(Unofficial translation)

LAW OF THE REPUBLIC OF BELARUS
No. 161-З dated July 20, 2006

on Medicine Circulation

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Amendments and addenda:

Law of the Republic of Belarus No. 428-З dated August 5, 2008 (National Register of Legal Acts of the Republic of Belarus, 2008, No.196, 2/1525);

Law of the Republic of Belarus No. 27-З dated June 15, 2009 (National Register of Legal Acts of the Republic of Belarus, 2009, No. 148, 2/1579);

Law of the Republic of Belarus No. 326-З dated December 22, 2011 (National Register of Legal Acts of the Republic of Belarus, 2012, No. 1, 2/1878);

Law of the Republic of Belarus No. 203-З dated November 17, 2014 (National Legal Internet Portal of the Republic of Belarus, 20.11.2014, 2/2201);

Law of the Republic of Belarus No. 386-З dated June 29, 2016 (National Legal Internet Portal of the Republic of Belarus, 02.07.2016, 2/2384);

Law of the Republic of Belarus No. 13-З dated May 13, 2020 (National Legal Internet Portal of the Republic of Belarus, 19.05.2020, 2/2732) – new version;

Закон Республики Беларусь от 14 октября 2022 г. № 213-З (Национальный правовой Интернет-портал Республики Беларусь, 20.10.2022, 2/2933)

Law of the Republic of Belarus No. 213-З dated October 14, 2022 (National Legal Internet Portal of the Republic of Belarus, 20.10.2022, 2/2933);

This Law is directed to enhancement of legal and organizational basis of state regulation in the sphere of medicine circulation for the purpose of providing the population of the Republic of Belarus with safe, effective and high quality medicines.

CHAPTER 1

MAIN PROVISIONS

Article 1. Main Terms Used in This Law, and Their Definitions

The following basic terms and definitions are used for the purposes of this Law:

antiseptic medicine is the medicine with antimicrobial, antiviral, antiparasitic, antifungal action and used mainly for external application for the purpose of medical prevention and treatment of infectious diseases;

pharmacy is a complex of specialized facilities (specialized facility) and equipment intended for the pharmacy manufacture, sale, dispense of medicines, medical devices and other pharmaceutical assortment goods and owned by, or belonging on another legal basis to legal entity of the Republic

of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization created in accordance with the legislation of foreign countries, if there is a representative office opened in accordance with the established procedure on the territory of the Republic of Belarus (hereinafter, unless otherwise specified, legal entities and individual entrepreneurs) licensed to carry out pharmaceutical activities;

medicine safety is a characteristic of medicine based on sufficient proof confirming the absence of an unacceptable risk associated with the possibility of harm and (or) damage to human health, subject to compliance with the requirements for medical use, transportation, storage;

excipient is a substance, except for pharmaceutical substances (active pharmaceutical substances) (hereinafter referred to as pharmaceutical substances), which is part of a medicine to impart it the necessary properties;

state registration of a medicine is a procedure for recognizing the compliance of a medicine with the requirements for safety, effectiveness and quality imposed on it, undertaken for the purpose of its admission to sale and medical use in the Republic of Belarus;

State Register of Medicines of the Republic of Belarus is a state information resource containing information about medicines registered in the Republic of Belarus;

Marketing Authorisation Holder is a legal entity of the Republic of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization established in accordance with the legislation of foreign countries to which the Marketing Authorisation has been issued and which are responsible for the safety, effectiveness and quality of the medicine;

pre-clinical (non-clinical) studies of medicine is a chemical, physical, biological, microbiological, pharmacological, toxicological or other experimental study or a series of studies to examine a medicine by applying scientific evaluation methods in order to study its specific action and (or) evidence of safety for human health;

inspection (pharmaceutical inspection) is an assessment of the stage (process) of the circulation of medicines in order to establish its compliance with the requirements of good pharmaceutical practices in the field of medicines circulation;

instruction for medical use (package insert) is a document placed in the package with the medicine containing information for the consumer;

investigational medicine is a medicine that is tested or used for comparison during a clinical trial (test), including a placebo, together with a registered medicine if the method of its use differs from the approved one, as well as if it is used according to a new indication for medical use or to obtain additional information on an approved indication;

quality of a medicine is a set of properties and characteristics of a pharmaceutical substance and a medicine, ensuring their compliance with the intended purpose for medical use;

clinical trial (testing) of a medicine is a study of diagnostic, therapeutic, preventive, pharmacological properties of a medicine in the process of its medical use by the subject of the study, including the processes of absorption, distribution, metabolism and excretion, through the use of scientific methods of evaluation in order to obtain evidence of the safety and effectiveness of the medicine, data on adverse reactions of the human body to the medicine and the effect of its interactions with other medicines and (or) food products;

dosage form is a state of a medicine, corresponding to the methods of its introduction, medical use and ensuring the achievement of the desired effect;

medicinal product is a product that represents or contains a substance or a combination of substances that comes into contact with the human body, intended for the treatment, medical prevention of human diseases or restoration, correction or modification of the physiological functions

of human body through pharmacological, immunological or metabolic effects or for the diagnosis of human diseases and conditions;

medicine is a medicinal product in the form of a dosage form

adverse reaction is an unintended, unfavourable reaction of the human body, associated with the use of a medicine or an investigational medicine and suggesting a possible relationship with the use of these medicines;

unexpected adverse reaction is an adverse reaction, the nature, severity or outcome of which is not consistent with the information contained in the summary product characteristic or the investigator's brochure for the investigational medicine;

regulatory quality document is a document of the manufacturer of a medicine that establishes requirements for quality control of a medicine, containing quality indicators and a description of methods and analytical techniques used in quality control of a medicine;

circulation of medicines is a development, pre-clinical (non-clinical) study, clinical trials (tests), expertise, inspection (pharmaceutical inspection), registration, pharmacovigilance, quality control, industrial production, pharmacy manufacture, storage, transportation, import, export, sale, dispense, medical use, return to the manufacturer or supplier, destruction of medicines;

Summary product characteristic is a document containing information for healthcare providers and pharmacists on the safe and effective medical use of a medicine, placed in the State Register of Medicines of the Republic of Belarus and (or) the Unified Register of Registered Medicines of the Eurasian Economic Union;

wholesale sale of medicines (distribution) (hereinafter reffered to as a wholesale sale of medicines) is an activity related to the purchase, storage, import, export, sale (except for sale to the population) without limitation of volumes, transportation, destruction of medicines;

orphan (rare) diseases are a group of severe chronic progressive diseases, which, as a rule, have a genetic nature and a prevalence rate of no more than one case per 10,000 people in the population, leading to a reduction in life expectancy, disability;

orphan (rare) medicine is a medicine intended for diagnosis, etiopathogenetic or pathogenetic treatment (treatment aimed at the mechanism of disease development) of orphan (rare) diseases;

