LAW ON MEDICINES

I BASIC PROVISIONS

Article 1

This Law regulates conditions for manufacturing and marketing medicines for human use and use in veterinary medicine, measures for quality assurance, safety and efficacy of medicines, as well as competencies of the administrative authority for medicines and medical devices and other administrative authorities in this field.

Article 2

A medicine is a substance or a combination of substances, manufactured and intended for treatment or prevention of diseases with humans and animals, determining diagnosis, improvement or modification in physiological functions, as well as for achieving other medically justified objectives.

The substance from Paragraph 1 of this Article can be:

1. of human origin (blood, products derived from blood, except blood and blood components intended for transfusion);
2. of animal origin (parts of organs, cells, secretions, toxins, extracts, blood and blood products);
3. of vegetable origin (plants, parts of plants, plant secretions, extracts);
4. of microbiological origin (micro organisms, and genetically modified organisms;
5. of chemical origin (natural and synthetic)
6. of natural origin (elements, chemical substances found in nature in any given form, or modifications thereof)

Products that are, for the purposes of this Law, considered medicines are determined as such by the administrative authority competent for medicines and medical devices, in compliance with this Law.

Article 3

Manufacturing and marketing of medical devices is the activity of public interest.

Manufacturing, marketing, examinations and control of medicines can be performed by legal entities that fulfill conditions determined by this Law and regulations passed for the purposes of implementation of this Law.

Article 4

It is prohibited to manufacture i.e. to trade in medicines:

1. That have not been granted a marketing authorization; or a special approval for purchase or import of the medicine
2. That have been manufactured by a legal entity that does not have a manufacturing authorization;
3. That are not labeled in accordance with the provisions of this Law;
4. The expiry date of which, indicated on the package, has expired, or that have been found to be of inadequate quality.

No medicines shall be dispensed outside pharmacies.

As an exception to Paragraph 2 of this Article, a doctor of veterinary medicine or a graduated veterinarian (hereinafter referred to as "veterinarian"), performing veterinary activities, may dispense the medicines needed for treatment of animals under his care, in accordance with this Law.

Article 5

Terms used in this Law have the following meanings:

1. A finished medicine **is a medicine that is marketed with a certain strength, form and package; a finished medicine can be marketed under a protected brand name determined by the manufacturer or under an international non-protected name (INN), defined by World Health Organization, with the name of the manufacturer;**
2. A magistral medicine **is a medicine made in a pharmacy on the basis of prescriptions (formulae) for an individual patient;**
3. A galenic medicine **is a medicine made in a galenic laboratory of a pharmacy in accordance with valid Pharmacopoeia or formulae that is sold in the pharmacy;**
4. A traditional medicine **is a medicine which is not based on scientific principles, but is an expression of tradition or other traditional therapy approaches (herbal and other traditional medicines);**
5. A homeopathic medicine **is a medicine made of products, substances or compounds, which are homeopathic raw materials, in accordance with homeopathic manufacturing procedure and methods or European Pharmacopoeia or other recognized Pharmacopoeia**
6. A blood medicine **is a medicine produced from human or animal blood;**
7. Immunology medicines **are sera, vaccines, specific and non-specific immunoglobulins, toxins and allergens;**
8. Radiopharmaceutical medicine is a **finished medicine or medicine prepared immediately before use containing one or several radio-nuclids (radioactive isotopes) intended for medicinal use.**
9. Medicines which contain narcotics and psychotropic substances **are narcotics and psychotropic substances of definite qualitative and quantitative composition used in medicinal, veterinary, educational, laboratory and scientific purposes;**
10. Veterinary medicine is **a medicine intended exclusively for use in veterinary medicine;**
11. Medicated pre-mix **is a pharmaceutical form of a veterinary medicine, prepared for manufacturing medicated feed;.**
12. Quality assurance **is a continual process by which quality is introduced into all stages of manufacturing, including the system of documented tracking of all ingredients and individual manufacturing process, i.e., quality control that includes all the controls related to the quality of medicine. Quality control is realized in the process of**

manufacturing (at the beginning and during the process), on the finished product (batches of medicines) and on samples taken from the market (post-marketing control);

13. Good Manufacturing Practice (GMP**) is a system of quality assurance which refers to organization, performance, expert supervision and quality control of medicine manufacturing; good control laboratory practice (cGMP) is a part of Good Manufacturing Practice which assures quality in the process of quality control of medicines.**
14. Good Storage Practice (GSP**) is a system of quality assurance which refers to organizing, conducting and expert supervision of storage of medicines before they are marketed**
15. Good Distribution Practice (GDP**) is a system of quality assurance which refers to organization, performance and expert supervision in distribution of medicines, from manufacturer to an end user;**
16. Good Pharmacy Practice (GPP**) is a system of quality assurance which refers to organization, performance, expert supervision and quality control in pharmacy activities**
17. Good Clinical Trial Practice (GCP**) is a system of quality assurance in the process of planning and conducting clinical trails for the purposes of obtaining valid clinical conclusions with the appropriate protection of participants in clinical trials**
18. Good Laboratory Practice (GLP**) is a system of quality assurance which refers to organization and performance of laboratory operations in pre-clinical pharmacological and toxicological examinations;**
19. Pharmacopoeia **is a collection of regulated norms and standards for substances and manufacturing of medicines which are used for the purposes of determination of their identification, characteristics, quality, the manner of preparation and analysis;**
20. Pharmaceutical form **is a form of medicine convenient for application (tablet, capsule, ointment, dissolution for injections, premix etc.)**
21. Internal package **is the package a medicine is in immediate contact with;**
22. Outer package **is the package containing internal package of a medicine;**
23. Essentially similar medicines **are medicines with the same quality and quantity composition of active medicinal substance in the same pharmaceutical form with the proved bio-availability /bio-equivalence, if it is needed, as the medicine which is used as referential, until it is scientifically proven that there is a significant difference in regard to the safety and efficacy of a medicine;**
24. Marketing authorization for a medicine **is a document which confirms that all the requirements for marketing authorization are met and that the medicine can be marketed**
25. Holder of marketing authorization **is a manufacturer with its main office in the Republic of Montenegro (hereinafter referred to as Montenegro) or a representative , that is , agent of a manufacturer if it has its main office in Montenegro;**
26. Unexpected adverse effect **is every damaging adverse effect of a medicine which is not listed in the summary of basic characteristics of the medicine;**
27. Adverse effect of a medicine **is a side damaging effect of the medicine when it is used in prescribed doses with patients and in the indication it is intended for;**
28. **Serious adverse effect of a medicine** is every damaging effect of a medicine that can cause death, immediate life threat, hospital treatment or prolongation of hospital treatment of a patient that have not been necessary before a medicine use, permanent or significant damage or disability, congenital abnormality or disorders in the course of breast-feeding;
29. Pharmacovigilance **is a process used for identification, monitoring and responding to**

new findings in terms of risks related to use of medicines or their interaction with other products or substances;

30. A clinical trial investigator **is a doctor of medicine, doctor of dentistry or a veterinarian that is immediately involved and responsible for treating patients, i.e. human beings or animals subject to trial and for their medical treatment;**
31. "Withdrawal period" (Carenza**) is the period of time that has to pass after the last administration of a medicine to an animal, before the treated animal and its products can be used for food;**
32. Maximum Residue Level (MRL) **is the maximum concentration of a medicine allowed to be present in food;**
33. Summary Product Characteristics (SPC**) is a document which contains basic information about a medicine and it is based on the manufacturer's proposal and intended to professional community and it is an obligatory part of marketing authorization;**
34. Clinical trial sponsor **is a physical or legal entity who assumes responsibility for initiating, conducting or financing a clinical trial;**
35. Multi-centric clinical trial **is a trial which is conducted according to a unique procedure in several health or veterinary institutions, so that it is conducted by more than one clinical trial investigator;**
36. Professional community **includes: health workers, veterinarians, students of School of medicine, School of veterinary medicine and Pharmacy, legal entities with manufacturing authorization and wholesale authorization, pharmacies, veterinary pharmacies and other health and veterinary medicine institution.**

II COMPETENCIES

Article 6

The Government of the Republic of Montenegro (hereinafter referred to as Government):

1. **Determine criteria for determining maximum prices of medicines that have a marketing authorization in Montenegro except for medicines that are dispensed without prescription (OTC medicines) as well as maximum prices of those medicines;**
2. **Take measure for the supply of medicines in cases of state of emergency and other emergency situations;**
3. **Perform other activities according to this Law.**

Article 7

The Ministry in charge of health services (hereinafter referred to as Ministry):

1. **Determine national Pharmacopoeia and magistral formulae;**
2. **Determine measures for encouraging rational consumption of medicines;**
3. **Determine in more details the conditions for : issuing of marketing authorization, manufacturing, trade, control, tracking of unwanted reactions, advertising and labeling of traditional and homeopathic medicines;**
4. **Determine the content and the manner of keeping records of issued licences, authorizations, permissions, certificates in accordance with this Law.**

