



LAW OF UKRAINE

On Medicines

(Bill of Verhovna Rada of Ukraine (BVR), 1996, No 22, art. 86)

{Implemented by resolution of Verhovna Rada No [124/96-BP](#) of 04.04.96, BVR, 1996, No 22, art. 87}

(As amended by Laws of Ukraine

of February 14, 1997 No 70/97-VR,
of June 30, 1999 No 783-XIV,
of January 19, 2006 No 3370-IV,
of November 16, 2006 No 362-V,
of May 17, 2007 No 1034-V,
of May 20, 2009 No 1364-VI,
of May 11, 2010 No 2165-VI,
of March 15, 2011 No 3141 VI
of May 12, 2011 No 3323-VI,
of September 08, 2011 No 3718-VI,
of November 03, 2011 No 3998-VI,
of November 17, 2011 No 4056-VI
of December 20, 2011 No 4196-VI
of March 13, 2012 No 4496-VI,
of April 13, 2012 No 4652-VI,
of July 03, 2012 No 5029-VI,
of July 4, 2012 No 5038-VI,
of October 16, 2012 No 5460-VI
of April 04, 2013 No 183-VII
of August 12, 2014 No 1637-VII
of October 20, 2014 No 1707-VII
of December 28, 2014 No 77-VIII
of January 15, 2015 No 126-VIII

of March 19, 2015 No 269-VIII – amendment valid till 01.04.2023, see [item 1](#), Section II, taking into account the changes introduced by Laws № 2629-VIII of 23.11.2018, № 114-IX of 19.09.2019, № 531-IX of 17.03.2020, № 2229-IX of 21.04.2022}

of May 31, 2016 No 1396-VIII
of June 19, 2018 [No 2462-VIII](#)
of September 04, 2018 No 2519-VIII
of September 19, 2019 No 114-IX
of March 17, 2020 [No 531-IX](#)

of March 30, 2020 No 539-IX – valid till 01.01.2021, considering the amendments by Law [No 737-IX](#) of 19.06.2020

of June 02, 2020 [No 644-IX](#)
of September 17, 2020 № 904-IX

of September 30, 2020 № 931-IX – implemented since 25.01.2021
of December 04, 2020 № 1075-IX – pertinent to the Law effect see item 1 of section II
of January 29, 2021 № 1159-IX – valid within one year

of March 19, 2021 № 1353-IX - valid within four years
of July 15, 2021 № 1668-IX
of November 02, 2021 № 1843-IX
of February 15, 2022 № 2054-IX
of May 22, 2022 № 2271-IX)

{In text of Law “Ministry of Health of Ukraine” in all cases is substituted by “central executive body for health care” in appropriate case according to the Law No 4196-VI as of 20.12.2011}

{In text of Law the words "central executive body for health care", " central executive body for health care or it's authorized body" in all cases and numbers substituted by words " central executive body, which ensures development of state policy for health care" in appropriate case; words "state executive authority" substituted by words "executive authority" according to the Law No 5460-VI as of 16.10.2012}

This Law regulates legal relations related to the development, registration, manufacturing, quality control and sale of medicinal products, including medicinal products made from human blood and blood plasma (blood products), processing, transportation, storage and distribution of blood components, used for manufacturing of medicinal products, defines the rights and responsibilities of enterprises, institutions, organizations and citizens, as well as the powers in this area of executive authorities and officials.

{Preamble in wording of Law № 931-IX of 30.09.2020 – shall be implemented since 25.01.2021}

Section I.

GENERAL PROVISIONS

Article 1. Legislation on medicinal products

The legislation on medicinal products shall comprise this Law and other legislation acts adopted in connection with it.

Article 2. Definitions

In the legislation on medicinal products terms shall be used in the following meaning:

medicinal product - any substance or combination of substances (one or more API and excipients) which has properties and intended for treating or preventing diseases in human beings; or any substance or combination of substances (one or more API and excipients) which can be intended for preventing pregnancy, restoring, correcting or modifying physiological functions in human beings by exerting a pharmacological, immunological or metabolic action, or for making a medical diagnosis;

(Paragraph two of part one of article 2 in wording
of the Law of 04.07.2012 No 5038-VI)

counterfeit medicinal product is a medicinal product which was deliberately non-identically (inconsistently) marked according to the materials (one or some of them) about medicinal product with the relevant name which had been entered to the State Register of Medicinal Products of Ukraine as well as a medicinal product deliberately faked in any other way and not corresponding to the materials (one or some of them), including composition, about medicinal product with the relevant name, which had been entered to the State Register of Medicinal Products of Ukraine.

(Part one of Article 2 as amended by the Law of
Ukraine of 08.09.2011 No 3718-VI)

Medicinal products shall include: API, “in bulk” products; finished medicinal products (medicinal preparations, drugs, medicaments); homoeopathic agents; agents used to detect and eliminate pathogenic organisms or parasites; cosmetic products and medicinal supplements to food products;

(Paragraph one of part two of article 2 as amended by Law of 04.07.2012 No 5038-VI)

finished medicinal products (medicinal preparations, drugs, medicaments) are dosed medicinal products in a form and state designed for usage, which have undergone all production (manufacturing) stages, including final packaging;

(Paragraph two of part two of article 2 in wording of the Law of 04.07.2012 No 5038-VI)

active pharmaceutical ingredient (drug substance, active substance, substance) (hereinafter – API or active substance) - any substance or mixture of substances intended for use in the manufacture of a medicinal product and during this use becomes its active ingredient. Such substances have pharmacological or other direct effect on human body, as part of finished forms of medicinal products they are used for treatment, diagnosis or prevention of disease, for changing the condition, structures or organism's physiological functions, for management, manipulation and relief of symptoms;

(Paragraph three of part two of article 2 in wording of the Law of 04.07.2012 No 5038-VI);

auxiliary substance (excipient) - any substance of pharmaceutical form that is not an API or finished medicinal product and therefore does not perform pharmacological, immunological or diagnostic action, is a part of medicinal product and is necessary for its manufacture (production), storage and/or use;

(Paragraph four of part two of article 2 in wording of the Law of 04.07.2012 No 5038-VI)

narcotic medicinal products are those as defined by the legislation;

poisonous medicinal products are those as defined by the central executive body, which ensures the development of state policy for health care;

drastic medicinal products are those as defined by the central executive body, which ensures the development of state policy for health care;

radioactive medicinal products are those used in medical practice to produce ionising irradiation due to their properties;

The State Register of Medicinal Products of Ukraine shall be the regulatory document comprising data on medicinal products permitted for manufacture and use in medical practice;

the pharmacopoeial monograph shall be the standard and technical document establishing the requirements for the medicinal product, its packaging, conditions of storage, shelf-life, and quality control methods;

the technological regulations on manufacturing the medicinal product (hereinafter referred to as 'technological requirements') shall be the regulatory document specifying technological methods, technical means, norms and standards for the manufacture of the medicinal product;

The State Pharmacopoeia of Ukraine shall be the legislative document including the general requirements for medicinal products, pharmacopoeial monographs, and also quality control methods for medicinal products;

quality of the medicinal product shall be the sum of the properties which make the medicinal product capable to satisfy consumers and to meet the requirements established by the legislation;

shelf-life of medicinal products shall be the period of time within which the medicinal product shall not lose its quality pursuant to the requirements of the standard and technological documentation;

pharmaceutical form is a combination of the form in which a medicinal product is presented by the manufacturer (form of presentation), as well as the form in which medicinal product is intended for use including the physical form (form of administration);

{Part two of Article 2 as amended by paragraph fifteen according to the Law of 04.07.2012 No 5038-VI)

“in bulk” products – any medicinal product, which is intended for manufacturing finished medicinal product, and which has undergone all stages of manufacturing process, except for pre-packaging and/or final packaging and labelling.

{Part two of Article 2 as amended by paragraph sixteen according to the Law of 04.07.2012 No 5038-VI)

The term “specialized procurement organizations” is used in the meaning referred to in the Law of Ukraine “On Public Procurement”. The meaning of other terms shall be specified by the legislation and by special dictionaries of terms issued by the World Health Organization.

(Part three, Article 2 amended according to the Law of [19.03.2015](#) No 269-VIII – amendment valid till 01.04.2023, see item 1, Section II, taking into consideration the amendments by the Law of 23.11.2018 No 2629-VIII, of 19.09.2019 No 114-IX, of 17.03.2020 No 531-IX; of 21.04.2022 № 2229-IX; amended according to the Law of 19.09.2019 No114-IX, of 17.03.2020 No 531-IX)

The term "person authorized to make health care procurement" is used in the meaning referred to in the Fundamentals of Health Care Legislation of Ukraine.

(New part four is added to Article 2 according to the Law of Ukraine № 531-IX of 17.03.2020)

Article 3. State policy in the sphere of development, manufacturing, quality control, and sale of medicinal products

The state policy in the sphere of development, manufacturing, quality control, and sale of medicinal products shall be directed to support scientific research, development, and introduction of new technologies, as well as to development of the manufacture of highly effective and safe medicinal products, which meet the demands of the population for medicinal products of proper quality and in assortment through maintaining State Register of Medicinal Products of Ukraine with public access being

ensured; utilising relevant national programs, priority financing, rendering low interest credits, tax remissions etc .

(Part one of Article 3 as amended by the Law of
Ukraine of 20.12.2011 No 4196-VI)

With the aim of protecting health of the citizens of Ukraine, the State shall ensure the availability of those medicinal products most in need, protect citizens in case of damage to their health after taking prescription-only medicinal products, and also shall establish the privileges and guarantees for special population groups and categories of citizens, providing them with medicinal products in case of illness.

Article 4. State administration in the sphere of development, manufacturing, quality control, and sale of medicinal products

The Verkhovna Rada of Ukraine shall determine the State policy and shall regulate the development, manufacture, quality control, and sale of medicinal products.

The Cabinet of Ministers of Ukraine through the system of executive authorities shall implement the state policy in the sphere of development, manufacture, quality control, and sale of medicinal products, shall provide the elaboration and performance of the relevant State programs and others within the limits of its authority, and shall control implementing the legislation on medicinal products.

Regulation in the sphere of development, manufacture, quality control, and sale of medicinal products within the limits of their competence shall be performed by the central executive body, which ensures development of state policy for health care, central executive body, which implements state policy for quality and safety control of medicinal products.

(Part three of Article 4 as amended by the Law of
Ukraine of 08.09.2011 No 3718-VI, of 16.10.2012
No 5460-VI)

Section II

DEVELOPMENT OF MEDICINAL PRODUCTS

Article 5. Subjects of development of medicinal products

Medicinal products may be developed by enterprises, institutions, organizations, and citizens.

The author (and co-author) of the medicinal products shall be the natural person (persons) developing the medicinal product by inventive, research work. Such person (persons) shall have the right to be rewarded for use of the medicinal product invented by him (them). Reward may be given in any form not prohibited by the legislation.

The author (and co-authors) may submit an application to central executive body, which implements state policy for intellectual property to obtain a patent on the medicinal product. Justification for issuing a patent shall be the positive opinion pertinent to its patentability of the central executive body, which implements state policy for health care.

{Part three of Article 5 as amended by the Law of
Ukraine of 16.10.2012 No 5460-VI}

The material and non-material rights connected with the development and manufacture of the medicinal product shall be regulated according to the legislation.

Article 6. Pre-clinical study of medicinal products

Pre-clinical study of medicinal products shall provide for chemical, physical, biological, microbiological, pharmacological, toxicological, and other scientific research in order to determine their specific action and safety.

Procedure for conducting pre-clinical study of medicinal products, the requirements for conditions of the conduct of separate researches, and also procedure for conducting expert assessment of materials pertinent to the pre-study of medicinal products shall be specified by the central executive body, which ensures development of state policy for health care, taking into account the standard procedures used internationally.

Article 7. Clinical trial of medicinal products

Clinical trials of medicinal products shall be performed in order to establish or prove the efficacy and safety of medicinal product. They may be performed at health care settings as determined by the central executive body, which implements state policy for health care.

(Part one of Article 7 as amended by the Law of
Ukraine of 12.05.2011 No 3323-VI, of 16.10.2012
No 5460-VI)

For conducting clinical trials of medicinal products, the enterprises, institutions, organizations, or the citizens shall submit an appropriate application to the central executive body, which implements state policy for health care.

(Part two of Article 7 as amended by the Law of
Ukraine of 16.10.2012 No 5460-VI)

This application shall be annexed by materials containing general information on the medicinal product, the results of its pre-clinical examination, samples of the medicinal product, and the proposal for the clinical trial program.

The decision on the clinical trial of medicinal product may be taken if the following is available:

positive opinions on the expert assessment of the pre-clinical data as to the safety and efficacy of the medicinal product;

data supporting that any risk of adverse reactions of the medicinal product (ADRs) shall be considerably lower than the expected positive effect.

