LAW ON MEDICINES

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I. GENERAL PROVISIONS

Article 1

This law shall regulate the conditions for the manufacturing, distribution and testing of medicines for human usage and veterinary usage, measures for provoding quality, safety and efficacy of medicines, competence of bodies in the field of medicines, as well as other relevant issues for performing this activity.

Article 2

Manufacturing and distribution of medicines is an activity of public interest.
Manufacturing, distribution, testing and control of medicines can be performed by legal entities that meet the requirements regulated by this Law and the regulations adopted for implementing of this Law.
In Montenegro, in distribution can only be the medicine that has a marketing authorization (hereinafter: the authorization for the medicine).

Article 3

It is prohibited the manufacturing, i.e. distribution of medicines:
1) for which it is not issued the autorization for the medicines or the approval for the procurement or import of the medicine;
2) which was manufactured by the legal entity that does not have the authorization for manufacturing;
3) which are not labeled in accordance with the provisions of this Law;
4) whose validity date expired labeled on the package or the inaccuracy is determined in terms of their specified quality;
5) which are falsified;
6) which are intended for the treatment of animals used for human consumption and which are made of substances that cannot be used for the manufacturing of medicines for usage in veterinary (hereinafter: veterinary medicine).
It is prohibited dispensing and selling of medicines outside pharmacies, contrary to the mode of dispensing of medicine.
Notwithstanding paragraph 2 of this Article, a doctor of veterinary medicine, or a veterinarian (hereinafter: veterinarian) who performes veterinary activity may dispense a medicine necessary for treating animals under his care, in accordance with the Law.
The list of medicines and substances referred to in paragraph 1, item 6 of this Article is brought by the state authority bodie responsible for veterinary care.

Article 4

The certain terms used in this Law shall have the following meanings:
1) **medicine** is a medicine which is industrially manufactured or by procedure involving an industrial process with the intention of placing on the market;
2) **marketing authorizaton holder** is a manufacturer seated in Montenegro, agent or representative for the manufacturer that is not seated in Montenegro, the representative of a foreign legal person that is the marketing authorizaton holder in the European Union countries and that is seated in Montenegro, as well as legal entity that is seated in Montenegro to whom the manufacturer that is seated in Montenegro transferred the autorization for the medicine, i.e. to whom he gave the right to acquire the status of the markting authorization holder from its manufacturing program;
3) **name of the medicine** is the name that can be either new, generic or scientific name. With generic, or scientific name shall be added a trademark or the name of the manufacturer or the marketing authorization holder, and if it is new name it must be different from generic and shall not be liable to confusion;

4) **international non-proprietary name (generic name) of the medicine** is an international non-proprietary name (INN) recommended by the World Health Organization or, if one does not exist, the usual common name;
5) **formal assessment of the documentation** is a procedure of determining whether the documents submitted to obtain the relevant authorizations, contain all the required parts in accordance with this Law and regulations adopted to implement this Law;
6) **reference medicine** is a medicine that obtained authorization for the medicine in Montenegro or in European Union or in countries that have the same requirements for issuing the authorization for the medicine based on the complete documentation on the quality, safety and efficacy according to valid requirements;
7) medicine with well-known usage of active substance is a medicine whose active substance or active substances have a well-known medical usage, with proven efficacy and acceptable safety, which are used at least ten years as a medicine in Montenegro or European Union and for which there is published harmoized vocationally recognized literature, that contains all the necessary data from required pharmaco-toxicological or clinical documentation for obtaining authorization for the medicine, by which is proven safety and efficiency of the medicine (bibliographic application);
8) medicine that contains a fixed combination of active substances is a medicine whose fixed combination of active substances is not used before issuing of the authorization for the medicine as a medicine for therapeutic purposes, and each of its individual active substance enters into the composition of medicine which has the authorization for the medicine in Montenegro or in European Union countries;
9) medicine with information of consent is a medicine with the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form which in the process of obtaining the authorization of medicine is used the documentation on quality, safety and efficacy of the medicine, which has the authorization for the medicine in Montenegro, with written consent of the marketing authorization holder;
10) generic medicine is a medicine that has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as a reference medicine and whose bioequivalence with the reference medicine is proven with appropriate bioavailability studies. The same active substance are considered different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the active substance, unless there are significant differences in their atributes in terms of therapeutic safety and / or efficiency. The same pharmaceutical form are considered different oral forms with immediate release;
11) generic medicine with mixed data in documentation on safety and efficacy (hereinafter: generic hybrid medicine) is a medicine that does not exactly match the definition of a generic medicine, i.e. for which it is not possible to prove the biological equivalence by the bioavailability studies testing or in the case of the change of the one or more active substances, therapeutic indications, strength, pharmacetutical form or dosage according to reference medicine;
12) biosimilar medicine is a medicine of biological origin, similar to the reference medicine of biological origin that does not meet the requirements for a generic medicine in relation to differences in raw materials and differences in the process of manufacturing of that biosimilar medicine in relation to the reference biologic medicine;
13) medicines that contain drugs and other psychotropic substances are medicines of specific qualitative and quantitative composition in certain pharmaceutical form which are used in medical, veterinary, educational, laboratory and scientific purposes;
14) centralized procedure is a procedure of obtaining an authorization for the medicine by the European Medicines Agency;
15) decentralized procedure is a procedure for obtaining an authorization for the medicine that starts at the same time in the reference and in other, in the procedure involved, in countries members of the European Union;
16) mutual recognition procedure is a procedure for obtaining an authorizaton for the medicine which after approval in referent country member of European Union, is approved in other countries involved in the proceedings of the European Union;
17) quality assurance represents a 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 medicine - in the

manufacturing process (at the beginning and during the process), on the finished product (batches) and on samples taken from the market (control after placing on the market);
18) Good Manufacturing Practice represents the part of the quality assurance system by which is provided that medicines are consistently manufactured and controlled according to quality standards appropriate for their purpose;
19) Good Control Laboratory Practice is a part of Good manufacturing practice which ensures quality in the process of medicines quality control;
20) guidelines for Good Manufacturing Practice are guidelines for the system of quality assurance related to the organization of medicine manufacturing, quality control of medicines and carrying out of supervision. Guidelines for Good manufacturing practice for active substances are the part of the guidelines of Good manufacturing practices;
21) Good Distribution Practice is a quality assurance system that relates to organizing, carrying out and supervision of the distribution of medicines, from manufacturer to end user;
22) Good Pharmacy Practice involves a quality assurance system, which refers to the organization, implementation, supervision and quality control in the pharmaceutical sector, providing quality services which the patient receives at the pharmacy;
23) Good Clinical Practice represents a set of internationally recognized ethical and scientific requirements and quality assurance system in planning, conducting, recording and reporting of clinical trials, in order to obtain valid clinical conclusions with adequate protection of participants in clinical trials;
24) Good Laboratory Practice is a quality assurance system related to the organization and conditions for conducting pre-clinical testings related to the safety of the people and the environment, their control, the manner of reporting and documentation;
25) pharmacopoeia is a collection of prescribed norms and standards for the substances and manufacturing of medicines by which is determined their identification, characteristics, quality, method of preparation and analysis;
26) pharmaceutical form is a form of the medicine suitable for the application (tablets, capsules, ointments, solution for injection, premix etc.)
27) inner package is the package by which the medicine is in direct contact;
28) outer package is the package containing internal packing of the medicine;
29) essentially similar medicines are medicines 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 medicine that is used for comparison until it is scientifically proven significant difference in terms of safety and efficacy of the medicine;
30) adverse effect of a medicine is harmful and unintendedly caused effect of the medicine;
31) adverse event is unwanted experience created in the period of medicine administration for which the cause - effect relationship with medicine use does not have to be proven and represents any unwanted and unintended sign (eg. an abnormal laboratory finding), symptom or disease, the timely associated with medicine application;
32) unexpected adverse reaction of medicine is any harmful side effect of the medicine that is not listed in the approved summary of basic characteristics of the medicine;
33) serious adverse effect of medicine is any adverse effect that can cause death, is life-threatening, hospitalization or prolongation of hospitalization if for that there was no need before the usage of medicine, persistent or significant impairment or disability, congenital anomalies or distortions during nursing and other medically significant condition;
34) pharmacovigilance is a set of activities related to the collection, detection, assessment, understanding, preventing and responding to the adverse effects of medicines as well as other problems related to their usage;
35) pharmacological and toxicological (pre-clinical) medicine testings is a testing which determines pharmacodynamic, pharmacokinetic and toxicological properties of the medicine;
36) clinical trial researcher is a medical doctor, dentist or veterinarian who is directly involved and responsible for the care of a patient, or a person or animal subjected to testing and for their treatment and is responsible for carrying out the clinical trials;
37) clinical trial (sponsor) is a natural or legal entity that takes responsibility for initiating, carrying out and / or funding of clinical trials;

38) multicenter clinical trial is a trial which is conducted by unique protocol in several health and veterinary institutions, so that it is carried by more than one clinical trial researchers, regardless of whether the clinical trial sites are in the same or in different countries;
39) informed consent is a written statement of the subject by which he voluntarily confirms his willingness to participate in a certain clinical trial after being fully informed of the purpose, nature, importance, process and risks to health, in language understandable to the person subjected to trial and in written form, signed by the subject and dated;
40) non-interventional clinical trial of the medicine is a trial in which the medicine is applied in accordance with the conditions specified in the authorization for the medicine and where the selection of patients is not pre-determined by clinical trial protocol but falls within current practice of the usual methods of treatment, provided that the prescribing of the medicine is clearly separated from the decision to involve the patient in the trial. Additional diagnostic procedures or follow-up procedures of the patients are not applied, and acquired results are analyzed using epidemiological methods;
41) medicine that is clinically tested is of pharmaceutically form of active substance or placebo which is tested in clinical trial or is used as a medicine for comparison in clinical trials, and includes medicines that have authorization for the medicine, but are used in a different way of approved or differ in the formulation or packaging, or used with unapproved indications or for getting additional data on the pharmaceutical form of the medicine that has a authorization for the medicine;
42) clinical trial protocol is a document which describes the objectives, plan, design, methodology, statistical overview and organization of clinical trials. Clinical trial protocol includes all versions of the basic protocol as well as its amendments;
43) expert public are: health workers and veterinarians, pharmacists and other professionals involved in the manufacturing and wholesale distribution of medicines, as well as in organization of compulsory health insurance;
44) waiting period is a period of time that must elapse since the last giving of a medicine to the animals, under normal conditions, and by the time when treated animal and its products can be used for food, in order to protect human health and to ensure that food produced does not contain residues in quantities exceeding the maximum allowable concentrations;
45) maximum residue level is the maximum allowed concentration of medicine existing in traces in food obtained from treated animals;
46) summary of the characteristics of the medicine is a document that contains basic information about the medicine, based on the proposal of the manufacturer, and is intended for the expert public:
47) instruction for the medicine is document that is attached to the medicine and contains basic information about the medicine and how the medicine is used properly and must be written in clear and understandable language;
48) active substance is any substance or combination of substances used in manufacturing of the medicine and that becomes an active ingredient of the manufactured medicine, and its purpose is to influence on pharmacological activity, or that otherwise directly influences in diagnosis, healing, mitigation, care , prevention of disease or to affect on the structure or function of the organism;
49) additional substance (excipient) is a substance used in manufacturing the medicine and it is not its active ingredient but helps in pharmaceutical shaping of the medicine, protects, promotes and improves stability, bioavailability and tolerability of the medicine and helps in identifying of the medicine;
50) starting substance i.e. raw materials for pharmaceutical use is any substance (active and auxiliary) used in the manufacturing of the medicine or for the making of galenic medicine;
51) quality of medicine is a characteristic of the medicine, which can be determined by examining the quality of all ingredients and represents acceptable physical, chemical, biological, pharmaceutical, technological and other characteristics of the medicine, in accordance with the applications for the authorization for the medicine;
52) safety of the medicine is an acceptable ration between medicine efficiency and adverse effects;
53) efficiency of the medicine is ability of the medicine proven by clinical trials conducted in accordance with this Law;
54) risk associated with the application of the medicine is any risk for the health of the patient or for the population associated with the quality, safety or effectiveness of the medicine, as well as any risk of adverse effects on the environment;
55) ratio of risk and benefit is an assessment of the positive therapeutic effects of the medicine due to risk from the item 54 of this Article;

56) Certificate for the needs for export of medicine is a document issued by competent agencies of the country of the manufacturer issued in accordance with the recommendations of the World Health Organization;
57) bioavailability is the speed and extent of availability of the active substance from the medicine, determined from the relationship between concentration-time in the systemic circulation or excreta;
58) bioequivalence assumes that two medicines that are pharmaceutical equivalents or pharmaceutical alternatives, have a similar bioavailability after application of the same molar dose to such an extent that can be expected the same effect, including efficacy and safety of the application;
59) pharmaceutical equivalents are finished medicines containing the same active substance in the same amount and in the same pharmaceutical form of the same application by answering to the same or comparable standards;
60) pharmaceutical alternatives are medicines containing the same active substance, but in the form of another salt, ester or alike or any other pharmaceutical form or in diferent strength;
61) sample of the medicine is the quantity of the medicine necessary for pharmaceutical testing;
62) falsified medicine is a medicine that is in the purpose of fraud incorrectly marked regarding to identity and / or origin, may contain the right or wrong ingredients in relation to the declared composition, to be without active substances or contain incorrect amounts of active substances and be in the wrong or forged package. Falsified can be original or generic medicine;
63) original medicine is a medicine that was the first to get the authorization for the medicine in the world based on the complete documentation on the quality, safety and efficacy of the applicable requirements;
64) countries that have the same or similar requirements for issuing authorization for the medicine are the countries that their regulations conform to the standards of European Union and the International Conference on Harmonization of technical requirements for issuing the authorization for the medicine.

II. AUTHORITIES

Article 5

Government of Montenegro (hereinafter: Government) shall:
1) establish criteria for determining maximum prices of medicines used in human medicine and are prescribed and issued as a burden of compulsory health insurance;
2) take measures for the provision of medicines in cases of emergencies and other emergencies and may provide a different method, procedure and conditions for issuing of the authorization for the medicine, clinical trials, manufacturing, distribution, quality control and labeling, and pharmacovigilance and advertising of medicines and usage of veterinary medicines, from the requirements regulated by this Law;
3) perform other duties in accordance with the Law.

