketing authorisation, marketing

authorisation holders shall submit PSUR to the Institute immediately upon request, i.e. in accordance with the following:

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

The obligation to submit PSUR in accordance with paragraph 3 of this Article shall be valid until a different frequency or different dates for the submission thereof are laid down in the marketing authorisation, or in line with EURD list.

Article 183

The Institute shall assess PSUR in order to determine any new risks related to safety profile of medicinal product, changes to the risks or changes to the risk-benefit ratio of medicinal product application.

Based on the assessment of PSUR, the Institute may request from the marketing authorisation holder to initiate the authorisation variation procedure or it may, ex officio amend the marketing authorisation, suspend it or revoke it.

Article 184

The Institute may participate in the work of CMDh for the purpose of the common assessment of PSUR related to more than one marketing authorisation.

If the assessment from paragraph 1 of this Article has an impact on the marketing authorisation in Montenegro, the Institute shall in consultations with the CMDh or in line with the decision of the European Commission, request from the marketing authorisation holder to initiate the authorisation variation procedure or it may ex officio amend the marketing authorisation, suspend it or revoke it.

Article 185

Regarding authorized medicinal products, the Institute shall take the following:

1) monitor the outcome of risk minimization measures contained in risk management plans and of the conditions referred to in Articles 64, 65 and 66 of this Law;
2) assess changes to the risk management systems;
3) monitor the data in national adverse reactions database to determine whether there are new risks or whether risks have changed and whether those risks impact on the risk benefit ratio of medicinal product. In the event of new risks or risks that have changed or changes to the risk-benefit ratio being detected, the Institute shall notify the marketing authorisation holder;
4) monitor the 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 ratio;
5) in the event of new risks or risks that have changed or changes to the risk-benefit ratio being detected, the Institute shall notify the EMA and the marketing authorisation holder.

If the marketing authorisation holder detects new risks or risks that have changed or changes to the risk-benefit ratio, he shall notify the Institute.

Marketing authorisation holder shall notify EMA of risks referred to in paragraph 2 of this Article.

Article 186

Marketing authorisation holder may conduct PASS, at own request, or at the request of the Institute or on the basis of the conditions or obligations of marketing authorisation.

PASS shall include the collection of safety data from patients and healthcare professionals.

Marketing authorisation holder may commence the PASS after obtaining the written consent from the Institute.

Costs of conduction of PASS shall be covered by the marketing authorisation holder.

PASS shall not be conducted so as to promote the use of the medicinal product.

Compensation for healthcare professionals that participated in the PASS is limited to compensation for time spent and incurred expenses.

Marketing authorisation holder is obliged to monitor collected data and assess their impact on the risk-benefit ratio of the medicinal product tested in the PASS.

Marketing authorisation holder is required to inform the Institute on any new information which may affect the risk-benefit ratio of the medicinal product and to take appropriate measures.

Marketing authorisation holder shall submit to the Institute the protocol of PASS. For any substantial amendments to the protocol, before their implementation marketing authorisation holder shall obtain written consent, by the Institute.

Marketing authorisation holder shall submit to the Institute the final report and summary of the results of PASS.

The final report and summary of PASS referred to in paragraph 10 of this Article, marketing authorisation holder shall submit to the Institute within 12 months from the completion of data collection.

Marketing authorisation holder may request the Institute approval for the extension of time for submitting the data, or an exemption from the obligation referred to in paragraph 11 of this Article.

Marketing authorisation holder shall submit to the Institute an application for variation, if the results of PASS referred to in paragraph 10 of this Article affect the marketing authorisation.

Article 187

Marketing authorisation holder shall submit to the PRAC the protocol for PASS that will be conducted in Montenegro and another Member Sate of the European Union based on the conditions or obligations of marketing authorisation.

Study referred to in paragraph 1 of this Article may commence in Montenegro after obtaining approval from the PRAC and after marketing authorisation holder submits approved protocol to the Institute.

Before implementation of any substantial amendments to the protocol, marketing authorisation holder shall submit to the Institute, PRAC approval for those amendments.

Marketing authorisation holder shall submit to the PRAC the final report and summary of the results of PASS within 12 months, unless PRAC approves extension of time for submitting the data, or an exemption from the obligation of submitting final report.

Marketing authorisation holder shall submit to the Institute an application for variation, if the results of PASS referred to in paragraph 1 of this Article affect the marketing authorisation.

Article 188

Veterinary and healthcare professionals, marketing authorisation holder for a veterinary medicinal product and a person performing wholesale of veterinary medicinal product are required to report suspected serious and/or unexpected adverse reactions to the veterinary medicinal product in animals and human adverse reactions to the Institute, without delay.

Veterinary and healthcare professionals shall report any suspected adverse reaction to a veterinary medicinal product, particularly serious and unexpected adverse reactions to the marketing authorisation holder.

Veterinary and healthcare professional may report suspected adverse reaction referred to in paragraph 1 of this article directly to the Institute or through the marketing authorisation holder for a veterinary medicinal product or wholesale authorisation holder for veterinary medicinal products.

Article 189

Marketing authorisation holder for a veterinary medicinal product shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance.

Person referred to in paragraph 1 of this Article shall reside in Montenegro and be responsible for the following:

1) establishing and maintaining a system which ensures that information about all suspected adverse reactions which have been reported to a marketing authorisation holder are collected and collated;
2) preparation of the Reports on the records referred to in Article 190 of this Law;
3) providing complete and timely submission of additional information necessary for the evaluation of the benefits and risks afforded by veterinary medicinal product at the request of the Institute, including the provision of data on the volume of sales or prescription of veterinary medicinal product concerned;
4) providing the Institute with other information relevant to the evaluation of the benefits and risks afforded by a veterinary medicinal product, including appropriate information on post-marketing surveillance studies.

Article 190

The marketing authorisation holder for a veterinary medicine is obliged to:

1) maintain detailed records of all suspected adverse reactions and save in exceptional circumstances, report them electronically in the form of a report in accordance with the guidelines referred to in Article 167 paragraph 4 of this Law;
2) maintain detailed record of all suspected serious adverse reactions and human adverse reactions, that are brought to his attention from a veterinary or health care professional, animal keeper or from other sources of which he can reasonably be expected to have knowledge and with no delay report them to the Institute no later than 15 days following receipt of the information;
3) all suspected serious unexpected adverse reactions of veterinary medicinal product and human adverse reactions and any suspected transmission via a veterinary medicinal product of any infectious agent occurring on the territory of a third country, report promptly and no later than 15 days following the receipt of the information, in accordance with the guidelines referred to in article 167 paragraph 4 of this Law, so that they are available to the EMA and the competent authorities of the Member States in which the veterinary medicinal product is authorized.

Unless other requirements have been laid down as a condition for the granting marketing authorisation, marketing authorisation holder shall report PSUR to the Institute immediately upon request or at least every six months after authorisation until the placing on the market.

After placing onto the market of veterinary medicinal product PSUR shall be submitted immediately upon request of the Institute or at least every six months during the first two years following the initial placing on the market and once a year for the following two years.

Upon the expiry of the period referred to in paragraph 3 of this Article, PSUR shall be submitted to the Institute at three-yearly intervals or immediately upon request.

PSUR shall include a scientific evaluation of the risk-benefit ratio for particular veterinary medicinal product.

Marketing authorisation holder may request the amendment of the periods referred to in paragraphs 2, 3 and 4 of this Article in line with the Article 64 paragraph 2 of this Law.

Marketing authorisation holder is obliged to act in accordance with the Article 167 of this Law.

Article 191

The Institute may, if necessary to protect human and animal health, after the assessment of veterinary data on pharmacovigilance, suspend, withdraw or amend the marketing authorisation for veterinary medicinal product, in order to restrict indications, change posology, add a contraindication or add a new precautionary measure and shall immediately inform the holder of the marketing authorisation on it.

