PROPOSAL

LAW ON CHANGES AND AMENDMENTS TO THE LAW ON MEDICINES

Article 1

In the Law on Medicine ("Official Gazette of the Republic of Montenegro" No.80/04) Article 1 shall be changed and shall read as follows:

“This Law regulates conditions for manufacturing, marketing and testing medicines for human use and use in veterinary medicine, measures for quality assurance, safety and efficacy of medicines, founding of Agency for medicines and medical devices (hereinafter referred to as Agency) as well as competencies of the administrative authority for medicines and medical devices and other issues significant for performing this activity.”

Article 2

In Article 2 Paragraph 3 the words: ‘’the administrative authority competent for medicines and medical devices” shall be replaced by the word ‘’Agency’’.

Article 3

In Article 5 Paragraph 1 Item 1 after the words ‘’is medicine’’ the words ‘’which is manufactured and ‘’ shall be added.
In Item 3, after the words ‘’medicine’’ the words ‘’of verified quality ‘’shall be added.
Item 7 shall be changed and shall read as follows:
“ 7) Immunology medicines are or contain sera, specific and non-specific immunoglobulins, toxins and allergens.”
In Item 11 after the words “medicine” the following words shall be added “ intended for mixing with feed or water for animals”.
In Item 14, after the word “supervision” the following words shall be added” of medicine storage in accordance with prescribed conditions’’.
At the end of Item 16, the semicolon shall be deleted and the following words shall be added “which assures the quality of services provided to a patient by a pharmacy”;.
In Item 26 after the word “damaging” the following words shall be added “and unintentionally caused”.
At the end of Item 30 the semicolon shall be deleted and the following words shall be added : “ and responsible for conducting clinical trials”.
In Item 32, after the word “food” the following words shall be added ”from treated animals”.
In Item 34 after the word “conducting” the word ‘’or’’ shall be replaced with the following words ’’and/or’’.
In item 35, the word “procedure” shall be replaced with the word “protocol”.
After Item 36 the following items shall be added and shall read as follows:
‘’37) active substance **is pharmacologically active ingredient which has the effect of pharmaceutical dosage form;**

38) quality of a medicine **is characteristics of a medicine that can be determined by testing the quality of all ingredients of a medicine and it is acceptable physical, chemical, biological ,pharmaceutical-technological and other characteristics of medicines in accordance with requirements for marketing authorization.**
39) safety of a medicine **is acceptable relation between efficacy and harm of medicine;**
40) efficacy of a medicine **is characteristic of medicine proved by clinical trials conducted in accordance with this Law;**
41) risk related to administration of a medicine **is any risk to patient health or to population related to quality, safety or efficacy as well as any risk of adverse effect on environment;**
42) relation between benefit and risk **is assessment of positive therapeutic effects of medicine in regard to the risk from Item 41 of this Article;**
43) instruction for patient-user **is a document enclosed with medicine which contains main information about medicine, it must be written in simple and understandable language and it is compulsory part of marketing authorization of medicine;**
44) certificate for export of medicine (CPP) **is a document issued by competent agency of a country of manufacture which certifies that the medicine is approved for usage and it is marketed in the country of manufacturer, issued in accordance with recommendation of World Health Organization;**
45) brand name of a medicine **is the name that can be new, generic or scientific name. Trade mark or the name of manufacturer or holder of marketing authorization is added to generic i.e. scientific name. A new name must be different from generic one and must not cause confusion;**
46) international nonproprietary name **(generic name) of a medicine is an international nonproprietary name (INN) that was recommended by World Health Organization or if there is no such a name, its usual name;**
47) bioavailability **is the time and degree of availability of active substance from pharmaceutical dosage that gets to systemic circulation and causes pharmacological effect;**
48) bioequivalence **means that two medicines which are pharmaceutical equivalent or pharmaceutical alternative, have similar biological availability after administration of the same molar dosage to the extent that the same effect including efficacy and safety of usage can be expected;**
49) pharmaceutical equivalents **are finished medicines which contain the same active substance in the same quantity and in the same form with the same manner of administration and are in accordance with the same or comparative standards;**
50) pharmaceutical alternatives **are finished medicines which contain the same active substance but in the form of different sal, ester or similar or in another pharmaceutical form or in another dosage;**
51) sample of medicine **is the quantity of finished medicine needed for pharmaceutical trials;**
52) false medicine **is the medicine which with intent of fraud has been labeled incorrectly in regard to identity or origin, may contain right or wrong ingredients, be without active substance or contain wrong quantity of active substance and be in wrong or false package. False medicine may be original or generic medicine;**
53) original medicine **is the medicine that was the first to obtain the marketing authorization in the world based on complete documentation on quality, safety and efficacy in accordance with current requirements;**
54) referential medicine **is the medicine that has obtained the marketing authorization in Montenegro or in EU or in a country with the same requirements for obtaining the**