Ministry, i.e. ministry in charge of veterinary medicine affairs shall, pursuant to this Law:

1. **Pass regulations for the purposes of implementation of this Law, according to the standards of European Union or other equally strict standards that are implemented**

in other countries;

2. **Propose criteria for determining maximum prices of medicines and maximum prices of medicines from the Article 6 of this Law, in cooperation with the ministry in charge of economy and foreign economic relations**
3. **Give consent to the enactment on establishment of commission and list of experts;**
4. **Pass decisions upon claims in a second instance procedure;**
5. **Perform other activities pursuant to this Law.**

Article 8

Administrative authority competent for medicines and medical devices (hereinafter referred to as competent administrative authority) performs administrative and administrative-related expert affairs regarding medical devices:

1. **Issue, modify, supplement and renew marketing authorization;**
2. **Issue authorizations for manufacturing, wholesale and retail in veterinary medicines ;**
3. **Issue approval for clinical trails of medicines which do not have marketing authorization and keep records of clinical trials of medicines that have marketing authorization;**
4. **Evaluate relations of risk and benefit of medicines on the basis of monitoring adverse effects of medicines;**
5. **Issues certificate on application of : good manufacturing practice, good clinical practice and other certificates according to this Law**
6. **Issue certificates for the needs of export of medicines according to the recommendations of World Health Organization;**
7. **Approve supply i.e. import of unregistered medicines intended for scientific and medical researches, for further processing or for the treatment of an individual patient or a group of patients;**
8. **Issue authorization for import and export of medicines which contain narcotics and psychotropic substances in accordance with international conventions;**
9. **Participate in international standardization in the field of medicines;**
10. **Perform collection and processing of data on trade and consumption of medicines;**
11. **Give information and encourage rational use of medicines;**
12. **Perform inspection supervision over manufacturers, holders of wholesale authorization, pharmacies and veterinary pharmacies and other entities this Law is applied to, as well as inspection supervision over advertising medicines and prices of medicines according to the law;**
13. **Undertake measures for quality control of medicines;**
14. **Classify medicines the market authorization is issued for, in the aim of determining relevant rules related to dispensing medicines;**
15. **Prohibit marketing i.e. order withdrawal of a medicine which does not comply to the quality, safety and efficacy standards;**
16. **Keeps records of issued licenses, permissions, authorizations and certificates;**
17. **Perform cooperation with international entities and national regulatory bodies in the field of medicines;**
18. **Perform other activities according to the law.**

If this Law does not regulate otherwise, the provisions of the Law regulating general administrative procedure shall be applied in performing the activities from the Paragraph 1, point 1, 2, 3, 5, 6 ,7, 8 and 15 of Article 8.

A complaint can be filed to the Ministry, that is, the ministry competent for veterinary medicine affairs in case of veterinary medicines regarding enactment of the competent administrative authority from the Paragraph 1 of this Article in relation to marketing authorization, manufacturing authorization, wholesale authorization, approval for clinical trial of medicines, certificates and approvals for supply and import of unregistered medicines as well as prohibition of marketing and suspension or withdrawal of medicines from the market.

Authorization from the Article 8 ,Paragraph 8, items 8 of this Law is subjected to review that is performed by the Ministry in accordance with the general enactment.

Review postpones the enforcement of the decision.

If the complaint is filed against the authorization from the Article 8, paragraph 1 , item 8 of this Law one decision is made for both the complain and the review.
In performing the review from paragraph 3 of this Article the consent can be given or authorization can be changed, revoked or inoperative.

An administrative procedure can be initiated against the decision of the Ministry , that is , Ministry competent for veterinary medicine affairs from paragraph 2 of this Article , that is, review decision from paragraph 6 of this Article.

Article 10

The costs related to the activities of evaluation of documentation, evaluation of quality, safety and effectiveness of a medicine and other expert activities in the process of issuing authorizations, certificates and permissions , from the Article 8, Paragraph 1, Items 1, 2, 3, 5, 7 and 8 of this Law, shall be covered by the entity submitting an application, if this Law does not regulate otherwise.

The method of payment and the fee from Paragraph 1 of this article which is based on real costs of performed activities is determined by Ministry , that is , the ministry competent for veterinary medicine affairs.

Fees from Paragraph 1 of this Article are revenue of the Budget of Republic of Montenegro and they are reallocated for financing the activities from Paragraph 1 of this Article.

Article 11

For performing certain expert-advisory activities in the process of issuing marketing authorization and approval for clinical trials of a medicine as well as other expert activities from the Article 8 of this Law, that require special expert knowledge from the field of pharmaceutical , pharmacological-toxicological and clinical trials of medicines the competent administrative authority, with consent of the Ministry, i.e. the ministry competent for veterinary medicine affairs, shall establish a commission, that is, shall determine a list of experts consisting of experts in medicine, dentistry, pharmacy, veterinary medicine or other related fields.

Fees for performed activities for members of the commission and experts from list of experts from Paragraph 1 of this Article are paid according to general enactment of the competent ministry .

Article 12

Heads and employees in the competent administrative authority cannot perform neither in their own name and for their own accounts, nor on behalf and for account of some other legal or physical entity the activities of manufacturing, trade and clinical trials devices .They also cannot have any other personal interest (ownership, shares, membership in management board or contractual relations) with entities performing there activities, which they will sign a statement about.

Persons from the Paragraph 1 of this Article as well as the members of commissions and experts from the list of experts may not represent legal and physical entities that are related to manufacturing and trade in medicines, which they will sign a statement about.

Persons from the Paragraph 2 of this Article may not participate in preparation of documentation submitted with application for obtaining a marketing authorization.

III MARKETING AUTHORIZATION

Article 13

Only a medicine with a marketing authorization duly issued by the competent administrative authority can be on the market in Montenegro.

Application for obtaining marketing authorization is submitted to the competent administrative authority.

The applicant can be:

1. **Manufacturer of medicines with its main office in Montenegro;**
2. **For manufacturer of medicines that does not have the main office in Montenegro, its representative or agent that has its main office in Montenegro.**

Applicant from the Paragraph 3 of this Article has to have a person responsible for pharmacovigilance of medicines for human use and/or for pharmacovigilance for veterinary medicines.

Person responsible for pharmacovigilance can be employed by the applicant from the Paragraph 3 of this Article or engaged by the applicant in some other way.

Person responsible for pharmacovigilance of medicines for human use has to have a university degree in pharmacy, medicine or dentistry, and the person responsible for pharmacovigilance of veterinary medicines has to have a university degree in pharmacy or in veterinary medicine.

Applicant is responsible for accuracy of data in the documentation submitted in the procedure for obtaining marketing authorization.

Representative from the Paragraph 3 Item 2 of this Article is obliged to have the contract with manufacture on whose behalf it submits the application for marketing authorization in order to determine the insurance liability for possible damaged caused by the use of the medicine in Montenegro.

Article 14

Request for obtaining marketing authorization contains:

1. **Administrative data, which include: name of the medicine, international non-protected name of the medicine (INN), pharmaceutical form and strength of the medicine, proposal of the summary of basic characteristics of medicine, name and address of the applicant for marketing authorization, name and address of manufacturer, manufacturing authorization issued by the national agency in the country of manufacturer, place of manufacturing, certificate of good manufacturing practice, proposal for internal and outer package , and the list of countries where the medicine is on the market;**
2. **Pharmaceutical-chemical-biological data, which include: quality and quantity data on the composition of the medicine, manufacturing procedure, quality control of all input raw materials, process control, quality control of the finished medicine, stability studies;**
3. **Pharmacological-toxicological data which include: data on pharmaco-dynamic and pharmaco-kinetic characteristics of the medicine, data on toxicity of the medicine, impact on reproductive functions, data on embryonic, fetus and perinatal toxicity, mutagenic and carcinogenic potentials, as well as data on local tolerance, i.e. for veterinary medicines the data on the proposed withdrawal period and maximum residue level;**
4. **Clinical data including the general data on testing, on performance of tests, test results, clinical-pharmacological data, the data on bio-availability/bio-equivalence,if it is needed, data on clinical safety and efficacy, documentation on extraordinary events during testing and experience in other countries in the period after the issuance of marketing authorization.**

In the procedure of issuing marketing authorization, the competent administrative authority can request other data important for obtaining the authorization, regulated by this Law , provided that those applying for marketing authorization are not brought in the position of inequality.
As an exception to Paragraph 1 of this article , the request for obtaining marketing authorization for traditional and homeophatic medicines does not have to include pharmacological-toxicological and clinical data , under conditions determined by the Ministry.

Article 15.