The Institute shall inform EMA and other Member States about measures referred to in paragraph 1 of this article.

If urgent action is necessary for protecting human or animal health, the Institute may suspend the marketing authorisation of a veterinary medicinal product, of which EMA, the Commission and the other Member States shall be informed on the following working day at the latest.

Article 192

The Institute shall conduct control of the pharmacovigilance system of marketing authorisation holder in the implementation of Good pharmacovigilance practice in accordance with this Law and regulations adopted to implement this Law.

In cases when outcome of control referred to in paragraph 1 of this Article show that marketing authorisation holder does not comply with the Good pharmacovigilance practice, the Institute shall inform other Member States, EMA and the Commission.

Article 193

The Institute may engage experts in the field of medicinal products for certain professional tasks in conducting control in the field of pharmacovigilance, if special expertise is necessary for the performance of such task.

Article 194

In the establishing a system for collecting data on adverse reactions to veterinary medicinal products, the Institute, in cooperation with competent authority for veterinary affairs shall monitor system of animals safety , safety system of persons administering medicinal products to animals, safety system of users of products of animal origin, as well as environmental protection in relation to veterinary medicinal products.

Article 195

The Institute shall cooperate with the authorized centre for adverse reactions of the World Health Organization and other institutes, agencies and institutions, in order to obtain the latest expert information regarding the safe use of medicinal products.

Article 196

The manner of data collecting and the manner of reporting and monitoring of adverse reactions to medicinal products are regulated by the Ministry, i.e. the state authority responsible for veterinary matters.

XI ADVERTISING OF MEDICINAL PRODUCTS

Article 197

The advertising of medicinal products is any form of providing information to the general and expert public about the medicinal product by the manufacturer or the manufacturer sponsorship or marketing authorisation holder, in order to encourage the prescribing, supplying, selling and consumption of medicinal products.

Advertising of medicinal products, as defined in paragraph 1 of this Article shall include:

1) advertising of medicinal products through media and Internet, in public places and other forms of advertising the public (by mail, visits, etc.);
2) promotion of medicinal products to healthcare professionals and veterinary professionals;
3) providing free samples to expert public;
4) sponsoring of scientific and promotional meetings involving the expert public, by covering the necessary costs for travel, accommodation, meals, and costs of mandatory participation in scientific and promotional meetings; and
5) encouraging the prescribing and dispensing of medicinal products by giving or promising the financial, material or other benefits.

Advertising of a medicinal product intended solely as a reminder shall include only the name of the medicinal product or its international non-proprietary name, or the trademark.

Article 198

Advertising to expert public of the medicinal product that are dispensed with medical prescription is allowed under the terms of the marketing authorisation in accordance with the approved summary of the product characteristics of the medicinal product.

It is allowed to provide one smallest package of a new medicinal product only to the expert public, in order to inform the expert public about the characteristics of a new medicinal product that is to be placed on the market, with a wording on the package: "Free sample, not for sale".

Article 199

Medicinal products that are dispensed without a medical prescription can be advertised in the media and in other manner, i.e. information about these medicinal products may be provided in accordance with the approved summary of the product characteristics of the medicinal product, which is the integral part of the marketing authorisation.

The advertising referred to in paragraph 1 of this Article shall be objective and shall not mislead the expert and general public.

The Institute shall determine a list of medicinal products referred to in paragraph 1 of this Article.

List of medicinal products referred to in paragraph 1 of this Article shall be published on the website of the Institute.

It is prohibited to advertise medicinal products referred to in paragraph 1 of this Article by direct addressing to children, which are intended for their treatment.

It is prohibited to attribute medicinal properties to non-medicinal products within the meaning of this Law.

Article 200

Manufacturers of medicinal products, the representatives of manufacturers and legal persons engaged in marketing of the medicinal products shall not offer the financial, material or other benefit to persons who prescribe, or dispense the medicinal products, nor to their families.

Notwithstanding paragraph 1 of this Article, the manufacturers of medicinal products, the representatives of manufacturers and legal persons engaged in marketing the medicinal

products may be the sponsors of scientific and promotional meetings involving the expert public, by covering the necessary costs for travel, accommodation, meals, and costs of mandatory participation in scientific and promotional meetings.

Article 201

Advertising of medicinal products that subject to medical prescription to the general public is prohibited, as well as medicinal products containing narcotic drugs.

Advertising of medicinal products which do not have the marketing authorisation and whose authorisation has expired is prohibited.

The method and conditions for advertising of the medicinal products shall be prescribed by the Ministry.

XII INSPECTION SUPERVISION

Article 202

Supervision over the implementation of this Law and regulations adopted pursuant to this Law shall be carried out by the Ministry, state competent authority for veterinary affairs and Institute.

Inspection supervision is performed by the competent inspector for medicinal products for human use and veterinary use in accordance with the law, as follows:

1) pharmaceutical inspector in relation to medicinal products in manufacture, wholesale of medicinal products for human use, clinical trials of medicinal products, as well as application of guidelines of Good manufacturing practice, Good distribution practice, Good practice in pharmacovigilance and Good clinical practice, in accordance with this the Law and the law governing inspection supervision;
2) health inspector in relation to medicines for human use in retail of medicinal products and in the use of medicines in health care institutions, in accordance with this Law and laws governing inspection supervision, health inspection, health care, health insurance and pharmacy;
3) veterinary inspector in relation to veterinary medicinal products, in accordance with this Law and the laws governing inspection supervision and veterinary medicine;
4) market inspector in relation to the prices of medicines in the wholesale and the retail of medicinal products, in accordance with this Law and laws governing inspection supervision and internal trade.

Article 203

Within the supervision, pharmaceutical 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 documents relating to the manufacture of medicinal products, wholesale of medicinal products, testing and quality control of medicinal products, system of pharmacovigilance, as well as the documentation relating to the application of Guidelines of Good manufacturing practice and Good distribution practice.
2) perform immediate insight into the implementation of Guidelines of Good manufacturing practice and Good distribution practice, as well as of standard and operational procedures in these areas;
3) perform immediate insight into the implementation of Good practice in pharmacovigilance and Good clinical practice;
4) hear and take statements from responsible and interested persons;

5) inspect business premises, facilities, installations, devices, equipment;
6) examine raw materials, active substances, excipients, intermediates, medicinal products, labelling of medicinal products;
7) take samples of medicinal products and raw materials for the purposes of quality control;
8) take copies of documents along with stating in the minutes;
9) examine personal documents of employees for the purpose of identification;
10) takes photographs, or records information about a person, area, object, accessory, medicinal products, etc. for the purpose of gathering evidence; search for data from official records and other databases relating to persons if they are necessary for the carrying out the inspection supervision;
11) carry out inspection supervision at the premises of the marketing authorisation holder, brokers and all laboratories contracted by the manufacturer.

Article 204

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) check the advertising of medicinal products for human use;
2) prohibit the 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 the advertising of a medicinal product that misleads the expert and general public whether it is published or in preparation;
3) prohibit marketing of a product for which is determined to contain an active substance or a substance similar to the active one, and it is not a medicinal product within the meaning of this Law;
4) take copies of documents with stating in the minutes;
5) request data from official records and other databases related to persons if they are necessary for conducting inspection supervision;
6) review personal documents of employees for identification;
7) photograph or record data on a person, space, object, accessories, medicines and other, for the purpose of collecting evidence.

Article 205

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 of veterinary medicinal products as well as documentation related to the application of the Guidelines of Good distributive practice;
2) provide direct insight into the application of the Guidelines of Good distributive practice;
3) take copies of documents with stating in the minutes;
4) review personal documents of employees for identification;
5) hear and take statements from responsible and interested persons;
6) inspect business premises, facilities, installations, devices, equipment and check the fulfillment of the prescribed conditions for wholesale and retail of veterinary medicinal products;
7) request data from official records and other databases related to persons if they are necessary for the implementation of inspection supervision;
8) monitor and control the advertising of veterinary medicinal products;

9) take samples of veterinary medicinal products for the purpose of quality control;
10) prohibit the 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 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;
12) review personal documents of employees for identification;
13) photograph or record data on a person, space, object, accessories, medicines and other, for the purpose of collecting evidence; and
14) perform other examinations in accordance with this Law and other regulations, according to the indicated needs.