The procedure for performing the expert assessment of the clinical data shall be specified by the central executive body, which ensures the development of state policy for health care.

The sponsor for clinical trials shall have the right to receive information concerning the clinical trial of the medicinal product, to acquaint himself with the results of the clinical experts appraisal, and may request a substitution of health care setting where the clinical trial is performed.

(Part six of Article 7 as amended by the Law of
Ukraine of 12.05.2011 No 3323-VI)

Clinical study of medicinal products shall be performed following obligatory appraisal of the ethical, moral, and legal aspects of the clinical trial program by Ethics Committees that are established and operate under health care settings where the clinical trials are conducted. The Model Regulations on the

Ethics Committee shall be approved by the central executive body, which ensures development of state policy for health care.

(Sentence two, part seven, Article 7 in wording of Law of Ukraine of 16.10.2012 No 5460-VI)

The decision on approval of the program for clinical trials and their conduct shall be made by the central executive body that implements the state policy for health care. Approval of protocols of clinical trials of medicinal products for the treatment of coronavirus disease (COVID-19), as well as vaccines or other medical immunobiological products for the specific prevention of coronavirus disease (COVID-19) and substantial amendments to them shall be made within five calendar days.

(Part eight of Article 7 as amended by the Law No 5460-VI of 16.10.2012, № 539-IX of 30.03.2020 – valid till 01.01.2021, considering the amendments by Law № 737-IX of 19.06.2020; in wording of Law № 1075-IX of 04.12.2020 - pertinent to the Law effect see item 1 of section II)

Clinical trials of domestic and foreign medicinal products shall be performed in full or in the form of a shortened program, taking into consideration international practice standards. In certain cases, at the discretion of the central executive body, which implements state policy for health care, clinical trial may not be required.

(Part nine of Article 7 as amended by the Law of Ukraine of 16.10.2012 No 5460-VI)

Article 8. Protection of the rights of the patient (the volunteer)

Clinical trials of medicinal products shall be conducted on a capable adult – a patient (volunteer) if his/her written consent to participate in such clinical trials is available.

(Part one of article 8 in wording of the Law of Ukraine of 12.05.2011 No 3323-VI)

Clinical trials of medicinal products on children under age 14 or minors shall be undertaken only if the medicinal product concerned is indicated to treat pediatric diseases or clinical trials aim at adapting doses or dosage regimen of a medicinal product to children under age 14 or minors.

(New part two is added to article 8 according to the Law of Ukraine of 12.05.2011 No 3323-VI)

Clinical trials of medicinal products on children under age 14 or minors aimed at adapting doses or dosage regimen of a medicinal product to such persons shall be conducted after the termination of the clinical trials of the respective medicinal products on capable adults.

(New part three is added to article 8 according to the Law of Ukraine of 12.05.2011 No 3323-VI)

Clinical trials of medicinal products on a child under age 14 may be conducted according to the procedure foreseen by the law if the written consent of his/her parents is available and a child under age 14 is given an information about the clinical trial according to his/her capacity of understanding and, on a minor - if his/her written consent and his/her parents' written consent are available. In case of clinical trials on children under age 14 and minors the appropriate information shall be submitted to guardianship

authorities in place of permanent residence of such persons according to the procedure established by the central executive body, which ensures development of state policy for health care.

(New part four is added to article 8 according to the Law of Ukraine of 12.05.2011 No 3323-VI)

Clinical trials of medicinal products on a child under age 14 or a minor devoid of parental custody, an adopted child or an orphan shall be prohibited.

(New part five is added to article 8 according to the Law of Ukraine of 12.05.2011 No 3323-VI)

Clinical trials of medicinal products on a person acknowledged incapable by the court or whose civil capacity is limited due to psychiatric diseases provided the scientific substantiation of benefits of potential success of the indicated trials over risks of grave sequela for health or life of such person is given, the written consent of his/her guardians is available.

(New part six is added to article 8 according to the Law of Ukraine of 12.05.2011 No 3323-VI, thus parts two-five shall be regarded as parts seven-ten respectively)

The patient (the volunteer) or his legally acceptable representative shall receive the information concerning the nature and possible consequences of the clinical trial, properties of the medicinal product, its expected efficacy and the level of risk.

The sponsor of the clinical trial shall, prior to its performance, make an Agreement on Insurance of Health and Life of the Patient (the Volunteer), according to the procedure envisaged by the legislation.

The person in charge of the clinical trial shall stop the clinical trial or its separate stages, should there be a trial associated threat to the health and life of the patient (the volunteer), or on demand of the patient (the volunteer) or his legally acceptable representative.

The central executive body, which implements state policy for health care, shall take the decision to stop the clinical trial of the medicinal product or its separate stages should there be a trial associated threat to the health and life of the patient (the volunteer), and in the case of lack or insufficiency of its efficacy, or if required on ethical grounds.

(Part ten of Article 8 as amended by the Law of Ukraine of 16.10.2012 No 5460-VI)

Article 8¹. Expanded patients' access programs to unregistered medicinal products and trial subjects' (patients') access programs to the investigational medicinal product after the end of clinical trial

1. The program of expanded patients' access to unregistered medicinal products provides free patients' access to unregistered medicinal products that are authorized for use under the specific indications or for which at least Phase II clinical trials (studies) have been initiated in the USA, European Economic Area countries, Australia, Canada, Japan, the United Kingdom, Israel or the Swiss Confederation and for which safety and efficacy data are available to assess the benefit/risk balance. The program is conducted in accordance with the conditions specified by this Law.

The program of trial subjects' (patients') access to the investigational medicinal product after the end of clinical trial provides further free trial subject's (patient's) access to the investigational medicinal product

after the completion of his participation in the clinical trial. The program is conducted in accordance with the conditions specified by this Law.

Medicinal products within the expanded patients' access programs to unregistered medicines and trial subjects' (patients') access programs to the investigational medicinal product after the end of clinical trial are provided free of charge, exclusively for ethical and humane reasons.

2. Procedures for approval and implementation of the expanded patients' access program to unregistered medicinal products and the trial subjects' (patients') access program to the investigational medicinal product after the end of clinical trial (hereinafter - expanded access programs) shall be established by the central executive body, which ensures the development and implements the state policy for health care.

3. In order to implement expanded access programs, enterprises, institutions, organizations or citizens shall submit an appropriate application to the central executive body that ensures the development and implements the state policy for health care.

4. The application shall be accompanied by materials containing general information about the medicinal product (name (if any), active pharmaceutical ingredient, units of measurement, dosage, manufacturer, expiration date, data on safety and efficacy of the medicinal product available to the applicant), justification to use expanded access programs and information about the patient or group of patients who will participate in the program.

5. The decision to approve the expanded patients' access program to unregistered medicinal products shall be made by the central executive body that ensures the development and implements the state policy for health care, under the following conditions:

patients have life-threatening, long-lasting or seriously debilitating illnesses or medical conditions;

in Ukraine, patients do not have access to effective treatment options and/or treatment options cannot effectively impact the course of disease or improve the patient's condition, and/or patients cannot be included in a clinical trial and at the doctor's discretion the use of an unregistered medicinal product is the best choice for the patient;

regarding the safety of the investigational medicinal product, the data obtained in clinical trial are sufficient to assess the risk-benefit ratio and the expected positive effect;

for the medicinal product, at least phase II clinical trials (studies) have been started and data from clinical trials (studies) confirm the efficacy of its use;

general characteristics available for potential patients complying with inclusion criteria for program and estimation of predicted number of patients who will receive medicinal products within the program.

6. The decision to approve the trial subjects' (patients') access program to the investigational medicinal product after the end of the clinical trial shall be made under the following conditions:

patients have life-threatening or serious medical condition that requires continued treatment with a medicinal product that has been studied in the appropriate clinical trial (study);

data available that the risks of use of medicinal product will be lower the expected positive effect;

the patient (patients) participated or completes (complete) participation in clinical trial of the medicinal product;

general characteristics available for potential patients complying with inclusion criteria for program and estimation of predicted number of patients who will receive medicinal product within the program;

information available on the numbers (codes) and initials of potential patients assigned during the clinical trial.

7. Provision with medicinal product within the trial subjects' (patients') access program to investigational medicinal product after the end of clinical trial is possible only if the patient participates till the end of clinical trial ensuring the continuity of treatment with the appropriate medicinal product.

8. The labeling of medicinal products used in expanded access programs shall include:

"Not for sale";

"Only for expanded patients' access programs to unregistered medicinal products" or "Only for trial subjects' access programs to investigational medicinal product after the end of clinical trial", respectively;

the number (code) of the appropriate program, assigned by the applicant.

9. The decision on approval of expanded access programs is made by the central executive body that ensures the development and implements the state policy for health care within 10 calendar days since the date of submitting of appropriate application and is a permit for import of unregistered medicinal products into the customs territory of Ukraine.

10. Expanded access programs begin only after conclusion of an agreement on conducting the appropriate program by the entity that will provide medicinal products within the appropriate program (or natural or legal person acting on behalf of such entity) with the health care setting or with a natural person - an entrepreneur who has a license to conduct economic activity in medical practice.

11. The appropriate ethics committee of the health care setting, which is planned to participate in the expanded access program, reviews the ethical and moral aspects of conducting expanded access programs and decides whether to approve or refuse to approve such programs within five calendar days.

12. An entity that will provide medicinal products within the expanded access programs may enter into a voluntary third party liability insurance agreement.

{The Law is supplemented by Article 8¹ in accordance with Law № 2054-IX of 15.02.2022}

Article 9. State registration of medicinal products

Medicinal products shall be allowed for use in Ukraine after their state registration, except for cases specified by this Law.

The state registration of medicinal products shall be performed pursuant to the application submitted to the central executive body, which implements state policy for health care.

(Part two of Article 9 as amended by the Law of Ukraine of 16.10.2012 No 5460-VI)

The following data shall be included in the application for state registration of medicinal product: name and address of the manufacturer; address of its location and manufacturing capacities; name of the product and its trade name; name of the active agent (in Latin); synonyms; dosage form; full composition of the product; indications and contra-indications; dosage; dispensing conditions; methods of use; shelf-

life and storage conditions; information about package; data on the registration status of the product in other countries including the name of country, number and date of registration.

(Part three of Article 9 as amended by the Law of Ukraine of 08.09.2011 No 3718-VI and of 12.08.2014 No 1637-VII)

The application shall be accompanied by: materials of the registration dossier, requirements for the content and volume of which are established by the central executive body, which ensures the development of and implements the state policy for health care; materials pertinent to quality control methods of a medicinal product; text of the packaging labelling; document confirming payment of the registration fee. The application for state registration of a medicinal product authorized by the competent authority of the United States of America, the Swiss Confederation, Japan, Australia, Canada, a medicinal product authorized according to the centralized procedure by a competent authority of the European Union and used in those countries or Member States of the European Union shall be accompanied by materials of the registration dossier; materials pertinent to quality control methods of a medicinal product; layout of the packaging mockup of the medicinal product and the text of the labeling of the primary and secondary (if any) packaging in the language for the labeling of medicinal products according to the requirements of this Law; instructions for use of the medicinal product in the language according to the requirements of this Law; document confirming payment of the registration fee.

(Part four of Article 9 amended by the Law of Ukraine № 1637-VII of 12.08.2014; in wording of the Law № 1396-VIII of 31.05.2016, № 531-IX of 17.03.2020)

The application for state registration of a medicinal product to be procured based on the results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between the central executive body, which ensures the development of and implements the state policy for health care, and the specialized procurement organization concerned shall be accompanied by materials of registration dossier; materials pertinent to quality control methods of a medicinal product (finished product); assessment report for this medicinal product drawn up by regulatory authority of the country, where this medicinal product has been registered, or assessment report for this medicinal product issued by WHO (if available, if the medicinal product has been WHO prequalified), and instructions for use of the medicinal product in the language according to the language requirements specified by this Law, mock-up of original packaging of MP, translations of labeling and instructions for use of MP in Ukrainian certified by signature of the applicant or his authorized representative. The fee for state registration of a medicinal product to be procured based on the results of procurement procedure conducted by a specialized procurement organization in pursuance of a procurement agreement between the central executive body, which ensures the development of and implements the state policy for health care, and the specialized procurement organization concerned, shall not be paid.