Exceptionally from the provision of the Article 14 of this Law, the applicant for marketing authorization for a medicine is not obliged to submit results of pharmacological-toxicological or clinical trials if he can prove that the medicine is:
1. **essentially similar to the medicine which:**

- has a marketing authorization in Montenegro or a marketing authorization in compliance with the standards of European Union or equally strict standards of other countries, and the holder of marketing authorization agrees to have the applicant for marketing authorization referring to his documentation for the purposes of obtaining marketing authorization for an essentially similar medicine;

-is on the market in Montenegro for at least 8 years or a medicine that has a marketing authorization in compliance with the standards of European Union or equally strict standards of other countries, for at least 8 years or

2. has a marketing authorization in compliance with the standards of European Union or equally strict standards of other countries for at least 10 years for which there is a published harmonized literature recognized by experts, which contains necessary data from the requested pharmacological-toxicological or clinical documentation for obtaining a marketing authorization, which prove safety and efficacy of the medicine (bibliographic application).

In the case from Paragraph 1 of this Article, for the purposes of determining bio-equivalence, for the medicines that it is required for, the bio-availability is obligatory to be proved.

If the medicine, for which the application from the Paragraph 1 of this Article is intended for, has a different indication, different dosing or a different way of application in comparison to the essentially similar medicine which is on the market, the applicant is to enclose the results of pharmacological-toxicological and clinical tests to the application he is submitting.

Article 16

The Ministry defines in more details the contents of the application and necessary documentation from the Articles 14 and 15 of this Law. The contents of pharmacological-toxicological and clinical documentation, which refer to veterinary medicines, are determined in more details by the ministry competent for veterinary medicine affairs.

Article 17

Competent administrative authority , at latest within 210 days after the receipt of the complete application from Articles 14 and 15 of this Law, shall issue a marketing authorization, i.e. shall pass a decision on rejecting the application for market authorization after obtaining expert opinion of the competent commission on validity of submitted documentation with evaluation of quality, safety and efficacy of a medicine. The time necessary for submitting additional documentation or giving additional explanations at the request of the competent administrative authority is not taken into account when calculating the deadline from the Paragraph 2 of this Article (clock stop). This period may not be longer than 180 days.

Exceptionally, in case from Article 15 , Paragraph 1, Item 1 , Line 2 of this Law, marketing authorization for essentially similar medicine cannot be issued within the period of 10 years from the date of issuance of marketing authorization for the referential medicine i.e. before expiration of exclusiveness of data on referential medicine.

Manufacturer has the right to exclusiveness of data that it manufactures for the period of time determined by the Ministry.

Article 18

Marketing authorization is issued , as a rule, for the period of five years.

A summary of basic characteristics and introduction for patients are a constituent part of the authorization from the Paragraph 1 of this Article.

Marketing authorization may contain special conditions and, if needed, it can be limited to application in experimental or not sufficiently established therapy.

The contents of marketing authorization is regulated in more details by the Ministry.

Article 19

Marketing authorization can also be issued for export only.

Holder of marketing authorization from the Paragraph 1 of this Article informs the competent administrative authority about the date of export of medicine.

Article 20

Marketing authorization, according to this Law, is not issued for magistral and galenic medicines.

Exceptionally, marketing authorization is also not issued for:

1. **medicines intended for scientific and medical researches;**
2. **medicines intended for further processing;**
3. **medicines intended for treatment of an individual patient or a group of patients with special needs for such medicines;**
4. **other medicines determined by the Ministry at the proposal of a competent administrative authority, according to this Law.**

In the case from Paragraph 2 of this Article, the competent administrative authority issues an approval for purchase or import of the medicine.

Approval from Paragraph 3 of this Article is issued:

- for the medicines from Paragraph 2, Item 1 of this Article at the request of a person who does scientific-research work;

- for the medicines from Paragraph 2, Item 2 of this Article at the request of a manufacturer of medicines;

- for medicines from Paragraph 2, Item 3 of this Article at the request of a health institution at tertiary level or veterinary clinic , veterinary surgery and veterinary surgery for pets.

Approval for purchase or import of medicines from Paragraph 2, Item 1 and 3 of this Article is issued for a certain quantity of the medicine. As for purchase or import of the medicine from Paragraph 2, Item 2 of this Article, the approval is issued for the period that cannot be longer than a year.

The approved quantity of medicines from Paragraph 2, Item 1 of this Article has to correspond to the needs of the scientific or medical research. The approved quantity of medicines from Paragraph 2, Item 3 of this Article cannot be larger than six-month needs of an individual patient or one-year needs of a health or veterinary institution.

Article 21

Holder of a marketing authorization is obliged constantly to inform the competent administrative authority about all the findings regarding the estimates of quality, safety and efficacy of the medicines on the market.

Holder of a marketing authorization can submit a request to the competent administrative authority for amendments and supplements to the authorization according to this Law .

The competent administrative authority passes the decision about the request from the Paragraph 2 of this Article within 90 days from the day on which it received the request.

Deadline from the Paragraph 3 of this Article does not include the time needed for submitting additional documents or providing additional explanations at the request of the competent administrative authority .

Ministry determines more detailed conditions, necessary documents and the manner of amending and supplementing marketing authorization.

Article 22

Holder of a marketing authorization is obliged to submit an application for renewal of the authorization within 90 days before the deadline from the valid marketing authorization expires.

In the process of passing decision on renewal of the marketing authorization the deadlines from the Article 21 of this Article are applied.

The contents of the documentation needed for renewal of the authorization is determined in more details by the Ministry.

Article 23

Marketing authorization ceases to be valid after the expiry of the period for which it was issued and at the request of the holder of marketing authorization.

The authorization from Paragraph 1 of this Article ceases to be valid also in case that the competent administrative authority determines:

1. **that the medicine is not in compliance with the requirements for quality, safety and efficacy;**
2. **that the marketed medicine is not in compliance with the conditions from the marketing authorization;**
3. **that the authorization is given on the basis of incomplete and inaccurate data;**
4. **that the holder of marketing authorization does not fulfill the approved conditions any more.**

The competent administrative authority passes decision on the cessation of validity of a marketing authorization in cases from Paragraph 1 and Paragraph 2 of this Article.

In cases referred to in Paragraph 2 of this Article, competent administrative authority suspend and prohibit marketing of a medicine and order withdrawal of the medicine from the market.

Article 24

A medicine for which a marketing authorization has expired without being renewed can be marketed even after such a date and up to the expiry date for the use of the medicine, and at most up to 180 days after the marketing authorization expires.

Article 25

If a manufacturer decides to stop manufacturing or marketing a medicine before the marketing authorization expires, it has to inform the competent administrative authority about it. It has to do so at least six months before it stops manufacturing or marketing the medicine.

Article 26

Documentation enclosed with the application for marketing authorization is the ownership of a manufacturer and is considered a business secret.

Article 27

In case of an epidemic, epizootic, natural disasters, i.e. emergencies, competent administrative authority may issue exceptional marketing authorization for a given type and quantity of medicines, even before the conditions for issuing such an authorization are met.

The authorization referred to in Paragraph 1 of this Article shall be issued only for the duration of the circumstances listed in Paragraph 1 of this Article.

Article 28

In the procedure of issuing a marketing authorization the competent administrative authority determines a regime of issuing medicines, i.e. classifies the medicines: prescription only and non-prescription medicines (OTC medicines).

Medicines that contain narcotics and psychotropic substances according to the international conventions in this field are dispensed according to a specific regime determined in the marketing authorization of such medicines.

Traditional and homeopathic medicines are dispensed without prescriptions, with the exception of traditional medicines intended for parenteral application.

Medicines cannot be dispensed contrary to the conditions determined in their marketing authorizations.

Article 29

Person who is entitled to give prescriptions for medicines according to the law may not be an owner or a co-owner of a Pharmacy.

Ministry, i.e. ministry in charge of veterinary medicine affairs shall regulate the template and contents of a prescription, criteria for classification of medicines, as well as the manner of dispensing and prescribing medicines and veterinary medicines.

Article 30

The list of medicines the marketing authorization is issued for, the list of medicines the marketing authorization of which ceased to be valid are published in the "Official Gazette of the Republic of Montenegro" within 30 days from the day on which the relevant decision of the competent administrative authority was passed.

Within 24 hours from the moment of issuing a prohibition of marketing, i.e. order on suspension of marketing of a medicine, the competent administrative authority is obliged to inform the professional community about it.

At the beginning of every calendar year , for the needs of professional community, the competent administrative authority issues a Register of medicines that are on the market in Montenegro.

IV TESTING MEDICINES FOR THE PURPOSES OF OBTAINING DOCUMENTATION IN THE PROCEDURE OF ISSUING MARKETING AUTHORIZATION

Article 31

For the purposes of obtaining a marketing authorization a medicine has to be tested in pharmaceutical , pharmacological-technological and clinical tests.

A manufacturer is responsible for performing the appropriate testing from the Paragraph 1 of this Article and expert documentation related to that testing.

A medicine can be tested in pharmaceutical, pharmacological-toxicological and clinical trials after obtaining marketing authorization. That testing is a part of laboratory quality control or is done for the purposes of obtaining additional data on the medicine.

A medicine is tested according to the standards of good manufacturing practice, good laboratory practice and good clinical practice.

1. Pharmaceutical testing of a medicine

Article 32

Pharmaceutical testing of a medicine includes chemical-pharmaceutical-biological testing of the quality of the medicine, according to the requirements for issuance of marketing authorization.

