(2023.08.14-ний өдрийн орчуулга) *Unofficial translation*

LAW OF MONGOLIA

May 27, 2010 **Ulaanbaatar city**

ON MEDICINES AND MEDICAL DEVICES

/Revised edition/

CHAPTER ONE GENERAL PROVISIONS

Article 1.Purpose of the Law

1.1.The purpose of this Law shall be to regulate relations in connection with operations of manufacturing, importing, exporting, storing, selling, distributing, using and controlling the medicines with human and veterinary purposes, specifically the traditional medicines, the biopreparation, and the diagnostic device /hereinafter referred to as "medicines"/, the medical devices, as well as the biologically active products.

Article 2.Legislation on medicines and medical devices

2.1.The legislation on Medicines and medical devices shall consist of the Constitution of Mongolia, the Law on Health, the Law on Livestock genetic resources, the Law on Livestock and animal health, this Law, and other legislative acts issued in conformity with them.

/This paragraph was amended by the law as of November 15, 2018/

2.2.If an international treaty, to which Mongolia is a party, provides otherwise than this Law, the provisions of the international treaty shall prevail.

Article 3.Definitions of the terms of the Law

3.1.The terms used in this Law shall have the following meanings:

3.1.1."medicines" shall mean substances which are originated from synthesis oranimals, plants or minerals, shaped in certain form and used in a specific dosage and amount for prevention of human, livestock or animals from diseases, for diagnosis and treatment of diseases, and immunization, the effect of which is proven by pharmaceutical and clinical experiment;

3.1.2."biological preparations" shall mean a product made of living organisms and their organs or cells and/or produced by laboratory methods for the purpose of treating and diagnosing diseases of human, livestock and animals, and preventing them from diseases;

3.1.3."traditional medicine" shall mean a naturally originated product prepared by traditional and industrial methods upon inserting plant, animal and minerals originated agents and valuable treasure in accordance with traditional medicine prescription, and used in a specific dosage and amount

with purposes of preventing humans, livestock or animals from diseases, and diagnosing and treating of such diseases;

3.1.4."diagnostic devices" shall mean a product with specific dosage, amount, composition, peculiarities, and effects that is used for testing to be conducted on humans, livestock and animals, and samples of environment, in order to prevent humans, livestock and animals from diseases, to diagnose the diseases, and control over the progress of such diseases;

3.1.5."medical device" shall mean an assistant tool that is used for preventing humans, livestock and animals from diseases, diagnosing and treating the diseases, nursing and supporting structure and function of organisms;

3.1.6."narcotic drug" shall mean drugs and preparations included in the list of the United Nations Convention on "Narcotic drugs" of 1961, which have addictive effects;

3.1.7."psychotropic drug" shall mean a substance included in the list of the United Nations Convention on "Psychotropic substances" of 1971, which have strong psychotropic effects;

3.1.8."orphan medicine" shall mean a medicine which are relatively seldom used nationally or used in treating a rare disease;

3.1.9."medicinal raw materials" shall mean pure root elements and item originated from synthetic, plant, animal, and minerals that contain active therapeutic substances;

3.1.10."medicinal supplementary substance" shall mean additional components necessary for manufacturing and compounding medicines;

3.1.11."batch" shall mean a lot number of medicinal products manufactured through one-off production technology;

3.1.12."medicine evaluation" shall mean an indication to the quality, safety and effects of a medicine, carefully determined through pharmaceutical and pharmacological analysis and clinical experiment;

3.1.13."medicine registry" shall mean operations of permitting to issue the medicines for consumption within the territory of Mongolia, which have been certified to be eligible for the usage in prevention, diagnosis and treatment, based on the chemical, biological, pharmacological analysis, as well as the medicine evaluation;

3.1.14."list of essential medicines and medical devices" shall mean names of medicines and medical devices approved by the state central administrative body in charge of health and agricultural matters to be used in first priority for medical care to be provided to humans, livestock and animals;

3.1.15."dispensing of medicine" shall mean as specified in sub-paragraph 3.1.17 of the Law on Health;

3.1.16."medicine prescription" shall mean a document specified the methods of preparing, dispensing, and using the medicines dedicate for the particular patients which prescribed by doctors addressing to pharmacists and medicine dispenser;

3.1.17."proper use of medicine" shall mean correct use of medicines, in accordance with instructions and recommendations of doctors and pharmacists, if necessary;

3.1.18."side-effects of the medicine" shall mean an adverse or negative impact that may or actually occur on organisms upon taking medicines in an appropriate dosage, with purposes of preventing humans, livestock and animals from diseases, and diagnosing and treating the diseases;

3.1.19."pharmacopoeia monograph" shall mean mandatory standards to be strictly adhered to which specifies the requirements to be set on medicines, quality indicators, and methods of assurance of them;