Article 6

The state authority body responsible for health matters (hereinafter: Ministry) shall:
1) establish a national pharmacopoeia, and the magistral formulas;
2) establish measures for the rational usage of medicines;
3) prescribe the closer requirements for: issuance of authorization for the medicine, manufacturing, distribution of medicines for human usage, control, monitoring of adverse effects, medicine advertising and labeling;
4) determine the content and manner of keeping records of issued authorizations, approvals, certificates, in accordance with Law;
5) perform inspections of manufacturers, authorization holder for wholesale and pharmacy as well as inspection of medicine advertising, in accordance with Law;
6) prohibit distribution, i.e. order suspension of the distribution or withdrawal from the market medicines that do not meet standards of quality, safety and efficacy of medicines;
7) suggest criteria for determining maximum prices of medicines referred to in Article 5 of this Law.
Ministry or state authority body responsible for veterinary care, in accordance with this Law shall:
1) adopt regulations to implement this Law, in accordance with European Union standards, or other equally strict standards that are applied in other countries;

2) give consent to the act on forming committee and a list of experts for the medicines;
3) decide on appeals in the second instance procedure;
4) perform other duties in accordance with the Law.
State authority body responsible for economy affairs inspects of the prices of medicines on the market.
Authority body responsible for veterinary care issues authorizations for the wholesale distribution and retail sale of veterinary medicines and inspects the distribution of medicines.

Article 7

The activities regarding the evaluation of quality, safety and efficacy of the medicine, and other professional activities in the field of medicines is performed by the Agency for Medicines and Medical Devices (hereinafter: the Agency) established by the Government.
The Agency is a legal entity with rights and obligations stipulated in this Law, article of incorporation and statute of the Agency.
Authorities, composition, election and duration of the mandate of Agency's bodies, as well as other issues of importance to the work is regulated by articles of incorporation and statute of the Agency.
The Statute of the Agency and act on internal organization and job classification is approved by the Ministry.

Article 8

The Agency has the authority to:
1) issue, modify, amend and renew the authorization for the medicine;
2) issue authorization for the manufacturing of medicines and wholesale distribution of medicines for usage in human medicine;
3) issue an approval for clinical trials of medicines which do not have authorization for the medicine, decide on amendments to the authorization, i.e. the protocol on conducting the clinical trial of medicines, record clinical trials of medicines which have authorization for medicine and performs the control of conducting the clinical trials;
4) perform entry and deleting in the Registry of the traditional herbal medicines, or entry in the Registry of homeopathic medicines;
5) establish and organize a system of pharmacovigilance in order to monitor safety of medicines in distribution and detect any changes in relation to benefits and risks of their use;
6) issue a certificate on the application of Good Manufacturing Practices, Good Clinical Practices and other certificates, in accordance with this Law;
7) issue certificates for export of medicines in accordance with the recommendations of the World Health Organization;
8) approve the procurement or import of medicines which do not have authorization for the medicine, medicines that are intended for scientific and medical researches, for further processing or for treating a specific patient or group of patients, as well as other medicines in accordance with this Law;
9) issue authorization for import, export and transit of medicines that are or contain drugs and psychotropic substances as well as pharmacologically active substances that can be used in the manufacturing of drugs and psychotropic substances (precursors);
10) participate in international standardization in the field of medicines;
11) perform collecting and processing of data on distribution and consumption of medicines;
12) perform activities of information and education on medicines, organized professional and educational meetings and provide information relevant to the implementation of measures for rational use of medicines;
13) take measures for quality assurance of medicines;
14) perform classification of medicines for which the authorization for the medicine is issued in order to determine the relevant rules regarding the dispensing of medicines;
15) keep records of issued authorizations, approvals and certificates;
16) carry out the cooperation with international entities and national regulatory bodies in the field of medicines;
17) propose the harmonization of regulations in the field of medicins with the EU regulations and with the regulations and guidelines of international institutions;
18) give expert advice on the classification of the products in the medicine or group of medicines as well as other expert advice within its jurisdiction;

19) perform the control of the quality of the medicine and issue a certificate of quality of medicine;
20) carry out activities related to disposal and destruction of waste for its own purposes;
21) issue approval for import and export of immunological medicines, medicines from the blood and plasma and radiopharmaceutical medicines;
22) establish maximum prices of medicines used in human medicine, in accordance with criteria established by the Government;
23) perform other activities in accordance with this Law and other Laws.
The activities referred to in paragraph 1 items 1, 2, 3, 4, 5, 6, 7, 8, 9, 11, 13, 14, 15, 18, 19, 21 and 22 of this Article shall be performed by the Agency as well as activities from delegated authority.

Article 9

Funding for the Agency are provided from its own resources, and from the fees established for performing activities referred to in Article 8, paragraph 1 items 1, 2, 3, 4, 5, 6, 7, 8, 9, 12, 15, 18, 19, 21 and 22 of this Law, as well as from other sources in accordance with the Law.
For medicines that are used to treat rare diseases in humans ("Orphan" medicines), to treat rare diseases in less abundant animal species ("MUMS") and medicines from the humanitarian aid, the Agency does not charge fees referred to in paragraph 1 of this Article.

Article 10

In the procedure of bringing the acts referred to in Article 8, paragraph 1 of this Law, are implemented the provisions of the Law by which is determined general administrative procedure, unless otherwise provided by Law.
In an act of the Agency referred to in paragraph 1 of this Article, relating to the authorization for the medicine, manufacturing authorization, authorization for wholesale distribution of medicines for human usage, approval for clinical trial of medicines, certificates, approval for procurement and import of medicines that do not have authorization for the medicine, can be appealed to the Ministry, i.e. to the state authority body responsible for veterinary care, for veterinary medicines.
The authorization referred to in Article 8, paragraph 1, item 9 of this Law shall be subjected to audit, conducted by the Ministry.
Audit does not have sunspensory effect.
If against authorization referred to in Article 8, paragraph 1, item 9 of this Law is appealed, about the filed appeal and the audit, shall be decided with the same decision.
In the performing of the audit referred to in paragraph 3 of this Article can be given the consent or the authorization can be modified, revoked or repealed.
Against the decision of the Ministry, or of the state authority body responsible for veterinary care referred to in paragraph 2 of this Article, or decision on the audit referred to in paragraph 6 of this Article can be initiated a general administrative procedure.

Article 11

The costs incurred in performing of the activities of documentation assessment, evaluation of quality, safety and efficacy of the medicine, and other professional activities in the procedure of issuing authorizations, certificates and approvals referred to in Article 8 paragraph 1 of this Law bears the applicant, unless otherwise provided by Law.
The way of payment of fees as well as the amount of fee referred to in paragraph 1 af this Article, which correspond to the actual costs of performed activities, is determined by the Agency.
The act of the Agency referred to in paragraph 2 of this Article shall be approved by the Government.

Article 12

Giving opinion on the quality, safety and efficacy of the medicine, in the procedure of issuing authorization for the medicine, the Agency with prior approval of the Ministry, for medicines used in human medicine, or state authority bodies responsible for veterinary care for veterinary medicine, form advisory bodies (hereinafter: commission).
Members of the commission referred to in paragraph 1 of this Article can be permanent, as well as members on call for certain types of medicines.
Permanent members of committee are appointed for four years and may be reappointed.

Member of the commission referred to in paragraph 2 of this Article shall not in any way participate in the procedure of preparation of documents for issuing authorization for the medicine or entry in the registrations kept by the Agency, neither in preparation and making reports on the assessment of documentation.
The Agency, with prior approval of bodies referred to in paragraph 1 of this Article, shall dismiss the member of the commission who acts in contravention with paragraph 4 of this Article, and in case of non-performance or negligent performance of activities within his jurisdiction.
The costs of the commission referred to in paragraph 1 of this Article shall be provided by the Agency funds.

Article 13

The Agency, with prior approval of the Ministry or of the state authority body responsible for veterinary care determines the list of experts for medicines, to assess the documentation of the medicines, and documentation of test quality, safety and efficacy of medicines and preparation of expert report in the process of issuing authorization for the medicine.
Experts from the list referred to in paragraph 1 of this Article shall be appointed for four years and may be reappointed.
Experts from the list referred to in paragraph 1 of this Article shall not in any way participate in the procedre of preparation of documentation for issuing the authorization for medicine or entry in registry kept by the Agency.
The Agency, with prior approval of the bodies referred to in paragraph 1 of this Article, shall dismiss the expert from the list of experts who acts in contravention of paragraph 3 of this Article, and in case of non-performance or negligent performance of acivities wrom his jurisdiction.
The costs of experts referred to in paragraph 1 of this Article shall be provided from the Agency funds.

Article 14

Director and employees in the Agency, members of boards and committees of the Agency, as well as experts from the list of experts can 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, distrtibution and testing of medicine nor can have other personal interests (property, shares, membership in management or contractual relations), with persons engaged in these activities, which they will sign the statement.
The persons referred to in paragraph 1 of this Article cannot participate in preparation of documentation submitted with the application for getting the authorization for the medicine.

Article 15

Persons referred to in Article 14, paragraph 1 of this Law, as well as employees of the Ministry, are obliged to the state authority body responsible for the veterinary care and authority body responsible for veterinary care to keep confidential all data from the documentation submitted with the application for getting the authorization for the medicine, as well as in other proceedings in accordance with this Law, especially if:
1) data are confidential, and which as a whole, or in the precise form and set its components 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 secrecy and for the duration of confidentiality;
3) data for which an applicant for getting authorization for the medicine, amendment or renewal of the authorization for the medicine is taking, under the circumstances, reasonable steps to keep them secret.
The persons referred to in paragraph 1 of this Article, keep confidential data from documentation for obtaining the authorization, amendment or renewal of authorization for the medicine 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 getting the authorization for the medicine, 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 applicant for obtaining the authoization for the medicine license and other procedures in accordance with this Law,as well as in the case needed of giving information on the medicine to the professional and

general public that are necessary for the use, or handling, as well as protection of human health and animals.
The documentation accompanying the application for issuing authorization for the medicine is the property of the manufacturer, and represents the business secret.

III.MEDICINES

Article 16

The medicine is a product placed on the market in a certain strength, pharmaceutical form and package, which contains a substance or combination of substances for which are shown to have the capacity to cure or prevent disease in humans or animals, as well as a substance or combination of substances which can be used or applied to humans or animals, either with intent to restore, enhance or modify physiological functions by pharmacological, immunological or metabolic action, or to set up a medical diagnosis.
The substance referred to in paragraph 1 of this Article is any substance, regardless of origin, which can be:
1) human origin (blood, blood derivatives and blood products);
2) animal origin (micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products);
3) plant origin (microorganisms, whole plants, plant parts, secretions, extracts);
4) chemical origin (chemical elements, chemical substances found in nature in a given shape, as well as chemical products obtained by chemical change or synthesis).
Blood and blood components intended for transfusion are not considered as medicine under this Law.
Products which are considered medicines determines the Agency, in accordance with this Law.

Article 17

Biological medicine is a medicine 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 (immune mediciness, medicines of human blood and plasma, medicines for advanced treatment, etc.).

Article 18

Immune medicine for use in human medicine is any medicine that consists of vaccines, toxins, serums or allergen.
Vaccines, toxins and serums include:
1) agents that are used to create active immunity (cholera vaccine, BCG, polio vaccines, smallpox vaccine, etc..)
2) agents that are used to diagnose the state of immunity (tuberculin and tuberculin PPD, toxins for Sikova test and Dikov, brucelin et al.)
3) agents that are used to create passive immunity (antitoxin diphtheria, smallpox globulin, globulin antilimfocitni et al.).
Allergen is designed to identify or cause specific acquired change of immune response to the agent that causes an allergic reaction (allergic agent).
Immune medicine for use in veterinary medicine is any medicine that is given to animals in order to create their active or passive immunity or to diagnose the state of their immunity.

Article 19

Medicines for advanced therapy are:
1) medicines for gene therapy;
2) medicines for somatic cell therapy;
3) medicines obtained from tissue by bioengineering.

Article 20

Medicines from blood and plasma are medicines made from blood and plasma of human or animal origin.Medicines referred to in paragraph 1 of this Article are manufactured by an industrial process based on blood components and include albumin, clotting factors and immunoglobulins of human origin.

Article 21

Radiopharmaceuticals are:
Radiopharmaceutical medicines, radionuclide generators, radiopharmaceutical completions (kits) and radionuclide precursors.
Radiopharmaceutical medicine is a medication which, when it is ready for use, contains one or more radionuclides (isotopes radioactive) which is used for medicinal purposes.
Radionuclide generator is eny system which contains mother radionuclide rom which is manufactured derived radionuclide, which is obtained by elution or some other method, and is used in radiopharmaceutical medicine.
Radiopharmaceutical completion (kit) is any product which is anticipated to be used by dissolving or combining with radionuclides in radiopharmaceutical medicine, and usually just before its application.
Radionuclide precursor is any other radionuclide manufactured for needs of marking some other substances before its application.

Article 22

Herbal medicine is any medicine whose active ingredients are only one or more substances of plant origin or one or more herbal preparations, or one or more substances of plant origin in combination with one or more herbal preparations.
The substance of plant origin is all the plants in the whole or in parts, i.e. algae, fungi, lichen in the unprocessed, fresh or dry condition, as well as certain exudates that have not undergone to specific processing procedures.
Substances of plant origin are determined from plant part used in the botanical name according to the binary nomenclature (genus, species, variety and author).
Herbal preparations are obtained by extraction, distillation, pressing, fractionating, purifying, concentrating, or fermentation of the substances of plant origin.
Herbal preparations are considered to be the ground or pulverized plant substances, tinctures, extracts, oils, juices obtained by pressing,as well as processed exudates.

Article 23

Traditional herbal medicine is a medicine that can be based on scientific principles and is the result of traditional or other traditional therapeutic approaches.
Traditional herbal medicine is a medicine that meets the following conditions:
1) there are indications that are specific to traditional herbal medicines 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) is intended solely for use in accordance with the prescribed dosage and strength;
3) is intended for oral use, outdoor use and / or inhalation;
4) expired his period of traditional use, or have passed at least 30 years of use prior to the date of of the submission of the application for issuing the authorization for the medicine, and of which at least 15 years in the European Union;
5) There is sufficient data on traditional use of medicine, i.e. is shown that it is not harmful in specified conditions of use, as well as it canbe expected its pharmacological effects or its effectiveness based on its long-term use and experience.