Article 33

The procedure of pharmaceutical testing, described in the documentation determined for obtaining marketing authorization, has to comply with contemporary scientific achievements, i.e. knowledge and principles of good control laboratory practice.

Documentation for conducting the procedure of pharmaceutical testing of a medicine has to include detailed descriptions of the methods of testing, description of the necessary equipment, reagents and other necessary data or references to European, national or other recognized pharmacopoeias or other validated methods of analysis, so that the pharmaceutical testing of a medicine can be repeated and the comparability of the results provided.

The Ministry determines in more details the content of pharmaceutical testing as well as documentation from the Paragraph 2 of this Article.

2. Pharmacological-toxicological testing of a medicine

Article 34

Pharmacological-toxicological testing of a medicine is a procedure of determining safety of a medicine and pharmacological characteristics of a medicine. It is performed according to the requirements for issuing marketing authorization.

Article 35

The procedure of pharmacological-toxicological testing of a medicine described in the documentation submitted for the purposes of obtaining marketing authorization has to correspond to the level of contemporary scientific development and the standards of good laboratory practice.

Documentation related to conducting the procedure of pharmacological-toxicological testing of a medicine has to contain detailed descriptions of the methods of testing so that the pharmaceutical testing of a medicine can be repeated and the comparability of the results provided.

Pharmacological-toxicological testing has to define pharmaco-dynamic, pharmaco-kinetic and toxicological characteristics determined on laboratory animals. It also has to envisage possible effects on humans, i.e. the effects on animals for veterinary medicines.

As for veterinary medicines, the documentation related to pharmacological-toxicological testing also has to include the data on metabolism, kinetics and the secretion of

residues, as well as the information about the routine pharmaceutical method that can be used for determining the level of residues.

More detailed content of pharmacological-toxicological testing, as well as the documentation from the Paragraph 2 of this Article is determined by the Ministry i.e. ministry competent for veterinary medicine for veterinary medicine.

In case of Paragraph 4 of this Article, the withdrawal period (carenza) is determined on the basis of the maximum level of residues determined by the ministry in charge of veterinary medicine affairs.

3. Clinical testing of a medicine

Article 36

Clinical testing of a medicine for use in human medicine is a trial conducted on healthy and ill persons, for the purposes of discovering or confirming clinical, pharmacological, pharmaco-dynamic and pharmaco-kinetic characteristics of the medicine tested or for the purposes of monitoring its adverse effects, in the aim of proving its safety and efficacy.

Clinical trail of a veterinary medicine is a trial conducted on healthy and ill animals, for the purposes of discovering or confirming clinical, pharmacological, pharmaco-dynamic and pharmaco-kinetic characteristics of the medicine tested or for the purposes of monitoring its adverse effects, in the aim of proving its safety and efficacy.

Article 37

Procedure of clinical testing of a medicine has to be in compliance with the standards of good clinical practice.

Clinical testing is conducted in health i.e. veterinary institution that meet the condition related to personnel, space and equipment.

More detailed content of clinical testing and conditions from Paragraph 2 of this Article , as well as the manner of issuing a certificate of good clinical practice is determined by the Ministry i.e. ministry competent for veterinary medicine affairs for veterinary medicine.

Article 38

Medicines are clinically tested on the basis of the results of pharmaceutical and pharmacological-toxicological trials.

Medicines that are used in human medicine are tested in compliance with the standards of medical ethics principles and with the obligatory protection of personal data of persons that are subjected to the trial.

Veterinary medicines are tested according to the principles of veterinary ethics and protection of well-being of animals.

Medicines that are used in clinical trials have to be manufactured according to good manufacturing practice and have to bear a label "for clinical trial".

Article 39

Clinical testing of a medicine from the Article 36, Paragraph 1 of this Law, can be conducted on healthy and ill persons only with their written consent.

For a minor or a person incapable of making judgements, the consent to be subjected to a clinical trial is to be signed by a parent or legal guardians.

Giving consent from the Paragraph 1 of this Article may not be encouraged by offering or giving any material or other benefits.

Consent from the Paragraph 1 of this Article can be withdrawn at any time.

Persons who are subjected to clinical trial have to be fully informed about the purposes, nature, procedure and possible risks of the trial, in the language understandable to the person subjected to the trail and in a written form.

Clinical trial from the Paragraph 1 of this Article may not be conducted if the possible danger of the application of the medicine is higher than the medical justification of its testing.

Article 40

Clinical testing of medicines cannot be conducted on:

1. **healthy persons under 18;**
2. **healthy pregnant women and those who breast-feed;**
3. **person who are put in social care institutions;**
4. **persons who are put in a correctional facility;**
5. **persons who can be influenced by coercion or other activities to give consent for participating in clinical trials and to give free consent for participating un clinical trials.**

Exceptionally , if needed, clinical testing can be conducted , under special measures of precaution, on persons under 18 , pregnant women and those who breast-feed , if they suffer from the disease or they have condition for which the medicine that is tested are intended to, provided that the clinical trials cannot be conducted on other groups of testees.

Article 41

Clinical trial of a medicine, according to this Law, can be proposed by a sponsor of the trial, as well as by a clinical trial investigator.

Article 42

Before the beginning of clinical trial of a medicine, the entity proposing the clinical trial (applicant) of the medicine that does not have a marketing authorization, has to submit to the competent administrative authority an application for approving the clinical trial and the documentation which is in compliance with good clinical practice.

The applicant for a clinical trail of a medicine, with the application for approval of the clinical trial for a medicine that does not have a marketing authorization, or for a new indication of a medicine, or for a new manner of dosing the medicine, encloses documentation which includes: summary of basic characteristics of the medicine, proofs on the trials conducted for the purposes of defining its pharmacological and toxicological characteristics, the clinical experience existing so far, positive opinion of the ethics committee of the health i.e. veterinary institution where the clinical trial is taking place, the certificate of good manufacturing practice, protocol of the proposed trial, list of all the investigators and health i.e. veterinary institutions included into the trial.

More detailed contents of the application and documentation for approving a clinical trial of a medicine, i.e. veterinary medicine is regulated by the Ministry, i.e. the ministry in charge of the veterinary medicine affairs.

Article 43

Competent administrative authority issues an approval for clinical trial of a medicine within 60 days from the day of receipt of the application with documentation.

Deadline from the Paragraph 1 of this Article does not include the time needed for submitting additional documents or providing additional explanations at the request of the competent administrative authority .

Competent administrative authority can recommend a clinical trial of a medicine, which already has a marketing authorization, when it is in the interest of public health.

Article 44

The applicant for a clinical trail of a medicine submits notification about conducting the clinical trial of a medicine that has a marketing authorization and submits the summary of basic characteristics of the medicine and data related to : the trials conducted for the purposes of defining its pharmacological and toxicological characteristics, the clinical experience existing so far, the testing procedure, the number of persons that are subjected to trials, the number of investigators and institutions where the trial is to be conducted., as well as the positive opinion of the ethics committee of the health i.e. veterinary institution where the clinical trial is taking place.

In case from Paragraph 1 of this Article , the clinical testing cannot commence within 30 days from the day on which the notification from Paragraph 1 of this Article was submitted.

For clinical testing of veterinary medicine that has the marketing authorization and it is used in veterinary medicine in accordance with approved summary of basic characteristics it is not necessary to submit the notification to the competent administrative authority.

More detailed content of a notification and documentation enclosed with the notification, as well as the manner of keeping records of clinical trials from Paragraph 1 of this Article is determined by the Ministry.

Article 45

An applicant for a clinical trial of a medicine is obliged to deliver documentation on the basis of which the competent administrative authority has approved the clinical trial and the approval of the competent administrative authority for clinical trial of the medicine i.e. the documentation enclosed with application for clinical trial and the proof of submitting the application to the competent administrative authority, to the health i.e. veterinary institution where clinical trial is taking place and to every investigator who participates in the clinical trial of a medicine.

Multicentric clinical trial of a medicine is conducted according to the provisions of this Law.

Article 46

If there is an unexpected or serious adverse effect, accident or any other unexpected event during a clinical trial of a medicine, the entity that proposed the clinical trial is obliged immediately to inform the competent administrative authority and ethics committee of the health i.e. veterinary institution.

In the case from Paragraph 1 of this Article, the competent administrative authority can suspend or prohibit the clinical trial of the medicine, on the basis of the estimate of the relation of risk and benefit of the medicine.

Article 47

The applicant for a clinical trial of a medicine is obliged to send periodically reports to the competent administrative authority about the course of the clinical trial of the medicine according to approval for clinical trial, as well as to prepare the final report on the results of the clinical trial of the medicine.

The report has to contain both positive and negative results of the clinical trial, detailed and presented in an appropriate manner, so that they provide for an objective estimate of the relation of risk and benefit, safety and efficacy of the medicine.

The final report on the results of the clinical trail of the medicine from Paragraph 1 of this Article has to be submitted to the competent administrative authority within a year after the clinical trial of the medicine is closed. The resume of this report has to be made available to the public.