Article 206

Within the supervision, 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 medicines in the wholesale of medicinal products and the retail of medicinal products;
2) take copies of documents with stating in the minutes;
3) review personal documents of employees for identification; and
4) request data from official records and other databases related to medicinal products prices if they are necessary for conducting inspection supervision.

Article 207

In addition to administrative measures and actions determined by the law governing inspection supervision, the pharmaceutical inspector, when he 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 it is engaged in testing, production, marketing, brokering, quality control of a medicinal product without the approval or authorisation of the Institute;
5) prohibit legal entities 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 critical non-compliance with the Guidelines of Good manufacturing practice and Good distribution practice;
6) suspend marketing of the medicinal product in wholesale, i.e. its series that do not meet the conditions prescribed by this Law and the regulations for the implementation of this Law;
7) order withdrawal of the medicinal product from the wholesale, i.e. its series in the market in cases prescribed by this Law and regulations for the implementation of this Law;

8) suspend wholesale of the medicinal product, i.e. its series which do not correspond to the conditions prescribed by this Law and the regulations for the implementation of this Law;
9) order withdrawal of the medicinal product from the wholesale, i.e. its series in the market in cases prescribed by this Law and regulations for the implementation of this Law; and
10) prohibit work and submit a proposal to the Institute to:
- revoke authorisation to perform activities,
- control the issued certificate on the application of Good manufacturing practice and Good distribution practice of medicinal products,
- control the issued certificate on the application of Good clinical practice and other certificates,
- control the issued certificate for the needs of drug export in accordance with WHO recommendations.

Article 208

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 prohibit:

1) trade of falsified medicinal product;
2) trade of medicinal products in retail whose shelf life has expired;
3) the use of medicinal products that are improperly stored handled;
4) use of a homeopathic medicine that does not have an approval;
5) 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) 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;
7) to suspend marketing of the medicinal product in retail, i.e. its series which do not correspond to the conditions prescribed by this Law and the regulations for the implementation of this Law;
8) to order withdrawal of a medicinal product from retail or its series in cases prescribed by this Law and regulations for the implementation of this Law;
9) to order destruction of a defective medicinal product in accordance with this Law;
10) order undertaking of other measures for which he is authorized by another law.

Article 209

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 engaged, in the sale 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) prohibit implementation of actions that are contrary to this Law;
7) suspend marketing of a veterinary medicinal product in wholesale, i.e. its series that do not meet the conditions prescribed by this Law and the regulations for the implementation of this Law;
8) order withdrawal of a veterinary medicinal product from wholesale or its series in trade in cases prescribed by this Law and regulations for the implementation of this Law;
9) prohibit marketing of falsified medicinal products;
10) prohibit marketing of a veterinary medicinal product in retail whose expiration date has expired;
11) prohibit the use of veterinary medicinal products that are improperly stored or handled;
12) 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;
13) to suspend retail of veterinary medicinal products, i.e. its series which do not correspond to the conditions prescribed by this Law and the regulations for the implementation of this Law;
14) order withdrawal of a veterinary medicinal product from retail or its series in cases prescribed by this Law and regulations for the implementation of this Law;
15) order destruction of a defective veterinary medicinal product and a falsified medicinal product in accordance with this Law; and
16) order undertaking of other measures for which he is authorized by another law.

Article 210

In addition to administrative measures and actions determined by the law governing inspection supervision, the market inspector, when he determines non-compliance with the requirements established by this law, and other regulations, has the authority and obligation to:

1) temporarily confiscate illegally acquired property gain in the case when the legal entity that carries out the wholesale of medicinal products, i.e. the retail of medicinal products, has stated higher prices of medicinal products than the determined prices; and
2) order undertaking of other measures for which he is authorized by another law.

Article 211

Legal and natural persons whose work is subject to supervision are obliged to enable the inspector unhindered access and supervision in accordance with this Law, regardless of whether it is announced or unannounced inspection, as well as to make a sufficient number available to him without compensation samples of the medicinal product for analysis, i.e. to provide him with all the necessary data at his disposal.

The inspector referred to in Article 202 of this Law shall control the fulfillment of requests for medicinal products by repeated inspections and, if necessary, unannounced inspections, by requesting the control laboratory referred to in Article 158 of this Law to examine samples, as well as control the business premises of the marketing 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 considers that there are reasons for doubt in compliance with the provisions of Art. 120, 121 and 122 of this Law.

The costs of taking samples of medicinal products shall be borne by the marketing authorisation holder, i.e. the holder of the entry in the registers kept at the Institute, health institution, private practice, i.e. veterinary organization, legal entity that carries out wholesale of medicinal products.

The inspector is obliged to act in accordance with this Law, regulations adopted for the implementation of this law, conscientiously and impartially, i.e. to keep as official secret the data obtained during the supervision.

XIII PENAL PROVISIONS

Article 212

A fine of 1000 euros to 20000 euros shall be imposed on a legal person if he:

1) fails to always notify the Institute of any new findings on the assessment of quality, safety and efficacy of medicinal products on the market (Article 68 paragraph 1)
2) fails to place a medicinal product on the market within 12 months from the day of submission of the decision of the Institute approving the variation in accordance with the approved variation (Article 68 paragraph 7)
3) does not take account of scientific and technical state of the art for the processes of manufacture and quality control and does not introduce any variations that enable the medicinal product to be manufactured and tested by means of generally accepted scientific methods (Article 69 paragraph 1 item 1)
4) fails to provide the Institute with any new information which might entail amendments to the data, documents and files of the medicinal product provided in the frames of the marketing authorisation procedure or the referral procedure in the European Union (Article 69 paragraph 1 item 2)
5) fails to immediately inform the Institute on any restriction, or prohibition imposed by the competent authorities of other states in which the medicinal product is marketed and of any other new information which might influence the risk-benefit ratio of the medicinal product concerned (Article 69 paragraph 1 item 3)
6) does not provide the Institute with both positive and negative results of clinical and other studies in all indications and populations of subjects, whether or not included in the authorisation, as well as data on the use of the medicinal product where such use is not covered by the authorisation (Article 69 paragraph 1 item 4)
7) fails to ensure that the product information is kept up to date with the current scientific knowledge, including conclusions of public reports relating to assessment of the medicinal product dossier and recommendations of the EMA made public by means of website (Article 69 paragraph 1 item 5)
8) within seven days after receipt of the request of the Institute, fails to forward data demonstrating that the risk-benefit ratio of the medicinal product remains favourable in order to enable its continuous assessment, as well as to submit a copy of the PSMF for medicinal products for human use (Article 69 paragraph 3)
9) fails to apply for renewal of marketing authorisation at least 9 months before the expiration of marketing authorisation (Article 71 paragraph 1)
10) fails to place a medicinal product on the market within 12 months from the day of submission of the decision on renewal of the authorisation, in accordance with the decision (Article 72 paragraph 2)
11) fails to notify the Institute within 60 days before the expiration of the period for which the marketing authorisation is issued that he will not initiate the procedure for renewal of the marketing authorisation (Article 72 paragraph 3)