List of Essential Medicines is a list of medicines established by the Ministry of Health that meet the vital needs of the population of the Republic of Belarus in providing medicines, as well as used for preferential, including free, provision of medicines to certain categories of citizens when providing medical care on an outpatient basis;

industrial production of medicines is an activity of a manufacturer of medicines, including the purchase of raw materials, materials and products, the implementation of one or more stages of the technological process, including the packaging process, quality control, issuance of permits for the release, storage and sale of medicines;

Marketing Authorisation Application is a set of documents submitted by the applicant for state registration (confirmation of state registration) of a medicine on the territory of the Republic of Belarus containing information on the safety, effectiveness and quality of a medicine, and other documents determined by the Council of Ministers of the Republic of Belarus;

Market Authorization is a document issued by the Ministry of Health based on the results of state registration (confirmation of state registration) of a medicine;

registration number is a code assigned to a medicine based on the results of its state registration;

Republican Formulary of Medicines is a list of medicines with proven effeciency, acceptable safety, and the most economically profitable when using budget funds allocated for healthcare;

risks associated with the use of the medicine are any risks to public health or the health of the patient related to the safety, efficiency and quality of the medicine; as well as any risks of undesirable environmental effects.

"risk-benefit balance" means an evaluation of the positive therapeutic effects of the medicine in relation to the risks associated with its medical use;

shelf life of a medicine is a period of time during which a medicine does not lose its safety, effectiveness and quality if properly stored under the conditions indicated on the package, in the summary product characteristics of the medicine and (or) instructions for medical use (package insert);

trial subject is an individual participating in a clinical trial (testing) of a medicine as part of a group receiving the investigational medicine, or as part of a control group;

falsified medicine is a medicine intentionally provided with false information about its composition and (or) manufacturer, as well as false information about all stages of the medicine supply chain;

pharmacovigilance is an activity, aimed at identifying, evaluating and preventing undesirable consequences of the use of medicines;

pharmacopoeial monograph is a technical regulatory legal act that establishes requirements for methods of quality control of medicines and equipment necessary for testing the quality of medicines, packaging materials, reagents, dosage forms, quality of medicines, pharmaceutical substances, medicinal plant raw materials, standard samples, excipients;

pharmaceutical substance is a medicinal product, intended for production and manufacture of medicines;

pharmaceutical inspector is a person, authorized by the Ministry of Healh to perform pharmaceutical inspection and included in the register of pharmaceutical inspectors of the Republic of Belarus;

efficacy of a medicine is a set of characteristics of the medicine, ensuring the achievement of a preventive, diagnostic or therapeutic effect or restoration, correction or modification of the physiological function of the human body.

The terms " similar biological medicine (biosimilar medicine)" (hereinafter reffered to as similar biological medicine), "biological medicine", "biotechnological medicine", "reproduced medicine (generic)" (hereinafter reffered to as reproduced medicine), "hybrid medicine", "homeopathic medicine", "immunological medicine (immunobiological medicine)" (hereinafter reffered to as immunological medicine), "medicinal plant raw materials", "generally accepted (grouping) name of a medicine", "original medicine", "radiopharmaceutical medicine" are used in this Law in the meanings defined by international legal acts constituting the law of the Eurasian Economic Union in the field of circulation of medicines.

The content of other terms shall be defined by certain articles of this Law.

Article 2. Legislative Regulation of Medicines Circulation

Relations in the field of medicines circulation are regulated by the legislation on the medicines circulation, international treaties of the Republic of Belarus, as well as international legal acts that constitute the law of the Eurasian Economic Union.

Legislation on the medicines circulation is based on the Constitution of the Republic of Belarus and consists of this Law and other legislative acts.

If an international treaty of the Republic of Belarus establishes rules other than those contained in this Law, the rules of the international treaty shall apply.

Article 3. Scope of this Law

This Law applies to legal entities and individuals, including individual entrepreneurs, involved in the medicines circulation, including original medicines, reproduced medicines, hybrid medicines, antiseptic medicines, homeopathic medicines, radiopharmaceutical medicines, biological medicines (including immunological medicines, biotechnological medicines, biosimilar medicines), orphan (rare) medicines, other medicinal products, as well as investigational medicines, pharmaceutical substances and medicinal plant raw materials (hereinafter, unless otherwise specified, medicines).

Article 4. Basic Principles of State Policy in the Sphere of Medicines Circulation

Basic principles of state policy in the sphere of medicines circulation are:

state regulation of medicines circulation;

availability of medicines;

support and advance of international cooperation.

Article 5. Availability of Medicines

The availability of medicines is a necessary condition for providing the population with timely medical care.

The state ensures the availability of medicines by:

the most complete saturation of the domestic market with safe, effective and high-quality medicines, primarily included in the Republican Formulary of Medicines, the list of essential medicines;

improving the system of medicines sale.

Preferential, including free, provision of medicines to certain categories of citizens is carried out according to prescriptions within the list of essential medicines.

Article 6. State Pharmacopeia of the Republic of Belarus

The State Pharmacopoeia of the Republic of Belarus is a systematic, up-to-date collection of general and private pharmacopoeial monographs approved by the Ministry of Health.

General pharmacopoeial monographs of the State Pharmacopoeia of the Republic of Belarus establish general requirements for methods of quality control of medicines and equipment necessary for testing the quality of medicines, packaging materials, reagents, dosage forms, pharmaceutical substances, medicinal plant raw materials, standard samples, excipients used in industrial production of medicines.

Private pharmacopoeial monographs of the State Pharmacopoeia of the Republic of Belarus establish requirements for the quality of medicines, pharmaceutical substances, medicinal plant raw materials, reagents, excipients, packaging materials used in the industrial production of medicines, pharmacy manufacture of medicines.