Article 48

Prior to the clinical trial, the applicant for the clinical trial of a medicine has to insure the persons subject to the trial from the possible damage created during the clinical trail, in accordance to the law.

The applicant for a clinical trial of a medicine in veterinary medicine has to specify in the contract the amount of compensation, which will be given to the owner of the animal in case of damage to the animal caused by the clinical trial.

Article 49

The applicant for a clinical trial is obliged to determine in a contract the amount of necessary costs that are to be covered for the persons who are subjected to the clinical trial.

V MANUFACTURING MEDICINES

Article 50

Manufacturing is a process which includes procurement of raw materials, production of a medicine, process control, batch release control, packaging and labeling of the finished medicine.

Manufacturing of medicines can be performed only by legal entities that have the main office in Montenegro and possess manufacturing authorizations issued according to this Law.

Producing galenic medicines in a pharmacy in the amount of 100 finished individual packaging per a day , as well as producing magistral medicines are not considered manufacturing in terms of this Law and they are performed in a pharmacy in accordance with the Law that regulates the conditions for the operation of pharmacies..

Article 51

A legal entity that manufactures medicines has to behave according to the standards of good manufacturing practice, good storage practice and good distribution practice.

Legal entity from the Paragraph 1 of this Article has to have:

1. **a qualified person responsible for manufacturing, who at all stages follows the preparation of manufacturing, manufacturing and storage of medicines;**
2. **a person responsible for quality control and every batch release;**
3. **an appropriate space, equipment and other staff.**

A legal entity who manufactures blood medicines, radio-pharmaceutical medicines and bio-technological medicines, has to meet special requirements regarding space, equipment and staff.

More detailed conditions and good practice from Paragraph 1 2 and 3 of this Article as well as the criteria for determining the fulfillment of conditions and issuing and withdrawing the certificate are to be determined by the Ministry.

Article 52

A legal entity collecting, treating, or processing blood, its components and derivates as substances for manufacturing blood medicines, has to meet special requirements regarding space, equipment and staff , according to this Law.
The Ministry determines conditions from Paragraph 1 of this Article.

Article 53

An application for manufacturing authorization contains:

1. **description of the procedure or a part of the procedure of manufacturing the medicine the application for manufacturing authorization is submitted for;**
2. **list of medicines and pharmaceutical forms the authorization is sought for;**
3. **main office of the manufacturer of the medicine, place of manufacturing, place of quality control, as well as place of batch release;**
4. **name of the person responsible for manufacturing and the person responsible for quality control and every batch release;**
5. **data about staff, equipment and space, according to this Law and the documents on implementation of this Law;**
6. **information on handling waste and protection of the environment**
7. **other data important for obtaining authorization according to this Law.**

More detailed content of the application from the Paragraph 1 of this Article is determined by the Ministry.

Article 54

Application for manufacturing authorization is submitted to the competent administrative authority.

Within 90 days from the day of receipt of the complete application, the competent administrative authority issues manufacturing authorization if the conditions regulated by this Law are fulfilled.

Deadline from the Paragraph 1 of this Article does not include the time needed for submitting additional documents or providing additional explanations at the request of the competent administrative authority .

Manufacturing authorization is issued for an unlimited period of time.

The content of the authorization is determined by the Ministry in more details

Article 55

Manufacturing authorization is issued for a specific place of manufacturing, pharmaceutical form and specific finished medicine.

Manufacturing authorization can refer to the procedure or parts of the procedure of manufacturing a medicine.

Manufacturer of a medicine that performs the manufacturing is responsible for the quality of his/her product.

Manufacturer of a medicine is obliged to inform competent administrative authority about every change in the procedure and place of manufacturing, change of person responsible for manufacturing, person responsible for quality control and batch release.

The manufacturer that releases a batch of medicine is responsible for quality, safety and efficacy of the medicine.

Article 56

Manufacturer is obliged without any delay to inform the competent administrative authority about any major accidents or mistakes in the process of manufacturing, as well as about any other situation due to which anybody could suspect the quality, safety and efficacy of the medicine.

In cases from Paragraph 1 of this Article the competent administrative authority, according to this Law, orders suspension i.e. prohibits the marketing of the medicine and orders withdrawal of the medicine from the market.

Article 57

Manufacturer is obliged to keep detailed records on all the relevant activities of the manufacturing process in the manner determined in the manufacturing authorization and in compliance with good manufacturing practice.

Article 58

Manufacturing authorization ceases to be valid :

1. **on the request of a manufacturer or**
2. **if manufacturer**
   - **changes the conditions from manufacturing authorization without submitting a request for change in the authorization, or if the competent administrative authority rejects the request for changing the authorization or**
   - **ceases to fulfill the conditions from Article 51 of this Law.**

Decision on cessation of validity of the authorization from the Paragraph 2 of this Article is brought by the competent administrative authority

Article 59

Manufacturer can sell medicines from his programme exclusively to legal entities with manufacturing authorization or wholesale authorization, manufacturers of medicated

feed, to pharmacies, veterinary pharmacies, as well as to the other health and veterinary institutions.

Manufacturer can give free of charge medicines from his programme in the manner and under the conditions determined by the Ministry.

Manufacturer is obliged to submit regular reports to the competent administrative authority about the total value of the sale of medicines, as well as about the volume of sale, for all the individual medicines (in packages) in Montenegro.

The report from Paragraph 3 of this Article is considered a business secret and the data on total volume of sale in Montenegro processed by the competent administrative authority are available to the public.

Ministry determines the form and the contents of the report from Paragraph 3 of this Article, as well as the period for which the report is submitted and the manner in which it is submitted.

VI MARKETING OF MEDICINES

Article 60

Marketing includes selling and dispensing medicines from a manufacturer to an end user , including purchase, transportation, storage and distribution;

Marketing of medicines is done as wholesale and retail trade.

Wholesale trade includes import and export of medicines in accordance with this Law..

Article 61

Legal entities with the main office in Montenegro and with the authorization issued by the competent administrative authority can perform the activities of wholesale trade in medicines.

Marketing of medicines from Paragraph 1 of this Article can be performed only with the medicines that have marketing authorization, as well as with medicines from the Article 20 of this Law.

Article 62

A legal entity dealing in wholesale of medicines is obliged to behave according to the standards of good distribution practice and good storage practice.

Legal entity from Paragraph 1 of this Article has to have:

1. **person responsible for storage and distribution of medicines;**
2. **other appropriate staff;**
3. **appropriate space and equipment for storage of medicines, keeping records, storage**

of documentation about the quality of medicines, as well as transportation means for safe transport

4. **and fulfills other conditions in case it imports medicines.**

Person responsible for storage and distribution of medicines has to be a graduated pharmacist, i.e. veterinarian or a graduated pharmacist for the wholesale of medicines for use in veterinary medicine.

Legal entity from Paragraph 1 of this Article has to have a copy of the certificate on the quality control performed for every batch of medicines it distributes.

Legal entity dealing in wholesale of medicines has right to repack the imported medicine in its own packaging in accordance with this Law.

More detailed conditions from Paragraph 1 and 2 of this Article are regulated by the Ministry.

Article 63

Application for wholesale authorization is submitted to the competent administrative authority.

In the procedure of issuing wholesale authorization the deadlines from the Article 54, Paragraph 2 and 3 of this Law are applied.

Wholesale authorization is issued for an unlimited period of time and it ceases to be valid according to this Law.

The content of the authorization from the Paragraph 3 of this Article is regulated in more details by the Ministry.

Article 64

Holder of a wholesale authorization is obliged to provide continual supply of pharmacies in Montenegro by the medicines from the ordinary range of medicines, as a rule, within 24 hours.

The ordinary range of medicines are medicines that holder of a authorization from Paragraph 1 of this Article in normal situation provides continual supply of.

Holder of a wholesale authorization from Paragraph 1 of this Article cannot refuse to include into the ordinary range of medicines a medicine with the marketing authorization in Montenegro

Holder of a wholesale authorization from Paragraph 1 of this Article is obliged within a reasonable period of time to supply any other medicine, which has an approval from the Article 20, of this Law.

Article 65

At the request of the Ministry, the holder of wholesale authorization founded by the state is obliged in cases of emergency and other similar situations to perform certain activities, which are out of the scope of regular obligations of a holder of wholesale authorization.

Article 66

Holder of a wholesale authorization is obliged without any delay to inform the competent administrative authority about every major accident or incident which could influence the quality of medicines and safe handling.

In cases from Paragraph 1 of this Article, the competent administrative authority can order suspension or withdrawal of medicines from the market.

Article 67

Wholesale authorization ceases to be valid :

3. **on the request of a holder of a wholesale authorization or**
4. **if a holder of a wholesale authorization**
   - **changes the conditions from the authorization without submitting a reguest for change in the authorization, or if the competent administrative authority rejects the request for changing the authorization or**
   - **ceases to fulfill the conditions from Article 62 of this Law.**

Decision on cessation of validity of the authorization from the Paragraph 2 of this Article is brought by the competent administrative authority

Article 68

Legal and physical entities, which in the course of their activities come to the possession of a medicine in any way (transporter, post office operator, owner of a customs storage etc.), are obliged to handle the medicine in accordance to the instruction for transport of the medicine that can be found on the package.