(New part five was added to Article 9 according to the Law of Ukraine № 269-VIII of 19.03.2015 – amendment valid till 01.04.2023, see item 1 section II, taking into consideration the amendments by the Law [№ 2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№ 531-IX](#) of 17.03.2020; № 2229-IX of 21.04.2022; in wording of the Law of [№ 531-IX](#)

of 17.03.2020 – amendments valid till 01.04.2023
taking into account the amendments by the Law №
2229-IX of 21.04.2022)

The applicant (holder of registration certificate) and/or its representative for performing state registration procedure of medicinal product, to be procured based on results of procurement procedure conducted by specialized procuring organization in pursuance of agreement of procurement between the central executive body of Ukraine, which ensures the development of and implements the state policy for health care, and appropriate specialized procuring organization, and medicinal product registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, as well as of medicinal product which had been registered by competent authority of the European Union through centralized procedure and used in these countries or Member States of the European Union **is a legal or physical person**, responsible for efficacy, safety and quality of medicinal product according to procedure specified by the legislation and who performs pharmacovigilance in Ukraine and is responsible for accuracy and completeness of information included in the materials attached to the application.

(Article 9 amended by new part according to the Law № 269-VIII of [19.03.2015](#)– amendment valid till 01.04.2023, see item 1, Section II; taking into consideration the amendments by the Law [№2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№531-IX](#) of 17.03.2020; № 2229-IX of 21.04.2022; in wording of the Law of [№ 1396-VIII of 31.05.2016](#); amended by the Law №531-IX of 17.03.2020)

Information about the applications submitted for state registration, state of revision of documents and decisions taken based on its results are published free of charge at the web-site of organization, which performs expert evaluation of registration materials.

(Article 9 amended by new part according to Law of 31.05.2016 №1396-VIII)

Based on the results of review of the aforementioned materials, the central executive body, which implements state policy for health care, shall take a decision to register or to refuse registration of the medicinal product within ten working days. Decision to register or refuse registration of medicinal product, which had been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, which had been registered by competent authority of the European Union through centralized procedure and used in these countries or Member States of the European Union shall be taken within seven working days. **Decision** to register or to refuse registration of medicinal product, to be procured based on results of procurement procedure conducted by specialized procuring organization in pursuance of agreement of procurement between the central executive body of Ukraine, which ensures the development of and implements the state policy for health care, and appropriate specialized procuring organization, **shall be taken based on results** of conducted verification of registration materials for such medicinal product pertinent to their authenticity specified by part five of this article **within seven working days**. The term of review of the mentioned materials for medicinal product, which had been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, which had been registered by competent authority of the European Union through centralized procedure and used in these countries or Member States of the European Union shall not exceed ten working days. The term of verification of registration materials for such medicinal products pertinent to their authenticity to be procured based on results of procurement procedure conducted by specialized procuring organization in pursuance of agreement of procurement between the central executive body of Ukraine, which ensures the development of and implements the state policy for health care, and appropriate specialized procuring organization, shall not exceed seven

working days. During review of the registration materials for medicinal product, which had been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, which had been registered by competent authority of the European Union through centralized procedure and used in these countries or Member States of the European Union and verification of registration materials for such medicinal products pertinent to their authenticity to be procured based on results of procurement procedure conducted by specialized procurement organization in pursuance of agreement of procurement between the central executive body of Ukraine, which ensures the development of and implements the state policy for health care, and appropriate specialized procuring organization, the expert evaluation of materials of registration dossier submitted to regulatory authority which has registered this medicinal product shall not be conducted.

(Part of Article 9 as amended by the Law No 5460-VI of 16.10.2012, No 1637-VII of 12.08.2014, No 269-VIII of [19.03.2015](#)– amendment valid till 01.04.2023, see item 1, Section II, taking into consideration the amendments by the Law [№2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№531-IX](#) of 17.03.2020; № 2229-IX of 21.04.2022 in wording of the Law [№ 1396-VIII of 31.05.2016](#); amended by the Law №531-IX of 17.03.2020)

A decision on state registration approves the quality control methods of a medicinal product, and assigns a registration number to the medicinal product that is entered in the State Register of Medicinal Products of Ukraine.

(Part nine of Article 9 in wording of the Law of Ukraine № 531-IX of 17.03.2020)

The following information on a medicinal product shall be entered into the State Register of Medicinal Products of Ukraine: name of the medicinal product (trade name, international non-proprietary name); manufacturer (name, location of the legal entity and its production capacities); data on the registration of medicinal product in the United States of America, the Swiss Confederation, Japan, Australia, Canada, and the Member States of the European Union, if such a medicinal product has been registered as a medicinal product, registered by the competent authority of the United States, the Swiss Confederation, Japan, Australia, Canada, a medicinal product registered under the centralized procedure by the competent authority of the European Union for use in those countries or Member States of the European Union, including the name of the country of registration, the registration authority and the date of registration; synonyms, chemical name, full composition of the medicinal product; pharmacological action, pharmacotherapeutic group of the medicinal product; indications, contraindications, precautions, interaction with other medicinal products; methods of administration, dose of active substance in each unit and number of units in the package; adverse effects, presentation, storage conditions, shelf life, dispensing category; instructions for medical use of the medicinal product; pharmacopoeial article or methods of quality control of medicinal product; data on previous registration, re-registration or cancelation of registration of the medicinal product.

(Part of Article 9 in wording of the Law of Ukraine of 08.09.2011 No 3718-VI; [of 31.05.2016](#) No 1396-VIII)

Information included in the application for state registration of medicinal product and its annexes (hereinafter – registration information) is subject to state protection against disclosure and unfair commercial use in compliance with the provisions of this Law and other regulatory documents of Ukraine. The central executive body, which implements state policy for health care, must protect such information against disclosure and prevent its unfair commercial use as well as provide free access to all results of preclinical study and clinical trials of medicinal products (preclinical study reports and clinical

trial reports drawn up in due form established by the central executive body, which ensures development of state policy for health care), which are public data, on its official web-site.

(Part of Article 9 as amended by the Law of Ukraine of 16.10.2012 No 5460-VI, of 04.09.2018 [No 2519-VIII](#))

If the medicinal product registered based on the complete set of registration-related information (hereinafter - reference/original medicinal product) is registered in Ukraine for the first time, the state registration of another medicinal product containing the same active substance as a reference/original medicinal product is possible, at least, five years after the day of the first registration of the reference/original medicinal product in Ukraine unless otherwise stated in this article. This requirement shall not be applied to cases where the applicant has obtained the right to refer to and/or use the registration information pertinent to the reference/original medicinal product or has submitted its own full registration information, which complies with requirements to the registration information pertinent to the reference/original medicinal product.

{Part of Article 9 in wording of Law № 3998-VI of November 3, 2011}

The term indicated in part twelve of this article may be prolonged up to six years if within the first three years after state registration of the reference/original medicinal product the central executive body, which implements state policy for health care, allowed its use for one or more of its indications which are considered as having significant advantages over existing ones. The central executive body, which ensures development of state policy for health care, shall establish rules and criteria for specifying indications having significant advantages over existing ones. The term specified in part twelve of this article shall be applied if the application for state registration of reference/original medicinal product in Ukraine is submitted within two years of the date of its first registration in any country.

(Part of Article 9 in wording of the Law of Ukraine of 03.11.2011 No 3998-VI, part of Article 9 as amended by the Law of Ukraine of 16.10.2012 No 5460-VI, [of 31.05.2016](#) No 1396-VIII)

According to the law, in order to ensure public health at the registration of the medicinal product the Cabinet of Ministers of Ukraine may allow to use the patented invention (useful model) pertinent to such medicinal product to a person defined by it without consent of the patent holder.

{Part of Article 9 in wording of Law № 3998-VI of November 3, 2011}

In addition to documents listed in part four of this article, attached to the application for state registration of medicinal product (except for API and medicinal products, to be procured based on results of procurement procedure conducted by the specialized procuring organization in pursuance of agreement of procurement between the central executive body of Ukraine, which ensures the development of and implements the state policy for health care, and appropriate specialized procuring organization) shall be a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for registration with the requirements to the manufacture of medicinal products in Ukraine issued by the central executive body, which implements the state policy for quality and safety control of medicinal products according to the procedure determined by the central executive body, which ensures the development of state policy for health care. For medicinal product, which had been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, which had been registered by competent authority of the European Union through centralized

procedure for use in these countries or Member States of the European Union submitted may be the commitment letter of manufacturer to manufacture the appropriate medicinal product for supply in Ukraine with similar manufacturing capacities used to manufacture medicinal products intended for use in the USA, the Swiss Confederation, Japan, Australia, Canada or Member States of the European Union, instead of specified certified copy of document confirming the compliance of manufacturing conditions of medicinal product submitted for registration with the requirements to manufacture medicinal products in Ukraine.

(Part of Article 9 in wording of the Law No 3998-VI of 03.11.2011; amended by the Law No 5038-VI of 04.07.2012, No 5460-VI of 16.10.2012, No 1637-VII of 12.08.2014, No 269-VIII of [19.03.2015](#)— amendment valid till 01.04.2023, see item 1, Section II, taking into consideration the amendments by the Law [№2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№531-IX](#) of 17.03.2020; № 2229-IX of 21.04.2022; in wording of the Law [№1396-VIII of 31.05.2016](#))

For disclosure, illegal use of registration information, guilty persons are subject to disciplinary, administrative, civil and/or criminal liability according to the laws of Ukraine. The applicant's reference to the registration information of the reference/original medicinal product and its use in the registration materials submitted by him for the registration of another medicinal product containing the same active substance as the reference/original medicinal product shall not be considered disclosure and unfair commercial use of such information.

{Part sixteen of article 9 amended according to Law № 644-IX of 02.06.2020}

For state registration of medicinal products based on or related to the intellectual property with the patent issued according to the Ukrainian legislation the applicant shall submit a duly attested copy of the patent or manufacturing and selling license for the registered medicinal product, and a document confirming the patent validity in Ukraine. Applicants shall submit a letter indicating that the rights of third parties being patent-protected or transferred according to the license are not violated because of the registration of the medicinal product.

(Part fourteen of Article 9 as amended by the Law of Ukraine of 03.11.2011 No 3998-VI)

The applicant shall be given a Certificate for the registered medicinal product, specifying the period of validity within which it shall be permitted for use in Ukraine.

The medicinal product may be used in Ukraine within the period of five years from the date of its state registration. At request of the person having submitted the application for state registration the term, within which it is permitted for use in Ukraine, may be reduced in accordance with the registration authority.

Should previously unknown dangerous properties of the medicinal product be detected, the central executive body, which implements state policy for health care, may take the decision to prohibit (totally or provisionally) the use of the product in Ukraine.

(Part seventeen of Article 9 as amended by the Law of Ukraine of 16.10.2012 No 5460-VI)

After expiration of the term within which the medicinal product is permitted for use in Ukraine its further use shall be possible after its re-registration. After re-registration the term of use of medicinal product in Ukraine shall have no limits.

(Part eighteen of Article 9 in wording of Law as of 20.10.2014 No 1707-VII)

Medicinal products, which have been put into circulation during the term within which the medicinal product is permitted for use in Ukraine, may be used in Ukraine until the end of their shelf life defined by the manufacturer and specified on the pack.

(Part of Article 9 in wording of Law as of 20.10.2014 No 1707-VII)

A decision on rejection of the state registration of the medicinal product shall be made when the conclusions about its efficacy and safety are not confirmed. Reason to refuse the state registration of medicinal product, which had been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, which had been registered by competent authority of the European Union through centralized procedure for use in these countries or Member States of the European Union shall be a failure to submit the appropriate materials for this medicinal product, envisaged by this article, or a submission of incomplete data package, revealed discrepancies in submitted materials affecting the efficacy, safety and quality of such medicinal product, noncompliance of manufacturer's name of such medicinal product, his location and address of his manufacturing capacities mentioned in the application for state registration, information on which basis this medicinal product had been registered by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada or the European Union. The grounds for rejection of state registration of the medicinal product to be procured based on results of the procurement procedure conducted by a specialized procuring organization in pursuance of the agreement on procurement between the central executive body, which ensures the development of and implements the state policy for health care, and appropriate specialized procuring organization, are the failure to submit the appropriate materials for this medicinal product (specified by part five of this article), or the submission of incomplete data package, revealed discrepancies in submitted materials affecting the efficacy, safety and quality of such medicinal product, noncompliance of the manufacturer's name of such medicinal product, his location and address of his manufacturing capacities mentioned in the application for state registration, information on which basis this medicinal product had been registered, detection of inauthentic translation of the text of packaging labelling of such medicinal product or instructions for use of such medicinal product. The state registration of medicinal products may be rejected or in accordance with the procedure established by the central executive body that ensures the development and implements the state policy for health care, the state registration of medicinal products may be revoked by terminating or reducing the validity period of the registration certificate of medicinal product, if it is found based on the results of expert evaluation and/or review of registration materials supporting the application for state registration, re-registration of a medicinal product or introduction of changes to registration materials for a medicinal product, that one, several or all stages of production of the medicinal product are carried out by enterprises whose manufacturing capacities are located on the territory of the aggressor state (the Russian Federation) or the Republic of Belarus. The state registration of all or individual medicinal products specified by the central executive body that ensures the development and implements the state policy for health care in the established order may be revoked by terminating the registration certificate or suspended by suspending the registration certificate until a decision is made by the central executive body that ensures the development and implements the state policy for health care, on the renewal or cancellation of state registration in case of establishing the fact that the applicant (holder of registration certificate) of these medicinal products or his authorized representative directly or indirectly related to economic entities, including their representatives, their separate subdivisions (branches, representative offices), licensees, applicants, manufacturers and suppliers engaged in direct or indirect activities for production of medicinal products on the territory of the aggressor state (the Russian Federation) or the Republic of Belarus, or

after February 23, 2022 committed transactions to participate in at least one stage of production of any medicinal product or API by an enterprise located on the territory of the aggressor state (the Russian Federation) or the Republic of Belarus, provided to such enterprise for use pharmaceutical tangible or intangible assets or related patents, permits, licenses, registration certificates, rights and other documents required for the production of pharmaceutical products, including medicinal products, as well as the production of APIs, carried out their transfer to hire (lease) or alienated them directly or indirectly to the property of residents of the aggressor state (the Russian Federation) or the Republic of Belarus for the production of pharmaceutical products. The decision to cancel the state registration of medicinal product in the cases provided for in the fifth sentence of this part may be made not earlier than three months after the decision to suspend the registration certificate for this medicinal product in agreement with the Cabinet of Ministers of Ukraine if the applicant (holder of the registration certificate) continues the activities provided for in the fifth sentence of this part.