Article 7. Good Pharmaceutical Practices in the Sphere of Medicines Circulation

Good Pharmaceutical Practices in the field of medicines circulation apply to all stages (processes) of medicines circulation and include:

Good Pharmacy Practice, approved by the Ministry of Health and representing a set of rules for pharmaceutical manufacture, quality control, shelf life control, packaging and labeling, storage conditions, pharmaceutical consulting and sales, dispensing of medicines, including requirements for premises, equipment and classification of pharmacies by categories;

Good Practice of Storing Medicines, approved by the Ministry of Health and representing a set of rules for the organization of storage of medicines, including requirements for premises and equipment, in order to ensure the quality and safety of medicines;

Good Manufacturing Practices approved by the Ministry of Health and representing a set of rules for the organization of industrial production and quality control of medicines;

The rules of Good Clinical Practice of the Eurasian Economic Union, approved by the decision of the Council of the Eurasian Economic Commission and representing a set of ethical and scientific requirements for planning, conducting, implementing, monitoring, auditing, documenting, analyzing and presenting the results of clinical trials of medicines that protect the rights, safety and well-being of subjects of study and receive within the framework of clinical trials (tests) of medicines with reliable and robust data;

The rules of Good Laboratory Practice of the Eurasian Economic Union, approved by the decision of the Council of the Eurasian Economic Commission and representing a set of requirements for the organization, planning and conduct of preclinical (non-clinical) studies of medicines, registration of results and quality control of these studies;

The rules of Good Distribution Practice of the Eurasian Economic Union, approved by the decision of the Council of the Eurasian Economic Commission and representing a set of rules for the organization and operation of a quality assurance system that guarantees the quality of medicines throughout all stages of the supply chain, including purchase, storage and transportation, from the manufacturer to legal entities and individual entrepreneurs engaged in industrial production, sale of medicines, as well as to healthcare organizations and other organizations, performing medical activities;

The rules of Good Practice of Pharmacovigilance of the Eurasian Economic Union, approved by the decision of the Council of the Eurasian Economic Commission and representing a set of rules for the organization and implementation of pharmacovigilance activities by marketing authorisation holder and the Ministry of Health;

The rules of Good Manufacturing Practice of the Eurasian Economic Union, approved by the decision of the Council of the Eurasian Economic Commission and representing a set of rules for the organization of industrial production and quality control of medicines produced for supply to the market of the Eurasian Economic Union.

Article 8. International Cooperation

The Republic of Belarus carries out international cooperation with foreign countries and international organizations in the field of medicines circulation through the development and implementation of international scientific programs, exchange of information, advanced methods of development and technologies of industrial production of medicines, pharmacy manufacture of medicines, as well as participation in other events for the provision of medicines to the population.

The Republic of Belarus supports and develops forms of international cooperation that do not contradict legislation in the fields of development, industrial production, pharmacy manufacture, registration, quality control, sale of medicines, pharmacovigilance, inspection (pharmaceutical inspections), as well as information interaction to identify and counteract the circulation of substandard and (or) falsified medicines.

CHARTER 2

STATE REGULATION IN THE SPHERE OF MEDICINES CIRCULATION

Article 9. State Regulation in the Sphere of Medicines Circulation

State regulation in the field of medicines circulation is carried out by the President of the Republic of Belarus, the Council of Ministers of the Republic of Belarus, the Ministry of Health, local executive and administrative authorities within their competence and in accordance with the procedure established by law.

The state policy in the field of medicines circulation is determined by the President of the Republic of Belarus.

The implementation of the state policy in the field of medicines circulation is provided by the Council of Ministers of the Republic of Belarus.

The Ministry of Health implements the state policy in the field of medicines circulation by:

issuing permitions for conducting clinical trials (tests) of medicines;

state registration of medicines;

licensing of pharmaceutical activities;

organizing and (or) conducting inspections (pharmaceutical inspections) of the stages (processes) of medicines circulation with the requirements of good pharmaceutical practices in the field of medicines circulation;

organization of the quality control system of medicines;

organization of the pharmacovigilance system;

organization of state pharmaceutical supervision over compliance by the audited entities with the requirements of legislation on the circulation of medicines, including in terms of conditions of industrial production, pharmacy manufacture, sale, storage, transportation and medical use in healthcare organizations of medicines (hereinafter – state pharmaceutical supervision over compliance with the requirements of legislation on the medicines circulation);

suspension of the sale and medical use of medicines or withdrawal from circulation of substandard and falsified medicines, as well as medicines with an established unfavorable benefit–risk balance;

implementation of other functions provided for by this Law and other legislative acts.

Local executive and administrative authorities carry out state policy in the field of medicines circulation within the competence defined by legislation.

Article 10. State Registration (Confirmation of State Registration) of Medicines. Registration (Confirmation of Registration) of Medicines within the framework of the Eurasian Economic Union

Medicines are allowed for sale and medical use on the territory of the Republic of Belarus after their state registration (confirmation of state registration) or registration (confirmation of registration) within the framework of the Eurasian Economic Union, unless otherwise provided by this Law or other legislative acts.

State registration is not subject to:

medicines manufactured in pharmacies;

medicines intended for use as exhibition samples;

medicines intended for examination during the implementation of state registration (confirmation of state registration) of medicines or registration (confirmation of registration) within the framework of the Eurasian Economic Union;

medicines intended for preclinical (non-clinical) studies, clinical trials (tests);

medicines imported into the territory of the Republic of Belarus by an individual for personal use;

medicines that have passed all stages of the technological process, except for the processes of packaging and (or) packaging;

medicines intended for industrial production only for export and not intended for sale in the Republic of Belarus;

pharmaceutical substances, if the marketing authorisation applications for the medicines they are part of contain documents from the manufacturers of these pharmaceutical substances, that meet the requirements for the documents that make up the marketing authorisation applications.

Medicinal plant raw materials after passing the stage of the production process of giving it a certain dosage form are subject to state registration as a medicine.

Original medicines for the treatment, medical prevention or diagnosis of life-threatening or severe disabling diseases, medicines for the treatment of orphan (rare) diseases in the absence of effective methods of medical care may be allowed for sale and medical use after passing the procedure of their conditional state registration (confirmation of conditional state registration).

For state registration (confirmation of state registration) of a medicine, conditional state registration (confirmation of conditional state registration) of a medicine, the applicant submits a marketing authorisation application.

The applicant may be:

a legal entity of the Republic of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization established in accordance with the legislation of foreign countries, producing medicines or placing an order for the industrial production of medicines in another organization engaged in the industrial production of medicines, or members of an association, which also includes the manufacturer of medicines;

a legal entity of the Republic of Belarus, an individual entrepreneur registered in the Republic of Belarus, a foreign legal entity, a foreign organization established in accordance with the legislation of foreign countries, who are official representatives of the marketing authorization holder.