marketing authorization based on complete documentation on quality, safety , efficacy in accordance with current requirements;
55) generic medicine **is the medicine with the same qualitative and quantitative composition of active substances and same pharmaceutical form as referential medicine and whose bioequivalence with referential medicine was proved by adequate testing of biological availability. Different sal, ester and ether, isomer, mixed isomer, complex or derivate of active substance are regarded as the same active substance except if there are significant differences in their characteristics in regard to therapeutic safety or efficacy. Different oral forms with instantaneous release are regarded as same pharmaceutical form;**
56) biological medicine **is the medicine whose active substance is biological substance. Biological substance is a substance produced or excreted from biological source and whose entire characteristics and quality are determined by physical, chemical, biological testing together with adequate data on manufacture procedure and manufacture procedure control;**
57) biologically similar medicine **is the finished medicine which has similar quality, safety and efficacy as original biological medicine;**
58) herbal medicine **is the medicine which has as active substance only one or more herbal substances or one or more herbal preparations or one or more herbal substances in combination with one or more herbal preparations.''**

Article 4

In Article 6 in Paragraph 1 the word ''Republic'' shall be deleted.
Item 1 shall be changed and shall read as follows:
''1) determine criteria for determining maximum prices of medicines as well as maximum prices of those medicines ''.

Article 5

In Article 7 in Paragraph 1 after Item 4 three new items shall be added and shall read as follows:
''5) 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 medicine according to the law;
6) prohibit marketing i.e. order withdrawal of a medicine which does not comply with the quality, safety and efficacy standards;
7) perform supervision over Agency.''
In Paragraph 2, in Item 2 the words: "and Ministry in charge of economy and foreign economic relations'' shall be deleted.
After Paragraph 2, new Paragraph 3 shall be added and it shall read as follows: ''Ministry in charge of trade perform inspection supervision over prices of medicine with marketing authorization''.

Article 6

After Article 7 six new articles shall be added and shall read as follows:

"Article 7a

The Agency shall be founded by the Government.

The Agency shall have the status of a legal entity with rights and obligations defined by this Law, Enactment on founding and its Statute.

Article 7b

The Agency shall be in charge of:

1. **issuing, modifying, supplementing and renewing marketing authorization;**
2. **issuing authorizations for manufacturing, wholesale and retail in veterinary medicines ;**
3. **issuing approval for clinical trails of medicines which do not have marketing authorization , keeping records of clinical trials of medicines that have marketing authorization and performing control over conducting clinical trials;**
4. **evaluating relations of risk and benefit of medicines based on monitoring adverse effects of medicines and performing expert assessment of quality, safety and efficacy of medicine application;**
5. **issuing certificate on application of : good manufacturing practice, good clinical practice and other certificates according to this Law**
6. **issuing certificates needed for export of medicines according to the recommendations of World Health Organization;**
7. **approving 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 as well as other medicines according to this Law ;**
8. **issuing authorization for import, transit and export of medicines that contain narcotics and psychotropic substances as well as substances which are used in their manufacturing (precursor) in accordance with international conventions;**
9. **participating in international standardization in the field of medicines;**
10. **performing collection and processing of data on trade and consumption of medicines;**
11. **performing activities regarding information and education about medicines and providing information relevant for carrying out measure for rational use of medicines;**
12. **undertaking measures for quality control of medicines;**
13. **classifying medicines the market authorization is issued for, with the aim of determining relevant rules related to dispensing medicines;**
14. **keeping records of issued licenses, permissions, certificates and authorizations ;**
15. **performing cooperation with international entities and national regulatory bodies in the field of medicines;**
16. **proposing harmonization of regulations with EU regulations and regulations and guidelines of international institutions;**
17. **issuing expert opinion on classifying products either as a medicine or group of medicines as well as other expert opinions under authority of the Agency;**
18. **performing quality control of medicine and issuing medicine quality certificate;**
19. **performing activities related to storage and disposal of waste for its own purposes;**
20. **issuing authorization for import and export of immunological medicines, medicines from blood, and plasma and radiopharmaceutical medicines;**
21. **performing other activities according to the Law.**