If in traditional herbal medicine have vitamins or minerals, and whose therapeutic safety is well-documented, it can be considered a traditional herbal medicine, if the effect of these vitamins or minerals just support in relation to the effect of active herbal ingredients in terms of declared indication (or indication).
A traditional herbal medicine that meets the requirements referred to in paragraphs 2 and 3 of this Article shall be entered in the Registry of traditional herbal medicines.
The Agency may reject the application for registration of the medicine in the Registry referred to in paragraph 4 of this Article, if the requirements referred to in of paragraphs. 2 and 3 of this Article are not met or if:
1) qualitative, or quantitative composition of the medicine does not match the declared composition;
2) indications are not in accordance with the requirements referred to in paragraph 3 of this Article;
3) medicine could be harmful under normal conditions of use;
4) data on traditional use are insufficient, especially if the pharmacological effect of the medicine or its effectiveness are not entirely convincing on the basis of long-term use and experience;
5) is not satisfactorily proven the of the quality medicine from the pharmaceutical aspect.
The Agency shall not enter a certain traditional herbal medicine in the Registery of traditional herbal medicines if it assess that medicine meets the requirements for issuing authorization for the medicine in accordance with this Law and regulations adopted to implement this Law.
In the case referred to in paragraph 6 of this Article an application shall be submitted to the Agency for issuing the authorization for the medicine.

Article 24

Homeopathic medicine is a medicine made from products, substances or compounds which are homeopathic raw materials in accordance with a homeopathic manufacturing procedure by methods of the European Pharmacopoeia or other Pharmacopoeia in force in any country of the European Union.
Homeopathic medicine may contain more active principles.
Homeopathic medicine is entered in the Registery of homeopathic medicines if it meets the following conditions:
1) is intended for oral or external use;
2) on its packaging nor in any other information related to the medicine that does not have these specific therapeutic indications;
3) there is a sufficient degree of dilution of the medicine which guarantees therapeutic safety of medicine therapy, as well as medicine does not contain more than one part of mother tincture to parts ten thousand or more from 1/100 part of a minimum dose used in conventional medicine, when it comes to active substance whose presence in conventional medicine otherwise puts an obligation for issuing with the prescription.
The Agency can, on the basis of altered scientific views, decides that the homeopathic medicine is entered in the Registery of homeopathic medicines, and if does not meet the requirements referred to in paragraph 3, item 3 of this Article.
The Agency shall not enter a ertain homeopathic medicine in Registery of homeopathic medicines if it estimates that the medicine meets the requirements for issuing the authorization for the medicine in accordance with this Law and regulations adopted to implement this Law.
In the case referred to in paragraph 5 of this Article the application shall be submitted to the Agency for issuing the authorization for the medicine.
The detailed conditions and manner of entry in the Registery of traditional herbal medicines and Registry of homeopathic medicines as well as issuing the authorization for traditional herbal and homeopathic medicine, manufacturing, distribution, control, monitoring of adverse reactions, labeling and advertising of these medicines is regulated by the Ministry.

Article 25

Veterinary medicine can be a medicine in accordance with Article 17 and Articles 21 to 25 of this Law.
Premix for medicated food is a pharmaceutical form of a veterinary medicine intended for mixing with the food for animals that is manufactured in a way to serve solely for the manufacturing of medicated food.

For treatment of certain animal species can only be used veterinary medicine for which the authorization for the medicine is issued and which is intended for treating or preventing disease, improving or changing physiological functions or achieving other medically justified goals with certain animal species.
If for treatment of certain animal species there is no medicine referred to in paragraph 3 of this Article, it can be used a medicine of same or similar attributes intented for use with other animal species, if for that medicine is issued authorization for the medicine and if there is no contraindication for its use.
If for treatment of certain animal species there is no veterinary medicine referred to in paragraphs 3 and 4 of this Article, for certain animal species can be used a medicine intended for use in human medicine, if for that medicine is issued the authorization for the medicine and if there is no contraindication for its use.
If for treatment of certain animal species there is no medicine referred to in paragraphs 3, 4 and 5 of this Article, for the treatment of certain animal species can be used the appropriate galenical or magstral medicine and if there is no contraindication for their use.
For medicines referred to in paragraph 3, 4 and 5 of this Article, when thay are prescribed for use on animals whose products are intended for human consumption or used to produce food for human consumption, the time of waitning period is determined that can not be less than:
- Seven days for milk;
- Seven days for eggs;
- 28 days for meat, fat tissue and edible by-products, birds and mammals;
- 500 degree-days for fish meat.
If with the medicines referred to in paragraphs 3 to 6 of this Article are treated the animals whose products are intended for human consumption or obtaining food for humans, these medicines as active substance must contain only substances referred to Article 39 paragraph 1 of this Law.

Article 26

Magistral medicine is a medicine made in the pharmacy according to prescriptions (formulas) for a specific patient or user.
Making of magistral medicines is not considered as a manufacturing under this Law.

Article 27

Galenic medicine is a medicine made based on the applicable pharmacopoeia or valid magistral formula in galenic laboratory when there is not or is not available medicine for which is issued the authorization for the medicine under the conditions prescribed in this Law and regulations adopted to implement this Law.
Galenic medicine can be prepared in a galenic pharmacy laboratory performing the activity as a health institution at the primary health care level (hereinafter: galenic pharmacy laboratory) in small quantities, up to 300 ready-made individual packages by series.
Galenic medicine made in galenic pharmacy laboratory is intended for issuing, sale or use and application for patients of that pharmacies, or pharmacy which is part of other health care facilities that perform activities on the primary health care level, as well as in appropriate veterinary institution with which the pharmacy in whose galenic laboratory is made a galenical medicine concluded a contract on delivery of certain quantities of that galenic medicine.
Galenic medicine referred to in paragraph 1 of this Article, which is exclusively used in veterinary care, shall be prepared in a galenic laboratory of veterinary facilities in the amount up to 100 ready-made individual packages by day. Active substances for which there waiting period period cannot be used for the preparation of galenic and the magistral medicines for use in veterinary care for the treatment of animals intended for human consumption or food manufacturing for human consumption.
Production of galenic medicine in quantities prescribed in paragraphs 2 and 4 of this Article shall not be considered manufacturing in terms of this Law.

Article 28

Galenic medicine can be prepared in a galenic pharmacy laboratory of health facilities which performes health activities at the secondary and tertiary health care level (hereinafter: galenaic laboratory of hospital pharmacy) in the quantity required for providing health care of the patients of that health facility.

Development of the galenic medicine in the galenic laboratory of hospital pharmacy is not considered manufacturing under this Law.
Galenic medicine referred to in paragraph 1 of this Article can not be found in wholesale distribution, or in retail distribution.
Each series of galenic medicine must have a certificate of analysis issued by a laboratory which meets the requirements for performing quality control.

Article 29

Requirements in terms of space, equipment and personnel, as well as other necessary conditions for the development of galenic medicines in galenic pharmacy laboratory, in galenic laboratory of hospital pharmacy, or galenic laboratory of veterinary facilities is regulated by the Ministry or the state authority body responsible for veterinary care.
Guidelines of Good practice in the preparation of galenic medicines is published on the website by the Ministry.
List of galenic medicines used in human medicine re established by the Ministry, and list of galenic medicines used in veterinary care, brings state authority body responsible for veterinary care.
If pharmacy referred to in Article 27, paragraph 2 of this Law performs supplying of other health institutions or veterinary facilities, based on the contract in accordance with this Law, for the needs of patients, or users of that health institution i.e. veterinary facility, such supplying shall be considered as retail sale in accordance with this Law.
Notwithstanding Article 28, paragraph 1 of this Law, based on a contract on the delivery of certain quantity of galenic medicine, can be performed supplying and other health institutions on secondary, tertiary level of health care for needs of patients of health institutions, with the approval of the Ministry.

IV. AUTHORIZATION FOR THE MEDICINE

Article 30

Application for obtaining the authorization for the medicine shall be submitted to the Agency.
The applicant can be:
1) medicine manufacturer seated in Montenegro;
2) for medicine manufacturers, who is not seated in Montenegro, his representative or its agent , who is seated in Montenegro;
3) representative of a foreign legal entity who is not the manufacturer of the medicine, but is a marketing authorization holder in the European Union countries, and who is which is seated in Montenegro;
4) legal entity seated in Montenegro on which the manufacturer referred to in item 1 of this paragraph transferred the authorization for the medicine or to whom he gave the right to acquire the status of the marketing authorization holder from its production program.
The applicant referred to in paragraph 2 of this Article must have responsible person for pharmacovigilance and for obtaining the authorization for the medicine, its amendments and renewals, with the signed full-time employment for an indefinite period.
The person responsible for pharmacovigilance of medicines for human use must have a degree in pharmacy, medicine or dentistry, and person for pharmacovigilance of veterinary medicines pharmaceutical or veterinary faculty.
The applicant is responsible for the accuracy of the data in the documentation in the procedure for obtaining the authorization for the medicine.
The applicant referred to in paragraph 2 items 2, 3 and 4 of this Article is obliged that with contract with a manufacturer, or marketing authorization holder on whose behalf is filled the application for issuing the authorization for the medicine determines the insurance for responsability for any damage caused by the use of the medicine in Montenegro.
Marketing authorization holder is obliged that in written form informs the Agency of the date of placing the medicine on the market within 15 days from the date of placing the medicine on the market.

Article 31

Application for obtaining the authorization for the medicine with full documentation shall include at least:

1) administrative data including the name of medicine, international non-proprietary medicine name, generic, if such name exists, or other common name, pharmaceutical form and strength of the medicine, the draft summary of basic characteristics of the medicine, the proposed guidelines for the medicine, the name and address of the applicant for issuing the authorization for the medicine, the name and address of the manufacturer, the authorization for manufacturing of medicines issued by national agency in the country of manufacturer, place of manufacturing, certificate of Good manufacturing practice, the proposal of inner and outer packaging, as well as a list of countries where the medicine is on the market, evidence that the medicine has the authorization for the medicine, or that is in the process of obtaining the authorization for the medicine in the country of origin or in another country with the same requirements for the authorization for the medicine as in Montenegro, as well as existing on the market, or the reasons for its absence from the market in that country;

2) pharmaceutical, chemical and biological data which include: qualitative and quantitative data of the composition of the medicine, manufacturing procedure of medicine making, quality control of all entry raw materials, process control, quality control of the medicine, stability studies, as well as data on assessment of environmental impact;

3) pharmacological and toxicological data which include: data on the pharmacodynamic and pharmacokinetic characteristics of medicines, data on medicine toxicity, effects on reproductive functions, data on embryonic, fetal and perinatal toxicity, mutagenic and carcinogenic potential, as well as data on local tolerance, or for veterinary medicines proposed waiting period and a maximum residue level;

4) clinical data which include: general information on testing, performance testing, test results, clinical and pharmacological data, data on bioavailability / biological equivalence, if it is necessary, data on clinical safety and efficacy, documentation of the extraordinary events in testing and the experiences gained after issuing the authorization for the medicine in other countries.

Article 32

Applicant is obliged that with application for obtaining the authorization for the medicine, which contains a fixed combination of active substances or active substance that are in the composition of medicines that have the authorization for placing on the market in Montenegro or in the European Union, or in countries which have the same requirements for issuing the authorization for the, but up to now are not used in that combination for therapeutic purposes, submit the results of new pre-clinical and clinical trials related to a given combination of active substances, with no need to provide professional references for each individual active substance.

Applicant for obtaining the authorization for the medicine with well-known medical use of active substance or active substances is not obliged to submit data of preclinical and clinical trials referred to in Article 31 paragraph 1 items 3 and 4 of this Law, but is obliged, instead of their own data, to submit the data from literature published in professional publications (bibliographic application).

The active substance or active substances with well-known medical use are the substances that have proven use for at least ten years of use as a medicine in Montenegro or in one of the countries of the European Union or in countries that have the same requirements for the issuing the authorization for the medicine and for which is published harmonized recognized professional literature, which contains all the necessary data required from the pharmaco-toxicological or clinical documentation for obtaining the authorization for the medicine, demonstrating safety and efficacy of the medicine.

Applicant is not obliged to submit their own data referred to in Article 31 paragraph 1 items 2, 3 and 4 if the application for medicine is submited with information on consent (informed consent), which is the medicine of the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form and for which in the process of obtaining the authorization for the medicine is used documentation on quality, safety and efficacy of the medicine, which has the authorization for the medicine in Montenegro, with the written consent of the marketing authorization holder.

The medicine with the informed consent is considered as a medicine with full documentation in accordance with this Law.

Medicins referred to in paragraph 1, 2, 3 and 4 of this Article and Article 32, paragraph 1 of this Law shall be considered as reference medicines in terms of this Law.

Article 33

Applicant for obtaining the authorization for the medicine, is obliged, with application for obtaining the authorization for the medicine, to submit samples of the medicine, at the request of the Agency and provided reference standards needed for pharmaceutical testing.

In the procedure of issuing the authorization for the medicine, the Agency can request other necessary data relevant for obtaining the authorization for the medicine, provided that applicants for issuing the authorization for the medicine do not put in a position of inequality.

The Agency in the procedure of issuing the authorization for the medicine exlusively can require to supervise the manufacturing of medicine, for which the application is submited for obtaining the authorization for the medicine, amendment or renewal of the authorization.

Article 34

Application for obtaining the authorization for the medicine with a short documentation is submitted for:

1) generic medicine;
2) hybrid generic medicine;
3) biologically similar medicine.

Application for obtaining the authorization for the medicine referred to in paragraph 1, item 1 of this Article, instead of their own data from the documentation referred to in Article 31 paragraph 1 items 3 and 4 of this Law, shall contain data on biological equivalence of generic medicine compared to the reference medicine based on appropriate bioavailability studies.

Application for obtaining the authorization for the medicine referred to in paragraph 1 items 2 and 3 of this Article must contain their own data referred to in Article 31 paragraph 1 items 3 and 4 of this Law on the safety and efficacy of the medicine that are different from the corresponding data of the reference medicine, or reference biological medicine.

Detailed requirements regarding the manner and procedure of proving the biological equivalence is regulated by the Ministry.