It is not allowed to use data on the results of preclinical (non-clinical) studies and clinical trials (tests) of original medicines as part of marketing authorisation application of reproduced and biosimilar medicines without the written consent of the owners of such data within four years from the date of state registration in the Republic of Belarus of these original medicines. In the case of dissemination (publication) of information by the owner or on his behalf by other persons about the results of preclinical (non-clinical) studies and clinical trials (tests) of original medicines in publicly available information sources before the expiration of the specified period, such dissemination (publication) is considered the consent of the owner of this information to its disclosure and commercial use.

The list of documents constituting the marketing authorisation application is established by the Council of Ministers of the Republic of Belarus. The requirements for the documents that make up the marketing authorisation application are established by the Ministry of Health.

State registration (confirmation of state registration) of medicines, conditional state registration (confirmation of conditional state registration) of medicines is carried out by the Ministry of Health.

According to the results of the state registration (confirmation of state registration) of a medicine or conditional state registration (confirmation of conditional state registration) of a medicine, a marketing authorisation is issued. The procedure for issuing a marketing authorisation is established by the Council of Ministers of the Republic of Belarus.

A registered pharmaceutical substance, a medicine, including one that has passed conditional state registration, as well as a pharmaceutical substance that is part of a medicine, are included in the State Register of Medicines of the Republic of Belarus, which is placed on the official website of the Ministry of Health in the World Wide Web.

The structure, procedure for the formation and maintenance of the State Register of Medicines of the Republic of Belarus are established by the Council of Ministers of the Republic of Belarus.

Upon state registration (confirmation of state registration) of a medicine, a decision is made to classify the medicine as:

medicines sold by prescription or without a prescription, or medicines for the provision of medical care in a hospital;

narcotic drugs or psychotropic substances;

medicines of the list "A", the toxicological properties of which pose a potential danger to human health and require special storage conditions. The procedure and conditions for maintaining this list are established by the Ministry of Health.

A marketing authorisation with a validity period of five years is issued for a medicine registered in the Republic of Belarus for the first time. After the expiration of the five-year validity period of the marketing authorisation, the medicine must undergo the procedure of confirming state registration. Upon confirmation of state registration for a medicine, a marketing authorisation of unlimited duration is issued.

Upon passing the conditional state registration procedure, a marketing authorisation with a validity period of one year is issued for a medicine registered in the Republic of Belarus for the first time. Confirmation of conditional state registration is carried out annually.

A medicine that has been put on sale during the period of validity of the marketing authorisation is allowed for sale and medical use before the expiration date indicated on the package, without confirmation of its state registration. Simultaneous sale of a medicine in a previously and newly agreed package and (or) with a previously and newly agreed instruction for medical use (package insert) is allowed until the expiration date of the medicine.

The sale and medical use of a medicine produced within 180 calendar days after the date of making a decision to confirm its state registration in accordance with the information contained in the documents constituting the marketing authorization application, before the date of making such a decision, before its expiration date, except in cases when a decision is made on the impossibility of further production of a medicine in accordance with the information contained in the documents constituting the registration dossier. in accordance with the previously agreed documents that make up the marketing authorization application.

For a registered medicine, the following are issued, approved by the Ministry of Health:

regulatory document on quality;

instructions for medical use (package insert);

general characteristics of the medicine;

packaging layouts.

An indefinite marketing authorisation and a regulatory quality document approved by the Ministry of Health are issued for a registered pharmaceutical substance. At the same time, the procedure for confirming state registration is not required.

For medicines intended for industrial production for export, the Ministry of Health issues a Certificate of Pharmaceutical Product intended for international trade in accordance with the recommendations of the World Health Organization, in accordance with the procedure established by the Council of Ministers of the Republic of Belarus.

When changing the information contained in the documents that make up the marketing authorisation application, appropriate changes are made to the marketing authorisation application.

The state registration (confirmation of state registration) of a medicine, making changes to the marketing authorisation application is refused in the case of:

failure by the applicant to submit the documents constituting the marketing authorisation application;

non-compliance of the documents constituting the marketing authorisation application with the established requirements;

failure to remove comments on the results of the examination of the documents that make up the marketing authorisation application;

the need for additional preclinical (non-clinical) studies, clinical trials (tests), as well as other studies to confirm the safety, efficacy and quality of the medicine;

obtaining negative results of clinical trials (tests) of a medicine or other studies to confirm the safety, efficacy and quality of a medicine;

inconsistencies of the conducted clinical trials (tests) of the medicine with the requirements of the Rules of Good Clinical Practice of the Eurasian Economic Union;

inconsistencies in the industrial production of a medicine with the requirements of Good Manufacturing Practice;

if, during the examination of the documents constituting the marketing authorisation application, it is established that the effectiveness of the registered medicine has not been confirmed or the risk of harm to human health due to the medical use of the medicine exceeds the effectiveness of its use;

the presence of a substance in the composition of a medicine that is not allowed for use in the Republic of Belarus;

submission for state registration of a medicine with a trade name identical to the trade name of a medicine already included in the State Register of Medicines of the Republic of Belarus, except for the use of an international nonproprietary name (the name of a pharmaceutical substance recommended by the World Health Organization) or a common (generic) name of a medicine;

submissions for state registration of medicines containing the same pharmaceutical substance under two or more trade names, except for the cases indicated in the instructions for medical use (package inserts) and general characteristics of medicines of different indications for medical use;

submissions for state registration of a medicine with a trade name that does not meet the criteria for trade names of medicines established by the Ministry of Health.

The validity of the marketing authorization is suspended for a period of no more than six months in the case of:

identification of changes in the benefit–risk balance during pharmacovigilance measures due to the medical use of a medicine in which the risk of harm to human health exceeds its effectiveness;

refusal of the holder of the marketing authorization to fulfill the obligations under pharmacovigilance established by the Ministry of Health;

refusal of the holder of the marketing authorization from conducting clinical trials (tests) of a medicine designated by the Ministry of Health;

identification of false information in the documents constituting the marketing authorization application, which were not and could not be established during the state registration (confirmation of state registration) of the medicinal product;

refusal of the holder of the marketing authorization from carrying out an inspection (pharmaceutical inspection) of the industrial production of a medicine appointed by the Ministry of Health for compliance with the requirements of Good Manufacturing Practice when recognizing a medicine as substandard;

inconsistencies in the industrial production of a medicine with the requirements of Good Manufacturing Practice.

The validity of the marketing authorization is terminated in the case of:

the expiration date of the marketing authorization;

failure by the holder of the marketing authorization to eliminate the circumstances that led to the suspension of the marketing authorization;

appeal of the holder of the marketing authorization with an application for termination of the marketing authorization;

the court's decision on the violation of the rights of the copyright holder of intellectual property objects in the medicines circulation.

