LAW OF MONGOLIA

May 27, 2010 Ulaanbaatar city

ABOUT MEDICINE AND MEDICAL EQUIPMENT
/ Revised version /

CHAPTER ONE
GENERAL PROVISIONS

Article 1. Purpose of the law

1.1. The purpose of this law is to produce, import, export, store, sell, distribute, use and control drugs for human and veterinary use, including traditional drugs, bio-preparations, diagnostics (hereinafter referred to as “drugs”), medical devices and biologically active products. to regulate relations related to activities.

Article 2. Legislation on medicines and medical devices

Legislation on medicines and medical devices shall consist of the Constitution of Mongolia, the Law on Health, the Law on Animal Genetic Resources, the Law on Animal Health, this Law and other legislative acts enacted in conformity with them.

/ This part was amended according to the law dated 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 legal terms

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

3.1.1. “Medicine” means a drug intended for the prevention, diagnosis, treatment and immunization of human and animal diseases, the action of which has been proven by pharmacology and clinical trials, and the synthetic or animal, plant or mineral substance has been converted into a certain form. , preparations used in moderation;

3.1.2. “Biopreparation” means a product obtained from a living body, body, its tissues, cells and laboratory methods for the purpose of treatment, diagnosis and prevention of human and animal diseases;

3.1.3. “Traditional medicine” means a traditional and industrial preparation of plants, animals, mineral substances and precious stones used in accordance with traditional medical prescriptions, used in certain doses and amounts for the purpose of prevention, diagnosis and treatment of human and animal diseases. natural products;

3.1.4. “Diagnostic” means a specific dose, amount, composition, specificity and active product used in the analysis of human, animal and environmental samples for the purpose of preventing human, animal and animal diseases, diagnosing and monitoring the disease;

3.1.5. “Medical device” means ancillary items used for the purpose of prevention of human and animal diseases, diagnosis, treatment, nursing and support of physical structure and function;

3.1.6. “Drugs” means drugs that have an addictive effect and are included in the list of the 1961 United Convention on Narcotic Drugs;

3.1.7. “Psychotropic drug” means a substance that has a strong effect on the psyche and is included in the list of the 1971 Convention on Psychotropic Substances;

3.1.8. “Orphan drug” means a drug that is used in the treatment of rare diseases and relatively little in the country;

3.1.9. “Pharmaceutical raw materials” means pure root substances, synthetics and plant, animal and mineral origin containing medicinal active substances;

3.1.10. “Drug excipients” means additional items necessary for the production and formulation of drugs;

3.1.11. “Series” means the quantity of a package of medicinal products produced by a single stage of production technology;

3.1.12. “Drug value” means an expression that specifies the quality, safety and efficacy of a drug in detail by pharmacology, pharmacology and clinical research;

3.1.13. “Drug registration” means the activity of allowing the release of drugs for use in the territory of Mongolia that have been proven to be used for prevention, diagnosis and treatment on the basis of chemistry, biology, pharmacology and drug evaluation;

3.1.14. “List of essential medicines and medical devices” means the names of medicines and medical devices approved by the state central administrative body in charge of health and agriculture for priority use in medical care for humans and animals;

3.1.15. “Taking medicine” means as specified in 3.1.17 of the Health Law;

3.1.16. “Drug prescription” means a document issued by a doctor to a pharmacist or pharmacist stating the method of preparation, administration and use of a drug for a given patient;

3.1.17. “Rational use of drugs” means proper use of drugs in accordance with the instructions and recommendations of doctors and pharmacists, if necessary;

3.1.18. “Side effects of drugs” means adverse effects that may occur or occur in the body when used in appropriate doses for the purpose of prevention, diagnosis and treatment of human and animal diseases;

3.1.19. “Pharmacopoeial article” means a mandatory standard specifying drug requirements, quality parameters and methods of their analysis;

3.1.20. “Pharmacopoeia” means a compilation of pharmacopoeial articles;

3.1.21. “Counterfeit drug” means a product manufactured using a fake label in the name of a drug manufacturer for the purpose of illegally making a profit;

3.1.22. “Manufacture of drugs and medical devices” means a legal entity licensed to produce finished products in accordance with pharmaceutical technology using drug raw materials and drug excipients;

3.1.23. “Organization for the supply of medicines and medical devices” means a legal entity licensed to supply pharmacies, health care organizations and veterinary clinics with drugs and medical devices at wholesale prices;

3.1.24. “Pharmacy” means a legal entity licensed to provide health care organizations, veterinary clinics and the population with medicines and medical devices at retail prices;

3.1.25. “Biologically active product” means a product that supports human body functions, replenishes it with essential minerals and prevents any diseases.