3.1.20."pharmacopoeia" shall mean a book containing pharmacopoeiamonographs;

3.1.21."counterfeit medicine" shall mean medicinal products manufactured in imitation, using a fake label named after the medicine manufacturer for the purpose of earning illegal gains;

3.1.22."medicine and medical device manufactory" shall mean a legal entity with special permit to manufacture final products by using medicinal raw materials and supplementary substances in accordance with pharmaceutical technology;

3.1.23."medicines and medical devices supplying organization" shall mean a legal entity with special permit to conduct activities of supplying pharmacies, health institutions, and veterinary hospitals with medicines and medical devices at wholesale prices;

3.1.24."pharmacy" shall mean a legal entity with special permit to conduct activities of supplying health institutions, veterinary hospitals, and population with medicines and medical devices at retail prices;

3.1.25."biologically active product" shall mean products with services for supporting human organism functions, supplementing with necessary minerals, and preventing from any diseases and disorders.

/This sub-paragraph was modified by the law as of December 20, 2012/

CHAPTER TWO

STATE POLICY AND REGULATIONS ON MEDICINES, MEDICINES SUPPLY SYSTEM AND MEDICINES DISPENSING OPERATIONS

Article 4.National policy on medicines

4.1.National policy on medicines shall be an inseparable part of the integrated policy on ensuring the Mongolian national security.

4.2.National policy on medicines shall be aimed to provide the health institutions, veterinary hospitals, and population with medicines with highly activeness, quality assurance, and are registered in medicine registry on uninterrupted, accessible, and evenly basis, as well as to maintain the proper use of medicines.

4.3.The State shall hold a policy to support national manufacturing of medicines and medical devices to substitute import products.

4.4.National policy on medicines shall be reflected in policies of the Government, state central administrative and local administrative bodies, and be implemented through the activities of the state administrative body in charge of control and regulation matters of medicine and medical devices.

/This paragraph was modified by the law as of August 28, 2020/

4.5.Lists of essential medicine and medical devices, and orphan drugs shall be approved by relevant state central administrative bodies.

4.6.The Government shall determine maximum level of prices of medicines included in the lists specified in paragraph 4.5 of this Law.

Article 5.Council of medicines

5.1.A council in charge of humans pharmaceutical matters shall be operated next to the state central administrative body in charge of health matters, and a council in charge of livestock pharmaceutical matters shall be operated next to the state administrative body in charge of livestock and animal health matters.

/This paragraph was modified by the law as of November 15, 2018/

5.2.Council of medicines shall be a non-staff, professional consulting organization to support implementation of the national policy on medicines, and its composition, charter, and procedures on making declaration on conflict of interest by its members shall be approved by the Cabinet members in charge of health and agricultural matters.

5.3.Council of medicines may have a professional branch council.

5.4.In the event of making amendment to the national policy on medicines and/or regulating supplies of medicines and medical devices during the state of emergency or disaster, the human and livestock medicine councils shall have a joint meeting to decide the issue.

5.5.The Council of medicines shall exercise the following powers:

5.5.1.to develop proposals and recommendations in regards with the national policy on medicines, and submit them to state central administrative body;

5.5.2.to develop proposals and recommendations on selection of medicines andmedical devices to be used in diagnosis and treatment;

5.5.3.to decide issues of registering and amending medicines and biologically active products within the scope of the national policy of medicines;

5.5.4.to issue conclusions and recommendations on matters in regards with manufacturing and importing medicines, medical devices, and biologically active products;

5.5.5.to provide professional recommendations toward making amendment to the list of the narcotic and psychotropic drugs, and controlling over use of such drugs;

5.5.6.to discuss on findings of pre-clinical survey and clinical experiment conducted on medicines newly developed in Mongolia, and make conclusions on the matter to issue them for usage;

5.5.7.to decide whether to conduct a clinical survey on the newly imported medicines, which are registered in Mongolia for the first time.

Article 6.State regulations on manufactory, import, export, sale, distribution, and control over of medicines, medical devices, and biologically active products

6.1.The state shall provide comprehensive and integrated regulations on activities related to manufactory, import, export, sale, distribution, and control over of medicines, medical devices, and biologically active products.

6.2.The state regulations specified in paragraph 6.1 of this Law shall be implemented through the following activities:

6.2.1.surveillance studies on registration, quality and safety in the market of medicines, and biologically active products;

6.2.2.special permit to manufacture, import, and sell;

6.2.3.registration, controlling, and regulations of imports and exports;

/This sub-paragraph was amended by the law as of January 6, 2023/

6.2.4.quality assurance;

6.2.5.certification of satisfying the requirement of pharmaceutical manufacturing standards (GMP-good manufacturing practices);

6.2.6.specialized inspection on pharmaceutical activities;

6.2.7.control over side-effects of medicines;

6.2.8.permission and control over of advertising of medicines and biologically active products;

6.2.9.price regulations and control over of essential medicines;

6.2.10.independent and accurate information in regards with medical specialist and medicines dedicated for public.