The procedure and conditions for the implementation of state registration (confirmation of state registration) of medicines, conditional state registration (confirmation of conditional state registration) of medicines, amendments to the marketing authorization application, as well as suspension and termination of marketing authorizations are established by the Council of Ministers of the Republic of Belarus.

Registration (confirmation of registration) of medicines within the framework of the Eurasian Economic Union and other procedures related to the registration of medicines are carried out by the Ministry of Health in accordance with the Agreement on Common Principles and Rules for the Medicines Circulation within the Framework of the Eurasian Economic Union dated December 23, 2014 and international legal acts constituting the law of the Eurasian Economic Union.

Article 11. Licensing of Pharmaceutical Activity

Licensing of pharmaceutical activities is carried out in accordance with the licensing legislation.

Article 12. System of Quality Control of Medicines

The quality control system of medicines is a set of measures carried out during their industrial production, pharmacy manufacture, sale, storage, transportation, medical use and allowing to guarantee the quality of medicines in circulation in the Republic of Belarus.

The manufacturer of the medicine for each released series (batch) of the medicine issues a document signed by an authorized person confirming that the quality of the series (batch) of the medicine meets the requirements of the regulatory document on quality, including confirmation that the series (batch) of the medicine was produced in accordance with the requirements of Good Manufacturing Practice and marketing authorization application.

For immunological medicines, the manufacturer additionally issues a master series (batch) record of an immunological medicine in accordance with the recommendations of the World Health Organization.

Medicines before being marketed, as well as medicines in circulation, are subject to quality control by testing laboratories accredited in the National Accreditation System of the Republic of Belarus for Medicines Trial. The list of testing laboratories, the procedure and conditions for quality control of medicines are established by the Ministry of Health, unless otherwise provided by legislative acts.

Quality control of a medicine includes testing for compliance with the quality indicators of a regulatory document on quality, as well as for compliance with the marketing authorization application on packaging, packaging labeling, instructions for medical use (package insert), a document confirming its quality. A medicine that does not meet the requirements of a regulatory document on quality is recognized as substandard.

Upon recognition of a medicine as substandard, an inspection (pharmaceutical inspection) of its industrial production is carried out for compliance with the requirements of Good Manufacturing Practice in cases and in accordance with the procedure established by the Ministry of Health.

The quality of medicines manufactured in pharmacies is determined by their compliance with the requirements of the pharmacopoeial monographs of the State Pharmacopoeia of the Republic of Belarus. Medicines manufactured in pharmacies are subject to quality control in accordance with the procedure and conditions established by the Ministry of Health, unless otherwise provided by legislative acts.

If a substandard medicine manufactured in a pharmacy is detected, an inspection (pharmaceutical inspection) of its pharmacy manufacture is carried out for compliance with the requirements of Good Pharmacy Practice and pharmacopoeial monographs of the State Pharmacopoeia of the Republic of Belarus in accordance with the procedure and conditions established by the Ministry of Health.

Article 13. Pharmacovigilance System

The pharmacovigilance system is a system organized by holders of marketing authorisation and the Ministry of Health to perform tasks and responsibilities for pharmacovigilance, designed to monitor the safety of medicines, timely identify all changes in the assessment of the benefit–risk balance of medicines, develop and implement measures to ensure the use of medicines when the benefit exceeds the risk.

Holders of marketing authorisations are obliged to ensure the organization and functioning of the pharmacovigilance system in accordance with the requirements of the Rules of Good Practice of Pharmacovigilance of the Eurasian Economic Union.

The procedure for inspection (pharmaceutical inspection) for compliance of the organization and functioning of the pharmacovigilance system of holders of marketing authorisations with the requirements of the Rules of Good Practice of Pharmacovigilance of the Eurasian Economic Union is established by the Ministry of Health.

Healthcare providers and pharmacists are required to provide information on identified adverse reactions to medicines in accordance with the procedure established by the Ministry of Health.

Article 14. State Pharmaceutical Supervision of Compliance with Requirements of Legislation on Medicines Circulation

The state pharmaceutical supervision of compliance with the requirements of legislation on the medicines circulation is carried out by the state institution "State Pharmaceutical Supervision in the field of medicines circulation "Gosfarmnadzor" in accordance with the legislation on control (supervisory) activities.

The main tasks of the state pharmaceutical supervision of compliance with the requirements of legislation on the medicines circulation are to prevent the entry into circulation and timely withdrawal from circulation of substandard, falsified medicines and medicines with expired shelf life, prevention, detection and suppression of violations of the requirements of legislation on the medicines circulation.

CHARTER 3

DEVELOPMENT, PRECLINICAL (NON-CLINICAL) STUDIES OF MEDICINES, CLINICAL TRIALS (TESTS) AND THE MEDICAL USE OF MEDICINES

Article 15. Medicines Development

The development of medicines includes the search for new pharmacologically active substances or new combinations of pharmacologically active substances, the subsequent study of their properties, pharmaceutical development and development of quality control methods, preclinical (non-clinical) studies of medicines and clinical trials (tests) of medicines.

Article 16. Preclinical (non-clinical) Studies of Medicines

Preclinical (non-clinical) studies of medicines are not conducted on individuals.

Preclinical (non-clinical) studies of medicines, including those using laboratory animals, are carried out in compliance with the requirements of the Rules of Good Laboratory Practice of the Eurasian Economic Union and to the extent determined by international legal acts constituting the law of the Eurasian Economic Union.

Article 17. clinical trials (tests) of medicines

The decision on the appointment of clinical trials (tests) of medicines is made by the Ministry of Health in the presence of:

positive results of preclinical (non-clinical) studies of the effectiveness and safety of medicines;

positive results of assessing the ratio of the expected benefit for the subject of the study and society and the foreseeable (predictable) risk and (or) inconvenience within the framework of the trial (test);

convincing data on the observance of the rights, safety and well-being of the trial subjects .

Clinical trials (tests) of medicines are conducted on trial subjects in state healthcare organizations in accordance with the procedure and conditions established by the Ministry of Health, in accordance with the requirements of the Rules of Good Clinical Practice of the Eurasian Economic Union and the program (protocol) of clinical trials (tests) of medicines approved by an Independent Ethics Committee and approved by the Ministry of Health.