/ This part was amended according to the law dated December 20, 2012 /

CHAPTER TWO GOVERNMENT POLICY, REGULATION, DRUG SUPPLY SYSTEM, DRUG ACTIVITIES

Article 4. National drug policy

4.1. The national drug policy is an integral part of the unified policy to ensure the national security of Mongolia.

4.2. The National Drug Policy shall be aimed at providing health care organizations, veterinary clinics and the population with highly active, quality assured, continuous, accessible and uniform drugs registered in the drug registry, and developing rational use of drugs.

4.3 The state shall pursue a policy to support the national production of import-substituting drugs and medical devices.

4.4. The national drug policy shall be reflected in the policies of the Government, state central and local administrative bodies and implemented through their activities.

4.5. The list of essential drugs, medical devices and orphan drugs shall be approved by the relevant central state administrative body.

4.6 The Government shall set the maximum price of drugs included in the list specified in Article 4.5 of this Law.

Article 5. Drug Council

5.1. The Council for Human Drugs shall operate under the State Central Administrative Body Responsible for Health Matters and the Council for Veterinary Drugs shall operate under the State Administrative Body Responsible for Animal Health.

/ This part was amended according to the law dated November 15, 2018 /

5.2. The Drug Council shall be a non-staff, professional advisory body to support the implementation of the national drug policy, and its composition, rules, and procedures for filing conflicts of interest shall be approved by the Cabinet member in charge of health and agriculture.

5.3. The Drug Council may have a professional sub-council.

5.4. In case of making changes in the national drug policy, regulating the supply of medicines and medical devices in case of disaster and emergency situation, the Human and Veterinary Drug Council shall meet jointly to resolve the issue.

5.5. The Drug Council shall exercise the following powers:

5.5.1. To develop proposals and recommendations on national drug policy and submit them to the relevant central state administrative body;

5.5.2. To develop proposals and recommendations on the selection of drugs and medical devices to be used for diagnosis and treatment;

5.5.3. Decide on the registration and modification of drugs and biologically active products within the framework of the national drug policy;

5.5.4. To issue conclusions and recommendations on production and import of medicines, medical devices and biologically active products;

5.5.5. To make professional recommendations on changing the list of narcotic and psychotropic drugs and monitoring their use;

5.5.6. To discuss the results of pre-clinical research and clinical trials of newly developed drugs in Mongolia and issue a conclusion on their use;

5.5.7 Decide whether to conduct a clinical trial on a new imported drug registered for the first time in Mongolia.

Article 6. State regulation on production, import, export, trade, distribution and control of medicines, medical devices and biologically active products

The state shall ensure unified regulation of activities related to production, import, export, trade, distribution and control of medicines, medical devices and biologically active products.

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

6.2.1. Registration of drugs and biologically active products, quality and safety monitoring in the market;

6.2.2. License to produce, import and sell;

6.2.3. Import and export licenses, control and regulation;

6.2.4 quality assurance;

6.2.5. Certificate of compliance with GMP standards;

6.2.6. Professional control over pharmaceutical activities;

6.2.7. Control over drug side effects;

6.2.8. Permission and control for advertising of drugs and biologically active products;

6.2.9. Regulation and control of essential drug prices;

6.2.10. Independent and factual information on medicines for medical professionals and the public.

6.3. The state central administrative body in charge of health matters shall carry out the regulation specified in 6.2 of this Law.

/ This part was amended according to the law dated August 17, 2012 /

Article 7. License

7.1. The state central administrative body in charge of drugs shall issue a license for the production, import and sale of human drugs, medical devices and narcotic and psychotropic drugs, their precursors and biologically active products.

/ This part was amended according to the law dated August 17, 2012 /

7.2. The state administrative organization in charge of agriculture shall issue a license for production and import of veterinary drugs and medical devices.

/ This part was amended according to the law dated January 20, 2011 /

Article 8. Conducting medical activities

8.1. A medical specialist licensed as specified in 22.3 of the Law on Health shall be engaged in drug production.

A veterinarian who has graduated from a school with a license to provide veterinary education and is accredited to work in his / her profession shall engage in veterinary medicine production.