6.3.The regulations specified in paragraph 6.2 of this Law shall be executed by the state administrative body in charge of health matters.

/This paragraph was amended by the law as of August 17, 2012/

/This paragraph was amended by the law as of August 28, 2020/

6.4.The state administrative body in charge of control and regulation matters of medicine and medical devices shall have a state inspector with duties to control over the implementation of relevant legislation, and the procedure on conducting inspection shall be approved by the state central administrative body in charge of health matters.

/This paragraph was added by the law as of January 6, 2023/

Article 7.Special permit

/This article was modified by the law as of January 6, 2023/

7.1.The state administrative body in charge of pharmaceutical matters shall issue the special permits for manufacturing, importing, exporting, selling, and supplying human medicines, medical devices, narcotic and psychotropic drugs and their precursors.

7.2.The state administrative body in charge of agricultural matters shall issue the special permits for manufacturing, importing medicines and medical devices for livestock and animal.

7.3.The state administrative body in charge of pharmaceutical matters shall control over whether or not the supply of medicine and medical devices, and diagnostics in accordance with the special permit.

7.4.The state administrative body in charge of pharmaceutical matters shall issue a permit for sale of household fleabane, rodenticides, decontaminates, and disinfectants, and the health department of the aimag and the Capital city shall issue a permit to engage in service thereto.

7.5.Applicants for a special permit to manufacture and import medicine and medical devices for livestock and animal shall complete the following documents:

- **7.5.1.application for requesting a special permit /clearly mention the type of activity to be engaged in/;**
- **7.5.2.a copy of the state registration certificate of the legal entity;**
- **7.5.3.evidence of no tax debt;**
- **7.5.4.evidence of connection to the electronic payment receipt system specified in Article 28 of the General Law on Taxation.**

7.6.Applicants for a special permit for the manufacturing livestock and animal medicines and medical devices shall submit evidence that satisfying the main requirements specified in paragraph 12.1 of this Law, in addition to those specified in paragraph 7.5 of this Law.

7.7.Applicants for a special permit to import livestock and animal medicine and medical devices shall submit the sale agreement concluded with a foreign medicine and medical equipment supplier organization that meets the international quality standards of the manufacturer or supplier, the power of attorney, or evidence proving the official representation, in addition to those specified in paragraph 7.5 of this Law.

7.8.Other relations in connection with permits specified in this Law shall be regulated by the Law on Permits.

Article 8.Engaging in dispensing activities of medicine

8.1.Medical specialist who hold a permit specified in paragraph 22.3 of the Law on Health shall engage in activities of dispensing medicines.

8.2.Veterinarians who have graduated from a school with special permit to provide with veterinary education and received accreditation to work in the profession shall engage in the activities of dispensing veterinary medicine.

Article 9.Medicines supplier organizations

9.1.The following bodies shall be included in the medicines supplier organizations:

- **9.1.1. medicine and medical device manufactory;**
- **9.1.2. medicine and medical device supplying organizations;**
- **9.1.3. pharmacies.**

9.2.Relations in connection with the medicines supplier organizations specified in paragraph 9.1 of this Law shall be regulated by the Law on Health, except obtaining a special permit to manufacture, import, and sell medicines and medical devices by the medicines supplier organizations.

9.3.The state central administrative body in charge of health matters may have a stockpile warehouse with purpose of storing medicines and medical devices to be used in clinical emergency and public health care and services.

Article 10.Principles and general obligations of the medicines supplier organizations

10.1.The medicines supplier organizations shall adhere to in their activities the principle to evenly supply the health institutions, veterinary hospitals, and population with medicines and medical devices registered in medicine registry and with the quality assurance.

10.2.The medicines supplier organizations shall undertake the obligation specified in Article 15 of the Law on Health.

10.3.The medicines supplier organizations shall carry out operations of manufacturing, storing and selling the medicines and medical devices in conditions that satisfy pharmaceutical technology requirements.

10.4.Structure and activities of the medicines supplier organizations shall satisfy thenational standard requirements.