Manufacturer, i.e. holder of wholesale authorization, who owns the medicine, is responsible for transport and handling of medicines at the territory of Montenegro.

Article 69

Retail of medicines, as a part of health protection, is performed in a pharmacy.

Retail of veterinary medicines is performed in a pharmacy and in a veterinary pharmacy, which has an authorization for trade in veterinary medicines.

Conditions for performing the activities of the veterinary pharmacy in terms of space, equipment and staff, are regulated by the ministry in charge of veterinary medicine affairs.

Retail of medicines from Paragraph 1 and 2 of this Article is performed in compliance with the standards of good pharmacy practice that is determined by the Ministry i.e. ministry competent for the veterinary medicine affairs

Competent administrative authority determines whether the conditions for performing the activities of the pharmacy from Paragraph 1 of this Article, according to the good pharmacy practice, are fulfilled. Competent administrative authority submits report about it to the Ministry.

Article 70

Manufacturer of medicines can export medicines from its programme, as well as import substances needed for manufacturing of medicines according to this Law.

Article 71

Holders of wholesale authorization, pharmacies, veterinary pharmacies and manufacturers of medicines are obliged to keep records regarding the kind and quantity of imported, exported and sold medicines for which a marketing authorization is issued. They are also obliged to keep special records about the medicines that are imported for the purposes of researches and treatment, according to the Article 20, Paragraph 2 of this Law.

The format of keeping the records from Paragraph 1 of this Article, and its more detailed contents are determined by the Ministry.

Article 72

Holders of wholesale authorization, pharmacies and veterinary pharmacies are obliged regularly to submit reports to the competent administrative authority about the total value of sale of all medicines, as well as about the volume of sale for all individual medicines (in packages) in Montenegro, according to the authorization.

The report from Paragraph 1 of this Article is considered a business secret and the data on total volume of sale in Montenegro processed by the competent administrative authority are available to the public.

The Ministry determines form and contents of the report from Paragraph 1 of this Article, as well as the period for which the report is submitted and the manner in which it is submitted.

Article 73

A holder of a wholesale authorization may not sell the medicines from his range of medicines to other legal or physical entities, apart from those who have manufacturing authorization, wholesale authorization, to manufacturers of medicated feed , pharmacies as well as to the other health and veterinary institutions.

A pharmacy may not sell any medicine to other legal or physical entities apart from patients, owners or keepers of animals and or health or veterinary institutions.

Legal entities from the Paragraph 1 and 2 of this Article may give for free medicines from its range of medicines in the manner and under the conditions determined by the Ministry.

Article 74

Applicant for marketing authorization can import samples of a medicine, a substance and other materials necessary in the procedure of obtaining marketing authorization, on the basis of a certificate of the competent administrative authority in accordance with this Law.

Competent administrative authority can import samples of finished medicines and substances that are used as referential values in the quality control of medicines in accordance with this Law.

Article 75

A person entering or leaving the country can take with him/her a reasonable quantity of medicines necessary for his/her personal use or for the use of an animal travelling with him/her, for six months at most.

Article 76

Medicines for which the expiry date has passed, or which are determined to be incorrect in terms of the regulated quality, as well as other medicines the marketing of which is prohibited or which are withdrawn from the Market, have to be destroyed in accordance with manufacturer documentation on basis of which the marketing authorization was issued.

VII ASSURANCE OF QUALITY OF MEDICINES

Article 77

System of quality assurance for medicines with marketing authorization in Montenegro, i.e. export of medicines, is performed by the competent administrative authority.

Medicines have to be manufactured according to the standards of good manufacturing practice recognized in European Union or according to other equally strict standards of other countries, which include the system of quality assurance and control of every batch.

Competent administrative authority assures that all the medicines are in compliance with the regulated standards of quality. The assurance is provided through the evaluation of documentation on quality, laboratory control of quality and inspection supervision.

Laboratory control of quality of every medicine, when it is necessary, is performed in compliance with European, national pharmacopoeia or other recognized pharmacopoeias and other validated methods of analysis.

In case of deviation from the standards of quality of medicines from Paragraph 3 of this Article, the competent administrative authority orders a suspension of trade in that medicine, i.e. prohibits the trade or withdraws the batch of such a medicine from the market.

Article 78

Competent administrative authority has the right to conduct the following laboratory quality controls:

1. pre-marketing quality control, according to this Law:

- quality control of the medicine in the procedure of issuing marketing authorization, especially for the medicines of manufacturers who do not apply the standards of good manufacturing practice, within the period from the Article 107 of this Law;
- quality control of the first batch of medicines after issuing marketing authorization
- quality control of a medicine for the purposes of renewal of the authorization and during the procedure of amendments and supplements to the authorization, within the period from the Article 107 of this Law;
- obligatory quality control (reanalysis) of every batch of the following medicines: sera, vaccines, and blood medicines;
- repeated quality control of a medicine which has a certificate of manufacturer on the performed quality control of the batch for the medicines of domestic and foreign manufacturers that are not completely in compliance with the standards of good manufacturing practice, within the period from the Article 107 of this Law.

2. Quality control of medicines on the market:
- taking random samples;
- at least once during the period of validity of marketing authorization;
- testing the quality of sensitive medicines;
- solving identified problems.

3. Quality control of magistral and galenic medicines.

Laboratory control is performed also by checking methodology, working out the standards, i.e. by developing pharmacopoeia and international cooperation in the aim of assuring quality of a medicine.

As for imported medicines and for the medicines of domestic manufacturers, holders of wholesale authorizations and manufacturers of medicines are obliged to submit to the competent administrative authority valid certificates on conducted quality control for every batch of medicine that enters the country or is manufactured in the country.

Competent administrative authority may conduct the control of a sample of every medicine it deems to be necessary for providing the appropriate quality provided that those having manufacturing and marketing authorization are not brought in the position of inequality.

Competent administrative authority shall issue a certificate on quality control from the Paragraph 1, 2, 3 and 4 of this Article.

Article 79

Quality control of medicines from the Article 78 of this Law is performed by the control laboratory for pharmaceutical testing of medicines, in compliance with good laboratory practice.

Competent administrative authority can establish its own laboratory from Paragraph 1 of this Article or can contract the quality control to other laboratory in Montenegro or national laboratory for quality control of some other country.

Ministry regulates the contents and the manner of pharmaceutical testing of a medicine for the purposes of quality control.

Article 80

Control laboratory submits to the competent administrative authority a report on the results of the quality control of medicines from the Article 78 , Paragraph 1, 2, and 4 of this Law.

Results from Paragraph 1 of this Article are considered a business secret, except when informing the general public about those results are in the interest of public health.

Article 81

Legal entities that manufacture and market medicines have to provide the competent administrative authority with the possibility to take a necessary number of samples for quality control from the Article 78 of this Law.

The costs of the samples taken , as well as the control of medicines from the Article 78 of this Law are to be covered by the applicant for issuing the marketing authorization, the holder of marketing authorization, i.e. the holder of wholesale authorization, pharmacy and veterinary pharmacy.

Exceptionally, the costs of quality control of a medicine from the Article 78 , Paragraph 1, Item 2 , line 1 of this Law, are covered by the competent administrative authority , provided that the quality of a medicine fulfills quality standards.

VIII LABELING MEDICINES

Article 82

Every medicine, which is on the market, has to be labeled in the language officially used in Montenegro and in compliance to the marketing authorization. The label also has to be in compliance with the summary of the basic characteristics of the medicine.

Article 83

Labeling traditional and homeopathic medicines has to contain the title of the therapy school on the basis of which it is approved, as well as other regulated labels.

Medicines that are used in veterinary medicine also has to have the label "for use in veterinary medicine" in the official language used in Montenegro. The instruction for the medicine also has to include the withdrawal period (carenza).

The obligation of labeling also refers to substances and combinations of substances intended for further processing, as well as to galenic medicines produced in pharmacies.

Article 84

Instruction for the patient is enclosed in the package of the medicine and it has to be in accordance with the approved short summary of the basic characteristics of the medicine.

Instructions for the patients have to be in the language that is in the official use in Montenegro and they have to be prepared in the manner which is understandable to the patients.

Article 85

Labeling of outer and internal package of a medicine and the contents of the instructions for patients enclosed to the package are to be approved by the competent administrative authority.

Contents and the manner of labeling the outer and internal package of a medicine as well contents of the instructions for patients are in more details determined by the Ministry i.e. ministry competent for the veterinary medicine affairs regarding veterinary medicines.

IX MONITORING ADVERSE EFFECTS OF THE MEDICINES ON THE MARKET

Article 86

Health and veterinary institutions, doctors of medicine and dentistry, veterinarians and pharmacists are obliged immediately to inform the competent administrative authority about a new unexpected adverse or serious effect of a medicine that they notice.