Activities referred to in Paragraph 1, Item1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 14, 17, 18 and 20 of this Article shall be performed by the Agency as activities entrusted to it.

Article 7c

The Agency shall have the following bodies: Managing Board, Supervising Board and the Director.

Article 7d

The Agency shall finance its activities from its own funds, that is, fees for performing activities referred to in Article 7b Paragraph 1 Item 1, 2, 3, 4, 5, 6, 7, 8, 12, 13, 14, 17, 18 and 20 of this Law, as well as from other sources pursuant to the law.

Article 7e

Enactment on founding of the Agency shall regulate: the Agency seat, authority, structure, appointment and duration of term of office of bodies of Agency, passing the Statue and other acts as well as other issues relevant to activities of the Agency.

Article 7f

The statute and act on internal organization and job specification of the Agency shall be authorized by the Ministry.''

Article 7

Article 8 shall be deleted.

Article 8

In Article 9 in Paragraph 1 the words: ''Article 8 Paragraph 1, Items 1, 2, 3, 5, 6, 7, 8 and 15 ''shall be replaced with the following words '' Article 7b , Paragraph 1, Items 1, 2, 3, 5, 6, 7, 8, 12, 13, 14, 18 and 20.''

In Paragraph 2 the words: ''competent administrative authority ''shall be replaced with the word ''Agency'', and after the word ''import'' the words ''unregistered medicines'', shall be replaced with the following words ''medicines without marketing authorization'' and the words ''as well as prohibition of marketing and suspension or withdrawal of medicines from the market'' shall be deleted.

In Paragraph 3 and 5 the words ''Article 8'' shall be replaced with the words ''Article 7b''.

Article 9

In Article 10, Paragraph 1 the words ''Article 8, Paragraph, Items 1, 2, 3, 5, 7 and 8'' shall be replaced with the following words : ''Article 7b, Paragraph 1, Items 1, 2, 3, 5, 6, 7, 8, 17, 18 and 20''.

Paragraphs 2 and 3 shall be changed and shall read as follows:

“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 the Agency.
The Act of the Agency from Paragraph 2 of this Article shall be authorized by the Government’’

Article 10

In Article 11, in Paragraph 1 the words ‘’competent administrative authority‘’ shall be replaced with the word ‘’Agency’’.

Paragraphs 2 shall be changed and shall read as follows:

Fees for performed activities for members of the commission and experts from Paragraph 1 of this Article are paid from the Agency funds’’

Article 11

In Article 12, Paragraph and in other provisions of this Law, the words ‘’competent administrative authority’’ in different cases shall be replaced with the word ‘’Agency’’ in correct case.

Article 12

In Article 13 in Paragraph 14, after words ‘’pharmacovigilance‘’ the following words shall be added ‘’and a person responsible for obtaining marketing authorization , its modification, supplements and renewal’’ and the words ‘’of medicines for human use and/or for pharmacovigilance for veterinary medicines’’ shall be deleted.

Article 13

After Article 13, a new Article shall be added and it shall read as follows:

‘’Article 13a

Holder of a marketing authorization is obliged to inform the Agency in writing about the date of putting a medicine on the market within 15 days from the day of putting a medicine on the market ’’.