Article 11.Activities prohibited in the operations of medicines supplier organizations

11.1.Followings shall be prohibited in the operations of medicines supplier organizations:

11.1.1.to manufacture, import and sell medicines and medical devices without the special permit specified in Article 7 of this Law;

11.1.2.to provide with medicines and medical devices, which are not registered in medicine registry of Mongolia, of which the quality is not assured and validity period is expired;

11.1.3.to receive medicines and medical devices from sources other than medicine supplying organizations;

11.1.4.to involve a person who does not licensed to compounding medicine in the operations of compounding, preparing, verifying, and issuing medicines;

11.1.5.to sell medicines and medical devices to citizens by medicines and medical devices supplying organizations;

11.1.6.to be involved a doctor in operations of selling medicine and medical devices, providing with premiums base on the performance result, and participating in activities similar thereto, in order to increase their profit and income;

11.1.7.to manufacture, import, and sell the counterfeit medicine.

11.2.Followings shall be prohibited in the operations of the hospitals:

11.2.1.to be engaged in medicine dispensing activities by professional who has no right to dispense the medicines;

11.2.2.to violate medicine storage and safety procedures.

11.3.It shall be prohibited to store and sell medicines and medical devices in non-designated places.

CHAPTER THREE

MANUFACTURING MEDICINES AND MEDICAL DEVICES

Article 12.Requirements on manufacturing medicines and medical devices

12.1.Following main requirements shall be met, in order to engage in manufacturing of medicines and medical devices:

12.1.1.to have manufacturing technologies of medicines and medical devices, which satisfy the national and international standard requirements;

12.1.2.to have premises and equipment that satisfy hygiene and sanitation standardrequirements to suit for storing and manufacturing medicines and medical devices;

12.1.3.to have medicinal raw materials registered in the medicine registry;

12.1.4.to be involved in the accredited laboratory analysis of the medicinal raw materials and supplementary substances prior to start of manufacturing a particular product;

12.1.5.to have provided with professional work force skilled to manage and control manufacturing stages as per technology standards;

12.1.6.to have created conditions on organizing the quality control over the manufacturing progress and final products, and issuing the quality guarantee at every production batch;

12.1.7.to have satisfied the manufactured medicines and medical devices, their containers, boxes, packages, and labels in compliance with the standards requirements.

12.2.Medicine manufacturers shall be responsible for the quality of their products.

12.3.The state administrative body in charge of pharmaceuticals shall issue a certificate, which assures the medicine manufacturers qualifies the standard requirements.

/This paragraph was amended by the law as of August 17, 2012/

/This paragraph was amended by the law as of August 28, 2020/

12.4.The followings shall be prohibited in production of medicines and medical devices:

12.4.1.to produce narcotic and psychotropic drugs without obtaining a special permit;

12.4.2.to produce medicines for humans through the same production lines and conveyers of the medicines for livestock and animals;

12.4.3.to produce medicines and medical devices by using raw materials without quality assurance.

Article 13.Compounding medicines in pharmacies

13.1.Medicines can be compounded in pharmacies, in accordance with doctor's prescription, using primary raw materials registered in the medicine registry and supplementary raw materials which satisfy the quality requirements.

13.2.The competent pharmaceutical specialist shall compound medicines in accordance with pharmaceutical technology in a pharmacy that satisfy standard requirements of compounding medicines.

CHAPTER FOUR

ENTERING MEDICINES AND MEDICAL DEVICES ACROSS THE STATE BORDERS

Article 14.Entering medicines and medical devices across the state borders

14.1.The Government shall determine the border ports for entering medicines and medical devices across the state border.

14.2.The issue of entering medicines by travelers for personal use across the state border shall be regulated under Article 227 of the Law on Customs.

Article 15.Importing and exporting medicines and medical devices

15.1.The medicine and medical devices supplier organization shall obtain the permits for importing and exporting medicines and medical devices from the state administrative body in charge of pharmaceutical matters. When importing and exporting livestock and animal feed supplement, medicine, and medical devices, the permits shall be obtained from the state administrative body in charge of livestock and animal health issues.

/This paragraph was amended by the law as of August 17, 2012/

/This paragraph was amended by the law as of August 28, 2020/

/This paragraph was modified by the law as of January 6, 2023/

~~15.2.The Cabinet members in charge of health and agricultural matters shall approve the procedures on issuing the license specified in paragraph 15.1 of this Law.~~

/This paragraph was invalidated by the law as of January 6, 2023/

15.3.The import and export registration documents shall specify names, forms, dosages, and quantities, names of manufacturers, period of entering them across the state border, and entering border port of the medicines and medical devices.

/This paragraph was amended by the law as of January 6, 2023/

15.4.The state central administrative body in charge of pharmaceutical matters shall register the medicines specified in sub-paragraphs 22.7.1-22.7.9 of this Law and the state administrative body in charge of livestock and animal health matters shall issue the permits specified in sub-paragraph 11.4 of Article 8.2 of the Law on Permits.