(Part of Article 9 as amended by the Law No 1637-VII of 12.08.2014, No 269-VIII of 19.03.2015 - amendment valid till 01.04.2023, see [item 1](#), Section II, taking into consideration the amendments by the Law [№2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№531-IX](#) of 17.03.2020; № 2229-IX of 21.04.2022; amended by the Law [№1396-VIII of 31.05.2016](#); in wording of the Law № 531-IX of 17.03.2020 – the third sentence of paragraph twenty-three is valid till 01.04.2023 taking into consideration the amendments by Law № 2229-IX of 21.04.2022, as amended by Law № 2271-IX of 22.05.2022 - valid until the end of the three-month period after the cessation or abolition of martial law)

The state registration of the medicinal product may be rejected if such a registration results in the violation of the ownership rights of intellectual property as well as during the process of manufacture, use, sale of medicinal products.

A central executive body which ensures development of and implements the state policy for health care shall send the applicant a motivated answer in writing on rejection of registration of the medicinal product within 10 days. For medicinal product to be procured based on results of the procurement procedure conducted by a specialized procuring organization in pursuance of the agreement on procurement between the central executive body of Ukraine which ensures the development of and implements the state policy for health care, and an appropriate specialized procuring organization, the term for sending answer on rejection shall not exceed three working days. The decision on rejection may be appealed according to the procedure established by the legislation.

(Part of Article 9 as amended by the Law No 5460-VI of 16.10.2012; in wording of Law No 269-VIII of 19.03.2015 - amendment valid till 01.04.2023, see [item 1](#), Section II, taking into consideration the amendments by the Law [№ 2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№ 531-IX](#) of 17.03.2020, № 2229-IX of 21.04.2022)

The procedure for state registration (or re-registration) of the medicinal product and amounts of fees for its state registration (or re-registration) of the medicinal product shall be established by the Cabinet of Ministers of Ukraine.

The medicinal products are not subject to the state registration, if they are prepared in pharmacies under the prescriptions of doctors and at the request of health care settings from active substances and excipients permitted for use.

(Article 9 in wording of the Law No 362-V of 16.11.2006; amended according to the Law № 531-IX of 17.03.2020)

Article 9¹. Peculiarities of state registration of medicinal products that may be procured by a person authorized to carry out health care procurement

If the state registration of a medicinal product is carried out for the purposes of procurement by a person authorized to make health care procurement, the medicinal product concerned may be registered via the state registration procedures specified in this Article. The state registration of such a medicinal product may be carried out via the procedure referred to in part four of this Article, or by the procedure referred to in part five of this Article, at the discretion of the applicant. The applicant's right to register the medicinal product concerned via any of the procedures specified in this Article shall not deprive him of the right to register the medicinal product concerned via any other state registration procedure for a medicinal product specified in Article 9 of this Law, as required by the legislation.

Medicinal products, the state registration of which is carried out according to this Article, shall be subject to the provisions of parts one-three, seven, nine, eleven-fourteen, sixteen-twenty-two, twenty-four, twenty-six of Article 9 of this Law. Other provisions of Article 9 of this Law shall not apply to the medicinal products the state registration of which is carried out according to this Article.

On the submission date of an application for state registration, the medicinal product shall be put on the List of medicinal products, medical devices and accessories to them, procured using the funds under the state budget to execute programs and take centralized health care measures approved by the Cabinet of Ministers of Ukraine.

State registration of a medicinal product procured by a person authorized to make health care procurement, which had been authorized by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada, medicinal product, which had been authorized by the competent authority of the European Union via centralized procedure and used in these countries or Member States of the European Union, has the following peculiarities (without prejudice to the possibility of state registration via the procedure specified in part five of this Article):

an application for state registration of such medicinal product shall be accompanied by a document confirming the registration of the medicinal product in the corresponding country or registration by the competent authority of the European Union via the centralized procedure and used in these countries or Member States of the European Union on the submission date of an application for state registration, which is certified by signature of the applicant or his representative; materials of registration dossier; quality control methods of the finished medicinal product (final product); assessment report of this medicinal product drawn up by regulatory authority of the country, where this medicinal product has been registered; instructions for use of the medicinal product in the original language (a language which differs from the state one), summary of product characteristics in the original language (a language which differs from the state one); layout of the packaging mockup of the medicinal product and the text of the labeling of the primary and secondary (if any) packaging of the medicinal product; translations of the text of the labeling of the primary and secondary (if any) packaging of the medicinal product and instructions for use, the summary of product characteristics of the medicinal product in the state language according to the structure established by the procedure specified by the central executive body that ensures the development of and implements the state policy for health care, which are certified by signature of the applicant or his representative; a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for registration with the requirements to the manufacture of medicinal products in Ukraine issued by the central executive body, which implements the state policy

for quality and safety control of medicinal products according to the procedure determined by the central executive body, which ensures the development of and implements the state policy for health care, or a commitment letter of manufacturer to produce the appropriate medicinal product for supply in Ukraine with the same manufacturing capacities as those used to manufacture medicinal products intended for use in the corresponding country of authorization (the United States of America, the Swiss Confederation, Japan, Australia, Canada or Member States of the European Union).

the term of verification of the registration materials' authenticity for the medicinal product concerned shall not exceed seven working days from the date of submission of these materials. During the verification of the registration materials' authenticity the expert evaluation of materials of the registration dossier submitted to the regulatory authority, which has registered this medicinal product shall not be conducted;

a decision on registration or rejection of registration of such medicinal product shall be made by the central executive body, which ensures the development of and implements the state policy for health care, based on the results of verification of the registration materials' authenticity for the medicinal product concerned within five working days;

the grounds for rejection of state registration of the medicinal product concerned are a failure to submit the appropriate materials pertinent to such medicinal product that are provided for in this article or the submitted materials are not complete, a detection of inconsistencies affecting efficacy, safety and quality of such medicinal product in the submitted documents, lack of correspondence between the manufacturer's name of such medicinal product, his location and address of his manufacturing capacities mentioned in the application for state registration and the information on the basis of which this medicinal product has been authorized by the competent authority of the USA, the Swiss Confederation, Japan, Australia, Canada or the European Union, a detection of inauthentic translation of the text of packaging labelling of such medicinal product, instructions for use of such medicinal product or a summary of product characteristics for such medicinal product;

the fee for state registration of such medicinal product shall not be paid.

The state registration of a medicinal product to be procured by a person authorized to make health care procurement has the following peculiarities regardless of the country of manufacture:

at the request of the applicant, the state registration of such medicinal product may be carried out with the labelling and instructions for use of the medicinal product, which meet the requirements of parts one, two, three and five of Article 12 of this Law, or with the labelling, instructions for use of the medicinal product and summary of product characteristics of the medicinal product in the original language (in a language other than the state language);

if the state registration of the medicinal product is conducted with the labelling and the instructions for use of the medicinal product, which meet the requirements of parts one, two, three and five of Article 12 of this Law an application for state registration of the medicinal product concerned shall be accompanied by: materials of registration dossier; materials pertinent to quality control methods of a medicinal product; a document confirming payment of registration fee; the labeling of the primary and secondary (if any) packaging of the medicinal product; instructions for use of the medicinal product; a certified copy of the document confirming the compliance of manufacturing conditions for the medicinal product submitted for the registration with the requirements to manufacture of medicinal products in Ukraine issued by the central executive body, which implements the state policy for quality and safety control of medicinal products according to the procedure determined by the central executive body, which ensures the development of and implements the state policy for health care;

if the state registration of the medicinal product is conducted with the labelling, instructions for use of the medicinal product, and summary of product characteristics of the medicinal product in the original language (in a language other than the state language) an application for state registration of the medicinal product concerned shall be accompanied by: materials of registration dossier; materials pertinent to quality control methods of a medicinal product; a document confirming payment of registration fee;

layout of the packaging mockup of the medicinal product; mock-up of original instructions for use of the medicinal product, and summary of product characteristics of the medicinal product; translations of the text of the labeling of the primary and secondary (if any) packaging and instructions for use of the medicinal product, the summary of product characteristics of the medicinal product in the state language according to the structure established by the procedure specified by the central executive body that ensures the development of and implements the state policy for health care, which are certified by signature of the applicant or his representative; a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for registration with the requirements to the manufacture of medicinal products in Ukraine issued by the central executive body, which implements the state policy for quality and safety control of medicinal products according to the procedure determined by the central executive body, which ensures the development of and implements the state policy for health care;

the term of expert evaluation of the registration materials shall not exceed 30 working days. The term of the expert work shall not include the period of finishing up the materials by the applicant, the time needed to receive answers from the third parties (including from the competent authorities of Ukraine and/or other countries) related to the expert evaluation, and the time needed to carry out the laboratory tests;

a decision on registration or rejection of registration of such medicinal product shall be made by the central executive body, which ensures the development of and implements the state policy for health care, based on the results of expert evaluation of the registration materials pertinent to this medicinal product concerned within five working days;

a decision on rejection of the state registration of the medicinal product concerned shall be made when the conclusions about its efficacy and safety are not confirmed, and when inconsistencies between translations of the labelling of the medicinal product, instructions for use of the medicinal product, summary of product characteristics are detected.

The applicant (holder of registration certificate) and/or his representative authorized for performing any state registration procedure of medicinal product provided for by this article is a legal or physical person responsible for efficacy, safety and quality of the medicinal product according to procedure specified by the legislation and who performs pharmacovigilance in Ukraine, and is responsible for accuracy and completeness of information included in the materials submitted by him in support of the application.

For medicinal products registered according to part four of this Article, and for medicinal products registered according to part five of this Article with labelling, instructions for use and summary of product characteristics of the medicinal product in the original language (in a language other than the state language) in addition to the details provided for in part ten of Article 9 of this Law, the State Register of Medicinal Products of Ukraine shall contain data on referring the medicinal product to the medicinal products that can be used in Ukraine solely for the purpose of free supply to the health care units of the regional state administrations, and the state administrations of the city of Kyiv and the city of Sebastopol, or entities licensed to conduct economic activity relating to medical practice based on the results of the procurement using the funds under the state budget and made by a person authorized to make health care procurement, in order to execute programs and take centralized health care measures.

When a decision is made on rejection of the state registration of the medicinal product submitted for state registration according to any procedure provided for by this article, the central executive body, which ensures the development of and implements the state policy for health care, shall send the applicant a motivated answer in writing within three working days. The decision on rejection may be appealed according to the procedure established by the legislation.

The medicinal product registered according to part four of this article with labelling, instructions for use and summary of product characteristics of the medicinal product in the original language (in a language other than the state language) can be used in Ukraine solely for the purpose of free supply to the health care units of the regional state administrations, and the state administrations of the city of Kyiv and the city of Sebastopol, or entities licensed to conduct economic activity relating to medical practice, based on

the results of the procurement using the funds under the state budget and made by a person authorized to make health care procurement, in order to execute programs and take centralized health care measures.