Article 35

If the authorization for the referent medicine is issued for the first time in Montenegro or European Union countries, every new authorization for the medicine based on amenmends in terms of the strength of the medicine, pharmacheutical form, dosage form, packaging, as well as all amendments and requests for extension of the authorization for the medicine should be included by the first authorization for the medicine and form the part of a unified, global system for issuing the authorization for the medicine (hereinafter: global authorization for the medicine).

Application for obtaining the authorization for the medicine with a short documentation can be submitted after at least eight years from the date when the global authorization for the reference medicine, on which applicant is called, issued in Montenegro, European Union or countries with the same or similar requirements for issuing the authorization.

Upon expiration of ten years from the date of issuing of the global authorization for the medicine, the applicant can obtain a the authorization for the medicine with a short documentation.

Period of ten years referred to in paragraph 3 of this Article shall be extended (cumulative) for an additional year if, during the eight years since the issuing of the global authorization for the medicine, the marketing authorization holder for reference medicine is obtaind a new authorization for one or more new indications that represent a significant improvement of therapy with that reference medicine.

Period of one year (not cumulative) for one or more new indications that represent a significant improvement of therapy is applied to the marketing authorization holder with a well-known substance, based on a new pharmaco-toxicological and clinical trials of that medicine, as well as medicine for which new classification is determined on the basis of significant pre-clinical and clinical trials in accordance with this Law.

Deadlines for data protection for medicines referred to in this Article and Article 36 of this Law shall commence to run from the date when the global authorization for the medicine is issued referred to in paragraph 1 of this Article.

Article 36

To veterinary medicines are applied the provisions of Article 35 of this Law, unless otherwise provided by this Law.

For veterinary medicines used to treat bees, fish and other less abundant species, the period referred to in Article 35 paragraph 4 of this Law shall be extended to three years cumulatively, if necessary.

If the new authorization is issued for the application of reference medicine on another animal species whose products are intended for human consumption, for a period of five years from the date of issuing the authorization for that medicine, the period referred to in Article 35 paragraph 4 of this Law shall be extended for another year (cumulative), a maximum of three years if used for the treatment of four animal species or more animal species whose products are used in human consumption.

Article 37

Content of the application and required documentation for issuing the authorization for the medicine referred to in Articles 31 and 34 of this Law is regulated by the Ministry, and the content of pharmaco-toxicological and clinical documentation relating to veterinary medicines, the state authority body responsible for veterinary care.

Article 38

The Agency is obliged to, within 30 days from the date of receipt of the application referred to in Article 30 paragraph 1 of this Law, conduct a formal evaluation of the documentation for obtaining the authorization for the medicine regulated by this Law and regulations adopted to implement this Law.

If the request referred to in paragraph 1 of this Article is not completed, the Agency in written form informs the applicant that the application shall be fulfiled with requested data within 30 days from the date of receipt of written notice.

In the period referred to in paragraph 2 of this Article is not included the time required that the applicant submits to the Agency requested additional data (clock stops).

The Agency, not later than 210 days from the date of receipt of a complete formal application, shall issue the authorization for the medicine, or make a decision on denial of the aplication for issuing the authorization for the medicine, based on the assessment documentation of the quality, safety and efficacy of the medicine, if by this Law is not otherwise specified.

In 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 Agency or providing additional clarifications (clock stops).

Article 39

The authorization for veterinary medicine used to treat animals whose products are intended for human consumption is issued only if the medicine contains the active substances safe for human health, or which is based on the acceptable daily intake, set a maximum residue level.

List of active substances referred to in paragraph 1 of this Article is determined by state authority body responsible for veterinary care.

Article 40

The authorization for the medicine is issued, as a rule, on a period of five years.

An integral part of the authorization referred to in paragraph 1 of this Article summarizes the characteristics of the medicine and instructions for the medicine, as well as approved package.

The contents of the authorization for the medicine is regulated by the Ministry.

Article 41

The authorization for the medicine at accelerated procedure can be issued for:

1) a medicine that is used in human medicine, which is of highest interest for the protection of public health, primarily in relation to therapeutic innovation;
2) a medicine that has already optained the authorization for the medicine in the European Union countries, by the centralized procedure, the procedure of mutual recognition or by decentralized procedure.
Application for issuing the authorization for the medicine referred to in paragraph 1 of this Article contains documentation regulated by Article 31 of this Law.
Wth the application for issuing the authorization for the medicine referred to in paragraph 1 item 2 of this Article documentation referred to in Article 34 of this Law is submitted and relevant statements of the responsible person of the applicant in relation to identity of submitted documentation with the documentation based on which is obtained the authorization for the medicine by centralized procedure, the procedure of mutual recognition or by decentralized procedure.
The authorization referred to in paragraph 1 of this Article is issued not later than 150 days after receipt of formally completed application.

Article 42

Conditional authorization for the medicine can be issued for:
- Medicines used to treat, prevent or diagnose serious and life threatening diseases;
- Medicines used in emergency situations;
- Medicines used to treat rare diseases;
- Medicines obtained the authorization by centralized procedure;
- Other medicines of public interest for public health.

The Agency can issue a conditional authorization for the medicine referred to in paragraph 1 of this Article with a prior agreement with the applicant to meet conditions and concrete obligations referred to in Article 31 of this Law.
Fulfillment of the conditions referred to in paragraph 2 of this Article shall be checked once in 12 months y the Agency from the date of issuing the conditional authorization for the medicine.
Conditional authorization for the medicine is issued on a period of 12 months and can be renewed until the meeting the conditions referred to in Article 31 paragraph 1 item 4 of this Law, if the use of application of thatmedicine for public health outweighs the risk due to missing certain data on clinical trials.
Notwithstanding, in urgent cases in which public health is threatened, conditional authorization for the medicine can be issued without meeting the conditions referred to in Article 31 paragraph 1 items 2 and 3 of this Law.
If a medicine which obtained a conditional authorization meets all the conditions referred to in of Article 31 of this Law, the Agency issues the authorization for the medicine in a period of five years, in accordance with this Law.
Conditional authorization for the medicine can be issued by the accelerated procedure referred to in Article 41 of this Law.
In summary of the characteristics of the medicine and instructions for the medicine must be given the fact that the authorization for the medicine is issued as a conditional authorization.

Article 43

Notwithstanding the conditions referred to in Article 31 of this Law, the Agency can, at the request of the applicant, to issue the authorization for the medicine under special circumstances with prior arrangement with the applicant, only for the medicine of special public interest for public health.
The authorization referred to in paragraph 1 of this Article is issued for a period of 12 months, with the obligation of the applicant to fulfill obligations relating to the safety of the medicine and to inform the Agency of any undesirable event while using the medicine, as well as and the taken security measures.
The Agency, at the request of the applicant, for a medicine which meets the requirements referred to in paragraphs 1 and 2 of this Article may extend the authorization for the medicine under special circumstances, for new 12 months.
Request for re-assessment meeting the requirements referred to in paragraphs 1 to 3 of this Article is submitted not later than 90 days before the date on which the authorization was issued under special

circumstances, with data justifying the special public interest for public health, as well as other data regulated by this Law and regulations adopted to implement this Law.

Article 44

The Agency shall refuse the application for issuing the authorization for the medicine if it determines that:
1) the relationship between risks and benefits of the medicine is not beneficial under usual conditions of use;
2) medicine does not have therapeutic effect of the medicine or that therapeutic effect of the medicine is not sufficiently proven by the applicant;
3) qualitative and quantitative composition of the medicine does not match the data in the submitted documentation;
4) documentation provided with the medicine is not in accordance with the conditions regulatet by this Law and regulations made under this Law.

Article 45

The authorization for the medicine, according to this Law, shall not be issued for the magistral medicines and galenic medicines.
Exceptionally, the authorization for the medicine shall not be issued for:
1) medicines that are intended for scientific and medical researches;
2) medicines intended for further processing;
3) medicines intended to treat a particular patient or group of patients who have special needs for such mediciness;
4) other medicines specified by the Ministry on the proposal of the Agency in accordance with this Law.
In the cases referred to in paragraph 2 of this Article, the Agency shall issue an approval for the procurement i.e. import of the medicine.
The approval referred to in paragraph 3 of this Article shall be issued:
- for medicines referred to in paragraph 2 item 1 of this Article, at the request of persons engaged in scientific research;
- for medicines referred to in paragraph 2 item 2 of this Article, at the request of medicine manufacturer;
- for medicines referred to in paragraph 2 item 3 of this Article, at the request of medical or veterinary facilities.
Approval for the procurement, or import the medicine referred to in paragraph 2 items 1 and 3 of this Article shall be issued for a specific amount of medication, and for a procurement, or import of the medicine referred to in paragraph 2 item 2 aof this Article, for a period not longer than one year.
Approved quantity of medicines referred to in paragraph 2 item 1 of this Article shall correspond to the needs of the scientific or medical research, and approved quantityof medicines referred to in paragraph 2 item 3 of this Article shall not exceed six-month needs of an individual or a one-year needs of health or veterinary facilities.
Delivery, or issuing of medicines referred to in paragraph 2 item 3 of this Article is performed by legal entity which has the authorization for the wholesale distribtion and authorized pharmacy.
Detailed requirements for the issuing the approval for procurement or import of medicines referred to in paragraph 2 of this Article is regulated by the Ministry.

Article 46

Marketing authorization holder is obliged to continuously inform the Agency of any new findings on the assessment of quality, safety and efficacy of medicines on the market.
Marketing authorization holder can submit the application to the Agency for amendmend of the authorization for the medicine (hereinafter: variation), in accordance with this Law.
The Agency 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 request referred to in paragraph 2 of this Article is not completed, the Agency in written form shall notify the applicant to fulfill the application with additional data within 30 days from the date of submitted written notification.

The Agency 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.
In the period referred to in paragraphs 4 and 5 of this Article is not included the time necessary for the applicant to submit to the Agency requested additional information (clock stops).
Detailed conditions, the manner and the necessary documentation for amending of the authorization or for the medicine is regulated by the Ministry.
Marketing authorization holder is obliged that within 12 months from the date of delivery of the decision to the Agency on approval of the variance, to place the medicine on the market in accordance with the approved variation.

Article 47

Marketing authorization holder is obliged to submit the application for the renewal of the authorization within 180 days at least and not later than 90 days prior to the expiration of the authorization for the medicine.
Authorization for the medicine is renewed based on reassessment between relationship of the risk and benefit of the medicine.

Article 48

Marketing authorization holder submittes to the Agency for renewal of the authorization for the medicine and submits documentation with the expert reports on the quality, safety and efficacy of the medicine, as well as a list of all variations for which the application is submitted to the Agency, or which are accepted, or approved until the date of application submission for renewal of the authorization.
The Agency is obliged, that within 30 days from the date of the receipt of the application referred to in paragraph 2 of this Article, performs formal evaluation of the documentation for the renewal of the authorization for the medicine in accordance with this Law and regulations adopted to implement this Law.
If the appliaction referred to in paragraph 2 of this Article is not completed, the Agency in written form informs the applicant to fulfil the application with aditional data within 30 days from the date of receipt of written notice.
The Agency brings the decision about the application referred to in paragraph 1 of this Article within 90 days from the date of the receipt of completed application.
In the period referred to in paragraphs 3 and 4 of this Article shall not include the time necessary that the applicant submits to the Agency requested additional information (clock stops).
A marketing authorization holder is obliged that within 12 months from the date of submission of the decision on renewal of the authorization for the medicine place on the makret medicine in accordance with this decision.

The medicine which has expired authorization for the medicine, and is not renewed, can be in distribution aftrer expiry date until the expiration period of the use of medicine, but not longer than 180 days after the expiry of the authorization for the medicine.
Marketing authorization holder in case referred to in paragraph 1 of this Article is obliged that 60 days before the expiry of the authorization for the medicine to inform the Agency that shall not initiate the procedure for renewal of the authorization for the medicine.

Article 49

If the Agency determines that a medicine which obtained the authorization for the medicine is safe, based on data on pharmacovigilance for a period of five years from the date of issuance or renewal of the authorization for the medicine, the Agency shall issue the authorization for the medicine indefinitely.
If the Agency within a period referred to in paragraph 1 of this Article dettermines that the medicine is not safe based on data on pharmacovigilance, the authorization for the medicine shall not be issued indefinitely, and in that case, the Agency decides to renew the authorization for the medicine on five years.
The Agency can only once to renew the authorization for the medicine in accordance with paragraph 2 of

this Article, and if it is determined based on data on pharmacovigilance that still there are reasonable grounds to suspect that the medicine is not safe, it shall revoke the authorization for the medicine.
The Agency is obliged to bring the decision on revoking the authorization for the medicine indefinitely, if based on pharmacovigilance data establish that the medicine is not safe for life and health of humans and animals.

Article 50

The authorization for the medicine expires upon the expiry of the deadline for which is issued at the request of the marketing authorization hoder.
The authoization referred to in paragraph 1 of this Article expires in the case that Agenccy or state authority body responsible for veterinary care establishes that:
1) medicine is not in accordance with the standards of quality, safety and efficacy of the prescribed conditions of use;
2) medicine in distribution does not meet the conditions from the authorization for the medicine;
3) the authorization is issued based on incomplete or incorrect data, or if the data have not been amended in accordance with this Law;
4) marketing authorization holder does not meets the approved conditions any longer;
5) medicine is placed on the market in contravention with the provisions of this Law.
The decision on termination of the authorization for the medicine in cases referred to in paragraphs1 and 2 of this Article shall be adopted by the Agency.
In the cases referred to in paragraph 2 of this Article, the Agency, or the authority body responsible for veterinary care proposes to the Ministry, or state authority body responsible for veterinary care suspension or prohibition of distribution and withdrawal of the medicine from the distribution.

Article 51

The authorization for the medicine can no longer be valid if the Agency or authority body responsible for veterinary care establishes that:
1) medicine was not in distribution in Montenegro the three years from the date of issuing the authorization for the medicine;
2) medicine that is after issuing if the authorization for the medicine was a certain period in the market in Montenegro, and after that period of three consecutive years was not in the market in Montenegro.
Before bringing the decision referred to in paragraph 1 of this Article, the Agency, or authority body responsible for veterinary care is obliged to inform the Ministry or the state authority body responsible for veterinary care that the conditions for termination of the authorization for the medicine are acquired.
Ministry or state authority body responsible for veterinary care can,due to protect the health of people and animals, to suggest that the Agency does not bring a decision on termination of the authorization for the medicine in cases referred to in paragraph 1 of this Article.
The provisions of paragraph 1 of this Article shall not be applied to the medicines which marketing authorization holder places on the market exclusively outside the territory of Montenegro.