/This paragraph was amended by the law as of August 17, 2012/

/This paragraph was amended by the law as of August 28, 2020/

/This paragraph was amended by the law as of January 6, 2023/

15.5.In the event that non-registered medicines, emergency medicines and medical devices to be imported from abroad under the necessary requirements during the circumstances of states of disaster or emergency, the registration for importing of such medicines and medical devices shall be issued by the decisions of the Cabinet member in charge of health matters and state administrative body in charge of livestock and animal health matters based on the conclusions of the Council of medicines specified in Article 5 of this Law.

/This paragraph was amended by the law as of January 6, 2023/

15.6.Medicine and medical device importer shall be required to conclude a contract with the foreign medicine manufacturer or its official contracted distributor. For an exporter, it shall be required to conclude a contract with the purchasing entity.

15.7.If the citizens and organizations receiving medicines and medical devices in the form of foreign aid or donation from abroad, they shall have a prior consultation with the state central administrative bodies in charge of health and agricultural matters, and have decided the issues on storage, usage, and distribution of the medicines and medical devices.

15.8.Procedures on receiving and using medicines and medical devices through foreign aid and donation shall be approved by the Cabinet members in charge of health and agricultural matters.

15.9.The followings shall be prohibited in the operations of importing and exporting medicines and medical devices:

15.9.1.to enter medicines and medical devices across the border port other than the determined ones to enter them;

15.9.2.to import medicines and medical devices with a label of "Made in Mongolia" and a standard number;

15.9.3.to import medicines, medical devices, and biologically active products by legal entities and citizens without the special permit;

15.9.4.to enter medicines and medical devices beyond or more than the names, forms, dosages, and quantities specified in the import and export registration document stated in paragraph 15.3 of this Law across the state border.

/This sub-paragraph was amended by the law as of January 6, 2023/

15.10.In accordance with the list approved by the Government, the state central administrative body in charge of health matters may issue a right to directly supply by importing the immunization products, medicines, and medical devices upon concluding a direct contract with internationally recognized medicine manufacturers and suppliers.

15.11.If it is determined that paragraphs 14.1, 14.2, and 15.9 of this Law were violated, the permit to import shall be revoked.

/This paragraph was added by the law as of January 6, 2023/

Article 15^1.Issuing permits to import and export livestock and animal medicine, medical devices, and feed supplement

/This article was added by the law as of January 6, 2023/

15^1.1.Applicants for permits to import and export livestock and animal medicines and medical devices shall submit the following documents to the state administrative body in charge of livestock and animal health matters along with the request:

15^1.1.1.a copy of the state registration certificate of the legal entity;

15^1.1.2.special permit for import of livestock medicine and medical devices, and special permit for manufacture of livestock medicine and medical devices in case of export;

15^1.1.3.sale contract concluded with a foreign medicine and medical device supplier organization, the power of attorney, or evidence proving the official representation;

15^1.1.4.state registration certificate of medicine;

15^1.1.5.certificate of origin, quality certificate, certificate of conformity of medicines, medicinal raw materials, and products;

15^1.1.6.quality confirmation of the drug batch of the exporting country for the import permit;

15^1.1.7.international and the respective country's quality confirmation and origin certificates of medical devices, diagnostics, instruments, and equipment, and certificates of compliance with international quality and standard requirements of the manufacturer or supplier of instructions for use;

15[1].1.8.information on names, forms, dosages and quantities /boxes, packages/, names of manufacturers, period of entering it across the border, and border port of entry of medicine and medical devices;

15[1].1.9.when importing medicines and biological preparations, original copies of loading and transporting documents registered at customs, detailed records of boxes and packages, copies of invoices, and certificates issued by the manufacturer.

15[1].2.Applicants for permits to import and export the livestock and animal feed supplement shall submit the following documents to the state administrative body in charge of livestock and animal health matters along with the request:

15[1].2.1.a copy of the state registration certificate of the legal entity;

15[1].2.2.sale contract concluded with the manufacturer and the official contracted distributor;

15[1].2.3.state registration certificate of livestock and animal feed supplement to be imported and exported;

15[1].2.4.the manufacturer's certificate of compliance with international quality standards;

15[1].2.5.composition, origin and quality certificate of livestock and animal feed supplement;

15[1].2.6.label design, instructions for use, translation in Mongolian language of instructions for use if necessary;

15[1].2.7.evidence that three quarters of the period of validity of the feed supplement has not expired.

15[1].3.The state administrative body in charge of livestock and animal health matters shall resolve the matter of issuing the permit within the period in accordance with the procedure specified in Article 5.2 of the Law on Permits.

15[1].4.If the permit holder upon using the permit entered the medicine across the border which is not registered in the medicine registry, without quality assurance and conformity certificate, or by completing the forged documents, or tried to enter the medicine and medical devices which have obtained from a place other than the pharmaceutical manufactory or a contracted medicine supply organization, that have expired to use, then the import permit shall be revoked.