Article 14

In Article 14 in Paragraph 1 in Item 1 after words ’’name of medicine (INN),’’ the following words shall be added ’’generic if such a name exist, that is, other usual name’’, and after words ‘’characteristics of medicine’’ the following words shall be added ‘’specimen instruction for a patient-user’’.

At the end of Item 2 semicolon shall be deleted and comma and the following words shall be added’’ as well as the data on assessment of impact on the environment‘’.

After Paragraph 1, a new paragraph 2 shall be added and it shall read as follows:

''Applicant is obliged to add a sample of the medicine to the request for obtaining the marketing authorization, and also on the request of the Agency prescribed referential standards needed for pharmaceutical testing .''

Paragraphs 2 and 3 shall become Paragraphs 3 and 4.

Article 15

Article 15 shall be changed and it shall run as follows:

"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 :

1) is essentially similar to the referential medicine and:

- has approval of holder of referential medicine authorization to use its pharmaceutical, preclinical and clinical data for the purpose of assessment of documentation of the medicine for which the authorization has been requested

- has been on market in Montenegro for at least 8 years or in any EU countries or in countries having the same requirements for issuing marketing authorization or

2) contains active substance or active substances which have been used for at least 1o years as a medicine in Montenegro or in any EU countries or other countries having the same requirements for issuing marketing authorization and 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 requirement).

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.

Ministry determines more detailed conditions regarding method and procedure for proving bioequivalence.

In the case from Paragraph 1 , Item 1, indented line 2 of this Article the 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, that is, until expiration of exclusivity of data on medicine used for comparison".

Article 16

After Article 15 two new articles shall be added and shall read as follows:

"Article 15a

Applicant for issuing marketing authorization from Article 13 of this Law is obliged to enclosed with application the results of relevant pharmacological-toxicological or clinical trials if:

- **the medicine does nor entirely correspond to notion of generic medicine or when bioequivalence cannot be proved by testing bioavailability or in the case of change one or more active substances , therapeutic indications, dosage,**

pharmaceutical form or routes of administration comparing to referential medicine;

- **biologically similar medicine does not correspond to notion of generic medicine, first of all because there is a difference in relation to raw material or because of difference in manufacturing process in relation to referential biological medicine;**
- **medicines contain active substance which are ingredients of medicines that have marketing authorization in Montenegro or in EU countries or other countries having the same requirements for issuing marketing authorization but up to now they have not been used in that combination for the therapeutic purposes.''**

Article 15b

"Ministry determines more detailed conditions for obtaining marketing authorization, manufacturing, marketing, control, monitoring of adverse effect, labeling and advertising of traditional herbal and homeopathic medicines.''

Article 17

In Article 17 Paragraph 3 shall be deleted.
Current Paragraph 4 shall become Paragraph 3.

Article 18

After Article 17 a new article shall be added and it shall read as follows:

"Article 17a

If application for obtaining, renewal, changing i.e. supplementing marketing authorization of medicine which was approved for use in EU countries by centralized procedure , mutual approval procedure or national procedure is submitted the applicant from Article 13, Paragraph 3 can obtain the authorization under special procedure by enclosing with the application from Article 14 relevant declarations and certificates which guarantee sameness, quality, safety, and efficacy of the medicine for which the marketing authorization is being requested.
Ministry determines more detailed conditions for obtaining authorization from Paragraph 1 of this Article''.

Article 19

In Article 18, Paragraph 2, after the word "patients" the following words shall be added: "– users, as well as the approved package,''.
At the end of Paragraph 3 the full stop shall be deleted, and a comma and the following words shall be added: ''i.e. can be issued for the period of less than five years.''

Article 20

In Article 20 in Paragraph 4 indented line 3 the words ''health institution at tertiary level or veterinary clinic, veterinary surgery and veterinary surgery for pets'' shall be replaced by the words: ''health or veterinary institution''.
After Paragraph 6 two new articles shall be added and they shall read as follows:

''Delivery i.e. dispensation of medicines from Paragraph 2 Item 3 of this Article is performed by a legal entity that is the holder of wholesale authorization and licensed pharmacy

Ministry determines more detailed conditions for issuing purchasing i.e. import authorization for the medicines from Paragraph 2 of this Article.''