12) fails to inform the Institute in writing on the date of placing the medicinal product on the market, within 15 days from the date of placing the medicinal product on the market for each pharmaceutical form, strength and package (Article 73);
13) fails to notify the Institute of the measures taken under Article 79 paragraph 1 of this Law, no later than 24 hours from the moment of learning of the existence of reasons for their initiation (Article 79 paragraph 3);
14) decides to temporarily, or permanently suspend marketing of a medicinal product or withdraws the medicinal product from the market before the expiry of the marketing authorisation or decides to apply for the termination of the marketing authorisation or decides not to apply for the renewal of the marketing authorisation, without notifying the Institute, at least 60 days before the discontinuation in the supply of the market with the medicinal products (Article 80 paragraph 1 and 2);
15) In case referred to in Article 80 paragraph 1 of this Law fails to notify the Health Insurance Fond on reasons for discontinuation supply of the market with the medicinal product (Article 80 paragraph 2);
16) for any reason, he ceases to be a marketing authorisation holder before the expiry of the validity period, and the medicinal product marketing authorisation has not been transferred in accordance with this Law, without delay informing the Institute, i.e. the competent authority for veterinary affairs, who carry out wholesale of that medicinal product in Montenegro (Article 82 paragraph 1);
17) fails to take all necessary measures to withdraw the medicinal product from the market before the expiry of the marketing authorisation for that medicinal product within 30 days from the day of termination of the capacity of the marketing authorisation holder (Article 82 paragraph 2);;
18) dispenses, or sells medicinal product contrary to conditions set out in the marketing authorisation, except in cases referred to in Article 39 and 40 of this Law (Article 85 paragraph 4)
19) conducts clinical trial of the medicinal product in contrary with provisions of Article 96 paragraphs 4, 5 and 6 of this Law;
20) fails to notify the Institute and the Ethics Committee on all significant, substantial amendments to the clinical trial (Article 97 paragraph 1)
21) does not conduct clinical trial in the legal person referred to in the article 92 with whom he has signed agreement on a clinical trial (Article 100 paragraph 2);
22) does not by the contract referred to in the Article 100 paragraph 2 of this Law specify the amount of necessary expenditures for the implementation of clinical trials of medicinal products, expenses of the sponsor, i.e. applicant for clinical trial, including costs of medical and other services of legal person referred to in the article 92 of this Law, as well as fees for investigators and clinical trial subjects (Article 100 paragraph 3);
23) does not pay compensations to investigators and trial subjects referred to in the article 100 paragraph 3 of this Law to the legal person with whom he has signed the clinical trial agreement (Article 100 paragraph 4);
24) prior to commencing clinical trial fails to insure the clinical trial subjects in case of damage connected to the clinical trial (Article 100 paragraph 5);
25) uses investigational medicinal product as a comparator product, manufactured in a third country and which has marketing authorisation, but the documentation confirming that each batch has been manufactured in accordance with the conditions referred to in Article 117 of this Law cannot be provided, and the person referred to in article 117, paragraph 2 item 2) of this Law does not ensure that the conditions referred to in Article

119 paragraph 4 item 3) of this Law are met for each production batch (Article 104 paragraph 4);

26) healthcare professional participating in a clinical trial as an investigator, does not report all serious adverse reactions to the sponsor, without delay, except those for which such action is not required by the clinical trial protocol, or investigator's brochure (Article 105 paragraph 1);
27) healthcare professional referred to Article 105 paragraph 1 of this Law does not report to the sponsor within the deadlines specified in the trial protocol adverse events that are not serious and/or laboratory abnormalities identified in the protocol as critical to safety evaluations (Article 105 paragraph 4);
28) does not assess reports referred to in Article 105 paragraph 1 and without delay inform all investigators, the Ethics Committee and the Institute on all the information that could cause harm to subjects' health, conducting clinical trials or suspension of clinical trials. (Article 105 paragraph 5);
29) fails to keep detailed records of all adverse reactions and adverse events reported by the investigator and assess their seriousness, causality and expectancy (Article 105 paragraph 6);
30) fails to reduce the degree of causality assessed by the investigator (Article 105 paragraph 7);
31) fails to report to the Institute and to the Ethics Committee immediately, or not later than seven days from the day of initial finding (initial report) of serious, unexpected adverse reactions occurred in the course of the clinical trials that are fatal or life-threatening (Article 107 paragraph 1);
32) fails to report to the Institute and to the Ethics Committee additional information regarding the reports referred to in Article 107 paragraph 1 of this Law, not later than eight days after the first, i.e. initial report (Article 107 paragraph 2);
33) fails to submit to the Institute reports on serious, unexpected adverse reactions that are not fatal in terms of Article 107 paragraph 1 of this Law and are not life-threatening not later than 15 days from initial report, and then he fails to submit the following report as soon as additional information becomes available (Article 107 paragraph 3);
34) fails to inform all investigators of the adverse reactions referred to in Article 107 paragraph 1 and 3of this Law (Article 107 paragraph 4);
35) fails to submit to the Institute and to the Ethics Committee list of all suspected serious and unexpected adverse reactions to the medicinal product (SUSAR) in all the countries in which the same clinical trial is conducted, at least once in six months, or more often at the request of the Institute; (Article 108 paragraph 1 item 1);
36) fails to submit to the Institute and to the Ethics Committee Development Safety Update Report at least once a year, and the final safety report of the investigated medicinal product after the completion of the clinical trial (Article 108 paragraph 1 item 2);
37) uses animals and products of animals which underwent clinical trial for the food production (article 114 paragraph 1);
38) performs manufacture of medicinal products and does not comply with the manufacturing authorisation issued by the Institute, Good manufacturing practice and Good distribution practice (Article 117 paragraph 1);
39) does not have person responsible for the manufacture, who at all stages monitors manufacture preparation, manufacture and storage of medicinal products (Article 117 paragraph 2 item 1);
40) does not have at least one qualified person for the release of a medicinal product batch on the market who should be permanently available (Article 117 paragraph 2 item 2);

41) given the scope and complexity of manufacture, does not have appropriate personnel consisting of qualified persons in the field of pharmacy, chemistry, biology, biochemistry, biotechnology, chemical technology, medicine, dental medicine, veterinary medicine, or other corresponding professions; (Article 117 paragraph 2 item 3);
42) does have suitable premises, equipment for the manufacture, quality control, storage and distribution of medicinal products (Article 117 paragraph 2 item 4);
43) does not allow the representatives of the competent authority access to manufacturing site/contracted manufacturing sites and documentation at any time (Article 117 paragraph 2 item 5);
44) does not enable the qualified person for batch release of the medicinal product on the market to independently carry out his duties by placing at his disposal all the necessary resources(Article 117 paragraph 2 item 6);
45) fails to without delay inform in writing the Institute and the marketing authorisation holder if he obtains information that medicinal products which come under the scope of his manufacturing authorisation are, or suspected of being falsified (Article 117 paragraph 2 item 8);
46) fails to verify that manufacturers, importers, or distributors from whom he obtains active substances are approved by the competent authority of the state in which they are established (Article 117 paragraph 2 item 9);
47) fails to verify the authenticity and quality of the active substances and the excipients (Article 117 paragraph 2 item 10);
48) fails to dispose pharmaceutical waste in accordance with a special law (Article 117 paragraph 2 item 11);
49) does not keep detailed record on all delivered veterinary medicinal products, including samples, and make it available for inspection to competent authorities for at least 3-year period (Article 117 paragraph 2 item 12);
50) does not ensure that excipients are of adequate quality for the manufacture of medicinal products, by establishing and proving that the guidelines of Good manufacturing practice are applied in their production (Article 117 paragraph 3);
51) performs manufacture of medicinal products derived from blood, radiopharmaceuticals and biotechnological medicinal products but fails to meet specific requirements regarding premises, equipment and personnel (Article 117 paragraph 5);
52) does not have the seat in Montenegro and fails to submit the evidence of fulfillment of Good manufacturing practice requirements, by providing a certificate issued by the regulatory body of one of a member state of the EEA or EUMRA (Article 118 paragraphs 1 and 2);
53) the person referred to in Article 117 paragraph 2 item 2) of this Law has not completed the faculty of pharmacy and doesn't have practical experience in the manufacture or control of medicinal products for at least two years at manufacturer of medicinal products (Article 119 paragraph 1);
54) the person referred to in Article 117 paragraph 2 item 2) of this Law has not completed another faculty (medicine, veterinary medicine, chemistry, biology, etc.) depending on the type of medicinal products manufacture (Article 119 paragraph 2);
55) the person referred to in Article 117 paragraph 2, item 2) of this Law fails to submit proof of acquired knowledge in accordance with the standards in the countries of the European Union (Article 119 paragraph 3);
56) fails to ensure that the manufacture and control of each batch of the medicinal product is performed in accordance with the law and regulations passed for the implementation

of this Law, as well as in accordance with the requirements for obtaining marketing authorisation (Article 119 paragraph 4 item 1);

