“This Law regulates cond
for human use and use ir

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**

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) prohibdg to thee 6 o.6(''..)]TJ 0 -1..

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 market62uer the

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“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:

‘’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 follo

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

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 preparationg1gra55,4i-.ui.9(w)-19.lg001 s/TT64-.004 Tw6(Pa1ma)-1.e.8( )8i-5.2( )5.iall be n for .c26 Tw4.n fo6.2(n)-1.5(c)-ats:ments'[hum.1(s:)0002229c TD5.0003 Tc-i.TD5.e. gc( )Tr)1.5(c)-atw TD5.a z

‘’ 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(l)9.2(e)1(ast on5.2((o)-1(g)6)-25.11)]Ts(h)

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 t2(iln(2(ilinre7623 -1).9(a)nr)-adua)-6.4(e7o).7(cting7-3.7(4(e7o). 1(Art)-10.i‘’)7.inre762l(d)1)6(e

Article362

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''.