Article 21

In Article 21 in Paragraph 2 the words: ''for amendments or supplements to the authorization'' shall be replaced by the following words: ''for amendment or supplement to the marketing authorization (variations).''

Article 22

After Article 22 two new articles shall be added and shall read as follows:

''Article 22a

Measures for urgent withdrawal of medicine or batch release from the market will be taken if the Agency determines that:

- **medicine is harmful if used according to prescription;**
- **medicine has no therapeutic effect;**
- **relation between risk and benefit is unfavourable in regard to approved usage;**
- **the qualitative and quantitative composition of the medicine does not correspond to stated data , or**
- **medicine is not manufactured in accordance to issued manufacturing authorization.**

The Agency is obliged to inform the public about the measures from Paragraph 1 of this Article no later than 24 hours after issuing order on prohibition, i.e. suspension of marketing of a medicine, i.e. batch release and withdrawal of medicine from the market.

Article 22b

If the medicine, after obtaining the marketing authorization, has not been marketed for three consecutive years in Montenegro, Agency can revoke the marketing authorization for that medicine.''

Article 23

In Article 23, in Paragraph 2 at the end of Item 1, the semicolon shall be deleted and the following words shall be added: ''in prescribed condition of use.''
After Item 4 a new item shall be added and shall read as follows:
''5) that the medicine is marketed contrary to the provisions of this Law.''
In Paragraph 4 the words ''suspend and prohibit marketing of a medicine and order withdrawal of the medicine from the market'' shall be replaced with the following words ''make proposal to the Ministry to suspend i.e. prohibit marketing of the medicine and to withdraw the medicine from the market.''

Article 24

In Article 28 after Paragraph 1 a new paragraph shall be added and it shall read as follows:
''Medicines with small toxicity, a wide range of therapeutic indications, small overdose possibility, minimal interactions, indications well-known to patient-user and that are used for self-medication can be dispensed without the prescription in a pharmacy."

Paragraph 3 shall be deleted.

In Paragraph 4 after the word ''dispensed'' the following words shall be added ''i.e. sold.''
Current Paragraph 4 shall become Article 3.

Article 25

In Article 30 Paragraph 1 shall be changed and shall read as follows:
"The list of medicines the marketing authorization is issued for i.e. amendments or supplements and renewal of the authorization, the list of medicines the marketing authorization of which ceased to be valid as well as the list of medicines whose batch release are suspended or prohibited for marketing i.e. whose batch release are withdrawn from the market are published by the Agency in the "Official Gazette of the Republic of Montenegro" within 30 days from the day on which the relevant decision of the Agency was passed.''

Paragraph 2 shall be deleted.

Current Paragraph 3 shall become Paragraph 2.

Article 26

In Article 41 the full stop shall be deleted and following words shall be added ''and they are responsible for conducting clinical trial.''
After Paragraph 1, two new articles are added and they shall read as follows:
''Entities referred to in Paragraph 1 of this Article can transfer their whole or partial authority for clinical trial by a contract to another physical or legal entity that then becomes the responsible entity for the clinical trials entrusted to them.
Entities referred to in Paragraph 2 of this Article, with the whole or partial authority for conducting a clinical trial are obliged to register with the Agency .''

Article 27

In Article 42 in Paragraph 2 the words ''basic characteristic" shall be replaced with the following words ''nature and characteristics.''

Article 28

In Article 43 in Paragraph 1 after the words ''receipt of the'' the following word shall be added ''complete.''

Article 29

In Article 46 in Paragraph 2 the words ‘’the competent administrative authority’’ shall be replaced with the following words ’’Ministry on proposal made by the Agency.’’