The compliance of clinical trials (tests) of medicines conducted on trial subjects in state healthcare organizations with the requirements of the Rules of Good Clinical Practice of the Eurasian Economic Union is confirmed by a document issued by the Ministry of Health based on the results of an inspection (pharmaceutical inspection) carried out in accordance with the procedure and conditions established by the Ministry of Health.

An Independent Ethics Committee is established under state healthcare organizations as an expert council and considers issues of ensuring the rights, safety and health of trial subjects, approves the program (protocol) of clinical trials of medicines, evaluates the qualifications of researchers and the availability of conditions in state healthcare organizations for conducting clinical trials of medicines.

The regulation on the Independent Ethics Committee is approved by the Ministry of Health.

Article 18. Rights of Trial Subjects

The participation of trial subjects in clinical trials of medicines is voluntary.

A clinical trial of a medicine is carried out with the written consent of the trial subject to participate in a clinical trial of this medicine. In the case of participation in a clinical trial (test) of a medicine of a minor trial subject, such a clinical trial (test) is conducted with the written consent of one of the parents, and in the case of participation in a clinical trial (test) of a person who is unable to make an conscious decision due to health reasons, with the written consent of a spouse or one of the close relatives (parents, adult children, siblings and grandchildren, grandfather (grandmother)).

Participation in clinical trials (tests) of medicines is prohibited for:

pregnant women, except in cases when the investigational medicine is intended exclusively for the treatment of this category of persons or when the purpose of clinical trials (tests) of this medicine is to optimize its dosage or mode of use in pregnant women, as well as when the necessary information can be obtained only in clinical trials (tests) of medicines on pregnant women provided that the risk of harm to the life and health of a pregnant woman and fetus is excluded;

minors, except in cases where the investigational drug is intended exclusively for the treatment of childhood diseases or when the purpose of clinical trials (tests) of this medicine is to optimize its dosage or mode of use in minors, subject to previous clinical trials (tests) of the drug on adult subjects of the study;

orphans and children left without parental care;

persons who are unable to make a conscious decision for health reasons, except in cases when the investigational medicine is intended for medical use according to indications corresponding to the diagnosis of the trial subject;

military personnel and persons who are subject to the status of military personnel, except in cases when the investigational medicine is intended exclusively for use in military medicine or when the purpose of clinical trials (tests) of this medicine is to optimize its dosage or mode of use in this category of persons;

persons in respect of whom a forensic examination is being conducted;

convicted persons and persons in custody;

persons recognized as legally incompetent, as well as persons suffering from mental disorders (diseases), forcibly hospitalized and undergoing compulsory treatment in a psychiatric hospital.

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The trial subjects and the persons specified in part two of this article have the right to refuse to participate in clinical trials (tests) of medicines at any stage of their implementation.

Clinical trials of medicines should be discontinued in the event of a threat to the life and health of the trial subject, violation of the requirements of the Rules of Good Clinical Practice of the Eurasian Economic Union or the norms of medical ethics and deontology, as well as in the case of insufficient efficacy and safety of the studied medicines.

Article 19. Medical Use of Medicines

The medical use of medicines registered in the Republic of Belarus is carried out according to the indications provided for in the instructions for medical use (package inserts) and summary of product characteristics, as well as in accordance with clinical protocols or methods of medical care approved by the Ministry of Health.

The medical use of the following medicines is prohibited:

not included in the State Register of Medicines of the Republic of Belarus, except for the cases provided for in paragraphs two, five and six of part two of the Article 10 of this Law;

substandard and falsified;

expired;

in cases of a decision to suspend their sale or withdrawal from circulation, provided for in parts 2-4 of the Article 26 of this Law.

The medical use of medicines intended for clinical trials (tests) is carried out according to the indications provided for in the program (protocol) of clinical trials (tests).

Medicines imported into the Republic of Belarus in the cases provided for in paragraphs five to eight of the first part of the Article 27 of this Law are allowed for medical use according to the indications specified in the relevant accompanying documents.

The medical use of original medicines that are in the process of clinical trials (tests) and are intended for the treatment, medical prevention or diagnosis of life-threatening or severe disabling diseases in order to ensure early access of patients to new treatment methods is allowed subject to:

the absence of effective methods of medical care;

absence of registered medicines;

exceeding the benefits of using these medicines over the risk to the health and life of patients.

The procedure and conditions for the medical use of original medicines to ensure early access of patients to new treatment methods are established by the Ministry of Health.

CHARTER 4

INDUSTRIAL PRODUCTION AND PHARMACY MANUFACTURE OF MEDICINES

Article 20. Industrial Production of Medicines

The industrial production of medicines is carried out on the basis of a license to carry out pharmaceutical activities in accordance with the requirements of Good Manufacturing Practice.

The compliance of the industrial production of medicines with the requirements of Good Manufacturing Practice is confirmed by a document (certificate) issued by the Ministry of Health based on the results of an inspection (pharmaceutical inspection).

The compliance of the production of medicines with the requirements of the Rules of Good Manufacturing Practice of the Eurasian Economic Union for medicines manufactured for supply to the market of the Eurasian Economic Union is confirmed by a document (certificate) issued by the authorized body of the member State of the Eurasian Economic Union.

The manufacturer of medicines, no later than 12 months after the decision to issue a license for pharmaceutical activities, must receive a document (certificate) confirming the compliance of industrial production of medicines with the requirements of Good Manufacturing Practice. Subsequently, at least once every three years, the manufacturer must ensure that it is possible to carry out an inspection (pharmaceutical inspection) of the industrial production of medicines to confirm compliance with the requirements of Good Manufacturing Practice in accordance with the procedure established by law.

The manufacturer of medicines appoints an authorized person (authorized persons) with higher education and work experience in the relevant type of work and services related to the industrial production of medicines.

The authorized person of the manufacturer of medicines is an official of the manufacturer, who is responsible for the quality of medicines produced and marketed, ensuring that each series (batch) of a medicine is produced and tested in accordance with the requirements of Good Manufacturing Practice, other legislative acts, as well as the marketing authorization application.

The authorized person passes certification to confirm his compliance with the requirements imposed on authorized persons of manufacturers of medicines. The requirements and procedure for certification of authorized persons of manufacturers of medicines are established by the Ministry of Health, taking into account the requirements of international legal acts that constitute the law of the Eurasian Economic Union.

Authorized persons of manufacturers of medicines who have passed certification are included in the register of authorized persons of manufacturers of medicines of the Republic of Belarus.

The formation and maintenance of the register are carried out by the Ministry of Health in accordance with the procedure established by this Ministry.