Article 52

Measures for the emargency withdrawal of the medicine or series of the medicines from distribution, suspension or prohibition of the distribution of the medicine is taken by Ministry of state authority body responsible for veterinary care, if the Agency or authority body responsible for veterinary care establishes that:
- medicine is harmful under the prescribed conditions of use;
- medicine does not have therapeutic action;
- the ratio risk-benefit is unfavourable in relation to the approved use;
- qualitative and quantitative composition of the medicine is not the one which is listed;
- medicine is not manufactured in accordance with the issued authorization for manufacturing;
- in distribution can be found a forged medicine;
- the medicine expired the validity date.

The Agency, or authority body responsible for veterinary care is obliged that about the measures referred to in paragraph 1 of this Article informs the public within 24 hours from the issuing of the decision of suspension or prohibition of distribution and withdrawal of the medicine, or batch of the medicine from the distribution.

Article 53

Cessation of manufacturing and distribution of a medicine before the expiration of the authorization for the medicine, marketing authorization holder is obliged to inform the Agency, at least 180 days before the cessation of manufacturing or distribution of medicine.

Article 54

Marketing authorization holder can submit to the Agency the application for transfer of authorization for the medicine to another marketing authorization holder, who meets the conditions referred to in Article 30 of this Law.

The Agency is obliged within 30 days from the day of the receipt of the application to transfer the authorization for the medicine, performs assessment of the documentation.

The Agency within 60 daysfrom the day of the receipt of a complete application for transfer of the authorization for the medicine, brings the decision to approve the transfer of the authorization for the medicine to the new marketing authorization holder or refuses the application for transfer the authorization for the medicine.

In the period referred to in paragraph 3 of this Article is not include the time necessary that the applicant submits to the Agency requested additional data (clock stops).

The new marketing authorization holder is obliged that within 12 months from the date of bringing the decision referred to in paragraph 3 of this Article, to place on the market the medicine in accordance with approved transfer of the authorization for the medicine.

The content of the application and required documentation for transfer of the authorization for the medicine is regulated by the Ministry.

Article 55

If the marketing authorization holder expires its qualification for any reason before the expiry of marketing authorization for medicine and was not performed the transfer of the marketing authorization in accordance with this Law, he is obliged to inform, without delay, the Agency i.e. authority body responsible for veterinary care, and all legal entities engaged in wholesale distribution of that medicine in Montenegro.

Marketing authorization holder referred to in paragraph 1 of this Article shall take all necessary measures to withdraw that medicine from the market within 30 days of expiry of marketing authorization holder.

If the marketing authorization holder does not act in accordance with paragraph 1 of this Article, the Ministry i.e. state authority body responsible for veterinary care, shall decide on the treatment of that medicine.

Article 56

In the event of epidemics, epizootic, natural disasters i.e. state of emergencies, the Agency, exceptionally, may issue the marketing authorization for a specific medicine and quantities of medicines before making the conditions for issuing the marketing authorization for medicine.

Marketing authorization for the medicine under paragraph 1 of this Article shall be issued only for the period of duration of circumstances referred to in paragraph 1 of this Article.

Article 57

The Agency during the procedure of issuing of marketing authorization shall determine the mode of dispensing of medicines, i.e. performs the classification of medicines: medicines with prescription and without a prescription.

Medicines which have low toxicity, high therapeutic width, safety in overdosing, minimal interactions, whose indications are well-known to the patient-user and serve for self-medication are issued in pharmacies without a prescription.

Medicines that contain drugs or psychotropic substances shall be dispensed in accordance with a specific regime of issuing set out in the authorization for distribution of these medicines.

It is prohibited the dispensing i.e. the sale of medicines contrary to conditions specified in the authorization for its distribution.
It is prohibited that the veterinary medicines, which are used for treatment of animals whose products are used in human nutrition, are dispensed or sold without prescription.
For the person who dispenses or sells the medicine contrary to paragraph 4 and 5 of this Article the competent chamber shall temporarily revoke the working permit in accordance with the Law.

Article 58

The person who has the right to prescribe the medicines in accordance with the Law cannot be owner or co-owner of the pharmacy.
The form and content of the prescription, the criteria for the classification of medicines, as well as the mode of dispensing and prescribing the medicines i.e. veterinary medicines shall be regulated by the Ministry or the state authority body responsible for veterinary care.

Article 59

List of medicines for which the marketing authorization was issued, i.e. the amendment, renewal or transfer of marketing authorization, the list of medicines for which the marketing authorization expired, and the list of medicines for whose batches was suspended or prohibited the distribution or whose batches were withdrawn from a distribution, the Agency shall publish on the website of the Agency.
The Agency, at the beginning of the calendar year, for the needs of expert public shall issue the Register of medicines which have the marketing authorization in Montenegro.

V. TESTING OF MEDICINES FOR THE PURPOSE OF PROVIDING THE DOCUMENTATION IN THE PROCEDURE OF ISSUING OF MARKETING AUTHORIZATION FOR MEDICINE

Article 60

In order to obtain the marketing authorization for medicine, the medicine must include pharmaceutical, pharmacological-toxicological and clinical tests.
The manufacturer shall carry out appropriate tests referred to in paragraph 1 of this Article and provide the expert documentation related to these tests.
The medicine can be pharmaceutically, pharmacological-toxicologically and clinically tested after the issuing the marketing authorization, as a part of laboratory quality control, or to obtain additional data on the medicine.
The medicine is tested in accordance with the guidelines of Good Manufacturing Practice, Good Laboratory Practice and Good Clinical Practice for human or veterinary medicines.
The guidelines referred to in paragraph 4 of this Article shall be published on the website of the Ministry and the Agency, and the guidelines of Good Clinical Practice for veterinary medicines shall be announced by the state authority body responsible for veterinary care.

Article 61

Pharmaceutical testing of medicine shall include chemical-pharmaceutical-biological testing of medicine quality, in accordance with the requirements for issuing of marketing authorization.

Article 62

The procedure of pharmaceutical medicine testing, as described in the documentation for obtaining the marketing authorization, must comply with contemporary scientific achievements or discoveries and principles of Good Control Laboratory Practice.
Documentation for carrying out the procedure of pharmaceutical medicine 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 the pharmaceutical medicine testing can be repeated and in order to ensure the comparability of results.

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

Article 63

Pharmacological-toxicological testing of medicine is the process of determining of medicine safety and pharmacological properties of the medicine, which is performed in accordance with the requirements for the issuing of marketing authorization.

Article 64

The procedure of pharmacological-toxicological testing of medicine, as described in the documentation submitted for issuing of marketing authorization, must correspond to the level of contemporary scientific development and the rules of Good Laboratory Practice.

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

Pharmacological-toxicological testing of medicines 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. for veterinary medicines the effects on animals.

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

Detailed content of pharmacological-toxicological testing of medicines, as well as the documentation referred to in paragraph 2 of this Article shall be regulated by the Ministry i.e. state authority body responsible for veterinary care for veterinary medicines.

In the case referred to in paragraph 4 of this Article the waiting period is determined based on the maximum level of residue which is regulated by the state authority body responsible for veterinary care.

Article 65

Clinical trial of medicine is any investigation carried out on human subjects in order to determine or confirm the clinical, pharmacological or pharmacodynamic effects of one or more tested medicines and / or to identify any adverse reaction to one or more tested medicines, to examine resorption, distribution , metabolism and excretion of one or more medicines so that its safety and / or efficiency can be determined.

Clinical trial of medicine shall include the clinical trial of bioavailability or biological equivalence.

Clinical trial of veterinary medicines is the testing on healthy and diseased animals for detecting and confirming the clinical, pharmacological, pharmacokinetic and pharmacodynamic properties of the medicine which is tested or the monitoring its adverse effects, in order to prove its safety and efficiency.

Article 66

The procedure of clinical trial of the medicine must correspond to the rules of Good Clinical Practice.

Clinical trial shall be carried out in health i.e. veterinary institution that meets the requirements in terms of personnel, premises and equipment.

Detailed content of the clinical trial of medicine and the conditions of paragraph 2 of this Article shall be regulated by the Ministry or state authority body responsible for veterinary care when it comes to veterinary medicine.

Guidelines of Good Clinical Practice shall be published on the website of the Ministry and the Agency.

Article 67

Medicines shall be clinically tested on the basis of the results of pharmaceutical and pharmacological-toxicological testing.

Medicines used in human medicine are tested in accordance with the principles of medical ethics and with the compulsory protection of personal data of individuals who are subjected to examination.

Veterinary medicines are tested in accordance with the principles of veterinary ethics and animal welfare protection.

Medicines used in clinical trials must be manufactured in accordance with the manufactoring authorization and Good Manufacturing Practice and shall be labeled with the mark "for clinical trial."

For the medicine that is clinically tested, the importer of that medicine must have the authorization for wholesale distribution of medicines.
The Agency shall issue an approval to import the medicine that is tested clinically in accordance with this Law and regulations adopted for implementing of this Law.

Article 68

Clinical trial of medicine under Article 65, paragraph 1 of this Law may be performed on healthy and diseased persons only with their informed consent.
For minor or a person who is incapable of reasoning, the consent to being subjected to clinical trial is given by the parent or guardian.
The consent referred to in paragraph 1 of this Article shall not be encouraged by offering or giving any material or other benefits.
The consent referred to in paragraph 1 of this Article may be withdrawn at any time.
Clinical trial referred to in paragraph 1 of this Article shall not be performed if the potential risk of the usage of medicine is greater than the medical justification of its testing.

Article 69

Clinical trials of medicines cannot be carried out on:
1) healthy persons under 18 years of age;
2) healthy pregnant women and nursing mothers;
3) persons who are placed in social care institutions;
4) persons who are placed in institutions for the enforcement of criminal sanctions;
5) persons in whose case the coercion or other activities may affect on the approval for participation in clinical trial and freely consent to participate in clinical trial.
Exceptionally, if necessary, clinical trial of the medicine can be performed, under special precautions, and on the persons under 18 years of age, pregnant and nursing women, who suffer from the disease or condition for which the tested medicine is intended , if that clinical trial cannot be carried out on other groups of examinees.

Article 70

The clinical trial applicant may be clinical trial sponsor seated in Montenegro, or a legal entity seated in Montenegro who, on behalf of the sponsor, pursuant to the authority, files the application for clinical trial.
The clinical trial sponsor is responsible for activities that were transferred to the legal entities referred to in paragraph 1 of this Article.
Clinical trial sponsor must have a person responsible for documentation in the process of obtaining the authorization for clinical trials of the medicine, its amendments and pharmacovigilance, and is obliged to inform the Agency on it.

Article 71

Prior to the clinical trial of medicine that does not have a marketing authorization, clinical trial applicant must submit to the Agency a request for approval of clinical trial and documentation in accordance with Good Clinical Practice.
The clinical trial applicant, with the request for approval of clinical trial of a medicine without a marketing authorization or for a new indication of medicine or new mode of dosage, shall submit documentation that includes: the summary of the nature and characteristics of the medicine, the evidence of researches carried out in order to define its pharmacological and toxicological properties, the current clinical experiences, a positive opinion of the ethics committee of the health or veterinary institution where the clinical trial is carried out, the certificate of Good Manufacturing Practice, the proposed trial protocol, a list of all researchers and health i.e. veterinary institutions involved in the trial.
Detailed content of requirements and documentation for approval of clinical trials of medicine i.e. veterinary medicine is regulated by the Ministry or the state authority body responsible for veterinary care.

Article 72

The Agency shall issue an approval for clinical trial of medicine within 60 days of receipt of complete application with documentation.

In the period referred to in paragraph 1 of this Article shall not be included the time needed to submit additional documentation or providing additional explanations at the request of the Agency (clock stops).
The deadline for issuing the authorization under paragraph 1 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 medicines for gene therapy or somatic cell therapy or medicines that contain genetically modified organisms.
The period referred to in paragraph 3 of this Article may be extended for another 90 days if are necessary professional consultations with expert groups in the country or abroad.

Article 73

The clinical trial applicant shall submit the application to the Agency on the carrying out of clinical trials for a medicine that has marketing authorization and the summary of basic characteristics of medicine and information relating to: researches carried out in order to define its pharmacological and toxicological properties, the current clinical experiences, examination procedures, the number of persons undergoing testing, the number of researchers and institutions in which the testing is performed, and the positive opinion of the ethics committee of the health institution where the clinical trial is taking place.
In the case of paragraph 1 of this Article the clinical trial of medicine cannot begin before the expiration of 30 days from the date of application submission referred to in paragraph 1 of this Article.
For clinical trials of veterinary medicine that has marketing authorization for medicine and is used in veterinary medicine in accordance with the approved summary of the basic characteristics of medicine it is not necessary to submit the application to the Agency.
Detailed content of the application and documentation submitted with the application and methods of keeping records of clinical trials referred to in paragraph 1 of this Article are regulated by the Ministry.

Article 74

The clinical trial applicant is obliged to submit to the health or veterinary institution in which the clinical trial is carried out and to each researcher taking part in clinical trials of the medicine, the documentation on which the Agency approved the clinical testing and the approval of the Agency for clinical trial of the medicine, and the documentation which was submitted with the application of clinical trials and the evidence of submission of application to the Agency.
Multicenter clinical trial of medicine is performed in accordance with this Law.

Article 75

If there is an unexpected or serious adverse effect, accidents or other unexpected events during clinical trials of medicine, clinical trial applicant is required to inform the Agency and the ethics committee of the health or veterinary institution on it.
In the case of paragraph 1 of this Article, the Ministry, at the request of the Agency, may suspend or prohibit the clinical trial of medicine, based on an assessment of the risk and benefits of the medicine.

Article 76

The clinical trial applicant is obliged to periodically, in accordance with the approval for clinical trial, inform the Agency on the clinical trial and to prepare the final report on the results of clinical trials of the medicine.
The report referred to in paragraph 1 of this Article shall contain both positive and negative results of clinical trials, detailed and in an appropriate manner described, in order to allow an objective assessment of the ratio of benefit and risk, safety and efficiency.
The final report on the results of clinical trials of the medicine under paragraph 1 of this Article shall be submitted to the Agency within one year after the completion of clinical trials of the medicine, and a summary of this report must be available to the public.