57) in the process of batch release of a medicinal products on the market fails to confirm in a register, or other relevant document designated for this purpose, that each batch is manufactured in accordance with this Law and regulations passed for the implementation of this Law (Article 119 paragraph 4 item 2);
58) for medicinal products coming from third countries, irrespective of whether the product has been manufactured in the EEA, fails to ensure that each manufactured batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all t active substances and all other tests or check-ups ensuring quality of medicinal products in accordance with the requirements of the marketing authorisation. (Article 119 paragraph 4 item 3);
59) for medicinal products intended to be placed on the market in the European Union, fails to ensure that the packaging is labelled in accordance with the requirements of Article 166 of this Law (Article 119 paragraph 4 item 4);
60) fails to update and make available to the pharmaceutical inspector for a period of five years register or other relevant document referred to in Article 110, paragraph 4, item 2) of this Law (Article 119 paragraph 7);
61) processes referred to in Article 120 paragraph 1 of this Law does not carry out in accordance with Good manufacturing practice for active substances (Article 120 paragraph 2);
62) does not meet the requirements of Good manufacturing practice for active substances (Article 120 paragraph 3);
63) performs manufacture, import and supply of active substances and is not enrolled in the Register of manufacturers, importers, or wholesalers of active substances (Article 122 paragraph 1);
64) in the case referred to in Article 122 paragraph 4 of this Law, prior to the conducted supervision, commence the activities referred to in Article 122 paragraph 1 of this Law (Article 122 paragraph 5);
65) once a year fails to notify the Institute on any changes in the documentation referred to in Article 122 paragraph 3 of this Law (Article 122 paragraph 8);
66) does not submit a request to the Institute for amending the decision on entry in the Register, if the changes can affect the quality or safety of active substance (Article 122 paragraph 9);
67) does not keep detailed records of all orders and deliveries of active substances that can be used for the manufacture of veterinary medicinal products and does not make it available to the competent authorities for a period of at least three years (Article 122 paragraph 12);
68) collects, processes or processes blood, its ingredients and derivatives as substances for the manufacture of medicinal products from blood but does not fulfill special conditions regarding premises, equipment and personnel, in accordance with a special law (Article 123 paragraph 1);
69) fails to inform the Institute on methods used to reduce or eliminate pathogenic viruses that may be transmitted to medicinal products derived from human blood, or human plasma (Article 123 paragraph 3);
70) fails to submit an application to the Institute for amending the manufacturing authorisation if the conditions from the manufacturing authorisation are changed (Article 127 paragraph 1);

71) fails to immediately inform the Institute on any major accidents or mistakes in the process of manufacture, as well as other situations for which one can doubt the quality, safety and efficacy of the medicinal product (Article 128 paragraph 1);
72) manufactures a medicinal product, i.e., active substance without asking the Institute's approval for monitoring of manufacturing site or the control of compliance with Good manufacturing practice announced from a third country (Article 128 paragraph 3);
73) does not keep detailed records of all relevant activities of the manufacturing process as defined in the manufacturing authorisation and in accordance with Good manufacturing practice (Article 129);
74) sells medicinal products from its program to legal persons to whom that is not allowed in accordance with Article 131 paragraph 1 of this Law;
75) imports or exports medicinal products from its manufacturing program, starting materials and starting substances for the manufacturing, intermediates and bulk products contrary to the manufacturing authorisation, marketing authorisation, i.e. contract on outsourced manufacture (Article 132 paragraph 1);
76) does not have a marketing authorisation for the medicinal product, and fails to submit a statement to the Institute stating the reason for which he has no authorisation for the medicinal product (Article 132 paragraph 3);
77) performs parallel import without notifying the Institute and the marketing authorisation holder not later than 15 days prior the parallel import (Article 135 paragraph 2);
78) prior the parallel import fails to notify the marketing authorisation holder and the EMA for any medicinal product which is authorised by EMA via centralised procedure (Article 135 paragraph 3);
79) does not have a plan for urgent recall of the medicinal product in line with the Institute's decision or in agreement with the manufacturer or the marketing authorisation holder and does not keep the documentation enabling such recall (Article 136 paragraph 6 item 1);
80) does not keep records of orders, deliveries and brokering in a written, electronic or any other form and make it accessible for inspection to competent authorities (Article 136 paragraph 6 item 2);
81) does not operate a quality assurance system which defines processes, responsibilities and risk management (Article 136 paragraph 6 item 3);
82) fails to immediately notify the Institute on any falsified medicinal product received or offered or any medicinal products suspected of being falsified (Article 136 paragraph 6 item 4);
83) does not act in accordance with Guidelines of Good distribution practice (Article 136 paragraph 6 item 5);
84) fails to enable inspection supervision at any time to the representatives of the competent body (Article 136 paragraph 7);
85) fails to notify the Institute that keeps records on the commencement of activities in the territory of Montenegro (Article 137 paragraph 1);
86) for the activity of wholesale does not meet the same conditions as a wholesaler that has an authorisation issued by the Institute, as well as the conditions prescribed by Article 144 of this Law (Article 137 paragraph 2);
87) fails to procure medicinal products directly from manufacturers, importers or other wholesalers who hold the relevant authorisation granted by the competent authority (Article 138 paragraph 1);
88) sale medicinal products from its program to legal persons to whom sale is not allowed in accordance with Article 138 paragraph 2 of this Law;

89) provides medicinal products from its program free of charge contrary to the manner and conditions prescribed by the Ministry (Article 138 paragraph 3);
90) exports medicinal products to third countries to legal persons for which it has not established that they have a marketing authorisation issued by the competent authority of the importing country (Article 138 paragraph 4);
91) receive medicinal products from third countries that are not intended to be placed on the market in the European Union, without ensuring that the medicinal products are procured from persons for whom they have established that they have a marketing authorisation issued by the competent authority of the exporting country (Article 138 paragraph 7);
92) fails to comply with Guidelines of Good distributing practice during the wholesale of medicinal products (Article 139 paragraph 1);
93) does not have qualified person for storage and distribution of medicinal products, as well as other relevant personnel (Article 139 paragraph 2 item 1 and 2);
94) does not have suitable premises and equipment so as to ensure proper storage of medicinal products, keeping record and storage of documentation on quality of medicinal products, as well as means for safe transport (Article 139 paragraph 2 item 3);
95) fails to enable at any moment to the Institute, i.e. pharmaceutical inspector to inspect fulfillment of conditions and the documentation (Article 139 paragraph 2 item 4);
96) does not have a plan for urgent recall of the medicinal product in line with the decision of the Institute, competent authority for inspection affairs or competent authority for veterinary affairs or in agreement with the manufacturer or the marketing authorisation holder and fails to keep documents enabling such recall (Article 139 paragraph 2 item 5);
97) does not keep records of orders, deliveries and mediation in written, electronic or other form and makes it available to the pharmaceutical inspector for inspection for a period of at least 5 years and which contains the following information: date, name of the medicinal product, quantity of received, delivered or brokered medicine, name and address of the supplier, batch number of a medicinal product for human medicines (Article 139 paragraph 2 item 6);
98) does not keep records of orders and deliveries in written, electronic or other form, which contains the following data: date, name of the medicinal product, quantity of the received or delivered medicinal product, name and address of the supplier, batch number, expiry period for veterinary medicinal products, information on orders and deliveries in relation to stock status and recorded deviations (Article 139 paragraph 2 item 7);
99) does not have established quality assurance system that defines processes, responsibilities and risk management for wholesale of medicinal products for human use (Article 139 paragraph 2 item 8);
100) fails to check received medicinal products for being falsified using thereby the security features on the packaging, in accordance with Article 165 paragraph 2 of this Law (Article 139 paragraph 2 item 9);
101) does not deliver to legal entities referred to in Article 139 paragraph 2 of this Law documentation with data referred to in Article 139 paragraph 2 items 6 and 7 of this Law for each delivery of medicinal products (Article 139 paragraph 2 item 10);
102) fails to immediately notify the Institute and marketing authorisation holder of any falsified medicinal product offered or received or any medicinal products suspected of being falsified (Article 139 paragraph 3);