In the implementation of the industrial production of medicines, the manufacturer:

implements and maintains the functioning of a pharmaceutical quality system that allows to ensure that the manufactured medicines comply with their intended purpose for medical use, documents constituting the marketing authorization application, and (or) programs (protocols) of clinical trials;

guarantees the use of pharmaceutical substances produced only in accordance with the requirements of Good Manufacturing Practices of the country of manufacture of the pharmaceutical substance in the process of industrial production of medicines;

ensures compliance with the requirements of the Rules of Good Distribution practice of the Eurasian Economic Union in the wholesale sale of medicines;

informs immediately the Ministry of Health about cases of detection of counterfeit medicines corresponding to the names of medicines produced by it;

in case of non-compliance with the quality of manufactured medicines, conducts an investigation to identify and eliminate the causes and informs the Ministry of Health of the results of the investigation in accordance with the procedure and deadlines established by the Ministry of Health, and also ensures the implementation of inspection (pharmaceutical inspection);

ensures the up-to-date maintenance of information on the industrial production of medicines contained in the documents submitted for licensing pharmaceutical activities in terms of works and services for the industrial production of medicines and their wholesale sale.

Industrial production of medicines is prohibited:

for medicines not included in the State Register of Medicines of the Republic of Belarus, with the exception of medicines intended for preclinical (non-clinical) study, state registration or registration within the framework of the Eurasian Economic Union, medicines intended for industrial production only for export, as well as intended for clinical trials);

in the absence (expiration) of a document (certificate) confirming the compliance of industrial production of medicines with the requirements of Good Manufacturing Practice, a document (certificate) confirming the compliance of industrial production of medicines with the requirements of the Rules of Good Manufacturing Practice of the Eurasian Economic Union, including medicines intended for industrial production only for export, as well as intended for clinical trials (tests).

Article 21. Inspection (Pharmaceutical Inspection) of industrial production of medicines

The inspection (pharmaceutical inspection) of the industrial production of medicines for compliance with the requirements of Good Manufacturing Practice is carried out by the Pharmaceutical inspectorate of the Ministry of Health and (or) an organization authorized by it in accordance with the procedure and conditions established by this Ministry.

The inspection (pharmaceutical inspection) of the industrial production of medicines for compliance with the requirements of Good Manufacturing Practice is carried out by pharmaceutical inspectors:

when licensing pharmaceutical activities in terms of works and services for the industrial production of medicines and their wholesale sale, including those intended only for export, of medicines for clinical trials (tests), when amending the license;

in the implementation of state registration (confirmation of state registration) of medicines or registration (confirmation of registration) of medicines within the framework of the Eurasian Economic Union;

to confirm the compliance of the industrial production of medicines with the requirements of Good Manufacturing Practice in accordance with the inspection plan approved annually by the Ministry of Health;

in case of detection of a substandard and (or) falsified medicine or upon receipt of information about a medicine indicating a threat to the life and health of the population.

If, during the inspection (pharmaceutical inspection) of the industrial production of medicines, facts that pose a threat of harm to the life or health of the population are identified, the pharmaceutical inspector, within his competence, takes measures aimed at prohibiting the sale of a medicine that constitutes a threat of harm to the life or health of the population, as well as prohibiting the implementation of activities related to the production and quality control of the medicine.

The formation and maintenance of the register of pharmaceutical inspectors of the Republic of Belarus is carried out by the Ministry of Health in accordance with the procedure established by this Ministry. The information contained in the register of pharmaceutical inspectors of the Republic of Belarus is posted by the Ministry of Health on its official website in the World Wide Web.

Article 22. Pharmacy Manufacture of Medicines

Pharmacy manufacture of medicines is carried out in pharmacies using pharmaceutical substances included in the State Register of Medicines of the Republic of Belarus, as well as excipients and medicinal plant raw materials.

Medicines are manufactured in pharmacies according to doctors' prescriptions or the requirements (requests) of healthcare organizations or their structural divisions.

Pharmacy manufacture of medicines is carried out in accordance with the requirements of Good Pharmacy Practice, as well as pharmacopoeia monographs of the State Pharmacopoeia of the Republic of Belarus on the basis of a license to carry out pharmaceutical activities.

CHARTER 5
SALE, DISPENSING, STORAGE, TRANSPORTATION, SUSPENSION OF SALE AND MEDICAL USE, WITHDRAWAL FROM CIRCULATION, RETURN TO THE MANUFACTURER OR TO THE SUPPLIER, DESTRUCTION, IMPORT, EXPORT OF MEDICINES

Статья 23. Sale of Medicines

The sale of medicines is carried out by legal entities and individual entrepreneurs on the basis of a license to carry out pharmaceutical activities.

It is prohibited to sell medicines that

are subject to state registration and are not included in the State Register of Medicines of the Republic of Belarus, with the exception of medicines imported into the territory of the Republic of Belarus in the cases provided for in paragraphs five to eight of the first part of the Article 27 of this Law;

specified in paragraphs three to six of the second part of the Article 10 of this Law;

in the absence of documents confirming their quality;

substandard and falsified;

expired;

in cases when a decision is made to suspend their sale or withdraw them from circulation, provided for in parts two to four of the Article 26 of this Law;

in other cases provided for by legislative acts.

Article 24. Wholesale Sale of Medicines

Legal entities and individual entrepreneurs, when carrying out the wholesale sale of medicines, are obliged to comply with the requirements of Good Practice of Storing Medicines, the Rules of Good Distribution Practice of the Eurasian Economic Union.

The compliance of the wholesale sale of medicines carried out by legal entities and individual entrepreneurs with the requirements of the Rules of Good Distribution Practice of the Eurasian Economic Union is confirmed by a document issued by the Ministry of Health based on the results of an inspection (pharmaceutical inspection) carried out in accordance with the procedure established by the Council of Ministers of the Republic of Belarus.

The wholesale sale of medicines is carried out to:

legal entities and individual entrepreneurs licensed to carry out pharmaceutical, medical, and veterinary activities;

state healthcare organizations, educational and social service institutions and the Belarusian Red Cross Society;

scientific research organizations for conducting scientific research;

military units (institutions) of the Armed Forces of the Republic of Belarus and other military formations, internal affairs authorities, emergency authorities and units;

the State Committee of Forensic Examinations;

medical equipment and property storage bases.

It is allowed a wholesale sale of medicines sold without a doctor's prescription to legal entities that do not have a license to carry out pharmaceutical or medical activities for their own use in accordance with the instructions for medical use (package inserts) without the right to resale.