The medicinal product registered according to part five of this article, with the labelling and instructions for use of the medicinal product, which meet the requirements of parts one, two, three and five of Article 12 of this Law can be used in Ukraine in order to execute of programs and take centralized health care measures, based on the results of the procurement using the funds under the state budget and made by a person authorized to make health care procurement, and without prejudice to the use according to the general requirements established by this Law.

(Section II is supplemented by Article 9¹ according to the Law of Ukraine № 531-IX of 17.03.2020 – amendments are valid till April 01, 2023, taking into account the amendments by the Law № 2229-IX of 21.04.2022)

Article 9². Peculiarities of state registration of medicinal products subject to obligations for emergency medical use and vaccines or other medical immunobiological products for the specific prevention subject to obligations for emergency medical use

1. In view of the spread of the coronavirus disease (COVID-19) pandemic to enable emergency medical use of specific medicinal products, vaccines or other medical immunobiological products during an emergency and/or quarantine according to the procedure established by the Cabinet of Ministers of Ukraine, such a medicinal product, vaccine or other medical immunobiological product for treatment and/or specific prevention of coronavirus disease (COVID-19) may be subject to accelerated state registration, if the central executive body, which ensures the development of and implements the state policy for health care, makes a decision on state registration of medicinal product, vaccine or other medical immunobiological product for treatment and/or specific prevention of coronavirus disease (COVID-19) for emergency medical use subject to specific obligations, provided the applicant can prove that he is unable to provide comprehensive data on the efficacy and safety of medicinal product, vaccine or other medical immunobiological product for treatment and/or specific prevention of coronavirus disease (COVID-19) under the normal conditions of use, for objective reasons and if:

1) data on the successful conduct of pre-clinical trials/studies, specific phases of clinical trials/studies are available, and the totality of results obtained contains scientifically sound evidence, including data from adequate and well-controlled studies that allow to believe that medicinal products, vaccines or other medical immunobiological products may be effective for emergency medical use during an emergency and/or quarantine;

2) vaccine or other medical immunobiological product for specific prevention of coronavirus disease (COVID-19) has been granted an emergency use authorization by the competent authority of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, the People's Republic of China or via a centralized procedure by the competent authority of the European Union according to the national legislation of a country of authorization or the European Union, or vaccine or other medical immunobiological product has been prequalified by the World Health Organization; or

medicinal product for the treatment of coronavirus disease (COVID-19) has been granted an emergency use authorization by the competent authority of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel or via a centralized procedure by the competent authority of the European Union according to the national legislation of a country of authorization or the European Union, or medicinal product has been prequalified by the World Health Organization; or

vaccine or other medical immunobiological product for specific prevention of coronavirus disease (COVID-19) has full production cycle or manufactured from "in bulk" in Ukraine;

3) such a medicinal product, vaccine or other medical immunobiological product for specific prevention of coronavirus disease (COVID-19) has not been developed in a state duly recognized as an aggressor state;

4) the known and potential benefits of medicinal products, vaccines or other medical immunobiological products when used to treat and prevent the coronavirus disease (COVID-19) outweigh the known and potential risks of use of such medicinal products, vaccines or other medical immunobiological products.

2. If the circumstances set out in part 1 of this Article exist, the medicinal products, vaccines or other medical immunobiological products for treatment and prevention of the coronavirus disease (COVID-19) may be registered for emergency medical use for a period that will allow the following obligations to be fulfilled:

an applicant shall provide information about the clinical trials completed, including their results, within a period agreed with the central executive body, which ensures the development of and implements the state policy for health care, which are to be the basis for expert assessment of the benefit-risk balance";

medicinal products, vaccines or other medical immunobiological products submitted for the state registration subject to obligations for emergency medical use shall be dispensed by healthcare settings only subject to prescription and, in certain instances, shall be used only under strict medical supervision, in particular in healthcare settings;

a summary of the characteristics of the medicinal products, vaccines or other medical immunobiological products, instructions for medical use and/or the package leaflet shall specify that the available characteristics of this medicinal product are insufficient.

If the obligations specified in paragraphs two-four of this part are fulfilled, the applicant shall notify the central executive body, which ensures the development of and implements the state policy for health care, of adverse reactions to medicinal products, vaccines or other medical immunobiological products according to the procedure and within the timeframe established by the central executive body, which ensures the development of and implements the state policy for health care.

For state registration of medicinal products, vaccines or other medical immunobiological products for treatment and/or specific prevention of coronavirus disease (COVID-19) subject to the obligations for emergency medical use instead of a certified copy of document confirming the compliance of manufacturing conditions for the medicinal product submitted for registration with the requirements to manufacture of medicinal products in Ukraine issued by the central executive body, which implements the state policy for quality and safety control of medicinal products submitted may be the above-mentioned body's decision on recognition of the results of GMP compliance inspections conducted by the national competent authority of the country of manufacture, which is issued according to the procedure established by the central executive body, which ensures the development of and implements the state policy for health care, provided that the manufacture of the medicinal product is carried out in compliance with the requirements of good manufacturing practice, harmonized with the legislation of the European Union.

The requirements of parts one, two, three and five of Article 12 of this Law shall not apply to medicinal products, vaccines or other medical immunobiological products registered for emergency medical use according to the procedure specified in this Article. Such medicinal products, vaccines or other medical immunobiological products when supplied and used in Ukraine must be accompanied by instructions for use in the state language, approved by the central executive body, which implements the state policy for health care.

3. The decision to issue a registration certificate for medicinal products, vaccines or other medical immunobiological products for treatment and/or specific prevention of coronavirus disease (COVID-19), which undergone the procedure for state registration subject to obligations for emergency medical use, shall specify the deadlines for the fulfillment of such obligations.

The registration certificate is issued for a period of one year and may be renewed annually.

The extension of the validity of registration certificate provides for an annual assessment of the fulfillment of specific obligations and submission of a report on the results of assessment to the central executive body, which ensures the development of and implements the state policy for health care. After fulfillment by the applicant of all obligations imposed within the established timeframe, the validity of registration certificate may be extended up to five years.

4. After making a decision to issue a registration certificate for medicinal products, vaccines or other medical immunobiological products for treatment and/or specific prevention of coronavirus disease (COVID-19) the central executive body, which ensures the development of and implements the state policy for health care may impose an obligation on the holder of registration certificate for such medicinal products, vaccines or other medical immunobiological products to:

1) conduct a post-registration safety study if there are concerns about the risks of medicinal products, vaccines or other immunobiological products registered for emergency medical use. If the concerns about the risks specified apply to more than one medicinal product, vaccine or other medical immunobiological product the central executive body, which ensures the development of and implements the state policy for health care shall encourage the registration certificate holders concerned to take part in a joint post-registration safety study;

2) conduct a post-registration efficacy study when the understanding of the disease or the clinical methodology indicates that previous efficacy evaluations might have to be revised significantly.

5. If a vaccine or other medical immunobiological product for a treatment and/or specific prevention of the coronavirus disease (COVID-19) has received an emergency use authorization granted by the competent authority of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, the People's Republic of China or via a centralized procedure by the competent authority of the European Union (according to the national legislation) of a country of authorization or the European Union, or has been prequalified by the World Health Organization, or a medicinal product for treatment of the coronavirus disease (COVID-19) has received an emergency use authorization granted by the competent authority of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, or via a centralized procedure by the competent authority of the European Union according to the national legislation of a country of authorization, or a medicinal product for treatment of the coronavirus disease (COVID-19) has been prequalified by the World Health Organization, such medicinal product, vaccine or other medical immunobiological product may be subject to accelerated registration for emergency medical use according to the procedure established by the Cabinet of Ministers Ukraine, taking into consideration the following peculiarities:

1) the application for state registration for emergency medical use shall be supplemented by the following documents only:

a document confirming the decision to grant an emergency use authorization or conditional marketing authorization in the appropriate country or conditional marketing authorization by the competent authority of the European Union (or other essentially identical decision under the applicable law of the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, the People's Republic of China (exclusively for vaccines or other medical immunobiological products), Israel or via a centralized procedure by the competent authority of the European Union in accordance with the national legislation of the country issuing the authorization or the European Union) as of the date of

submitting application for state registration for emergency medical use certified by the signature of the applicant or his authorized representative; assessment report for medicinal product, vaccine or other medical immunobiological product drawn up by the regulatory authority of the country where the medicinal product, vaccine or other medical immunobiological product has been authorized (if available, if such a document is envisaged by legislation of the appropriate country; if there is no such document, the appropriate tick shall be made in the application for state registration for emergency medical use); a risk assessment and management document approved by a decision to grant an emergency use authorization or conditional marketing authorization in the country concerned or a conditional marketing authorization by the competent authority of the European Union (if available, if such a document is envisaged by the legislation of the appropriate country; if there is no such document the appropriate tick shall be made in the application for state registration for emergency medical use); instructions for use in original language (in language other than the state language), a summary of product characteristics in original language (in language other than the state language) (if available, if such a document is envisaged by the legislation of the appropriate country; if there is no such document the appropriate tick shall be made in the application for state registration for emergency medical use); the mock-up(s) of packaging and text(s) of labeling of primary and secondary (if any) packaging. For the purposes of state registration for emergency medical use, the applicant has the right to submit several such mock-ups and labeling texts at the same time to ensure the most prompt supply in the packaging and with the labeling available at the time of supply; translations of the text(s) of labeling of primary and secondary (if available) packaging of medicinal product, vaccine or other medical immunobiological product, instructions for use, summary of product characteristics in the state language of the structure according to the procedure established by the central executive body that ensures the development and implements the state policy for health care, which are certified by the signature of the applicant or his authorized representative; for vaccines or other medical immunobiological products a written commitment of a manufacturer to produce a vaccine or other medical immunobiological product in order to supply it in Ukraine at the same production capacities as those employed for production intended for the use in the appropriate country of authorization (the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, the People's Republic of China or countries of the European Union); for medicinal products a written commitment of a manufacturer to produce a medicinal product concerned in order to supply it in Ukraine at the same production capacities as those employed for production intended for the use in the appropriate country of authorization (the United States of America, the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, or countries of the European Union);

2) the term of verification of the authenticity of registration materials submitted by the applicant shall not exceed five working days after the date of submission of such materials. During verification of the authenticity of registration materials the expert evaluation of materials of the registration dossier submitted to the regulatory authority which has registered a medicinal product, vaccine or other medical immunobiological product shall not be conducted;

3) the decision on registration for emergency medical use or refusal to register such a medicinal product, vaccine or other medical immunobiological product for emergency medical use shall be made by the central executive body that ensures the development and implements the state policy for health care, based on verification of the authenticity of registration materials during a period not exceeding three working days;

4) the state registration for emergency use may be refused only in the case of: a failure to submit the appropriate materials provided for in this part of the article, or incomplete package of materials, or discrepancies revealed in the submitted materials, which affect efficacy, safety and quality of the medicinal product, vaccine or other medical immunobiological product, or an inauthenticity of translation of the text(s) of the package labeling, instructions for use or summary of product characteristics;

5) variations to the registration materials shall be made in accordance with the procedure established by the central executive body, which ensures the development and implements the state policy for health care, according to the decision made by the same competent authority of the United States of America,

the United Kingdom, the Swiss Confederation, Japan, Australia, Canada, Israel, the People's Republic of China (exclusively for vaccines and other medical immunobiological products) or via the centralized procedure by the competent authority of the European Union in accordance with the national legislation of the country or the European Union, which was submitted during the procedure for state registration for emergency medical use;

6) no fee for state registration for emergency medical use and for making changes to registration materials shall be paid;

7) registration of medicinal product, vaccine or other medical immunobiological product for emergency medical use shall be effective for the period of validity of the appropriate authorization or conditional marketing authorization.

6. After the state registration of medicinal products, vaccines or other medical immunobiological products for a treatment or specific prevention of the coronavirus disease (COVID-19) subject to obligation for emergency medical use, the central executive body, which ensures the development and implements the state policy for health care, according to the decision of the Cabinet of Ministers of Ukraine, has the right to make commitments on behalf of Ukraine related to the purchase, use of medicinal products, vaccines or other medical immunobiological products for a treatment and/or specific prevention of coronavirus disease (COVID-19), the state registration of which has been conducted in accordance with the requirements of this article, including pertinent to denial of sovereign immunity in respect of such commitments, as well as the release from liability of the manufacturer and/or holder of the registration certificate, including their employees, healthcare workers, if such medicinal products, vaccines or other medical immunobiological products were used in accordance with instructions approved by the central executive body, which ensures the development and implements the state policy for health care, and other persons involved in the implementation of measures related to vaccination and/or use of medicinal products, for any consequences of the use of such medicinal products, vaccines or other medical immunobiological products for a treatment or specific prevention of coronavirus disease (COVID-19).

In the event of such consequences, the state shall ensure payment of appropriate compensation according to the procedure established by the Cabinet of Ministers of Ukraine.