Article 30

In Article 48 before Paragraph 1 a new paragraph shall be added and shall read as follows:

‘’Clinical trials can be conducted only in legal entity with whom the applicant for clinical trial has made a contract with for clinical trial of a medicine.’’
Current Paragraph 1 and 2 shall become Article 2 and 3.

Article 31

Article 49 shall be changed and shall read as follows:

‘’The applicant for a clinical trial is obliged to determine in a contract the amount of necessary costs for conducting clinical trials including costs of medical and other services of legal entity where the trials are to be conducted as well as fees for researchers and for the persons who are subjected to the clinical trial.’’

Article 32

In Article 51 in Paragraph 1 after words: ’’according to’’ the following words shall be added: ’’manufacturing authorization issued by the Agency,.’’

Article 33

In Article 53 in Paragraph 1 Item 3 before the word ‘’main office’’ the following words shall be added ‘’name and‘’.

Article 34

In Article 55 in Paragraph 4, the words ‘’inform competent administrative authority’’ shall be replaced with the following words ‘’submit an application for approval by the Agency’’.

Article 35

In Article 56 in Paragraph 2 the words ‘’competent administrative authority’’ shall be replaced by the following words ‘’Ministry on proposal made by the Agency.’’

Article 36

Article 60 shall be changed and shall read as follows:

‘’Marketing of medicines is performed as wholesale and retail of medicines.
Wholesale of medicines includes procurement, storage and distribution of medicines.
The wholesale of medicines can be performed by:

1) legal entities with seat in Montenegro that have wholesale authorization issued by the Agency (hereinafter referred to as wholesaler);
2) manufacturers of medicines with their seat in Montenegro for medicines they manufacture.

Marketing of medicines from Paragraph 1 of this Article can be performed only of those medicines with marketing authorization as well as of medicine from Article 20 of this Law.''

Article 37

Article 61 shall be changed and shall read as follows:

''Import and export of medicines can be performed by the wholesaler from Article 60 Paragraph 3 Item 1 of this Law and other domestic and foreign legal entities (hereinafter referred to as importers) registered with the Agency.

Importers of medicines can supply wholesalers with imported medicines but they cannot perform distribution or marketing of medicines.
Ministry determines more detailed conditions for importers registration from Paragraph 1 of this Article.''

Article 38

After Article 61 a new article shall be added and shall read as follows:

''Article 61a

Wholesalers can procure medicine directly from manufacturer of medicines, importers and other wholesalers.

Manufacturers of medicines from Article 60 Paragraph 3 Item 2 of this Law can export medicines they manufacture.''

Article 39

In Article 62 after Paragraph 2 a new paragraph shall be added and shall read as follows:

''Legal entity from Paragraph 1 of this article is obliged to keep documentation in a manner that will make possible urgent withdrawal of a medicine i.e. batch release from the market by the order of the Ministry on the proposal made by the Agency or by mutual agreement in cooperation with manufacturer or holder of marketing authorization".

Current paragraphs 3, 4, 5 and 6 shall become 4, 5, 6 and 7.

Article 40

After Article 63 a new article shall be added and shall read as follows:

''Article 63a

Holder of wholesale authorization is obliged to submit to the Agency the application for approval of any amendments or supplements to wholesale authorization for any amendments or supplement to the documentation that was used for issuing the wholesale authorization.

Ministry determines more detailed conditions for Paragraph 1 of this Article.

Article 41

In Article 64 Paragraph 3 shall be changed and shall read as follows:

"Holder of authorization from Paragraph 1 of this Article cannot refuse to include into ordinary range of medicines and within a reasonable period of time to supply a medicine with the marketing authorization in Montenegro as well as the medicine from Article 20 of this Law.''
Paragraph 4 shall be deleted.

Article 42

In article 66 in Paragraph 2 the words ''competent administrative authority'' shall be replaced with the following words ''Ministry on the proposal made by the Agency.''

Article 43

In Article 68 in Paragraph 2 after the word ''wholesale'' the following word shall be added '' and retail'', and words '' who owns the medicine '' shall be deleted.