103) person responsible for storage and distribution of medicinal products is not graduated in pharmacy or for the wholesale of veterinary medicinal products in veterinary medicine in pharmacy (Article 139 paragraph 4);
104) fails to conclude a full-time employment contract with persons referred to in Article 139 paragraph 2 item 1 of this Law (Article 139 paragraph 5);
105) does not ensure permanent availability of persons referred to in Article 139 paragraph 2 of this Law (Article 139 paragraph 6);
106) does not have a copy of the certificate on the performed control of every batch of medicinal product that is distributed (Article 139 paragraph 7);
107) fails to submit to the Institute, i.e. competent authority for veterinary affairs the application for approval of any amendment to wholesale authorisation (Article 143);
108) fails to provide a continuous supply of medicinal products in accordance with the wholesale authorisation and marketing authorisation (Article 144 paragraph 1);
109) at the request of health care institution, i.e. veterinary institution fails to deliver the medicinal product for which he obtained the wholesale authorisation, in the shortest term in which human health, i.e. the health of animals is not endangered (Article 144 paragraph 2);
110) in order to provide continuous supply fails to provide necessary supplies of medicinal products, i.e., does not timely begin the procurement, import and certificate of the performed quality control in order to avoid an interruption in the supply of market with the medicinal products (Article 144 paragraph 3);
111) at the request of the Ministry, i.e. the state competent authority responsible for veterinary affairs within the requested term, fails to deliver other medicinal product that is authorised for marketing in Montenegro, as well as the medicinal products specified in Article 5 of this Law (Article 144 paragraph 4);
112) does not conclude the contract on wholesale of medicinal products with all legal persons that perform the wholesale of medicinal products and at the request of the Institute, i.e. the competent authority for veterinary affairs does not submit the list of those legal persons (Article 144 paragraph 5);
113) fails to promptly inform the Institute, i.e. the competent authority for veterinary affairs of any major accident or incident which could affect the quality and safe handling of medicinal products (Article 145 paragraph 1);
114) in any way get in the possession of medicinal product (transporter, postal operator, the holder of customs warehouse, etc.) and fails to act in accordance with the instruction provided on the package of the medicinal product for transport (Article 147 paragraph 1);
115) fails to keep records on the type and quantity of imported and exported, as well as sold, i.e. dispensed medicinal products for which the marketing authorisation, or import authorisation was issued in accordance with Article 5 of this Law (Article 149 paragraph 1);
116) without confirmation from the Institute imports the samples of medicinal products, substances or other materials that are required in the procedure of obtaining the marketing authorisation (Article 151 paragraph 1);
117) fails to destroy 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, medicinal products with an expired shelf-life or an inaccuracy in terms of its prescribed quality and other medicinal products prohibited for marketing or recalled from the market (Article 153);
118) fails to submit valid certificates of quality control for each batch of imported medicinal product and/or active substances and excipients and intermediaries in

accordance with the requests referred to in Article 46 paragraph 1 item 9) of this Law, upon request of the Institute, (Article 160, paragraph 1);

119) fails to provide the inspection with necessary number of samples for quality control of medicinal products referred to in Article 156 of this Law (Article 160, paragraph 1);

120) fails to immediately inform the Institute in writing about the defect in the quality of medicinal product that he found out about (Article 161 paragraph 3);

121) in case of suspicion that a medicinal product is falsified, the person referred to in Article 161 paragraph 3 of this Law fails to immediately inform the Institute, the competent authority for inspection affairs, i.e. the competent authority for veterinary affairs and the holder of the medicinal product marketing authorisation (Article 161 paragraph 4);

122) instruction for use of medicinal product submitted in the package of medicinal product does not comply with the approved summary of the medicinal product authorized by the Institute (Article 164 paragraph 1);

123) a medicinal product dispensed with prescription, other than radiopharmaceuticals, does not have a safety feature on the packaging that allows persons who carry out wholesale and retail of medicinal products to check the authenticity of the medicinal product, identify each individual packaging, as well as a safety accessory that allows checking whether the outer packaging has been changed (Article 165 paragraph 2);

124) fails to establish a system of pharmacovigilance in order to implement obligations related to pharmacovigilance, in accordance with the law (Article 171 paragraph 1);

125) through the pharmacovigilance system fails to evaluate all data regarding the safety of the medicinal product, does not consider possibilities for reduction and prevention of risks and does not take appropriate actions in accordance with this Law (Article 171 paragraph 1 item 2);

126) fails to conduct a regular control of the pharmacovigilance system and does not record data on the main findings of the verification in the local system and PSMF and based on them fails to enable preparation and implementation of appropriate corrective actions (Article 172 paragraph 1 item 3);

127) does not ensure the continuous availability of the person responsible for pharmacovigilance in Montenegro (Article 172 paragraph 1 item 1);

128) fails to update the PSMF and does not submit it to the Institute upon request (Article 172 paragraph 1 item 2);

129) fails to follow the outcome of risk minimization measures contained in the RMP or which are designated as a condition in accordance with Article 64 of the Law (Article 172 paragraph 1 item 4);

130) fails to update the RMS and does not monitor pharmacovigilance data in order to identify new risks , change existing risks or change in relation to the risks and benefits of the use of medicinal products (Article 172 paragraph 1 item 5);

131) does not keep a record of any suspected adverse reactions the medicinal product that have been reported in Montenegro, reported spontaneously by a patient or healthcare professional or recorded during the examination of the medicinal product after obtaining marketing authorisation (Article 174 paragraph 1 item 1);

132) does not monitor and collect each information that may influence the assessment of the risk-benefit ratio of the medicinal product and does not submit it to the Institute without delay, as soon as possible (Article 174 paragraph 1 item 2);

133) fails to send to the Institute within 15 days from the date of receipt of any notification of a suspected adverse reaction to a medicinal product that has been found on the territory of Montenegro (Article 174 paragraph 1 item 3);