Article 77

Clinical trial of the medicine can be carried out only in a legal entity with whom clinical trial applicant concluded the contract on a clinical trial of medicine.
The clinical trial applicant of the medicine must insure, before the medicine testing, the persons subjected to the trial in case of damage during a clinical trial, in accordance with the Law.
The clinical trial applicant in veterinary medicine must specify in the contract the amount of fee to the owner of the animal in case of damage caused by a clinical trial.

Article 78

The clinical trial applicant is obliged to indicate in the contract the amount of necessary expenditures for carrying out of the clinical trials of the medicine, including the costs of medical and other services of legal entity in which the testing is performed, as well as fees for researchers and persons undergoing clinical trials.

Article 79

The clinical trial applicant shall monitor the scientific and technological development of profession, the results of pharmacovigilance and other important information and on that basis reports to the Agency the administrative and basic amendments to the protocol i.e. the approval for carrying out of clinical trials of the medicine, in accordance with this Law and regulations adopted for implementing this Law.

If during the carrying out of clinical trials of the medicine result fundamental changes which could materially affect the safety or physical and mental integrity of participants, the scientific value of clinical trials, on the future course of carrying out of clinical trials, as well as on the quality and safety of tested medicine, the clinical trial applicant shall submit to the Agency the request for approval of substantial amendments to the protocol i.e. the approval for carrying out of the clinical trial of the medicine. With the request for approval of basic amendments to the protocol i.e. the approval for carrying out of clinical trials of medicine the positive opinion of the ethics committee shall be submitted.

The Agency shall consider the request for approval of basic amendments to the protocol i.e. the approval for carrying out clinical trials of medicine and make a decision within 30 days from the date of request submission.

In the period referred to in paragraph 3 of this Article shall not be included the time needed for the applicant to submit to the Agency requested additional information (clock stops).

Article 80

The control of carrying out of clinical trial of medicine is performed by the Agency, in accordance with the clinical trial protocol, Good Clinical Practice guidelines and guidelines of Good Clinical Practice for veterinary medicines.

The clinical trial applicant may request that the Agency controls the carrying out of clinical trials of medicines in places where it is performed clinical trial.

Article 81

Prior to control of carrying out of clinical trial, the Agency is obliged to inform the applicant and the researcher of the clinical trial of medicine on the control of clinical trial of medicine.

The Agency shall submit to the applicant a report on performed control of carrying out of clinical trial of medicine.

Article 82

In the process of control of carrying out of clinical trial of the medicine in the place where is performed, the Agency may direct in writing that certain irregularities in the carrying out of clinical trials shall be eliminated within 60 days.

The Agency may suspend or prohibit the carrying out of clinical trials if in the paragraph 1 of this Article were not eliminated irregularities, and if it determines that the carrying out of clinical trials is not in accordance with this Law.

Article 83

The Agency may suspend or prohibit the carrying out of clinical trials which are authorized for carrying out the clinical trials of medicine in Montenegro if it is in the interest of protecting the health of persons who are subjected to clinical trial, i.e. if it is in the interest of science and society.

If on the basis of the performed control the Agency determines that initiated clinical trial does not have to be necessary suspended urgently, in order to protect the health of persons who are subjected to clinical trial of medicine, i.e. the interests of science and society as a whole, it is obliged from the applicant or the researcher of clinical trial to seek additional information on carrying out of clinical trials.

The clinical trial applicant or clinical trial researcher is obliged to, within eight days of the requested data, to provide to the Agency all requested information on which the Agency shall inform the applicant, the researcher of clinical trial and ethics committee of the proposed measures, in accordance with this Law.

VI. MANUFACTURE OF MEDICINES

Article 84

The manufacture of medicines is a process that includes the procurement of raw materials, making of medicine, processing control, batch of medicine control, packaging and labeling of the medicine.
Manufacture of medicines in Montenegro can be performed only by legal entities that have manufacturing authorization in accordance with this Law.

Article 85

A legal entity that manufactures the medicines must comply with the manufacturing authorization issued by the Agency, Good Manufacturing Practice and Good Practice in distribution.
The legal entity referred to in paragraph 1 of this Article shall have:
1) the person responsible for the manufacture, who at all stages monitors manufacture preparation, manufacture and storage of medicines;
2) the person responsible for quality control and placing on the market of each batch;
3) adequate premises, equipment and personnel.
A legal entity that manufactures medicines from the blood, radiopharmaceutical medicines and biotechnological medicines must meet specific requirements regarding premises, equipment and personnel.
Manufacturer of medicine, not seated in Montenegro must submit the evidence of completion of requirements provided by Good Manufacturing Practice, attaching a certificate issued by the regulatory body of one of a member country of the European Union.
Detailed requirements in paragraphs. 1, 2 and 3 of this Article, as well as the mode of verifying of completion of requirements are regulated by the Ministry.
Guidelines of Good Manufacturing Practice shall be published on the website of the Ministry and the Agency.

Article 86

The legal entity that is involved in collecting, treating or processing blood, its components and derivatives, as the substances for the manufacture of medicines from the blood, must meet specific requirements regarding premises, equipment and personnel, in accordance with the Law.

Article 87

The application for obtaining the manufacturing authorization shall include:
1) a description of the whole or a part of the manufacturing procedure for which the authorization is sought;
2) a list of medicines and pharmaceutical forms for which the authorization is sought;
3) name and head office of the manufacturer of medicines, the place of manufacture, the place of quality control, as well as place of marketing of batch of medicines;
4) the name of the person responsible for the manufacturing and the person responsible for quality control and marketing of each batch of medicines;
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 authorization, in accordance with this Law.

Article 88

The application for obtaining the manufacturing authorization shall be submitted to the Agency.
The Agency, within 90 days of receipt a complete application, shall issue the manufacturing authorization if all fulfilled requierements are regulated by this Law.
In the period referred to in paragraph 1 of this Article shall not be included the time needed for the submission of additional documentation or providing additional explanations at the request of the Agency (clock stops).

Manufacturing authorization shall be issued for the indefinite period.
Manufacturing authorization for medicines containing drugs and psychotropic substances shall be issued in accordance with the specific Law.
The content of manufacturing authorization of paragraph 4 of this Article is regulated by the Ministry.

Article 89

Manufacturing authorization shall be issued for a certain place of manufacturing, pharmaceutical form and specific medicinal product.
Manufacturing authorization may be related to the procedure or parts of the procedure of manufacture of medicines.
Manufacturer of medicines who performs the manufacturing is responsible for the quality, safety and efficiency of the medicine which is manufactured.
If he changes the conditions of the manufacturing authorization, the medicine manufacturer is obliged to submit to the Agency the application for amendment of manufacturing authorization.
The Agency, within 90 days of receipt a complete application, shall issue a decision on amending the manufacturing authorization based on assessment of data from the application.
In the period referred to in paragraph 5 of this Article shall not be included the time needed for submission of additional documentation or providing additional explanations at the request of the Agency (clock stops).
For the quality, safety and efficiency of the medicine is responsible the manufacturer of medicine who places the batches of medicines on the market, as well as the manufacturing authorization holder.

Article 90

Manufacturer is obliged, without delay, to inform the Agency of any major accidents or mistakes in the process of manufacture, as well as other situations for which one can doubt the quality, safety and efficiency of the medicine
In the cases referred to in paragraph 1 of this Article, the Ministry, at the Agency's proposal, in accordance with this Law, shall order the suspension of manufacturing or distribution of a medicine i.e. prohibit placing on the market or order the withdrawal of the medicine from the market.

Article 91

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

Article 92

Manufacturing authorization shall be revoked:
1) at the request of the manufacturer;
2) if the manufacturer:
- changes the conditions of the manufacturing authorization, without submitting a request to amend the authorization,
- no longer comply with the requirements of Article 85 of this Law.
The decision on termination of the manufacturing authorization referred to in paragraph 1 of this Article shall be brought by the Agency.

Article 93

Manufacturer may sell medicines from his program exclusively to legal entities who have the manufacturing authorization, the authorization for wholesale, manufacturers of medicated aliments, pharmacies and other health and veterinary institutions.
The manufacturer can provide free medicines from his program, in the manner and under conditions regulated by the Ministry.
Manufacturer is obliged to submit ordinarily the report to the Agency on the total value of the performed sale of medicines, as well as the scope of sale for all individual medicines (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 Agency 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 are regulated by the Ministry.

VII. DISTRIBUTION OF MEDICINES

Article 94

Distribution of medicines is performed as the wholesale and the retail sale.
The wholesale shall include the import and export of medicines, procurement, storage and distribution of medicines.
Wholesale distribution of medicines shall be carried out by:
1) legal entities seated in Montenegro, which have the authorization for wholesale distribution issued by the Agency (hereinafter: wholesale pharmacy), i.e. the authority body responsible for veterinary care;
2) manufacturers of medicines seated in Montenegro for the medicines they manufacture.
Distribution of medicines referred to in paragraph 1 of this Article may only be performed with medicines which have marketing authorization, and the medicines referred to Article 45 of this Law.
Under the wholesale distribution is considered the wholesale distribution of medicines from humanitarian aid.

Article 95

Import and export of medicines can be carried out by domestic and foreign legal entity without authorization of the wholesale distribution (hereinafter: importers), recorded by the Agency i.e. the authority body responsible for veterinary care.
Importers shall import and export medicines and customs of medicines in accordance with customs regulations.

Article 96

Wholesale pharmacies may procure the medicines directly from manufacturers of medicines, importers and other wholesale pharmacies.

Article 97

The legal entity which performs the wholesale distribution of medicines is obliged to comply with the guidelines of Good Distribution Practice.
The legal entity referred to in paragraph 1 of this Article shall have:
1) the person responsible for the storage and distribution of medicines;
2) other appropriate personnel;
3) adequate premises and equipment for the storage of medicines, record keeping, storage and keeping of documentation on the quality of medicines, as well as the vehicles for the safe transport.
The person responsible for the storage and distribution of medicines must be the graduate pharmacist, i.e. the veterinarian or graduate pharmacist for the wholesale distribution of veterinary medicines.
With the persons referred to in paragraph 2 item 1 of this Article, the holder of wholesale authorization is obliged to conclude the full-time employment contract for indefinite period of time.
The legal entity which performs the wholesale distribution of medicines is obliged to ensure continuous availability of the persons referred to in paragraph 3 of this Article.
The legal entity referred to in paragraph 1 of this Article must have a copy of the certificate on the perfomed quality control for every batch of medicines which is distributed.
The legal entity referred to in paragraph 1 of this Article is obliged to keep the records in a manner that will allow immediate withdrawal of the medicine, i.e. batch of the medicine from the market by the decision of the Ministry i.e. the the state authority body responsible for veterinary care or by agreement in cooperation with the manufacturer or marketing authorization holder.
A legal entity which performs the wholesale distribution of medicines has the right to repack imported medicines in its own packaging in accordance with this Law.
The guidelines of Good Practice in the distribution of medicines are published on the website of the Ministry and the Agency.
The conditions referred to in paragraph 2 of this Article and the contents of the authorization, and the method of determining compliance with the requirements are regulated by the Ministry i.e. the state authority body responsible for veterinary care.

Article 98

The application for the wholesale distribution of medicines for the usage in human medicine, shall be submitted to the Agency and for the veterinary medicines to the authority body responsible for veterinary care.

The application under paragraph 1 shall include at least:

1) name and seat of the legal entity and the place of storage of medicines;
2) list of types and groups of medicines for which the wholesale authorization is requested;
3) name of the responsible pharmacist under whose supervision is perfomed the receipt, storage, preservation and delivery of medicines;
4) plan for the immediate withdrawal of the medicine from the market;
5) evidence of available vehicles for the transport of medicines;
6) other information relevant for obtaining of wholesale distribution authorization in accordance with this Law.

The authorization for the wholesale distribution of medicines may be issued only for a particular type i.e. group of medicines as required, based on fulfillment of prescribed conditions.

The authorization for the wholesale distribution of medicines, except for distribution of medicines containing drugs and psychotropic substances shall be issued for an indefinite period.

Article 99

For any amendments to wholesale distribution authorization the holder of authorization shall submit to the Agency, i.e. authority body responsible for veterinary care, the request for approval of such amendments.

In the procedure of issuing the authorizations for wholesale distribution, i.e. its amendments shall be implemented the deadlines specified in Article 89 paragraph 5 and 6 of this Law.

Article 100

Holder of authorization for wholesale distribution is obliged to ensure a continuous supply of medicines in accordance with the authorization for the wholesale distribution of medicines.

Holder of authorization for wholesale distribution shall submit, at the request of health or veterinary institution, the medicine for which he obtained the authorization for wholesale distribution in the shortest term that does not endanger the life and the health of people i.e. animals.

The holder of authorization referred to in paragraph 1 of this Article shall provide, for continuous supply of market with the medicines, the necessary supplies of medicines, i.e. promptly begin the procurement, the import, and providing the confirmation of the performed quality control in order to avoid interruption in the supply of market with the medicines.

The holder of authorization referred to in paragraph 1 of this Article shall deliver, upon request of the Ministry i.e. the state authority body responsible for veterinary care, within required time, the medicine which has the marketing authorization in Montenegro, as well as the medicines specified in Article 45 of this Law.

Holder of the marketing authorization is required to conclude, with all legal entities, who perform the wholesale distribution of medicines of that authorization holder, the contract on the wholesale of medicines, and at the request of the Agency, i.e. the authority body responsible for veterinary care to submit a list of these legal entities.

Article 101

Holder of authorization for wholesale distribution is obliged to inform, without delay, the Agency, i.e. the authority body responsible for veterinary care of any major accident or incident which could affect the quality of medicines and safe handling.

In the cases referred to in paragraph 1 of this Article, the Ministry i.e. the state authority body responsible for veterinary care, at the proposal of the Agency, or the authority body responsible for veterinary care, may order the suspension or withdrawal the medicines from the market.

Article 102

Agency i.e. authority body responsible for veterinary care can make a decision on termination of the authorization for the wholesale distribution of medicines, if the holder of the authorization for wholesale distribution:
1) no longer fulfils the conditions for the wholesale distribution of medicines based on which the authorization was issued;
2) changes the conditions of the authorization without submitting a request to amend the authorization;
3) within a specified period does not remove the deficiencies and irregularities identified by the competent inspection, in accordance with this Law;
4) does not fulfil the obligation of continuous supply of market with the medicines for which the authorization for wholesale distribution was issued, in accordance with this Law;
5) submits the request for termination of authorization for wholesale distribution of medicines.