(Article 9² is added to Section II according to the Law of Ukraine № 1159-IX of 29.01.2021- valid within one year; as amended by the Law of Ukraine of 19.03.2021 № 1353-IX – valid within four years; in wording of the Law of Ukraine № 1843-IX of 02.11.2021)

Section III

MANUFACTURE OF MEDICINAL PRODUCTS

Article 10. Conditions of manufacture of medicinal products

Manufacture of medicinal products shall be performed by natural or legal persons on the grounds of a license issued pursuant to the procedure established by the legislation. License shall annex a list of forms of medicinal products allowed the licensee to manufacture and special conditions of business activity.

(Part 1, article 10 amended by the Law of Ukraine of 19.01.2006 № 3370-IV, of 20.12.2011 № 4196-VI)

The grounds for issue of a license to manufacture medicinal products is an availability of appropriate material and technical basis, qualified personnel (qualification of a citizen in the case of individual manufacturing), and also of conditions necessary to guarantee the quality control of the medicinal products to be manufactured. The compliance of material and technical basis, staff qualification and conditions of quality control of medicinal products to be manufactured with the acting requirements and characteristics specified in the documents submitted by the applicant for obtaining license is subject to obligatory pre-inspection within the set terms, at place of licenser activity in order established by the central executive body, which ensures the development of state policy for health care.

(Part 2, article 10 amended by the Law of Ukraine of 19.01.2006 № 3370-IV, of 20.12.2011 № 4196-VI)

General requirements to material and technical basis for manufacturing medicinal products, manufacturing inspection of their quality, and technological regulations are determined by central executive body, which ensures development of state policy for health care.

(Part three of Article 10 in wording of the Law of Ukraine of 08.09.2011 № 3718-VI; amended by Law of Ukraine of 16.10.2012 № 5460-VI)

Article 11. General requirements for manufacture of medicinal products

Active ingredients, excipients, and packaging materials permitted for use by the central executive body, which ensures development of state policy for health care, may be used in the manufacture of medicinal products.

The manufacture of medicinal products shall be performed pursuant to the technological requirements, the pharmacopoeial monographs and other state standards and technical conditions, taking into consideration the international standards on manufacture of the medicinal products.

Should the active substance or excipient be changed, the manufacturer of the medicinal product shall apply for registration of the medicinal product.

Article 12. Labelling of medicinal products

Information included on the label, outer and immediate packaging of the medicinal product shall contain the following data: name of the medicinal product; name and address of the manufacturer; registration number; batch number; conditions of use; quantity of the active agent per unit of pharmaceutical form and their number in the package; the shelf-life; storage conditions; precautions.

On the secondary packaging the name of medicinal product, strength of active substance and pharmaceutical form shall also be specified in Braille format. The central executive body, which ensures development of state policy for health care, shall specify medicinal products, which packagings do not require labeling in Braille format or Braille format is used to specify the name of medicinal product only.

(New part two is added to Article 12 according to the Law of Ukraine of 20.05.2009 No 1364-VI, in wording of the Law of Ukraine of 11.05.2010 No 2165-VI)

Additional requirements on labelling and packaging specific to use of particular medicinal product may be approved at the time of state registration (or re-registration).

Medicinal products intended for clinical study shall carry the text 'For clinical research'.

Each medicinal product sold shall be accompanied by instructions for use of the medicinal product comprising information as follows: name of the medicinal product; general description (chemical name, main physical and chemical properties, composition); pharmacological data; indications for use; contraindications; interactions with other medicinal products; method of use and dosage; adverse effects; precautionary measures; pharmaceutical forms; storage conditions and shelf-life; dispensing conditions.

The language of the labeling of medicinal products, instructions for their use is a state language unless otherwise established by the Law.

(Article 12 amended by part according to Law No 5029-VI of 03.07.2012; in wording of the Law of Ukraine of № 531-IX of 17.03.2020)

Requirements of parts one, two, three and five of this article shall not apply to medicinal products to be procured based on results of the procurement procedure conducted by a specialized procuring organization in pursuance of the agreement on procurement between the central executive body of Ukraine which ensures the development of and implements the state policy for health care, and an appropriate specialized procuring organization.

(Part seven is added to Article 12 according to the Law No 269-VIII of 19.03.2015 - amendment valid till 01.04.2023, see [item 1](#), Section II, taking into consideration the amendments by the Law [№ 2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№531-IX](#) of 17.03.2020, № 2229-IX of 21.04.2022)

Labelling, instructions for use/summary of product characteristics of the medicinal products procured by a person authorized to make health care procurement the state registration of which has been conducted according to Article 9¹ of this Law or the validity period of the registration certificates for which has been extended according to this Law, may be in the original language (in a language other than the state language) provided that the supplier provides each package of the medicinal product imported into Ukraine with a copy of the translation of labelling and instructions for use/summary of product characteristics of the medicinal products in the state language which is certified by signature of the applicant or his representative; a confirmation of the intended use of such import submitted according to the procedure established by the Cabinet of Ministers of Ukraine.

(Part eight is added to Article 12 according to the Law of Ukraine of № 531-IX of 17.03.2020 - amendments valid till 01.04.2023, taking into account the amendments by the Law № 2229-IX of 21.04.2022)

If the unregistered medicinal product is imported into Ukraine for the purpose of supply based on the results of the procurement made by a person authorized to make health care procurement in order to execute programs and take centralized health care measures, or procurement using the funds under the local budgets and made with involvement of a person authorized to make health care procurement according to the provisions of article 17 of this Law the labelling and instructions for use/summary of product characteristics of the medicinal product concerned may be in the original language (in a language other than the state language) only if each package of the medicinal product imported into Ukraine is

provided by the supplier with a copy of the translation of labelling and instructions for use/summary of product characteristics of the medicinal products in the state language, which is approved by the central executive body, which ensures the development of and implements the state policy for health care, and a notification is available being issued by the central executive body, which ensures the development of and implements the state policy for health care according to the procedure established by the legislation.

(Part nine is added to Article 12 according to the Law of Ukraine of № 531-IX of 17.03.2020)

The requirements of part one, two, three and five of this Article shall not apply to medicinal products imported into Ukraine with the labelling and the instructions for use/summary of product characteristics of the medicinal product in the original language (in a language other than the state language), based on the results of the procurement made by a person authorized to make health care procurement, or procurement using the funds under the local budgets and made with involvement of a person authorized to make health care procurement provided that the requirements established by part eight or nine of this Article respectively are met.

(Part ten is added to Article 12 according to the Law of Ukraine of № 531-IX of 17.03.2020 - amendments valid till 01.04.2023, taking into account the amendments by the Law № 2229-IX of 21.04.2022)

Section IV

STATE QUALITY CONTROL OF MEDICINAL PRODUCTS

Article 13. Definition and tasks of the state quality control of medicinal products

The state quality control of medicinal products shall incorporate the combination of organizational and legal measures designed the subjects of economic activity irrespective of their ownership forms and subordination to follow the legislative requirements to assurance quality of medicinal products.

The state quality control of medicinal products shall be performed by executive authorities within the limits of their competence specified by the legislation of Ukraine.

Article 14. State authorities for quality and manufacturing control of medicinal products

The control of the quality and manufacturing conditions of medicinal products shall be exercised by the central executive body, which implements state policy for quality and safety control of medicinal products, according to the law.

The central executive body, which implements state policy for quality and safety control of medicinal products, shall be headed by the Chief State Inspector of Ukraine for Quality Control of Medicinal Products. His Deputies are Deputy Chief State Inspectors of Ukraine for Quality Control of Medicinal Products.

The Chief State Inspectors for Quality Control of Medicinal Products at appropriate territories and their Deputies shall exercise control of quality of medicinal products in the Autonomous Republic of Crimea, oblasts, Kyiv and Sevastopol.

Other specialists of the central executive body, which implements state policy for quality and safety control of medicinal products, responsible for exercising state quality control of medicinal products shall be the State Inspectors for Quality Control of Medicinal Products.

(Article 14 amended by the Law of Ukraine of 17.05.2007 No 1034-V; in wording of the Laws of Ukraine of 08.09.2011 No 3718-VI, of 16.10.2012 No 5460-VI)

Article 15. Competence of the officials of central executive body, which implements state policy for quality and safety control of medicinal products

(Title of article 15 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

The officials of central executive body, which implements state policy for quality and safety control of medicinal products, within the limits of their competence specified by the legislation shall be entitled to:

(Paragraph one, part one, Article 15 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

check the compliance with requirements of legislation as per quality of medicinal products including good practices (manufacturing, distribution, storage, pharmacy) at all stages of circulation, including their manufacture, storage, transportation and sale by the subjects of economic activity, utilization and destruction;

(Paragraph two, part one, Article 15 in wording of Law of Ukraine of 16.10.2012 No 5460-VI)

once permission has been granted, perform freely an examination of any manufacturing, storing, or trading premises of the subjects of economic activity (taking into consideration the established schedule of work);

receive from subjects of economic activity all necessary data on the compliance with standards, technical conditions, the pharmacopoeial monographs and technological requirements, and also measures to ensure the quality of the medicinal product at the time of manufacturing, transportation, storage, and sale;

select samples of the medicinal products for laboratory testing of their quality. The cost of selected samples and of performing the quality control tests shall be included in the production costs of subjects whom have been taken these samples. The procedure for selection of the medicinal product samples shall be specified by the Cabinet of Ministers of Ukraine;

give binding recommendations to eliminate breaches of the standards and technical conditions, the pharmacopoeial monographs and technological requirements, and also breaches at the time of manufacturing, storing, transportation, and sale of the medicinal products;

transfer the materials of inspections, containing the signs of any criminal offense, to the authorities of pre-trial inquiry;

(Paragraph seven, part one, Article 15 amended according to Law of Ukraine of 13.04.2012 No 4652-VI)

impose a fine on the subjects of economic activity irrespective of their ownership forms in the event of a breach of the standards and technical conditions, the pharmacopoeial monographs and Technological Regulations at the time of manufacturing, storing, transportation, and sale of the medicinal products;

draw up the protocols on administrative offences and consider cases of administrative offences in the events, envisaged by the law;

(Paragraph nine, part one, Article 15 in wording of Law of Ukraine of 16.10.2012 No 5460-VI)

(Paragraph 10, part 1, article 15 deleted on the basis of the Law of Ukraine of 16.10.2012 No 5460-VI)

take (in established order) decisions on withdrawal from circulation and prohibition (stoppage) of the manufacture, sale and use of medicinal products incompliant with the requirements established by legislation as well as those imported to Ukraine and exported from Ukraine with infringements of the established procedure. The procedure of prohibition (temporary prohibition) and withdrawal from circulation of medicinal products at Ukraine is established by the central executive body, which ensures development of state policy for health care;

(Paragraph 11, part 1, article 15 in wording of the Law of Ukraine of 16.10.2012 No 5460-VI)

prohibit the storage, sale, and use of the medicinal products should their quality not meet the established requirements;

approve passports of pharmacies (structural units) through procedure established by the central executive body, which ensures development of state policy for health care, perform branch attestation of laboratories for quality control of medicinal products, attestation of pharmacists and chemists.

(Part 1, article 15 amended by paragraph 13 according to the Law of Ukraine of 16.10.2012 No 5460-VI)

The regulatory requirements of the officials providing the state quality control of the medicinal products must be met.

The officials of the central executive body, which implements state policy for quality and safety control of medicinal products, shall be responsible for disclosure of the information known to them after performance of their duties pursuant to the acting legislation.

(Part 3, article 15 amended by the Law of Ukraine of 16.10.2012 No 5460-VI)

Article 16. Law protection of officials of central executive body, which implements state policy for quality and safety control of medicinal products

(Title of article 16 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

The officials of central executive body, which implements state policy for quality and safety control of medicinal products, shall be under the protection of the law.

Interference with the activity of the officials of central executive body, which implements state policy for quality and safety control of medicinal products, which impedes them in the execution of their duties, shall constitute an offence pursuant to the acting legislation of Ukraine.

The officials of central executive body, which implements state policy for quality and safety control of medicinal products, shall be subject to the obligatory state social insurance according to the legislation on obligatory state social insurance.