Article 87

Holder of a marketing authorization and every other legal entity that in its work identifies up to that moment unknown or serious adverse effects or interactions of a medicine or that suspects that such effects exist (pharmacovigilance) are obliged to inform the competent administrative authority about it.

Competent administrative authority monitors the data from Paragraph 1 of this Article to make the information about them available to professional community, and if needed to the public.

Competent administrative authority can, in case from Paragraph 1 of this Article, order suspension of marketing of the medicine or withdraw the medicine from the market. It can change the conditions from the marketing authorization or pass the decision that the marketing authorization ceases to be valid.

Article 88

In establishing the system for collecting the data on adverse effects of veterinary medicines, the competent administrative authority, in cooperation with the administrative authority competent for veterinary medicine affairs, also monitors the following systems: a system for safety of animals, system for safety of persons who give medicines to animals, system for safety of consumers in using the products of animal origin and environment protection.

Article 89

Competent administrative authority cooperates with the authorized centre for adverse effects of the World Health Organization and other agencies and institutions for the purposes of obtaining the latest expert information related to the safe use of medicines.

Article 90

The manner of collecting data and the manner of monitoring adverse effects of medicines, i.e. veterinary medicines, are in more details regulated by the Ministry, i.e. the ministry in charge of the veterinary medicine affairs.

X ADVERTISING MEDICINES

Article 91

Advertising medicines is every form of information about a medicine given to the general public and professional community by a manufacturer, or every form of sponsorship by manufacturer or holder of marketing authorization, done for the purposes of encouraging prescribing, supplying, sale and use of the medicine.

Advertising medicines in terms of Paragraph 1 of this Article includes:

1. **Advertising medicines through media and Internet, advertising on public places and other forms or advertising in public (through post, visits etc.)**
2. **Advertising medicines to health and veterinary employees;**
3. **Giving free samples to professional community;**
4. **Sponsoring scientific and promotional gatherings in which professional community participates, by covering necessary costs of transport, accommodation, food, as well as costs of obligatory participation in scientific and promotional gatherings;**
5. **Encouraging prescribing and dispensing medicines by giving or promising financial,**

material or other benefits.

Only stating the name of a medicine is not considered advertising.

Article 92

Advertising of a prescription-only medicine to professional community is allowed under the conditions defined in marketing authorization. It contains the data in compliance with the summary of basic characteristics of the medicine.

It is allowed to give one smallest package of a new medicine exclusively to the members of professional community, for the purposes of informing them about the characteristics of the new medicine that is marketed. The package has to bear the following note: "Free sample, not for sale".

Article 93

Medicines that are dispensed without prescription can be advertised in the media and in other ways, i.e. the information about these medicines can be given only in compliance with the summary of the basic characteristics of the medicine and that is a constituent part of marketing authorization.

Advertising from Paragraph 1 of this Article has to be objective and it may not be misleading.

It is prohibited to advertise medicines from Paragraph 1 of this Article to children through direct addressing to children whose treatment the medicines are intended for.

Article 94

Manufacturers of medicines, representatives of manufacturers and legal entities that trade in medicines shall not offer financial, material or other benefit neither to the persons prescribing or dispensing medicines nor to the members of their families.

Exceptionally to Paragraph 1 of this Article, manufacturers of medicines, representatives of manufacturers and legal entities who trade in medicines can sponsor scientific and promotional gatherings the professional community participates in. They can do it by covering necessary costs for transport, accommodation, food and the costs for obligatory participation in scientific and promotional gatherings.

Article 95

The manner and conditions for advertising medicines are in more details determined by the Ministry.

Article 96

It is prohibited to advertise to general public the medicines that are prescription-only or that contain psychotropic substances or narcotics.

It is prohibited to advertise the medicines without marketing authorization or whose marketing authorization ceased to be valid.

XI INSPECTION

Article 97

The activities of inspection in the field of medicines are performed by competent administrative authority.

Activities of inspection from the Paragraph 1 of this Article are performed by inspectors for medicines according to the law.

XII PUNITIVE PROVISIONS

Article 98

A fine in the amount of three hundred minimum labor rates in Montenegro shall be imposed on a legal entity if:

1. **manufactures a medicine or trades in medicine without a marketing authorization or approval for purchase i.e. imports, manufactures medicines without a manufacturing authorization; trades in medicines that are not labeled according to the provisions of this Law; trades in medicines whose expiry date, labeled on the package, has passed or for which the incorrectness has been determined in terms of the required and regulated quality; and dispenses a medicine in places other than a pharmacy (Article 4 , Paragraph 1 and 2).**

For the violations referred to in Paragraph. 1 of this Article, a fine in the amount of twenty minimum labor rates in Montenegro shall also be imposed on the responsible person in the legal entity.

Along with the fine from the Paragraph 1 of this Article, a protective measure of prohibition of performing the activities in duration of one month to one year can be pronounced

Article 99

A fine in the amount of two hundred to three hundred minimum labor rates in Montenegro shall be imposed on a legal entity if it:

1. manufactures medicines but behaves contrary to good manufacturing practice, good storage practice and good distribution practice or does not have a person responsible for

manufacturing or a person responsible for quality control and marketing of a batch of medicine or does not have the appropriate space, equipment and other staff (Article 51);

2. does not inform the competent administrative authority on every change in the procedure and place of production, person responsible for manufacturing and person responsible for quality control and marketing a batch of medicines (Article 55, Paragraph 4);
3. does not without any delay inform the competent administrative authority on every major accident or incident in the process of manufacturing or about other situations due to which one can doubt the quality, safety and efficiency of the medicine or about any major accident or incident in trade that can influence the quality of the medicine or safe handling (Article 56 , Paragraph 1 and Article 66 , paragraph 1).
4. does not keep detailed records related to all the relevant activities of the process of manufacturing in the manner determined in the manufacturing authorization and in compliance with the good manufacturing practice (Article 57);
5. sells medicines or gives free samples contrary to the provisions of Article 59, Paragraph 1 and 2 and Article 73 of this Law;
6. performs wholesale of medicines, i.e. retail of veterinary medicines without an authorization according to this Law (Article 61, Paragraph 1 and Article 67, Paragraph 2);
7. does not behave according to good distribution practice and good storage practice, or does not have the appropriate space and equipment for storage of medicines, keeping records, storage of documentation on the quality of medicines, transport means for safe transport or staff, as well as a person responsible for storage and distribution of medicines or other conditions in case it imports medicines and or does not have a copy of the certificate on the performed control of every batch of medicines it distributes (Article 62, Paragraph 1 , 2 and 4);
8. does not provide continual supply of pharmacies in Montenegro by the medicines from the ordinary range of medicine, as a rule, within 24 hours , refuses to include into the ordinary range of medicines a medicine with the marketing authorization in Montenegro or does not supply within a reasonable period of time a medicine according to the article 20 of this Law (Article 64).
9. performs retail of medicine without fulfilling the conditions for performing the activities of pharmacies according to the standards of good pharmacy practice (Article 69, Paragraph 4);
10. exports medicines that are not in their production programme or imports substances for manufacturing that are not in their production programme (Article 70);
11. imports samples of medicines, substances and other materials that it needs in the procedure of obtaining marketing authorization without having the certificate of the competent administrative authority (Article 74, Paragraph 1)

For the violations referred to in Paragraph. 1 of this Article, a fine in the amount of ten to twenty minimum labor rates in Montenegro shall also be imposed on the responsible person in the legal entity.

Along with the fine from the Paragraph 1 of this Article, a protective measure of prohibition of performing the activities in duration of one month to one year can be pronounced

Article 100

A fine in the amount of hundred and fifty to two hundred and fifty minimum labor rates in Montenegro shall be imposed on a legal entity if it:

1. conducts clinical testing of a medicine on a person without his written consent or does not obtain a consent for subjecting minors to a clinical trials or persons incapable of making judgments or does not fully inform the person subjected to clinical trial about the purpose, nature, procedure and possible risks of the trial, in the manner which will be understandable to them and in a written form (Article 39 , Paragraph 1, 2 and 5);
2. **conducts clinical testing on healthy persons under 18, healthy pregnant women and those who breast-feed, person who are put in social care institutions, persons who are put in a correctional facility and persons who can be influenced by coercion or other activities to give consent for participating in clinical trials and to give free consent for participating un clinical trials (Article 40 , Paragraph 1).**
3. **conducts clinical testing on persons under 18 , pregnant women and those who breast-feed , that suffer from the disease or they have condition for which the medicine that is tested are intended to contrary to conditions from Article 40 , Paragraph 2 of this Law.**
4. **conducts clinical testing of a medicine without marketing authorization for the medicine without the approval of the competent administrative authority (Article 43 , Paragraph 1);**
5. **does not submit notification about conducting the clinical trials for a medicine with marketing authorization to the component administrative authority or commences clinical trials within 30 day from the day on which the notification was submitted (Article 44 . Paragraph 1 and 2)**
6. **does not immediately inform the competent administrative authority and ethics committee of the health i.e. veterinary institution in which the trials takes place about unexpected or serious adverse effect, accident or any other unexpected event during a clinical trial of a medicine (Article 46 , Paragraph 1);**
7. **does not inform the competent administrative authority about the course of a clinical trial periodically in accordance with the authorization for clinical testing of medicines or does not prepare a final report on the results of a clinical trial, i.e. it does not deliver to the competent administrative authority the final report on the clinical trial within a year after the trial is completed (Article 47 , Paragraph 1 and 3);**
8. prior to the clinical trial of a medicine, does not insure the persons subjected to the trial against any damage which may be caused by the clinical trial (Article 48, Paragraph 1);
9. does not put in the contract for clinical trial the amount of compensation that the owner of the animal is to get in case of damage caused by a clinical trial (Article 48, Paragraph 2);
10. **does not determine in a contract the amount of necessary costs that are to be covered for the persons who are subjected to the clinical trial (Article 49).**

For the violations referred to in Paragraph. 1 of this Article, a fine in the amount of five to fifteen minimum labor rates in Montenegro shall also be imposed on the responsible person in the legal entity.