134) fails to notify the Institute of the suspected adverse reaction to a medicinal product that has been shown on the territory of Montenegro, which is not of a serious nature, within 90 days from the date of receipt of such notification (Article 174 paragraph 1 item 4);
135) fails to establish a procedure for obtaining accurate and verifiable data for the scientific assessment of suspected adverse reactions to medicinal products referred to in Article 74 paragraphs 3 and 4 of this Law, as well as fails to collect additional information on the case (Article 174 paragraph 1 item 5);
136) at the request of the Institute, fails to submit reported cases of suspected serious and unexpected adverse reactions to medicinal products that are found in the territory of the European Union or a third country, within 15 days from the date of receipt of the report (Article 174 paragraph 1 item 6);
137) does not cooperate with the Institute in detecting duplicate reports of suspected adverse reactions (Article 174 paragraph 1 item 7);
138) fails to electronically report to the EudraVigilance database any suspected adverse reactions that have occurred in Montenegro, within 90 days from the date of receipt of the report (Article 175 paragraph 1 item 1);
139) fails to electronically report to the EudraVigilance database any suspected serious adverse reactions that have occurred in Montenegro, within 15 days from the date of receipt of the report (Article 175 paragraph 1 item 2);
140) fails to electronically report to the EudraVigilance database any suspected adverse reaction that have occurred in the Member States of the European Union within 90 days of receipt of the report (Article 175 paragraph 1 item 3);
141) fails to electronically report to the EudraVigilance database any suspected serious adverse reactions occurring in the Member States of the European Union within 15 days of receipt of the report (Article 175 paragraph 1 item 4);
142) fails to electronically report to the EudraVigilance database any suspected serious adverse reactions occurring in third countries, within 15 days of receipt of the report (Article 175 paragraph 1 item 5);
143) fails to establish a procedure for obtaining accurate and verifiable data for the scientific evaluation of reports of suspected adverse reactions to medicines referred to in Article 175 paragraph 1 of this Law, as well as to collect additional case information and not submit them to the EudraVigilance database (Article 175 paragraph 2);
144) does not cooperate with the Institute and the EMA in detecting duplicate reports of suspected adverse reactions (Article 175 paragraph 3);
145) forward to the expert and general public information on pharmacovigilance, which affect the use of the medicinal product, without prior notification to the Institute (Article 176 paragraph 1);
146) does not ensure that all information provided on the pharmacovigilance of a particular medicinal product is displayed objectively and does not mislead the expert and general public (Article 176 paragraph 2);
147) fails to submit to the EMA and the European Commission information's referred to in Article 176 paragraph 1 of this Law before submitting to the public (Article 162 paragraph 3);
148) fails to report to the Institute suspected serious adverse reactions, within 30 days from the day of detection, and, if necessary, with a subsequent the additional information (Article 179 paragraph 1 item 2);
149) fails to report to the Institute suspected adverse reactions that resulted in the death of a person, without delay, in writing or by telephone with a subsequent written notification (Article 179 paragraph 1 item 3);

150) fails to submit PSUR to the Institute for marketing authorisations issued for generic, bibliographic applications, entering into the register of traditional herbal and homeopathic medicinal products, upon the Institute's request, based on obligations referred to in Articles 64 and 66 of this Law (Article 181 paragraph 2 item 1);
151) for medicinal product marketing authorisations issued for generic, bibliographic applications, entry in the register of traditional herbal and homeopathic medicinal products, does not submit to the Institute PSUR based on the Institute's request regarding pharmacovigilance data or due to non-existence of PSUR for a certain active substance (Article 181 paragraph 2 item 2);
152) fails to submit the PSUR in accordance with Article 182 paragraph 3 of this Law;
153) commences PASS prior to obtaining the approval of the Institute (Article 186 paragraph 3);
154) PASS is implemented by promoting the use of the medicinal product (Article 186 paragraph 5);
155) does not monitor collected data and does not assess their impact on the benefit and risk of the tested medicinal product during the implementation of PASS (Article 186 paragraph 7);
156) fails to notify the Institute of any new information that may affect the risk-benefit ratio from the use of the medicinal product, as well as to take appropriate actions (Article 186 paragraph 8);
157) fails to submit to the Institute approval all significant amendments to the PASS protocol, prior to their implementation (Article 186 paragraph 9);
158) fails to submit to the Institute the final report and a summary of the PASS results referred in Article 186 paragraph 10 of this Law within 12 months from completion of data collecting (Article 186 paragraph 11);
159) for PASS that will be implemented in other EU Member States in addition to Montenegro, fails to submit to the PRAC the PASS protocol which will be implemented in accordance with the conditions or obligations of the marketing authorisation (Article 187 paragraph 1);
160) tests referred to in Article 187 paragraph 1 of this Law are initiated in Montenegro without the written approval of the PRAC(Article 187 paragraph 2);
161) any significant amendments to the PASS protocols, which are approved by the PRAC, are not submitted to the Institute before their implementation (Article 187 paragraph 3);
162) upon completion of the trial, within 12 months from the completion of the trial, fails to provide the PRAC final report and a summary of the results of the trial, unless the PRAC in writing authorizes extension of the deadline or exclusion from the obligation to submit the final report (Article 187 paragraph 4);
163) results of the trial referred to in Article 187 paragraph 1 of this Law affect marketing authorisation and fails to submit to the Institute an application for approval of the variation (Article 187 paragraph 5);
164) fails to inform the Institute about the suspected serious and/or unexpected adverse reaction of veterinary medicinal product in animals, i.e. adverse reactions in humans immediately after finding about them (Article 188 paragraph 1);
165) fails to report to the holder of veterinary medicinal product marketing authorisation any suspected adverse reaction to a veterinary medicinal product, especially serious and unexpected adverse reactions (Article 188 paragraph 2);
166) does not ensure continuous availability of the person responsible for pharmacovigilance (Article 189 paragraph 1);

167) fails to establish and maintain a system that enables collecting and merging information on all suspected adverse reactions reported to the marketing authorisation holder (Article 189 paragraph 2 item 1);
168) fails to provide complete and timely delivery of additional information necessary for assessing the benefits and risks of the use of the veterinary medicinal product at the request of the Institute, including the submission of data on the scope of the sale or prescription of that veterinary medicinal product (Article 189 paragraph 2 item 3);
169) fails to provide the Institute other information of importance for assessing the benefits and risks of the use of a veterinary medicinal product, including a post-marketing veterinary medicine monitoring study (Article 189 paragraph 2 item 4);
170) fails to keep a detailed record of any suspected adverse reaction and, except in exceptional circumstances, does not report them electronically in the form of a report, in accordance with the guidelines referred to in Article 167 paragraph 4 (Article 190 paragraph 1 item 1);
171) fails to keep a detailed record of any notification of a suspected serious adverse reaction to a veterinary medicinal product and adverse reactions in humans for which he learned from a veterinarian or healthcare professional, animal keeper or from other sources for which it can reasonably be assumed that they are known to him and without delay, report to the Institute no later than 15 days after receipt of the information (Article 190 paragraph 1 item 2);
172) fails to report any suspected serious unexpected adverse reaction to a veterinary medicinal product and adverse reaction in humans, as well as any suspicion of the transmission of any infectious agent through a veterinary medicinal product in the territory of a third country without delay, and within 15 days of receipt of the information in accordance with the guidelines referred to in Article 167 paragraph 4 of this Law, in order to be available to the EMA and to the competent authorities of the Member States in which the veterinary medicinal product is authorised (Article 190 paragraph 1 item 3);
173) fails to submit PSUR to the Institute for veterinary medicinal product immediately upon request of the Institute or at least every six months after obtaining the authorisation for the medicinal product until placing on the market, unless other requirements have been established as a condition for granting marketing authorisation (Article 190 paragraph 2);
174) after placing the veterinary medicinal product on the market, fails to submit PSUR right upon the request of the Institute or at least every six months during the first two years from the date of placing the medicinal product on the market, and then once a year during the next two years (Article 190 paragraph 3);
175) after the deadline referred to in Article 190 paragraph 3 of this Law, fails to submit PSUR to the Institute at three-year intervals or immediately after receiving the Institute's request (Article 190 paragraph 4);
176) PSUR does not contain a professional assessment of the risk-benefit ratio for a particular veterinary medicinal product (Article 190 paragraph 5).

For the misdemeanour referred to in paragraph 1 of this Article the responsible person in the legal person shall be liable to a fine of 250 euros to 2000 euros.

For the misdemeanour referred to in paragraph 1 item 26, 27, 53, 54, 55, 56, 111, 119, 147, 148, 149, 163 i 164 of this Article the natural person in the legal person shall be liable to a fine of 500 euros to 2000 euros.

In addition to the fine for misdemeanour referred to in paragraph 1 of this Article, security measure of prohibition of performing the activity for a period of six months may be imposed.