Article 25. Retail Sale, Dispense of Medicines

Retail sale of medicines is an activity related to the purchase, storage and sale of medicines to the population, healthcare organizations and other organizations for medical use.

The retail sale of medicines is carried out in pharmacies, except for the cases provided for in parts three to five of this article.

In order to provide medicines to the population of rural settlements in which there are no pharmacies, the retail sale of medicines may be carried out by a healthcare provider of a state health organization or its structural subdivision located in rural settlements, as well as by such a healthcare provider during mobile team medical examinations of the population in accordance with the procedure established by the Ministry of Health.

The retail sale of medicines by remote method is carried out in accordance with the procedure established by the Ministry of Health.

Retail sale of medicines at the venues of international thematic exhibitions, international sports, as well as cultural events is allowed in cases and in accordance with the procedure established by the Ministry of Health.

The retail sale of medicines is carried out by prescription and without a doctor's prescription. The list of medicines sold without a prescription is established by the Ministry of Health in accordance with the Rules for Determining Categories of Medicines sold without a prescription and by prescription, approved by the decision of the Eurasian Economic Commission.

Information on medicines to be sold by prescription and without a doctor's prescription, after their state registration and entry into the State Register of Medicines of the Republic of Belarus, is posted on the official website of the Ministry of Health in the World Wide Web.

The procedure for making out a prescription for medicines, including in the form of an electronic document, and prescription forms for medicines, with the exception of the procedure for making out prescriptions for medicines and prescription forms for medicines for preferential, including free, provision of medicines, are established by the Ministry of Health. The procedure for making out prescriptions for medicines and the prescription forms for medicines for preferential, including free, provision of medicines are established by the Council of Ministers of the Republic of Belarus.

In the retail sale of medicines, legal entities and individual entrepreneurs are obliged to:

carry out their activities in compliance with the requirements of Good Pharmacy Practice;

have available medicines included in the list of essential medicines.

The release of medicines is carried out by pharmacies of healthcare organizations providing medical care in hospitals (hereinafter referred to as hospital organizations).

The release of medicines is carried out according to the requirements (requests) of hospital organizations and (or) their structural divisions for the direct provision of medical care to patients in these hospital organizations and (or) their structural divisions.

Article 26. Storage, Transportation, Suspension of Sale and Medical Use, Withdrawal from Circulation, Return to the Manufacturer or to the Supplier, Destruction of Medicines

Medicines should be stored in accordance with the requirements of Good Storage Practice of medicines and transported in accordance with the requirements of the Rules of Good Distribution Practice of the Eurasian Economic Union in conditions that ensure their safety and quality.

In case of detection during quality control of a medicine of non-compliances with the marketing authorization application on packaging, package labeling, instructions for medical use (package insert), a document confirming its quality, the sale and medical use of this medicine are suspended. The decision on the possibility of further sale and medical use of the medicine is made by the Ministry of Health, provided that there is no risk to the health of patients when using it after receiving and reviewing the manufacturer's written explanation of the reasons and conclusions based on the results of the investigation of the identified non-compliances.

The sale and medical use of medicines with a suspected adverse change in the benefit–risk balance are suspended.

Medicines for which an unfavorable benefit–risk balance has been established during medical use are subject to withdrawal from circulation.

Substandard medicines, medicines with expired shelf life are subject to withdrawal from circulation, return to the manufacturer or supplier, or destruction. Counterfeit medicines are subject to withdrawal from circulation and destruction.

The procedure and conditions for storage, transportation, suspension of sale and medical use, withdrawal from circulation, return to the manufacturer or supplier, destruction of medicines are established by the Council of Ministers of the Republic of Belarus, unless otherwise provided by legislative acts.

Article 27. Import and Export of Medicines

. It is allowed to import into the territory of the Republic of Belarus medicines included in the State Register of Medicines of the Republic of Belarus, as well as medicines

intended for preclinical (non-clinical) study, state registration (confirmation of state registration), use as exhibition samples without the right to further sale;

intended for conducting clinical trials (tests);

imported by an individual for personal use;

designed to prevent and eliminate the consequences of natural and man-made emergencies, including epidemic diseases;

imported as foreign gratuitous aid;

designed to provide medical care for the life of a particular patient or to provide medical care to a limited contingent of patients with proven inefficiency or intolerance to registered medicines, or with orphan (rare) diseases and (or) life-threatening diseases, or with severe disabling diseases;

designed to ensure early access of patients to new treatments;

imported in other cases provided for by international legal acts that constitute the regulatory legal framework of the Customs Union and the Single Economic Space and (or) the law of the Eurasian Economic Union.

It is prohibited to import substandard, falsified medicines, as well as medicines with expired shelf life into the territory of the Republic of Belarus.

The import to the customs area of the Eurasian Economic Union in the Republic of Belarus and the export from the customs area of the Eurasian Economic Union in the Republic of Belarus of medicines are carried out in compliance with the requirements established by international legal acts constituting the regulatory and legal framework of the Customs Union and the Common Economic Space and (or) the law of the Eurasian Economic Union, this Law and other legislative acts.

CHARTER 6
INFORMATION ON MEDICINES. ADVERTISING OF MEDICINES

Article 28. Information on Medicines

Information on medicines sold without a prescription is provided by means of information transfer, including indicated in the instructions for medical use (package inserts), summary of product characteristics.

Placement of information on medicines sold by prescription is allowed only in specialized publications, venues of medical and pharmaceutical exhibitions, seminars, conferences and other similar events, on internet resources and within the framework of online events intended for healthcare providers and pharmacists, in instructions for medical use (package inserts), summary of product characteristics.

Healthcare providers and pharmacists are informed on medicines included in the State Register of Medicines of the Republic of Belarus by representatives of manufacturers of medicines in accordance with the procedure and conditions established by the Ministry of Health.

Article 29. Advertising of Medicines

Advertising of medicines is carried out in accordance with the legislation on advertising.

CHARTER 7
RESPONSIBILITY FOR VIOLATION OF LEGISLATION ON MEDICINES CIRCULATION

Article 30. Responsibility for Violation of the Procedure of Medicines Circulation

Persons having violated the procedure of medicines circulation established by the legislation, shall bear responsibility in accordance with the legislative acts.

Article 31. Compensation for the Harm, Caused to the Health and Life of an Individual as a Result of Medical Use of Medicines

The harm caused to life and health of an individual as a result of medical use of medicines, including during clinical trials (tests), is subject to compensation in accordance with the procedure established by the legislation.

President of the Republic of Belarus **A. Lukashenko**