Article 101

A fine in the amount of hundred to two hundred and minimum labor rates in Montenegro shall be imposed on a legal entity if it:

1. determines the prices of medicines contrary to the provision of the Article 6, Paragraph 1 , Item 1 of this Law;
2. encourages giving consent for being subjected to clinical trial by offering or giving any material or other benefits (Article 39 , Paragraph 3)
3. does not destroy medicines for which the expiry date has passed or it is determined to be incorrect in terms of the regulated quality, as well as other medicines the marketing of which is prohibited or which are withdrawn from the market (Article 76);
4. does not provide the competent administrative authority with the possibility to take a necessary number of samples for quality control (Article 81 , Paragraph 1);
5. advertises to the professional community a prescription-only medicine contrary to the provisions of the Article 92 of this Law;
6. advertises medicines that are dispensed without prescription contrary to the provisions of the Article 93 of this Law;
7. offers financial, material or other benefit to the persons prescribing or dispensing medicines as well as to the members of their families (article 94);
8. advertises to general public the medicines that are a prescription-only or that contain psychotropic substances or narcotics or medicines without marketing authorization or whose marketing authorization ceased to be valid (Article 96)

For the violations referred to in Paragraph. 1 of this Article, a fine in the amount of ten to twenty minimum labor rates in Montenegro shall also be imposed on the responsible person in the legal entity

Article 102

A fine in the amount of seventy to one hundred and fifty minimum labor rates in Montenegro shall be imposed on a legal entity if it:

1. **does not inform the competent administrative authority about the date of export of a medicine that has marketing authorization issued for export only (Article 19, Paragraph 2);**
2. **purchases or imports medicines intended for scientific and medical research or for further processing or treatment of an individual patient or a group of patients with special needs for such a medicines or other medicines without authorization and contrary to conditions from Article 20 , Paragraph 3, 5 and 6 of this Law;**
3. **does not inform the competent administrative authority about all the new findings related to the estimate of quality, safety and efficacy of a marketed medicine (Article 21, Paragraph 1);**
4. **markets a medicines for which marketing authorization has expired without being renewed after the deadlines from the Article 24 of this Law;**
5. **does not inform the competent administrative authority 180 days prior to**

cessation of manufacturing or marketing of a medicine (Article 25);

6. **dispenses medicines contrary to the conditions determined in their marketing authorization (Article 28 , Paragraph 4);**
7. **does not deliver documentation on the basis of which the competent administrative authority has approved the clinical trial and the approval of the competent administrative authority for clinical trial of the medicine i.e. the documentation enclosed with application for clinical trial and the proof of submitting the application to the competent administrative authority, to the health i.e. veterinary institution where clinical trial is taking place and to every investigator who participates in the clinical trial of a medicine. (Article 45, Paragraph 1).**

For the violations referred to in Paragraph. 1 of this Article, a fine in the amount of seven to fifteen minimum labor rates in Montenegro shall also be imposed on the responsible person in the legal entity.

Article 103

A fine in the amount of forty to hundred minimum labor rates in Montenegro shall be imposed on a legal entity if it:

1. does not submit a report to the competent administrative authority about the total volume of the sale of medicines as well as about the volume of sale for all the individual medicines (in packages) in Montenegro (Article 59 Paragraph 3, Article 72 Paragraph 1)
2. does not keep records on the kind and quantity of imported, exported and sold medicines with marketing authorization and it does not keep separate records about the medicines that are imported for the purposes of research and treatment and does not inform the competent administrative authority about it (Article 71, Paragraph 1);
3. markets a medicine which is not labeled in the language which is in the official use in Montenegro according to the marketing authorization and the summary of basic characteristics of the medicine, (Article 82)
4. markets a medicine labeled contrary to the provision of the Article 83 of this Law;
5. instruction for the patient is not in accordance with the approved short summary of the basic characteristics of the medicine or it is not written in the language which is in the official use in Montenegro and it is nor prepared in the manner which is understandable to the patients (Article 84).
6. does not inform the competent administrative authority about up to then unknown adverse effects and interactions of a medicine or suspicions thereof (pharmacovigilance) that it determines in its work (article 87 Paragraph 1).

For the violations referred to in Paragraph. 1 of this Article, a fine in the amount of four to ten minimum labor rates in Montenegro shall also be imposed on the responsible person in the legal entity.

Article 104

A fine in the amount of twenty minimum labor rates in Montenegro shall be imposed on members of commissions and experts from the list of experts, from this Law, if they violate provisions of the Article 12 of this Law.

XIII TRANSITIONAL AND FINAL PROVISIONS

Article 105

Administrative authority competent for medicines and medical devices shall be established within six months from the day on which this Law comes into force.

Up to the establishment of the administrative authority from Paragraph 1 of this Article, the activities from its competence shall be performed by the Ministry i.e. administrative authority competent for veterinary medicine affairs.

Article 106

Regulations for implementation of this Law shall be passed within six months from the day on which this Law comes into force.

Until the regulations from Paragraph 1 of this Article are passed, the regulations passed for implementation of the Law which was in force up to the date on which this Law came into force shall be applied if they are not in collision with the provisions of this Law.

Article 107

Legal entities that manufacture medicines are obliged to bring their business operation and activities in accordance to this Law and regulations passed for the purposes of implementation of this Law. They are obliged to do so within five years from the day on which this Law comes into force.

Article 108

Activities from the Article 65 of this Law are performed by the Pharmacy Institution of Montenegro established by the Decision on Establishment of Public Institutions in the Field of Health Protection in the Socialist Republic of Montenegro. ("Official Gazette of the Socialist Republic of Montenegro" and the "Official Gazette of the Republic of Montenegro", Issue 21/91 and 34/91)

Within six months from the day on which this Law comes into force the Government shall pass the enactment on harmonization of the organization and operation of the Institution from Paragraph 1 of this Article with the provisions of this Law.

Article 109

Legal entities that deal in wholesale, the institution from the Article 108 of this Law, pharmacies and veterinary pharmacies shall put their operation and activities in accordance with the provisions of this Law and regulations passed for implementation of this Law. They shall do so within two years from the day on which this Law comes into force.

Article 110

Marketing authorization issued on the basis of regulations that were in force when the authorization was issued remains valid until the period for which it was issued expires.

Competent administrative authority passes a decision on termination of the authorization from Paragraph 1 of this Article, i.e. it can make a decision on suspension and prohibition of marketing, that is, withdrawal of a medicine from the market if there are reasons from the Article 23, Paragraphs 2, 3, and 4 of this Law.

Article 111

Provisions of the Article 15 , Paragraph 1, Item 1, Line 2 and Article 17 , Paragraph 4 of this Law shall be applied after five years from the date on which this Law comes into force.

Article 112

On the day when this Law comes into force, the Law on Manufacture and Marketing of Medicines ("Official Gazette of the FRY", Issues 18/93 and 23/02, 24/94 and 28/96) pertaining to medicines, as well as the provisions of Article 3, Item 12, Article 31, Paragraph 1, pertaining to transportation of veterinary medicines , Paragraph 2 , pertaining to veterinary medicines, Paragraph 4 pertaining to veterinary medicines, Paragraph 5 pertaining to veterinary medicines, Article 32, Paragraph 1 pertaining to veterinary medicines, Article 96 , Paragraph 1, Item 6 pertaining to trade in veterinary medicines and Paragraph 9 pertaining to regulations for marketing veterinary medicines and Paragraph 2 Item 1 pertaining to veterinary medicines, Article 97 , Item 6 pertaining the trade in veterinary medicines , Item 8 and 10 pertaining to veterinary medicines of the Law on Veterinary Medicine ("Official Gazette of the Republic of Montenegro", Issue 11/04) shall be abrogated.

Article 113

This Law shall come into force on the 8th day after being published in the "Official Gazette of the Republic of Montenegro".