15[1].5.Export and import permits for veterinary medicine and medical devices, and nutritional supplement shall be valid for 30 days after issuance.

CHAPTER FIVE

DISTRIBUTION OF MEDICINES

Article 16.Operations of selling medicines, medical devices, and biologically active products

16.1.Local administrative body shall be responsible for determining location and scope of service of pharmacies in compliance with the respective local peculiarities, and coordinating the operations of supplying the medicines and medical devices.

16.2.Pharmacies can serve with medicine, medical devices, tools, instrument, biologically active products, health, beauty and sanitary products.

16.3.The doctors of soum and bagh shall provide service to the population of the respective territory by medicines and medical devices obtained from local pharmacies under the jurisdiction.

16.4.Veterinarians shall provide service to the citizens with livestock and animals by the medicines and medical devices for animal use obtained from medicine supply organizations.

16.5.The following activities shall be prohibited to the operations of the pharmacies:

16.5.1.to issue prescription medicines without or with invalid prescription;

16.5.2.to issue medicines and medical devices of animal use for human use;

16.5.3.to sell the compulsory vaccination preparation, medicines prescribed to use exclusively in hospitals, and subsidized medicines and medical devices intended for free distribution;

16.5.4.to serve with medicines, except traditional ones, in places other than pharmacies or branch pharmacies.

16.6.Biologically active products shall be sold at pharmacies and food stores which meet the standard requirements.

Article 17.Proper use of medicines

17.1.Hospitals shall have a medicine treatment coordination committee in charge of proper usage matters of medicines.

17.2.Doctors shall prescribe medicines by international names and in accordance with standards, and explain to clients the instructions and duration of the usage of medicine, potential side-effects and others.

17.3.When issuing medicines, the pharmacist shall give advice to citizens on usage methods, storing conditions, and proper usage of the medicines.

Article 18.Medicine labeling and marking

18.1.Labeling and marking on the boxes and packages of medicines shall contain thefollowing information:

18.1.1.sale and international name and type of the medicine;

18.1.2.dosage, size, and quantity;

18.1.3.name of manufacturer;

18.1.4.batch number;

18.1.5.instructions of usage;

18.1.6.dates of production and expiration;

18.1.7.conditions of issuance;

18.1.8.storage conditions;

18.1.9.state drug registration number of Mongolia.

18.2.On the package of medicines registered as for livestock and animals, there shall be a statement saying "For livestock and animal use".

18.3.On the package of blood, blood products, human organs and tissues, there shall be a statement saying "Doesn't contain any antibody of human immunodeficiency virus".

18.4.On the package of the blood serum, it shall be indicated from which animal blood and organs were taken, and on the package of immunization preparation, it shall be indicated the nutrient medium in which the bacteria were grown.

18.5.Instructions for use the medicine shall be written in Mongolian language and contain the following information:

18.5.1.name and official address of the manufacturer;

18.5.2.sale and international name of the medicine;

18.5.3.composition, dosage and size of medicine;

18.5.4.instructions of usage;

18.5.5.prohibition provisions;

18.5.6.side-effects;

18.5.7.interactions with other drugs;

18.5.8.methods of use;

18.5.9.date of expiration;

18.5.10.storage conditions and warnings;

18.5.11.conditions of issuance.

CHAPTER SIX

CREATION OF NEW MEDICINE

Article 19.Introducing new medicines for public usage

19.1.New medicines manufactured in home country shall be introduced for usage upon completion of pre-clinical survey and clinical experiment, and registration in the medicine registry.

19.2.Issuance of a patent for new medicines shall be regulated under the relevant legislation.

Article 20.Pre-clinical survey

20.1.Pre-clinical survey shall be carried out on pharmaceutical, toxicology and pharmacological or kinetic and dynamic directions of medicine.

20.2.Pharmaceutical survey shall determine and assure the following indicators:

20.2.1.quality and purity of active substances;

20.2.2.special reaction to recognize medicinal substance and amount of quantitative component;

20.2.3.amount of active substance determined by biological method, in case if necessary;

20.2.4.stability and solubility of medicine;

20.2.5.bio-digestion;

20.2.6.relevant test findings.

20.3.The following conclusion shall be drawn under toxicology survey:

20.3.1.the results of pathological and histological studies and have confirmed that if they contain pure chemical substances, they do not affect embryos, cause tumors, or affect genetics;

20.3.2.results of experiments carried out on animals and dose and amount of chronic or acute toxicity.

20.4.Kinetic survey of medicine shall have determined the absorption and excretion time and bio-digestion of the medicine.