Article 213

A fine of 500 euros to 20000 euros shall be imposed for misdemeanour on a legal person if:

1) fails to take all necessary measures when the transfer of a medicinal product marketing authorisation has not been carried out in order to withdraw that medicinal product from the market, within 30 days from the date of cessation of the status of the marketing authorisation holder (Article 82 paragraph 2);
2) fails to notify the Institute on the course of conducting the clinical trial, as a rule, quarterly, until the accession EudraCT database of the European Union (Article 102 paragraph 1);
3) fails to notify the Institute of termination of the clinical trial before the time specified in the plan of clinical trial or temporarily suspension, within 15 days from the date of termination of the clinical trial and does not state detail explanation of the cause of clinical trial termination (Article 102 paragraph 2);
4) fails to notify the Institute of completion of the clinical trial according to a clinical trial plan, within 90 days from the date of completion of the clinical trial of the medicinal product (Article 102 paragraph 3);
5) fails to submit the report on the completed clinical trial to the Institute, within one year from the completion of the clinical trial (Article 102 paragraph 4);
6) does not allow the representatives of the competent authority access at any time to the manufacturing site and contracted manufacturing site and documentation; (Article 117 paragraph 2 item 5);
7) provides medicinal products from its program free of charge, contrary to the manner and conditions prescribed by the Ministry (article 131 paragraph 2);
8) fails to regularly submit the report to the Institute on the total value of the performed sale of medicinal products, as well as the quantity of sale for all individual medicinal products (in packages) in Montenegro (Article 131 paragraph 3);
9) fails to conclude a full-time employment contract with persons referred to in Article 130 paragraph 2 item 1 of this Law (Article 139 paragraph 5);
10) fails to regularly, at least annually, report to the Institute on total value of performed sale of all medicinal products, as well as the quantity of sale for individual medicinal products (in packages) in Montenegro, in accordance with the authorisation (Article 150 paragraph 1);
11) advertises to expert public medicinal product subject to medical prescription contrary to the terms of the marketing authorisation and approved summary of the product characteristics of the medicinal product (Article 198, paragraph 1);
12) advertises medicinal product referred to in Article 199, paragraph 1 of this Law by directly addressing children, who are intended for their treatment (Article 199 paragraph 5)
13) attributes medicinal properties to non-medicinal products within the meaning of this law (Article 199 paragraph 6);
14) advertise the general public medicinal product subject to medical prescription as well as medicinal products containing drugs (Article 201 paragraph 1)
15) advertises medicinal products which do not have marketing authorisation and whose authorisation has expired (Article 201 paragraph 2)

For the misdemeanour referred to in paragraph 1 of this Article the responsible person in the legal person shall be liable to a fine of 250 euros to 2000 euros.

XIV TRANSITIONAL AND FINAL PROVISIONS

Article 214

Regulations for the implementation of this Law shall be adopted within 2 years from the date of entry into force of this Law.

Until the adoption of regulations referred to in paragraph 1 of this Article, regulations adopted for implementing this Law that were in force until the day of entry into force of this Law, and which are not inconsistent with this Law, shall be applied.

Article 215

The Agency for Medicines and Medical Devices, established in accordance with the Law on Medicines („Official Gazette of Montenegro“ No 56/11 and 06/13) shall continue to operate under the name the Institute for medicines and medical devices, with the rights and obligations established by this Law.

On the day this Law enters into force, the Institute shall take over the employees, business premises, funds, equipment, rights and obligations of the Agency for medicines and medical devices.

The Institute shall comply its business operations with this Law and regulations adopted for the implementation of this Law within 2 years from the date of entry of this Law into force.

Article 216

Adoption of the statute of the Institute and entry in the Central register of business entities shall be made within 90 days from the date of entry into force of this Law.

The act on the internal organization and systematization of the Institute's workplaces shall be adopted within 90 days from the day this Law enters into force.

Article 217

The assignment of employees in the Institute in accordance with the act referred to in Article 216 paragraph 2 of this Law shall be made within 30 days from the day of enactment of the act on internal organization and systematization of jobs.

Until the adoption of the act referred to in paragraph 1 of this Article, the employees of the Institute shall perform the duties of the position to which they have been assigned.

Article 218

The Steering Board will be appointed within 90 days from the day this Law enters into force.

Until the appointment of the Steering Board referred to in paragraph 1 of this Article, the Steering Board of the Agency for Medicinal Products and Medical Devices appointed in accordance with the Law on Medicinal Products ("Official Gazette of Montenegro", No. 56/11 and 6/13) shall continue to operate, with the competencies determined by this Law.

Article 219

Until the appointment of the general manager of the Institute, the existing general manager of the Agency for Medicines and Medical Devices will be responsible for managing the work of the Institute.

Article 220

Expert-scientific Board shall be appointed within 90 days from the date of appointment of the Steering Board.

Article 221

Legal person manufacturing and performing wholesale and retail of medicinal products are obliged to adjust the business and activities with this Law and the regulations adopted for implementation of this Law within 2 years from the day of entry into force of this Law.

Article 222

Authorisations issued pursuant to the regulations that were in force at the time when they were issued shall remain in force until the expiry of their original term.

Article 223

Procedures initiated by applications until the day of entry into force of this Law shall be completed in accordance with regulations that were in force at the time the application is submitted.

Article 224

Provisions of Article 3 paragraph 4, Article 36 paragraphs 2 and 4, Article 44 paragraph 3, Article 47 paragraph 3, Article 48 paragraph 8, Article 57 paragraphs 5 and 6, Article 58 paragraph 3, Article 61 paragraph 5, Article 63, Article 66 paragraphs 9 and 10, Article 80 paragraph 3, Article 83 paragraph 4, Article 84, Article 94 paragraph 2, Article 98, Article 106 paragraph 3, Article 112 paragraph 5, Article 113 paragraphs 2, 3, and 4, Article 119 paragraph 5, Article 121 paragraph 4, Article 122 paragraph 11, Article 130 paragraphs 4 and 5, Article 134, 135, 136, 137, Article 138, paragraphs 4, 5, 6 and 7, Article 139, paragraph 2, item 9, Article 142, paragraph 6, Article 154, Article 157, paragraphs 1 to 6, Article 161, paragraph 7, Article 165 paragraphs 2, 3 and 4, Article 166, Article 168 paragraph 1 item 12), Article 169, 170, 175, Article 176, paragraphs 3, 4, 5 and 6, Article 184, Article 185, paragraph 1, item 4) and 5) and paragraph 3, Article 187, Article 190 paragraph 1 item 3), Article 191 paragraphs 2 and 3, Article 192 paragraph 2 shall be implemented as of the day of accession of Montenegro to the European Union.

Article 225

The provision of the Article 133 paragraph 3 shall cease to be valid at the date of accession of Montenegro to the European Union.

Article 226

On the day this Law enters into force, the Law on Medicinal Products ("Official Gazette of Montenegro", No. 56/11 and 6/13) and the provisions of Article 9 paragraph 1 item 8) in the part relating to the taking of samples of finished medicinal products on the market in in quantities necessary for quality control; item 9) in the part related to the control of manufacture and placing on the market of medicinal products for human use, in accordance with the Law on medicinal products; Article 10 paragraph 1 item 7) in the part related to the prohibition of wholesale of medicinal products, if they do not meet the prescribed conditions for placing the medicinal product on the market, item 8) in the part relating to the prohibition of wholesale of medicinal products not meeting the prescribed quality requirements medicinal products, item 9) in the part relating to the suspension or order of withdrawal from wholesale of the finished medicinal product or its batch in cases prescribed by law, item 10) in the part relating to the order of destruction of a defective medicinal product or expired medicinal product found in wholesale of the Law on Health inspection ("Official Gazette of Montenegro", No. 30/17).

Article 227

This Law shall enter into force eight days from the day of its publication in "Official Gazette of Montenegro".