Article 103

Legal and natural entity that in carrying out their activities in any way get the possession of medicine (transporter, postal operator, the holder of customs warehouse, etc..) are obliged to act in accordance with the instruction provided on the package of the medicine for transport.
For the transport and handling of medicines in the territory of Montenegro is responsible the manufacturer, i.e. holder of the wholesale and retail sale.

Article 104

Retail sale of medicines, as a part of health care, is performed in the pharmacy.
For the distribution of medicines referred to in paragraph 1 of this Article, the person responsible for preparation, handling and issuing of medicines must be a graduate pharmacist.
The retail sale of medicines specified in paragraph 1 of this Article shall be in accordance with the guidelines of Good Pharmacy Practice.
Compliance with the conditions for doing pharmacy business referred to in paragraph 1 of this Article, in accordance with Good Pharmacy Practice, is regulated by the Agency which gives an opinion in the procedure of issuing of approvals for the work of pharmacies.
Requirements regarding premises, equipment and personnel for carrying out retail sale of veterinary medicines are regulated by the state authority body responsible for veterinary care.
Guidelines of Good Pharmacy Practice shall be published on the website of the Ministry and the Agency.

Article 105

Manufacturers, holders of authorization for the wholesale distribution of medicines, 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 medicines for which the marketing authorization was issued and a separate record of the medicines that are imported for research and treatment in accordance with the regulation of Article 45 of this Law.
The method of keeping records referred to in paragraph 1 of this Article, as well as its detailed content is regulated by the Ministry, i.e. the state authority body responsible for veterinary care.

Article 106

The manufacturer may import or export medicines from his manufacturing program, the starting materials and the starting substance for the manufacturing, intermediate products, semi-finished products, in accordance with the manufacturing authorization, marketing authorization, i.e. the contract on service manufacture.

Article 107

Holders of wholesale distribution of medicines, pharmacies and veterinary institutions are obliged to regularly report to the Agency, at least annually, on total value of performed sale of all medicines, as well as the scope of sale for individual medicines (in packages) in Montenegro in accordance with the authorization.
The report referred to in paragraph 1 of this Article is confidential and the data on total sale in Montenegro, processed by the Agency, are available to the public.
The form and content of the report referred to in paragraph 1 of this Article, for a period for which is submitted and the manner of submission are regulated by the Ministry.

Article 108

Holder of the wholesale distribution shall not sell medicines from his range to other legal or natural entities, except to those who have the manufacturing authorization, the authorization for the wholesale, to manufacturers of medicated aliments, pharmacies and other health and veterinary institutions.

Pharmacy shall not sell medicines to other legal and natural entities, except to patients, owners or keepers of animals and the health and veterinary institutions.

Legal entities from paragraphs 1 and 2 of this Article may give free medicines from the range in a manner and under conditions regulated by the Ministry.

Article 109

The applicant for the obtaining the marketing authorization can import the samples of medicines, substances and other materials that are required in the procedure of obtaining the marketing authorization for the medicine, based on confirmation from the Agency, in accordance with this Law.

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

Article 110

The person who enters or exits the country can carry a reasonable amount of medicines that is necessary for personal usage or for the animal traveling with him for maximum six months, except those medicines containing drugs and psychotropic substances, in accordance with the separate Law.

Article 111

Medicines whose validity has expired or there is a inaccuracy in terms of its prescribed quality and other medicines prohibited on the market or are withdrawn from the market must be destroyed in accordance with the documentation of the manufacturer on which basis the authorization for the medicine is issued and in accordance with the Law.

VIII. PROVIDING OF QUALITY OF MEDICINES

Article 112

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

Laboratory quality control of each medicine, for which is necessary, shall be perfomed in accordance with European, national pharmacopoeia or other recognized pharmacopoeia or other valid methods of analysis.

The elements of quality of medicines shall be determined and documented for each stage of manufacture and distribution in accordance with Good Manufacturing Practice for all medicines.

Article 113

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

1) quality control of medicines before its placing on the market, in accordance with this Law, as follows:
- quality control of medicines in the procedure of issuing the marketing authorization for medicine,
- quality control of the first batch of medicine after issuing the marketing authorization,
- quality control of medicines for the renewal of authorization and during the procedure for amending the authorization, if necessary,
- obligatory quality control (reanalysis) of each batch of the following medicines: immunological medicines, radiopharmaceutical medicines and the medicines from blood or plasma;

2) quality control of medicines on the market:
- by taking random samples at least once during the validity of authorization of medicine,
- of each batch of imported medicines,
- by testing the quality of risky medicines,

- by solving identified problems;
3) quality control of magistral and galenic medicines.
Laboratory quality control is performed by checking the methodology, the elaboration of standards, i.e. by the development of pharmacopoeia and international cooperation in order to ensure quality of medicines.
Holder of the wholesale distribution of medicines and the manufacturer are obliged for the imported medicines and the medicines of the local manufacturers, to deliver to the Agency the valid certificates on perfomed quality control for each batch of imported medicine or medicines manufactured in the country.
The Agency may carry out the control of the sample of each medicine for which considers it is necessary, in order to ensure adequate quality, provided that the legal entities that are authorized for manufacturing and distribution of medicines are not in the mutual unequal position.
The Agency shall issue a certificate for quality control of the medicine from the paragraph 1, 2, 3 and 4 of this Article.

Article 114

Quality control of medicines referred to in Article 113 of this Law shall be carried out by the control laboratory for pharmaceutical medicine testing in accordance with the guidelines of Good Control Laboratory Practice.
The Agency may establish its own control laboratory or can by contract entrust the quality control of medicines to other laboratory in Montenegro or national laboratory for quality control of medicines of other country.
The content and the manner of pharmaceutical testing of medicine, for the purpose of quality control, is regulated by the Ministry.

Article 115

On the results of quality control of medicines referred to in Article 113 paragraph 1, 2 and 4 of this Law the control laboratory shall submit the report to the Agency.
The 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 116

Legal entities that manufacture and perform the distribution of medicines must provide the Agency the taking the required number of samples of medicines for quality control referred to in Article 113 of this Law.
The costs of taken samples and the control of medicines referred to in Article 113 of this Law shall be covered by the applicant for the marketing authorization, the holder of marketing authorization, i.e. the holder of the authorization for wholesale distribution of medicines, pharmacy and veterinary institution.
Exceptionally, the costs of quality control of medicines from the Article 113 paragraph 1 item 2 item 1 indented line 1 of this Law shall be covered by the Agency for the second and each subsequent time during the validity of the marketing authorization, if it is proved that the quality meets the standards of medicine.

Article 117

Health workers, i.e. veterinary workers who come into contact with the medicine or patient-user of medicine, natural and legal entities who manufacture or distribute the medicines are required to inform, on inaccuracy of quality control for which they found out, in writing, the Agency.
In case of doubt that it is a falsified medicine, the persons referred to in paragraph 1 of this Article shall immediately inform the Agency, i.e. state authority body responsible for veterinary care and the holder of marketing authorization for medicine.

IX. LABELLING OF MEDICINES

Article 118

Any medicine that is on the market must be labeled in the Montenegrin language in accordance with the marketing authorization and must be in accordance with the approved summary of the characteristics of the medicine.

Name of the medicine on the package must be indicated in Braille system.

Article 119

The labelling of the traditional and homeopathic medicines must contain the name of the therapeutic school based on which was approved, and other prescribed labels.
Veterinary medicines must be labeled with the: "for the usage in veterinary medicine," and in the instruction for the medicine must be specified the waiting period.
The obligation of labelling refers to the substances and combinations of substances intended for further processing, as well as the galenic medicines produced in the pharmacy.

Article 120

Instructions for the medicine is enclosed in the package of medicine and the medicine must be in accordance with the approved summary of the characteristics of the medicine.
Instructions for the medicine must be in Montenegrin language and the languages in official use in Montenegro.

Article 121

Labelling of outer and inner packaging of medicine and the content of the instruction for the medicine attached to the package is approved by the Agency.
The content and method of labelling of the outer and inner packaging of the medicine, as well as the content of the instruction is regulated by the Ministry. i.e. the state authority body responsible for veterinary care when it comes to veterinary medicine.

X. PHARMACOVIGILANCE

Article 122

The Agency and the holder of marketing authorization organize the pharmacovigilance system with the aim of collecting and assessing the information related to the adverse effects of medicines, and other information that may be relevant for the assessment of the benefit and risks of medicines on the market.
Based on the data referred to in paragraph 1 of this Article, the Agency may change the conditions from the marketing authorization or make a decision on the termination of the marketing authorization for medicine, i.e. to temporarily revoke the marketing authorization.
In the case referred to in paragraph 2 of this Article, the Agency may propose that the Ministry, i.e. state authority body responsible for veterinary care suspends or prohibits the distribution, i.e. to withdraw the medicine from the market.
The Agency shall monitor and make available information relevant to the safe implementation of medicines in the distribution to the expert, and if necessary, to the general public, in order to protect the public health of population.

Article 123

Holder of the marketing authorization is required to monitor and collect all information that may affect the assessment of the ratio of benefits and risks of the medicine and to submit it to the Agency, without delay, in the shortest possible time.
Holder of the marketing authorization is obliged to forward each received notification on the adverse effect of the medicine manifested in the territory of Montenegro to the Agency, not later than 15 days from the receipt of this information.
Holder of the marketing authorization shall, at the request of the Agency, submit the reported cases of doubt on serious and unexpected adverse effects of the medicine or on the transmission of infectious agents by some medicine which are manifested in the territory of the countries of European Union, i.e. another third country within 15 days of receipt of the request.
Holder of the marketing authorization shall not forward to the general public the information under paragraphs 1, 2 and 3 of this Article, without prior notice to the Agency.
Holder of the marketing authorization is obliged to ensure that all information provided on pharmacovigilance of particular medicine must be shown objectively, and not to mislead the expert and general public.

Holder of the marketing authorization shall submit , at the request of the Agency, the report on the safety of the medicine that contains expert assessment of the ratio of benefits and risks of the implementation of the medicine, in accordance with the act referred to in Article 127 of this Law.
Holder of the conditional marketing authorization for the medicine, i.e. the marketing authorization under special conditions, is obliged to submit to the Agency the report referred to in paragraph 6 of this Article, every six months, and earlier at the request of the Agency.

Article 124

Health, i.e. veterinary institutions, health i.e. veterinary workers are obliged to report any doubt on manifested adverse effect, without delay, to the Agency, especially in case of serious and / or unexpected adverse effects.
Health i.e. veterinary workers shall inform , without delay, the Agency about cases of abuse, misuse, or doubt in the quality of medicines on the market.

Article 125

In establishing the system of collecting of data on adverse effects of veterinary medicines, the Agency, in cooperation with the authority body responsible for veterinary care, shall monitor the animal safety system, the safety system of persons who give to animals the medicines, the safety system of users of products of animal origin, and environmental protection as well.

Article 126

The Agency shall cooperate with the authorized center for adverse effects of the World Health Organization and other agencies and institutions, in order to obtain the latest expert information regarding the safe usage of medicines.

Article 127

The manner of data collecting and the manner of reporting and monitoring of adverse effects of medicines are regulated by the Ministry, i.e. the state authority body responsible for veterinary care.

XI. ADVERTISING OF MEDICINES

Article 128

The advertising of medicines is any form of giving information to the general and expert public about the medicine by the manufacturer or the manufacturer sponsorship or the holder of the marketing authorization for the medicine, in order to encourage the prescribing of medicines, the supplying, selling and consumption.
Advertising of medicines, as defined in paragraph 1 of this Article shall include:
1) advertising of medicines through media and Internet, in public places and other forms of advertising the public (by mail, visits, etc.);
2) promotion of medicines to veterinary and health workers;
3) giving of 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;
5) encouraging the prescribing and dispensing of medicines by giving or promising the financial, material or other benefits.
It is not considered as advertising of medicine only the stating the name of medicine, i.e. unprotected international name, i.e. trademark exclusively if it serves only as a reminder.

Article 129

Advertising to expert public of the medicine which is prescribed, is allowed under the terms of the marketing authorization in accordance with the approved summary of the characteristics of the medicine.
It is allowed to provide a minimum one package of a new medicine only to the expert public, in order to inform the expert public about the characteristics of a new medicine that is distributed, with a note on package: "Free sample, not for sale."

Article 130

Medicines that are dispensed without a prescription can be advertised in the media and otherwise, i.e. may be provided the information about these medicines in accordance with the approved summary of the characteristics of the medicine, which is the integral part of the marketing authorization.

The advertising in paragraph 1 of this Article shall be objective and shall not mislead the expert and general public.
The Agency shall determine a list of medicines referred to in paragraph 1 of this Article.
List of medicines referred to in paragraph 1 of this Article shall be published on the website of the Agency.
It is prohibited the advertising of medicines referred to in paragraph 1 of this Article by direct addressing to children, which are intended for their treatment.

Article 131

Manufacturers of medicines, the representatives of manufacturers and legal entities engaged in distributing the medicines shall not offer the financial, material or other benefit to persons who prescribe or dispense the medicines, and their families as well.
Exceptionally of paragraph 1 of this Article, the manufacturers of medicines, the representatives of manufacturers and legal entities engaged in distributing the medicines 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 132

It is prohibited the advertising of medicines to the general public that are dispensed with prescription.
It is prohibited the advertising of medicines which do not have the marketing authorization and whose authorization has expired.
The method and conditions for advertising the medicines are regulated by the Ministry.

XII. INSPECTIONAL SUPERVISION

Article 133

The supervision over the implementation of this Law and regulations made under this Law shall be regulated by the Ministry, through the health-sanitary inspection and the state authority body responsible for veterinary care, unless otherwise is provided by this Law.
Inspectional supervision over the implementation of this Law and the regulations made under this Law, in relation to veterinary medicines, are regulated by the authority body responsible for veterinary care, through the veterinary inspection.