Article 44

In Article 69 after Paragraph 1 a new paragraph shall be added and it shall read as follows:

''For marketing of medicines from Paragraph 1 of this Article a responsible person for preparation, handling and dispersion of medicines must be graduate pharmacist for humane medicine i.e. graduate veterinarian or graduate pharmacist for veterinary medicine.''

Current Paragraphs 2, 3, 4 and 5 shall become Paragraphs 3, 4, 5, and 6.

Article 45

In Article 72 Paragraph 1 after the word ''report'' the following words shall be added '', at least once a year.''

Article 46

In Article 77 Paragraphs 1 and 2 shall be deleted.

In Paragraph 3 the words ''inspection supervision'' shall be replaced with the following words ''control procedure by the Agency in accordance with this Law.''

After paragraph 2 a new paragraph shall be added and shall read as follows:

‘’ Elements of the quality of a medicine are determined and are documented for every phase of manufacturing and marketing in accordance with good manufacturing practice.’’

Paragraph 5 shall be deleted.

Current Paragraphs 3 and 4 shall become Paragraphs 1 and 3.

Article 47

In Article 78 In Paragraph 1 in Item 1 indented line 4 the words ‘’sera, vaccines, and blood medicines’’ shall be replaced with the following words “immunological medicines, radiopharmaceutical medicines and medicines from blood, and plasma.’’

In Item 2 at the end of indented line 1 the semicolon shall be deleted and the following words shall be added ‘’at least once during the period of marketing authorization validity.’’

In Item 2 at the end of indented line 2 semicolon shall be deleted and the following words shall be added ‘’every batch release of imported medicine.’’

Article 48

In Article 81 in Paragraph 3 after the words ‘’ to be covered’’ the following words shall be added ‘’ by the Agency for the second and any subsequent time while the marketing authorization is valid.’’

Article 49

After Article 81 a new article shall be added and it shall read as follows:

‘’ Article 81a

Heath care workers who have contact with a medicine or patient-user of a medicine, legal and physical entities that manufacture or market a medicine are obliged to report to the Agency any faulty quality of a medicine they might have been informed about.

If there is a doubt that it is a false medicine, entities from Paragraph 1 of this Article are obliged to inform the Agency and holder of marketing authorization within 24 hours.’’

Article 50

In Article 82 the words ‘’in the language officially used in Montenegro‘’ shall be replaced with the following words ’’in Montenegrin language’’ and after the word ‘’to the‘’ the following word shall be added ‘’approved.’’

Article 51

In Article 83 in paragraph 2 the words ‘’in the language officially used in Montenegro’’ shall be replaced with the following words ’’in Montenegrin language.’’

Article 52

In Article 84 in Paragraph 1 after the word ‘’patient’’ the following word shall be added:’’ – user.’’

Paragraph 2 shall be changed and shall read as follows:

‘’Instructions for the patient-user have to be in Montenegrin language and in regions with significant ethnic minorities and other national minority groups in their language and script and prepared in the manner which is understandable to the patient-user.’’

Article 53

In Article 85 Paragraph 1 after the word ‘’patient’’ the following word shall be added: ‘’-user.’’

Article 54

Chapter: “IX MONITORING ADVERSE EFFECTS OF THE MEDICINES ON THE MARKET‘’ shall be changed and shall read as follows:

‘’ IX PHARMACOVIGILANCE.’’

Article 55

In Article 87 in Paragraph 1 the word “(pharmacovigilance) shall be deleted
In Paragraph 3 the word ‘’order’’ shall be replaced with the following words: ’’make proposal to the Ministry.’’

Article 56

In Article 91 at the end of Paragraph 3 the full stop shall be deleted and the following words shall be added: “in accordance with this Law.’’

Article 57

In Article 92 Paragraph 1 after the words: ’’with the‘’ the following word shall be added: ’’approved.’’

Article 58

In Article 93 Paragraph 1 after the words: ’’with the‘’ the following word shall be added: ’’approved.’’
After Paragraph 2 two new paragraphs shall be added and they shall read as follows:
The Agency shall determine the list of medicines from paragraph 1 of this Article.
The list of medicines from Paragraph 1 of this Article shall be published in ‘’Official Gazette of Montenegro.’’
Current Paragraph 3 shall become Paragraph 5.