20.5.Dynamic survey of medicine shall have determined the following indicators:

20.5.1.basic instructions of how to use the medicine and its dosage;

20.5.2.effects to other organs and system;

20.5.3.medicine interactions;

20.5.4.summary of identified effects.

20.6.Findings of the pre-clinical survey of new medicines shall be discussed amongst academic organizations, which carry out research and analysis in the medical field, and academic council of medical universities and institutions providing medical education, and conclusions shall be drawn by them.

Article 21.Clinical experiment

21.1.In the operations of conducting clinical experiment, principles of rule of laws, to respect human rights, and to be effective shall be adhered to.

21.2.In case if a medicine is determined to be safe and to have high clinical activity through the pre-clinical survey, a clinical experiment shall be conducted with scientifically acceptable and proven methodologies, and methodologies of such experiment shall be approved by the academic council specified in paragraph 20.6 of this Law.

21.3.The methodologies specified in paragraph 21.2 of this Law shall reflect methods of clinical experiment, its duration, coordinator, implementer and partner organizations, number of respondents of the survey, justifications, sampling methods, external control and others.

21.4.Permits to conduct the clinical experiment shall be issued by the Ethics committee next to the state central administrative body in charge of health matters, based on conclusions of the academic council.

21.5.The clinical experimenter shall explain the respondents to be involved in the experiment the goal, methods, and potential positive and negative impact of the experiment to be arisen, and make a contract with them. Template of the contract shall be approved by the Cabinet member in charge of health matters.

21.6.The contract specified in paragraph 21.5 of this Law shall be approved by the respondent parties participated in the clinical experiment and be verified by external witnesses.

21.7.The clinical experimenter shall have a special form dedicated for informing about side-effects might be occurred during the experiment, and in the event of appearance of serious side-effects, it shall be informed the relevant organizations, and the necessary actions shall be taken.

21.8.Unless it is performed differently for the purpose of preventing from risks of potential damages to health of the person participating in the experiment, the clinical experiment shall be prohibited to be conducted by any methodology other than the approved one.

21.9.Costs occurred in relation to the clinical experiment shall be borne by the experimenter.

21.10.Completion of the clinical experiment or termination of the experiment prior to its completion deadline shall be informed to the Ethics committee specified in paragraph 21.4 of this Law and the academic council specified in paragraph 20.6 of this Law respectively.

21.11.Findings of the clinical experiment shall be discussed and made a conclusion by the meeting of the same academic council, which has approved the methodology of the experiment.

CHAPTER SEVEN

QUALITY AND SAFETY OF MEDICINES AND MEDICAL DEVICES

Article 22.Medicine registry

22.1.Medicines, medicinal raw materials, and biologically active products to be manufactured, imported and sold in Mongolia shall be registered in the state medicine registry under all circumstances, except those specified in paragraph 22.7 of this Law.

22.2.When registering medicines, medicinal raw materials, and biologically active products in the medicine registry, it shall be based on request of the manufacturer, results of the analysis, relevant documents, and opinion drawn by the expert on those documents.

22.3.Medicines, medicinal raw materials, and biologically active products shall be registered in the medicine registry by each of their country of manufacturer, the permit holder, form, and dosage respectively.

/This paragraph was amended by the law as of January 6, 2023/

22.4.When registering medicines in the medicine registry, the conditions to use the medicine exclusively at hospitals and/or to be dispensed with or without prescription shall be determined, and the instructions of usage shall be certified.

22.5.Registration of medicines, which have been registered at the internationally recognized drug control institution, shall be made on an accelerated basis.

22.6.Procedures on registration of medicines, medicinal raw materials, and biologically active products in the state medicine registry, registration under the accelerated procedure, determining the period and registration fee, and spending of them shall be approved by the Cabinet members in charge of health and agricultural matters.

22.7.Under the following circumstances the medicines, medicinal raw materials, and biologically active products shall not be registered in the state medicine registry:

- **22.7.1.registration samples of medicines and biologically active products;**
- **22.7.2.donation and aid medicines;**
- **22.7.3.medicines procured through international organizations in accordance with Government contract;**
- **22.7.4.medicines, for which a sale contract could be made with only one entity, under the reason of protecting an intellectual property right, and there is no body to replace the contracted entity;**
- **22.7.5.orphan drugs;**
- **22.7.6.medicines to be used in an analysis, research work and clinical experiments;**
- **22.7.7.samples of medicines, medical devices, and biologically active products to be launched at exhibitions and fairs;**
- **22.7.8.supplementary medicinal substance;**
- **22.7.9.raw materials of traditional medicine;**
- **22.7.10.medicines to be used in the state of emergency and disaster;**
- **22.7.11.preparations made in pharmacies according to the doctor's prescription;**
- **22.7.12.medicines for personal use of travelers.**

Article 23.Quality assurance and control of medicines and medical devices

23.1.The quality assurance of medicines and medical devices to be used for human and veterinary purposes in Mongolia shall be made in accordance with the relevant legislation.