XIII. PENAL PROVISIONS

Article 134

Legal entity shall be liable to a fine between 10 000 euros and 20 000 euros for the following misdemeanours:
1) procuring i.e. importing the medicines that are intended for scientific and medical researches or for further processing or for the treatment of particular patient or group of patients who have special needs for such medicine or other medicines without authorization and contrary to the terms of Article 45, paragraph 2 of this Law;
2) dispensing or selling without a prescription veterinary medicines that are used to treat animals whose products are used in human alimentation (Article 57, paragraph 5);
3) performing the manufacture of medicines, and does not comply with the manufacturing authorization issued by the Agency, Good Manufacturing Practice and Good Practice in distribution (Article 85, paragraph 1);
4) if the legal entity does not have the person responsible for the manufacture and / or person responsible for quality control and placing the batches of medicines on the market and / or does not have adequate premises, equipment and other staff (Article 85, paragraph 2);
5) does not file the application to the Agency to amend the manufacturing authorization if the conditions change from the manufacturing authorization (Article 89, paragraph 4);
6) does not immediately inform the Agency of any major accidents or mistakes in the process of manufacture, as well as other situations for which one can doubt the quality, safety and efficiency of the medicine (Article 90, paragraph 1);
7) does not keep detailed records of all relevant activities of the manufacturing process as defined in the manufacturing authorization and in accordance with Good Manufacturing Practice (Article 91);
8) selling the medicines out of its program to legal entities that do not have the manufacturing authorization, the authorization for the wholesale distribution, manufacturers of medicated aliments, pharmacies and other health and veterinary institutions (Article 93 paragraph 1 and Article 108, paragraph 1);

9) importing or exporting medicines from its manufacturing range, starting materials and starting substances for the manufacturing, intermediate products and semi-finished products contrary to the manufacturing authorization, marketing authorization, i.e. contract on service production (Article 106);
10) giving free medicines from his range contrary to manner and conditions regulated by the Ministry (Article 93, paragraph 2 and Article 108, paragraph 3);
11) performing the distribution of medicines referred to in Article 94, paragraph 1 of this Law without a authorization regulated by the Ministry (Article 94, paragraph 4);
12) failing to comply with the guidelines of Good Practice in distribution during the wholesale distribution of medicines (Article 97, paragraph 1);
13) does not have the person responsible for the storage and distribution of medicines and other appropriate staff, adequate premises and equipment for the storage and keeping of medicines, keeping of records, storage of documentation on the quality of medicines, vehicles for safe transport (Article 97, paragraph 2);
14) the person responsible for the storage and distribution of medicines is not a graduate pharmacist,i.e. veterinarian or a graduate pharmacist for wholesale distribution of medicines (Article 97, paragraph 3);
15) fails to conclude a contract with a full-time employment for an indefinite period with the persons referred to in Article 97 paragraph 2 item 1 of this Law (Article 97, paragraph 4);
16) does not have a copy of the certificate on the perfomed control of every batch of medicine that is distributed (Article 97, paragraph 6);
17) does not keep records in a manner that will allow the immediate withdrawal of the medicine, i.e. the batch of medicine from the market by the decision of the Ministry, i.e. the state authority body responsible for veterinary or by agreement in cooperation with the manufacturer or holders of marketing authorization for the medicine (Article 97, paragraph 7);
18) does not provide a continuous supply of medicines in accordance with the authorization for wholesale distribution (Article 100, paragraph 1);
19) at the request of health care institution i.e. veterinary institution does not submit the medicine for which obtained the authorization for the wholesale distribution, in the shortest term in which it is not endangered human health i.e. the health of animals (Article 100, paragraph 2);
20) does not provide the necessary supplies of medicines, i.e. promptly does not begin the procurement, importing and providing of confirmation of the perfomed quality control in order to avoid an interruption in the supply of market with the medicines (Article 100, paragraph 3);
21) at the request of the Ministry, i.e. the state authority body responsible for veterinary care within the requested term, does not deliver the other medicine that has marketing authorization in Montenegro, as well as the medicines specified in Article 45 of this Law (Article 100, paragraph 4);
22) does not conclude the contract on wholesale distribution of medicines with all legal entities that perform the wholesale distribution of medicines of the authorization holder, and at the request of the Agency, i.e. the authority body responsible for veterinary care does not submit the list of those legal entities (Article 100, paragraph 5) ;
23) does not promptly inform the Agency, i.e. the authority body responsible for veterinary care of any major accident or incident which could affect the quality and safe handling of medicines (Article 101 paragraph 1);
24) the person responsible for the preparation, handling and dispensing of medicines in distribution in Article 104, paragraph 1 of this Law does not have the degree in pharmacy (Article 104, paragraph 2);
25) does not perform the retail sale of medicines referred to in Article 104, paragraph 1 of this Article in accordance with the guidelines of Good Pharmacy Practice (Article 104, paragraph 3);
26) without confirmation from the Agency imports the samples of medicine, substances or other materials that are required in the procedure of obtaining the marketing authorization (Article 109, paragraph 1);
27) does not immediately inform the Agency, i.e. the authority body responsible for veterinary care and the holder of marketing authorization, in case of doubt that it is a matter of falsified medicine (Article 117, paragraph 2);
28) offers the financial, material or other benefit to persons prescribing or dispensing the medicines, and their family members as well. (Article 131, paragraph 1).
For the misdemeanour referred to in paragraph 1 of this Article the responsible person in legal entity shall be liable to a fine between 1 000 euros and 2 000 euros.
For the misdemeanour referred to in paragraph 1, item 25 of this Article, the natural entity shall be liable to a fine between 500 euros and 2 000 euros.

In addition to the misdemeanour of referred to in paragraph 1 of this Article may be imposed the security measure of prohibition of performing the activity for a period of one month to one year.

Article 135

A fine of 10 000 euros to 20 000 euros shall be imposed on a legal entity if:

1) prior to clinical trial of medicine without the marketing authorization does not submit the application to the Agency for approval of clinical trial and documentation in accordance with Good Clinical Practice (Article 71, paragraph 1);

2) fails to notify the Agency and the ethics committee of the health i.e. veterinary institution if there is an unexpected or serious adverse effect, accidents or other unexpected event during a clinical trial of medicine (Article 75 paragraph 1).

For the misdemeanour referred to in paragraph 1 of this Article the responsible person in the legal entity shall be liable to a fine of 500 euros to 1000 euros.

Article 136

A fine of 5 000 euros to 15 000 euros shall be imposed on a legal entity if:

1) fails to notify the Agency of the carrying out of clinical trial for the medicine that has the marketing authorization or begins with clinical trial prior to the expiration of 30 days from the date of application of Article 73, paragraph 1 of this Law (Article 73 paragraph 1 and 2);

2) does not submit to the health i.e. veterinary institution in which the clinical trial is carried out and to each researcher taking part in clinical trial of the medicine, the documentation on which basis the Agency has approved the clinical trial, and approval of the Agency for clinical trial, i.e. the documentation that is submitted to the application of clinical trial and the evidence on the submission of application to the Agency (Article 74 paragraph 1);

3) does not periodically inform the Agency of the clinical trial in accordance with the approval for clinical trial and does not prepare a final report on the results of clinical trials of medicines (Article 76, paragraph 1);

4) does not submit to the Agency the final report on the results of clinical trials of the medicine within one year after the clinical trial of medicine (Article 76, paragraph 3);

5) carries out the clinical trial in the legal entity without signed contract on a clinical trial (Article 77, paragraph 1);

6) prior to the clinical trial does not insure the persons subjected to the trial in case of damage during the clinical trial (Article 77, paragraph 2);

7) in the contract does not specify the amount of the fee to the owner of the animal in case of damage caused by a clinical trial (Article 77, paragraph 3);

8) the contract does not specify the amount of necessary expenditures for the implementation of clinical trials of medicines, including the costs of medical and other services of legal entities in which the testing is carried out, as well as fees for researchers and persons who undergo clinical trials (Article 78).

For the misdemeanour referred to in paragraph 1 of this Article the responsible person in legal entity shall be liable to a fine of 200 euros to 1 000 euros.

Article 137

A fine of 5 000 euros to 15 000 euros shall be imposed on a legal entity if:

1) does not have the person responsible for pharmacovigilance and for obtaining the marketing authorization, its amendments and renewal, with the signed contract on full-time employment for an indefinite period (Article 30, paragraph 3);

2) does not always notify the Agency of any new findings on the assessment of quality, safety and efficiency of medicines on the market (Article 46 paragraph 1);

3) does not apply for renewal of marketing authorization within 180 days but not later than 90 days before the expiration of marketing authorization (Article 47 paragraph 1);

4) does not distribute the medicine within 12 months from the day of submission of decision on renewal of marketing authorization in accordance with the decision (Article 48, paragraph 6);

5) fails to submit regularly report to the Agency on the total value of the sale of medicines, as well as the range of sale for individual drugs (in packages) Montenegro (Article 93, paragraph 3 and Article 107, paragraph 1);

6) does not keep records on the type and quantity of imported or exported, as well as sold or dispensed medicines for which the marketing authorization was issued, indivudual records on medicines which are imported for researches and treatment in accordance with Article 45 of this Law (Article 105 paragraph 1);
7) places the medicine on the market which is not labeled in Montenegrin language in accordance with the marketing authorization and in accordance with the approved summary of the characteristics of the medicine (Article 118);
8) does not destroy the medicines whose validity has expired or there is the inaccuracy in terms of its prescribed quality and other medicines prohibited on the market or those which are withdrawn from the market in accordance with the documentation of the manufacturer on whose basis the marketing authorization was issued and in accordance with the Law (Article 111);
9) does not allow the Agency to take a necessary number of samples of medicines for the quality control of medicines referred to in Article 113 of this Law (Article 116 paragraph 1);
10) in writing does not inform the Agency on the inaccuracy of quality control of medicine for which they found out (Article 117, paragraph 1);
11) distributes traditional and homeopathic medicine that does not contain the name of the therapeutic school based on which is approved, as well as other prescribed labels (Article 119, paragraph 1);
12) fails to label the veterinary medicines with the inscription: "For the usage in veterinary medicine," and in the instruction for medicine does not indicate the waiting period (Article 119, paragraph 2);
13) fails to mark the substances and combinations of substances that are intended for further processing, and galenic medicines made in pharmacies (Article 119, paragraph 3);
14) instruction for the medicine attached to the medicine package does not comply with the approved summary of the characteristics of the medicine (Article 120, paragraph 1);
15) instruction for the medicine is not in Montenegrin language and the languages in official use in Montenegro (Article 120, paragraph 2);
16) does not organize pharmacovigilance system (Article 122, paragraph 1);
17) does not submit to the Agency, not later than 15 days from receipt of this information, each application received on adverse effects of the medicine, manifested on the territory of Montenegro (Article 123 paragraph 2);
18) at the request of the Agency fails to submit the reported cases of suspected serious and unexpected adverse effects of medicines or the transmission of infectious agents by some medicine, which are manifested in the territory of the European Union countries, i.e. another third country within 15 days of receipt of the request (Article 123 paragraph 3);
19) forwards to the general public the information referred to in Article 123 paragraph 1, 2 and 3 of this Law without prior notice to the Agency (Article 123, paragraph 4);
20) does not ensure that all information provided on pharmacovigilance of particular medicine are shown objectively, and not to mislead the expert and the general public (Article 123, paragraph 5);
21) at the request of the Agency fails to submit a report on the safety of a medicine containing a professional assessment of the ratio of benefit and risks of the medicine in accordance with the act referred to in Article 127 of this Law (Article 123, paragraph 6);
22) the holder of the conditional marketing authorization i.e the marketing authorization under special circumstances, does not submit the report under Article 123, paragraph 6 of this Law every six months, at the request of the Agency and earlier (Article 123, paragraph 7);
23) does not report to the Agency any doubt on manifested adverse effect without delay, especially in case of serious and / or unexpected adverse effects (Article 124, paragraph 1);
24) advertises to expert public the medicine prescribed contrary to the terms of marketing authorization by approved summary of the characteristics of the medicine (Article 129, paragraph 1);
25) advertises the medicines that are dispensed without a prescription contrary to regulations of Article 130 paragraph 1 of this Law;
26) advertises the medicines to the general public that are dispensed with the prescription, or the medicines which do not have the marketing authorization or whose marketing authorization has expired (Article 132 para. 1 and 2).
For the misdemeanour referred to in paragraph 1 of this Article the responsible person in legal entity shall be liable to a fine of 1 000 euros to 2 000 euros.
For the misdemeanour referred to in paragraph 1 item 10 and 23 of this Article the natural entity shall be liable to a fine of 200 euros to 1 000 euros.

XIV. TRANSITIONAL AND FINAL PROVISIONS

Article 138

Regulations for the implementation of this Law shall be adopted within 18 months from the date of entry into force of this Law.

Until the adoption of regulations referred to in paragraph 1 of this Article, shall be implemented the regulations that were adopted for implementing the Law that was in force until the day of entry into force of this Law, and which are not inconsistent with this Law.

Article 139

Legal entities that manufacture medicines and which perform wholesale distribution and retail sale of medicines are obliged to adjust the business and activities with this Law and the regulations adopted for implementation of this Law, within 24 months from the day of entry into force of this Law.

Article 140

Authorizations for placing medicines on the market issued pursuant to the regulations that were in force at the time when the authorization was issued shall remain in force until expiry of their original term.

The Agency shall decide on termination of authorizations under referred to in paragraph 1 of this Article, i.e. may decide to suspend or prohibit the distribution, i.e. to withdraw the medicine from distribution, in the cases referred to in Article 50 of this Law.

Article 141

Procedures initiated by requests to the Ministry i.e. the Agency until the day of the entry into force of this Law shall be completed by the regulations that were in force at the time the request is submitted.

Article 142

Agency for Medicines and Medical Devices established in accordance with the Law on Medicines ("Official Journal of Montenegro" No. 80/04 and "Official Journal of Montenegro" no. 18/08 and 34/10) shall continue to operate under the name of the Agency for Medicines and Medical Devices.

Article 143

On the day of entry into force of this Law, the Law on Medicines ("Official Journal of Montenegro" No. 80/04 and "Official Journal of Montenegro" no. 18/08 and 34/10) shall cease to have effect and the implementation of the Law on manufacturing and distribution of medicines(" Official Journal of Montenegro "no. 18/93 and 23/02).

Article 144

This Law shall enter into force eight days from the day of its publication in "Official Journal of Montenegro".

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EPA 674 XXIV
Podgorica, November 17th 2011

Parliament of Montenegro of 24th assembly

President
Ranko Krivokapić