Article 59

In Article 97 Paragraph 1 shall be changed and it shall read as follows: “Supervision of putting this Law and regulations passed in accordance with this Law into effect is performed by the competent Ministry through inspections.’’

Paragraph 2 shall be deleted.

Article 60

In Article 99 Paragraph 1 Item 1 after the words ‘’contrary to’’ the following words shall be added ‘’manufacturing authorization issued by the Agency.’

In Item 2 the words: ’’does not inform the competent administrative authority’’ shall be replaced by the following words: ’’does not submit the application for approval to the Agency.’’
In Item 6 the words: ’’(Article 61 Paragraph1 and Article 69 Paragraph 2) shall be replaced with the following words: ’’(Article 60 Paragraph 3 and Article 69 Paragraph 3)’’.
In Item 7 after the word: ’’distribution of medicines’’ the following words shall be deleted: ’’or other conditions in case it imports medicines’’ and the words: ’’and 4’’ shall be replaced with the following words: ’’and 5’’.
In Item 8 after the words ‘’include’’ the following words shall be added ‘’and within reasonable period time supply.’’
In Item 9 the words: ’’Paragraph 4’’ shall be replaced with the following words: ’’paragraph 5’’.

Article 61

In Article 100 paragraph 1 after Item 7 a new item shall be added and it shall read as follows:
‘’7a) conducts clinical trails of medicine in legal entity without a contract on clinical trials of a medicine (article 48 Paragraph 1);’’.
In Item 8 the words: ’’paragraph 1” shall be replaced with the following words: “Paragraph 2”.
In Article 9 the words; ‘’Paragraph 2’’ shall be replaced with the following words: ’’Paragraph 3’’.
Item 10 shall be changed and it shall reads as follows:
‘’10) does not determine in a contract the amount of necessary costs for conducting clinical trials including costs of medical and other services of legal entity where the trials are to be conducted as well as fees for researchers and for the persons who are subjected to the clinical trial (Article 49);’’.

Article 62

In Article 101 in Paragraph 1 after Item 4 a new item shall be added and shall read as follows:
‘’4a) failing to act according to Article 81a;’’.

Article 63

In Article 102 in Paragraph 1 in Item 6 after the word ‘’dispenses’’ the following words shall be added: ’’i.e. sells’’, and the words: ’’Paragraph 4’’ shall be replaced with the following words: ’’ Paragraph 3”.

Article 64

In Article 103 in Paragraph1 in Item 3 the words: '' in the language which is in the official use in Montenegro:'' shall be replaced with the following words: ''In Montenegrin language'', and after the words: ''marketing'' the following word shall be added: "approved ''.
In Item 5 the words: ''and in language that is in official use in Montenegro and in language and script of ethnic minorities that is in official use at least in one municipality" shall be replaced with the following words: ''in Montenegrin language and in regions with significant ethnic minority population and other national minority groups in their language and script''.
In Item 6 after the words: ''thereof'' the word ''(pharmacovigilance)'' shall be deleted.

Article 65

Article 105 shall be changed and shall read as follows:
"The Agency for medicines and medical devices shall be established within six months from the day when this Law comes into force.
Up to the establishment of the Agency from Paragraph 1 of this Article, the activities from its competence shall be performed by the Department for medicines and medical devices.
Funds and assets for founding and launching the activities of the Agency are funds and assets of the Department for medicines and medical devices.
On the day of launching activities the Agency takes over the employees, movables and immovables as well as rights and liabilities of the Department.''

Article 66

After Article 110 a new article shall be added and it shall read as follows:

''Article 110a

Medicines without marketing authorization issued in accordance with this Law can be marketed in Montenegro if the marketing authorization was issued in EU countries, the USA, Canada, Switzerland, Norway and FYR until the requirements are met for issuing marketing authorization in accordance with this Law but no longer than two years from the day when this Law comes into force.

Article 67

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