(Part three, Article 16 in wording of Law as of 28.12.2014 No 77-VIII)

(Article 16 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

Section V

IMPORTATION OF MEDICINAL PRODUCTS INTO UKRAINE AND EXPORTATION OF THE MEDICINAL PRODUCTS FROM UKRAINE

Article 17. Procedure of importation of medicinal products into Ukraine

Medicinal products which have been registered in Ukraine may be imported to Ukraine provided there is a batch quality certificate of medicinal product issued by the manufacturer and import license for medicinal products (except for API) issued to importer (manufacturer or person representing manufacturer of medicinal products in Ukraine) in due established order. License shall annex a list of medicinal products, allowed the licensee to import, and special conditions for conducting activity. The availability of appropriate material and technical basis, qualified personnel and conditions for quality control of medicinal products to be imported to Ukraine is the basis for issuing import license for medicinal products. The compliance of material and technical basis, personnel qualification and conditions for quality control of medicinal products to be imported to Ukraine with the established requirements and claimed characteristics in documents submitted by applicant for obtaining license is subject to obligatory pre-inspection within the terms envisaged for license issuing in place of conducting activity by licensing authority in order established by the central executive body, which ensures development of state policy for health care. The shelf-life of medicinal products to be imported to Ukraine shall be at least half of term established by the manufacturer provided that manufacturer has established the term less than one year or at least six months provided that manufacturer has established the term of more than one year. The procedure for importing medicinal products to Ukraine is established by the Cabinet of Ministers of Ukraine.

(Part one of Article 17 as amended by the Law of Ukraine of 20.12.2011 No 4196-VI; in wording of Law of 04.07.2012 No 5038-VI; amended by Law of 15.01.2015 No 126-VIII)

Control over the importation of medicinal products to the customs territory of Ukraine shall be performed by the central executive body, which implements state policy for quality and safety control of medicinal products. All medicinal products imported to the customs territory of Ukraine for further sale or use in the manufacture of finished medicinal products are subject to state quality control. The procedure for state quality control of medicinal products imported to the customs territory of Ukraine is established by the Cabinet of Ministers of Ukraine.

(Part two of Article 17 amended by Law of 08.09.2011 No 3718-VI, of 16.10.2012 No 5460-VI; in wording of Laws of 04.04.2013 No183-VII, of 20.10.2014 No 1707-VII)

Requirements of parts one and two of this article shall not apply to medicinal products to be procured based on results of the procurement procedure conducted by specialized procuring organization in pursuance of the agreement on procurement between the central executive body of Ukraine which ensures the development of and implements the state policy for health care, and an appropriate specialized procuring organization. The medicinal products registered in Ukraine may be imported to Ukraine to be procured based on results of the procurement procedure conducted by the specialized procuring organization only in pursuance of the agreement on procurement between the central executive body of Ukraine which ensures development of and implements the state policy for health care, and appropriate specialized procuring organization provided a batch quality certificate of medicinal product issued by the manufacturer is available.

(New part is added to Article 17 according to Law No 269-VIII of 19.03.2015 - amendment valid till 01.04.2023, see [item 1](#), Section II, taking into consideration the amendments by the Law [№ 2629-VIII](#) of 23.11.2018, [№ 114-IX](#) of 19.09.2019, [№531-IX](#) of 17.03.2020, № 2229-IX of 21.04.2022)

The requirement of part one of this article for availability of license for import of medicinal products and their shelf lives shall not apply to the import of medicinal products procured and imported into Ukraine by a person authorized to make health care procurement according to the list approved by the Cabinet of Ministers of Ukraine provided there is a confirmation of the intended use of import into Ukraine of such medicinal products according to the procedure established by the Cabinet of Ministers of Ukraine. Such medicinal products shall be imported into Ukraine provided there is a quality certificate for batch of the medicinal product issued by the manufacturer. If a person authorized to make health care procurement has no license to conduct economic activity for import of medicinal products, ensuring compliance with the requirements of legislation on licensing specific economic activities during the importation into Ukraine, storage, quality control, issue of approval for the batch release (sale) of medicinal products procured by a person authorized to make health care procurement shall be carried out with involvement of economic entities licensed to carry out economic activity for import of medicinal products, according to the public procurement legislation. The shelf life of such medicinal products shall be at least 70 percent of the shelf life of medicinal product established by the manufacturer. Based on an individual decision of the central executive body, which ensures the development of and implements the state policy for health care, in the cases specified by it the shelf life of medicinal products procured by a person authorized to carry out health care procurement, according to the list approved by the Cabinet of Ministers of Ukraine, and if there is a confirmation of the intended use of import of such medicinal products, may be reduced.

(New part is added to Article 17 according to Law of № 531-IX of 17.03.2020 - amendments valid till 01.04.2023, taking into account the amendments by the Law № 2229-IX of 21.04.2022)

A person authorized to carry out health care procurement shall be exempted from licensing the importation of medicinal products in the case of medicinal products procured by this person and using the funds under the state budget according to the list approved by the Cabinet of Ministers of Ukraine.

(New part is added to Article 17 according to Law № 531-IX of 17.03.2020- amendments valid till 01.04.2023, taking into account the amendments by the Law № 2229-IX of 21.04.2022)

Medicinal products not registered in Ukraine may be imported in the customs territory of Ukraine for:

transit through Ukraine or placement in the warehouse under customs control for further re-export according to procedure established by the Customs Code of Ukraine (4495-17). At the same time importation to the customs territory of Ukraine for placement in the warehouse under customs control for further re-export is allowed only for medicinal products which have been registered in the country of manufacturer, supported by quality certificate and which import to the customs territory of Ukraine does not contradict provisions of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health. Re-export of such medicinal products should be performed at least six months before expiration of their validity period;

(Part three of Article 17 as amended by new paragraph according to the Law of Ukraine of 13.03.2012 No 4496-VI, in wording of Law of Ukraine of 04.04.2013 No 183-VII)

pre-clinical studies, pharmaceutical development studies and clinical trials;

(Paragraph two of part three of article 17 as amended by the Law of Ukraine of 17.11.2011 No 4056-VI)

registration of the medicinal products in Ukraine (samples of preparations in dosage forms);

purposes of exhibiting at fairs and conferences, without the right to sale;

medical support (without a right to sell) of units of armed forces of other countries, which according to the law are allowed in Ukraine;

(Part three of article 17 is amended by new paragraph according to the Law of 15.03.2011 No 3141-VI)

treatment of rare (orphan) diseases according to the decision of the central executive body that ensures development of the state policy for health care. This provision applies only to medicinal products developed solely to treat rare (orphan) diseases which according to the established procedure are permitted for use in the United States of America or member-states of the European Union whether they are authorized or not as medicinal products by the competent authorities of the United States of America or the European Union;

(Part three of article 17 is amended by new paragraph according to the Law of 12.08.2014 No 1637-VII)

individual consumption by citizens;

a supply based on the results of the procurement made by a person authorized to make health care procurement in order to execute programs and take the centralized health care measures, and using the funds under the state budget, or procurement made with involvement of a person authorized to make health care procurement and using the funds under the local budgets provided all of the following circumstances exist:

(Paragraph nine is added to part six of Article 17 according to Law of № 531-IX of 17.03.2020)

in Ukraine there are no alternative remedies for the prevention and/or treatment of the relevant diseases (there are no registered medicinal products with the relevant active substance in Ukraine);

(Paragraph 10 is added to part six of Article 17 according to Law of № 531-IX of 17.03.2020)

the need for such medicinal products in Ukraine is limited, that is, the medicinal product is intended for use by a small number of patients;

(Paragraph 11 is added to part six of Article 17 according to Law of № 531-IX of 17.03.2020)

the medicinal products concerned are permitted for use via the established procedure in the United States of America, the Swiss Confederation, Japan, Australia, Canada, or in Member States of the European Union, via the centralized procedure and used in one of the specified countries;

(Paragraph 12 is added to part six of Article 17 according to Law of № 531-IX of 17.03.2020)

conducting the expanded patients' access programs to unregistered medicinal products, approved by the central executive body, which ensures the development and implements the state policy for health care;

{Paragraph 13 is added to part six of Article 17 according to Law № 2054-IX of 15.02.2022}

conducting the trial subjects' (patients)' access programs to the investigational medicinal product after the end of clinical trial, approved by the central executive body that ensures the development and implements the state policy for health care.

{Paragraph 14 is added to part six of Article 17 according to Law № 2054-IX of 15.02.2022}

The importation procedure for medicinal products in these cases (except for import for transit through Ukraine or placement in the warehouse under customs control) shall be specified by the central executive body, which ensures development of state policy for health care.

(Part four of Article 17 as amended by the Law of Ukraine of 13.03.2012 No 4496-VI, of 04.04.2013 No 183-VII)

In the event of natural disasters, catastrophes, and epidemic diseases, and under the separate permission of the central executive body, which implements the state policy for health care, the importation of medicinal products not registered in Ukraine shall be allowed, provided that documents confirming the registration and use of such medicinal products in the exporting countries are available. In addition, according to a separate decision of the central executive body, which implements the state policy for health care, the import of medicinal products not registered in Ukraine is permitted with the purpose of medical provision (medical use) of servicemen, soldiers and officers and other persons, who according to the law, are sent by Ukraine to participate in operation to maintain international peace and security as part of a national contingent or national personnel, who carry out tasks during anti-terrorist operation, a Joint Forces operation, taking measures for ensuring the national safety and defense, repulse and deterrence of armed aggression of the Russian Federation in Donetsk and Lugansk Oblasts, at emergency, in a special period if documents confirming the registration and use of medicinal products in such states are available.

(Part of article 17 amended by Law No 5460-VI of 16.10.2012 and No 1637-VII of 12.08.2014 and No 2462-VIII of 19.06.2018, [No](#) 644-IX of 02.06.2020)

The unregistered medicinal products, which can be imported into Ukraine for the purpose of supply based on the results of the procurement, which are made using the funds under the state budget by a person authorized to make health care procurement in order to execute programs and take the centralized health care measures, or procurement made using the funds under the local budgets with involvement of a person authorized to make health care procurement shall be supplied free of charge to the health care units of the regional state administrations, and the state administrations of the city of Kyiv and the city of Sebastopol, or entities licensed to conduct economic activity relating to medical practice, and used in medical practice. A list of unregistered medicinal product (by INN), which can be imported into Ukraine for the purpose of supply based on the results of the procurement made using the funds under the state budget by a person authorized to make health care procurement in order to execute programs and take the centralized health care measures, or procurement made using the funds under the local budgets with involvement of a person authorized to make health care procurement, and a procedure for making this list shall be approved by the Cabinet of Ministers of Ukraine. The central executive body, which ensures the development of and implements the state policy for health care, is responsible for safety and efficacy, and performs pharmacovigilance in Ukraine of the unregistered medicinal products imported into Ukraine and put into circulation (use) according to the procurement procedure conducted by a person authorized to make health care procurement.

(Part nine is added to Article 17 according to Law of № 531-IX of 17.03.2020)

Article 18. Exportation of medicinal products from Ukraine

Exportation of medicinal products from Ukraine shall be performed pursuant to the order established by the legislation of Ukraine.

For the period of martial law in Ukraine, the Cabinet of Ministers of Ukraine may, at the request of the central executive body that ensures the development and implements the state policy for health care, temporarily suspend the export of medicinal products in case of failure to meet the needs of the health care system of Ukraine in such medicinal products in full.

{Article 18 is supplemented by part two in accordance with the Law № 2271-IX of 22.05.2022 - valid until the end of the three-month period after the cessation or abolition of martial law}

SECTION VI

SALE OF MEDICINAL PRODUCTS

Article 19. Procedure of sale of medicinal products

The wholesale, retail trade of medicinal products in Ukraine shall be conducted by economic entities in accordance with the licence issued in compliance with the procedure established by the legislation.

(Part one of Article 19 as amended by the Law № 4196-VI of 20.12.2011; in wording of Law № 904-IX of 17.09.2020 – implemented after three months from the day of the Law coming into effect)

The available material and technical basis, qualified staff which compliance with the established requirements and characteristics specified in the documents submitted by the applicant for obtaining license being subject to obligatory pre-inspection within the set terms, at place of licenser or its territorial subdivisions activity in order established by central executive body, which ensures development of state policy for health care, shall be the grounds for issuing license.

(New part is added to Article 19 according to the Law of Ukraine of 20.12.2011 No 4196-VI, thus paragraph two shall be regarded as paragraph three)

The economic entity can be a whole-seller; retail seller of medicinal products provided the compliance with the licence terms on a certain activity performance.