23.2.The quality of medicines shall be assured based on the pharmacopoeia and other equivalent documents.

23.3.National pharmacopoeia of Mongolia and procedures on developing, approving and numbering it, the composition and operational procedures of the pharmacopoeia committee shall be approved by the Cabinet members in charge of health and agricultural matters.

23.4.A non-staff pharmacopoeia committee with duties of discussing draft pharmacopoeia monographs and drawing conclusions shall be operated next to the state central administrative bodies in charge of health and agricultural matters. Secretary of the pharmacopoeia committee shall be a full-time employee.

Article 24.Control on narcotic and psychotropic drugs

24.1.Relations in connection with issuance, suspension, and revocation of special permits for manufacturing, importing, and selling narcotic and psychotropic drugs and their precursors shall be regulated by relevant laws.

24.2.List of narcotic and psychotropic drugs to be used in Mongolia and procedures on regulating the manufacture, import, storage and sale of those drugs shall be approved by the Cabinet member in charge of health matters.

Article 25.Registration and information on the side-effects of the medicine

25.1.The Cabinet member in charge of health matters shall approve the procedure on registration and information of side-effects of the medicine.

CHAPTER EIGHT

MEDICINE INFORMATION AND ADVERTISEMENT

Article 26.Information on medicines

26.1.Information on medicines to be dispensed with prescription or be availableexclusively at hospitals, shall be delivered to medical specialist only.

26.2.Information on medicines shall be aimed at rational, proper and effective usage of medicines and protecting rights and interests of consumers.

26.3.Information on medicines shall be accurate, realistic, and independent from manufacturers and suppliers.

Article 27.Advertisement of medicine

27.1.Medicines and biologically active products to be dispensed without prescription may be advertised through professional press and public media means.

27.2.Content of advertisement of medicines and biologically active products shall be reviewed by the state central administrative body in charge of agricultural matters and state administrative body in charge of control and regulation matters of medicine and medical devices.

/This paragraph was amended by the law as of August 17, 2012/

/This paragraph was modified by the law as of August 28, 2020/

27.3.Medicine advertisement information shall be based on pharmacological specifications and results of clinical experiment regardless of the form of the medicine.

27.4.Followings shall be prohibited in advertisement of medicine, in addition to those specified in Article 13 of the Law on Advertisement:

- **27.4.1.advertise medicines through means of press and media for the purpose of importing and selling;**
- **27.4.2.conduct medicine advertisement addressed to the children;**
- **27.4.3.advertise medicines to be issued under the prescription;**
- **27.4.4.disseminate information, which in nature gives an idea to deny doctor's advice, treatment and surgery;**
- **27.4.5.mislead the consumers by indicating that a particular medicine is rare or important, or the only one, highly active, more effective compared to other medicines, or safe and free of side-effects, and/or new and patented medicine;**
- **27.4.6.advertise publicly to be issues incentives for the buying medicines and medical devices, or price discounts thereof.**

CHAPTER NINE

MISCELLANEOUS

Article 28.Participation of non-governmental organizations in the operations of supply of medicine

28.1.Professional and non-governmental organizations shall exercise the following obligations in regulating the operations of manufacturing, importing, exporting, storing,selling, using and controlling the medicines and medical devices:

28.1.1.to exercise public controlling on implementation of the Law on Medicines and medical devices and relevant procedures and instructions enacted in conformity with the respective law, to demand for elimination of any detected violation, and to address the issue to competent body for the settlement;

28.1.2.to descend its opinion on issues of expressing interests of supply medicine organizations and pharmacists to relevant state central administrative body and management of the administrative and territorial units;

/This sub-paragraph was amended by the law as of August 17, 2012/

28.1.3.to exercise some functions of the state body on a contractual basis;

28.1.4.to organize trainings and promotion events on professional skills and ethics of pharmacists in cooperation with relevant organizations;

28.1.5.to conduct research and analysis, and to implement projects on issues in connection with medicine manufacturing, supply and service,.

Article 29.Liabilities to be imposed on the violators of the Law

29.1.If the act of an official who violates this Law is in not criminal nature, he or she shall be liable as provided in the Law on Civil Service.

29.2.Any person or legal entity that violates this Law shall be subject to the liability in accordance with Criminal Code or Law on Violations.

/This article was modified by the law as of December 4, 2015/

Article 30.Entry into force of the Law

30.1.Article 6 of this Law shall enter into force on July 1, 2011.

THE CHAIRMAN OF THE STATE GREAT KHURAL OF MONGOLIA DEMBEREL.D