An economic entity that has a license to conduct economic activity in the retail trade of medicinal products may carry out retail trade of medicinal products using information and communication systems remotely (e-retail trade of medicinal products), as well as delivery of medicinal products to the final consumer provided that the following requirements are fulfilled:

information on the right of an economic entity licensed to conduct economic activity in the retail trade of medicinal products to carry out e-retail trade of medicinal products shall be contained in the Licensing Register for Production of Medicinal Products (in Pharmacy), Wholesale and Retail Trade of Medicinal Products of the Licensing Authority;

the licensee must be included in the List of economic entities entitled to carry out e-retail trade of medicinal products, which is maintained and placed on the official website of the licensing authority, indicating the following information: the name of the economic entity; location and place of activity address (indicating the pharmacies from which the medicinal product is delivered); date of initiation of activity on the e-retail trade of medicinal products; the website address used for these purposes; e-medical information system used for these purposes (if available). The list of economic entities that have the right to carry out the e-retail trade of medicinal product is maintained according to the procedure approved by the central executive body, which ensures the development of and implements the state policy for health care;

the website of the economic entity entitled to carry out e-retail trade of medicinal products shall contain: information on the contact details of the licensing authority, the state bodies for medicinal products quality control; a logo with a hyperlink that appears on each page of the website and takes the consumer to the page with the List of economic entities entitled to carry out e-retail trade of medicinal products (such logo is used by pharmacies only included in the List of economic entities entitled to carry out e-retail trade of medicinal products); the option to consult a pharmacist (if necessary) when ordering a medicinal product through the pharmacy website; the cost of medicinal product delivery. The description, image and procedure for using the logo to identify licensees entitled to e-retail trade of medicinal products shall be approved by the central executive body, which ensures the development of and implements the state policy for health care;

availability of its own delivery service, equipment and facilities that ensure compliance with the storage conditions of medicinal products specified by the manufacturer during their delivery, or involvement of other entities - postal operators on a contractual basis. In case of involvement of other economic entities for delivery of medicinal products to the final consumer, the essential conditions of the contract on such delivery are: the economic entities involved in the delivery of medicinal products to the final consumer shall have the equipment and facilities that ensure compliance with the manufacturer's storage conditions for medicinal products during their delivery, and the obligation to comply with these requirements; provisions on the possibility to monitor the compliance with the storage conditions of medicinal products during their delivery by the economic entity engaged in e-retail trade of medicinal products - at least once a year and by the bodies for state quality control of medicinal products - within the implementation of measures of state quality control of medicinal products; rights and obligations of the parties; liability of the parties (subject to the provisions set forth in this article); the validity period of the contract. The

standard form of the contract on delivery of medicinal products to the final consumer is approved by the Cabinet of Ministers of Ukraine;

delivery of a medicinal product exclusively from pharmacies included in the List of economic entities entitled to carry out e-retail trade of medicinal products in accordance with this Law.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

An economic entity that has a right to carry out e-retail trade of medicinal products in accordance with this Law may additionally use e-medical information systems connected to the central database of the e-health care system. In the case of using an e-medical information system connected to the central database of the e-health care system, which allows to receive orders from users of such a system, such e-medical information system shall contain: a link to the official website of the licensing authority where there is a List of economic entities entitled to carry out e-retail trade of medicinal products; the option of consulting a pharmacist of an economic entity entitled to carry out e-retail trade of medicinal products (if necessary) when ordering a medicinal product through the website of the e-medical information system.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

E-retail and delivery of the following medicinal products is prohibited to the final consumer:

medicinal products, the sale (marketing) of which to citizens is subject to medical prescriptions (except for medicinal products subject to e-prescription in accordance with the procedure established by the central executive body that ensures the development of and implements state policy for health care);

medicinal products, the circulation of which according to the law may be carried out if there is a license to conduct activities on the circulation of narcotic drugs, psychotropic substances and precursors;

potent, toxic, radioactive and immunobiological medicinal products, the list of which is determined by the central executive body that ensures the development and implements the state policy for health care.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

Requirements of the procedure for e-retail trade of medicinal products and their delivery to consumers are determined by the license conditions for conducting economic activity in the retail trade of medicinal products.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

It is prohibited to set a mandatory minimum quantity of medicinal products and the size of the minimum order for e-retail trade of medicinal products.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

An economic entity that entitled to carry out e-retail trade of medicinal products is obliged to ensure the confidentiality of personal data of consumers in accordance with the requirements of the law.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

An economic entity licensed to conduct economic activity in the retail trade of medicinal products shall be liable to the final consumer for maintaining quality of medicinal product and compliance with the storage conditions specified by the manufacturer, including during delivery to the final consumer of medicinal product sold remotely, regardless of whether he makes delivery by his own delivery service or involves other economic entities, as well as bears administrative and criminal liability for violation of the rules of marketing and delivery of medicines in accordance with the law. Economic entities that are involved in the delivery of medicinal products to the final consumer on a contractual basis, are administratively and criminally liable for violation of the established requirements for the delivery of medicinal products in accordance with the law.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

Information on the legislation pertinent to the e-retail trade of medicinal products, the logo of economic entities entitled to carry out e-retail trade of medicinal products, the List of economic entities entitled to carry out e-retail trade of medicinal products, and their web-site addresses, as well as information on the risks associated with medicinal products, e-retail trade of which is illegal, are placed on the official website of the licensing authority.

(Article 19 amended by new part according to the Law № 904-IX of 17.09.2020 – implemented in three months since the Law is effective)

Requirements of this article shall not apply to a person authorized to make health care procurement, who procures medicinal products according to the List approved by the Cabinet of Ministers of Ukraine regarding medicinal products entered in this List. If a person authorized to make health care procurement has no license to carry out economic activity on wholesale of medicinal products, ensuring compliance with the requirements of the legislation on licensing of specific types of economic activity during storage, transportation of medicinal products procured by a person authorized to make health care procurement, legislation on quality control of medicinal products during the wholesale shall be carried out with involvement of economic entities licensed to carry out economic activity on wholesale of medicinal products, observing the public procurement legislation.

(Part is added to Article 19 according to Law № 531-IX of 17.03.2020; part twelve of Article 19 with the following amendments valid till April 01, 2023 – see Laws № 904-IX of 17.09.2020, № 531-IX of 17.03.2020, taking into account the amendments by the Law № 2229-IX of 21.04.2022)

(Article 19 in wording of Law № 3370-IV of 19.01.2006)

Article 20. General requirements to sale of medicinal products

Only registered medicinal products may be marketed in Ukraine, with the exception of the cases specified by this Law.

Sale of medicinal products may be performed provided that the certificate of quality issued by the manufacturer (for imported medicinal products - by importer (manufacturer or a person representing the manufacturer of medicinal products in Ukraine) is made available.

(Part two of article 20 as amended according to the Law of 04.07.2012 No 5038-VI)

Free provision and/or receipt of medicinal products within the clinical trials, within the expanded patients' access programs to unregistered medicinal products or trial subjects' (patients) access programs to the investigational medicinal product after the end of clinical trial is not a sale (wholesale and retail sale).

{Part three is added to Article 20 according to the Law № 2054-IX of 15.02.2022}

Article 21. Sale (dispensing) of medicinal products to the general public

Sale (dispensing) of medicinal products to the public shall be permitted either subject to or without medical prescriptions.

The sale (dispensing) of low quality medicinal products to the public, or those for which shelf-life has expired, or those without certificate of quality issued by the manufacturer, shall be prohibited.

The medicinal products being subject to prescription shall be sold (dispensed) to the public in due order established by the central executive body, which ensures development of state policy for health care.

(New part is added to Article 21 according to the Law of Ukraine of 20.12.2011 No 4196-VI, thus paragraph three shall be regarded as paragraph four)

The Rules on Prescribing Medicinal Products and the list of medicinal products, which may be sold without medical prescription, shall be approved by the central executive body, which ensures development of state policy for health care.

The sale (supply) of medicinal products (including with the use of remote information and communication systems) to minors, as well as the delivery of medicines to the final consumer - a minor is prohibited. If a person who directly retails medicinal products and/or delivers medicinal products to the final consumer has doubts about reaching the age of 14 by the buyer who buys medicinal products, the person who directly retails medicinal products and/or delivers medicines to the final consumer, must apply to such a buyer with a request to present a passport of a citizen of Ukraine or other document confirming his age. If the buyer refuses to provide such a document, the sale (supply) of medicinal products to this person is prohibited.

{Article 21 amended by part five according to Law № 1668-IX of 15.07.2021}

Article 22. Providing the population with medicinal products in the case of natural disaster, catastrophe, epidemic diseases

To establish and preserve the state reserves of medicinal products to be used in the case of natural disaster, catastrophe, epidemic diseases the Cabinet Ministers of Ukraine or the body authorized by the latter shall establish and determine specialized state institutions and organizations. For this purpose it may make all necessary agreements with the subjects of business activities of any form of property.

The procedure whereby the State reserves of medicinal products are prepared and used, and the amount of these reserves shall be specified by the Cabinet of Ministers of Ukraine.

The Council of Ministers of the Autonomous Republic of Crimea, the regional state administrations, and the state administrations of the city of Kyiv and the city of Sevastopol shall form their own reserves of the medicinal products for the case of the natural disaster, catastrophe, and epidemic diseases.

(Part 3, article 22 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

Article 23. Utilization and destruction of medicinal products

Medicinal products of low quality, including those for which the shelf-life has expired, shall be utilized and destroyed.

The utilization and destruction of medicinal products shall be performed according to the Rules approved by the central executive body, which ensures development of state policy for health care, and other requirements of the legislation.

Section VII.

FINAL PROVISIONS

Article 24. Funding

Development, pre-clinical examination, clinical trial, manufacturing, and quality control of the medicinal products shall be financed through the State Budget of Ukraine, local budgets, non-budget funds, assets of enterprises, institutions, organizations, and citizens, and also from any other sources not prohibited by the legislation.

(Part 1, article 24 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

The expenses for financing scientific works on development of new medicinal products shall be included in the cost of the products pursuant to the procedure established by the Cabinet of Ministers of Ukraine.

{Part three of Article 24 becomes void on the basis of the Law № 783-XIV of June 30, 1999 - the wording enters into force simultaneously with the entry into force of the Law on the State Budget of Ukraine for 2000}

Article 25. Material and technical provision

The State shall organize material and technical provisions for the development, manufacturing, quality control, and sale of medicinal products in the amount required to provide the population with the guaranteed level of health care.

Norms for minimum provision of the population with medicinal products, the sale of which is provided by state health care settings are determined by the Cabinet of Ministers of Ukraine.

Article 26. Provision of information

The State shall establish proper conditions for the provision of information in the sphere of development, manufacturing, quality control, and sale of medicinal products in Ukraine.

The central executive body, which implements state policy for health care, shall inform the population on those medicinal products registered or excluded from the State Register of the Medicinal Products of Ukraine.

(Part 2, article 26 amended by Law of Ukraine of 16.10.2012 No 5460-VI)

Information about medicinal product (including non-registered or being developed or introduced in manufacture products) shall include name, characteristics, treatment properties, possible adverse effect and be published in medical and pharmaceutical literature and in the documents distributed at specialized medical workshops, conferences and symposia.

(New part is added to Article 26 according to the Law of Ukraine of 20.12.2011 No 4196-VI)

Advertising of medicinal products which are dispensed without medical prescription is allowed unless those are included in the list of medicinal products prohibited for advertising. The list of medicinal products prohibited for advertising shall be approved by the central executive body, which ensures development of state policy for health care. The requirements to advertising of such medicinal products are set by the Law of Ukraine "On Advertising". The criteria used for determining the medicinal products, whose advertising is to be banned, shall be approved by the central executive body, which ensures development of state policy for health care, in accordance with provisions of the law. The decision on referring the medicinal products to those, whose advertising is prohibited, shall be made during the state registration (re-registration) of such medicinal products along with the introduction of the relevant information to the State Register of Medicinal Products of Ukraine. Advertising of medicinal products, whose use and dispensing is permitted only under the medical prescription, as well as those included in the list of medicinal products prohibited for advertising, is forbidden.

(Part 4, article 26 in wording of the Law of Ukraine of 14.02.97 No 70/97-VR, in wording of the Law of Ukraine of 20.12.2011 No 4196-VI)

(Part 5, article 26 is excluded according to the Law of Ukraine of 14.02.97 No 70/97-VR)

(Part 6, article 26 is excluded according to the Law of Ukraine of 14.02.97 No 70/97-VR)

(Part 7, article 26 is excluded according to the Law of Ukraine of 14.02.97 No 70/97-VR)

Article 27. Responsibility for breaching the legislation on medicinal products

Persons found guilty of breaching the legislation on medicinal products shall receive disciplinary administrative, civil, or criminal action pursuant to the legislation.

Article 28. International collaboration

Ukraine shall participate in international collaboration in the sphere of development, quality control, and sale of medicinal products. For this purpose international scientific programs shall be developed and implemented, the exchange of information; progressive methods and technologies for development and manufacture of medicinal products, their exportation and importation, professional and scientific communication of health care providers, etc. shall be provided.

The State shall develop and support all forms of international collaboration in the sphere of development, manufacturing, quality control and sale of the medicinal products, which is not in contradiction to the legislation of Ukraine.

L. KUCHMA

President of Ukraine

Kyiv

4 April, 1996

No 123/96-VR