Article 9. Drug supply organization

9.1. The following organizations shall belong to the drug supply organization:

9.1.1. Pharmaceutical and medical device factory;

9.1.2. Organization for the supply of medicines and medical devices;

9.1.3. Pharmacy.

9.2. Relations related to the drug supply organization other than obtaining a license to manufacture, import and sell drugs and medical devices of the drug supply organization specified in 9.1 of this Law shall be regulated by the Law on Health.

9.3. The state central administrative body in charge of health matters may have a reserve warehouse for storage of medicines and medical devices to be used for emergency medical and public health care and services.

Article 10. Principles of operation and general responsibilities of drug supply organizations

10.1. The drug supply organization shall adhere to the principle of equal provision of health organizations, veterinary clinics and the population with quality drugs and medical devices registered in the drug registry.

10.2. The drug supply organization shall have the responsibilities specified in Article 15 of the Health Law.

10.3. The drug supply organization shall conduct production, storage and trade of drugs and medical devices in conditions that meet the requirements of pharmaceutical technology.

10.4. The structure and activities of the drug supply organization shall meet the requirements of state standards.

Article 11. Prohibitions on the activities of drug supply organizations

The following shall be prohibited in the activities of a drug supply organization:

11.1.1. To produce, import and sell drugs and medical devices without a license specified in Article 7 of this Law;

11.1.2. To use expired drugs and medical devices that are not registered in the Mongolian Drug Registry, do not have quality certification;

11.1.3. To obtain medicines and medical devices from sources other than drug supply organizations;

11.1.4. To involve a person who does not have a permit to take drugs in the process of preparing, preparing, inspecting and dispensing drugs;

11.1.5. The organization supplying drugs and medical devices shall sell drugs and medical devices to citizens;

11.1.6. In order to increase his / her profit and income, to sell drugs and medical devices to doctors, to reward them based on their results or to participate in similar activities;

11.1.7. Production, import and sale of counterfeit drugs.

11.2 The following is prohibited in medical activities:

11.2.1. To engage in drug production activities by a specialist who does not have the right to take drugs;

Violation of drug storage and protection regulations.

11.3. It is prohibited to store and sell drugs and medical devices in non-designated places.

CHAPTER THREE
MANUFACTURING OF MEDICINE AND MEDICAL EQUIPMENT

Article 12. Requirements for conducting production of medicines and medical devices

The following basic requirements shall be met for the production of medicines and medical devices:

12.1.1 have the technology to produce drugs and medical devices that meet the requirements of national and international standards;

12.1.2. To be provided with purpose-built premises and equipment that meet sanitary and hygienic requirements for storage and production of medicines and medical devices;

12.1.3. Drug raw materials shall be registered in the drug registry;

12.1.4. To include drug raw materials and drug excipients in accredited laboratory tests before starting production of the product;

12.1.5 be provided with professional personnel to manage and control the production process in accordance with the technology;

12.1.6. To organize conditions for quality control of production process and final products and meet conditions to issue quality assurance for each series;

12.1.7. Manufactured drugs and medical devices, their packaging and label shall meet the standard requirements.

The pharmaceutical industry shall be responsible for the quality of its products.

12.3. The state central administrative body in charge of drug matters shall issue a certificate confirming that the pharmaceutical company meets the requirements of the standard.

/ This part was amended according to the law dated August 17, 2012 /

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

12.4.1. To produce narcotic and psychotropic drugs without a license;

12.4.2. To produce human medicine on the same line and line as animal medicine;

12.4.3. To produce drugs and medical devices from uncertified raw materials.

Article 13. Preparation of drugs in pharmacies

13.1. Drugs may be prepared in a pharmacy using the main raw materials registered in the drug registry and auxiliary raw materials that meet the quality requirements according to the doctor's prescription.

13.2. A specialist authorized to store drugs in a pharmacy that meets the requirements of drug preparation standards shall perform drug preparation activities in accordance with pharmaceutical technology.

CHAPTER FOUR
INTRODUCTION OF MEDICINE AND MEDICAL EQUIPMENT INTO THE BORDER

Article 14. Transfer of medicines and medical devices across the state border

The Government shall determine the border crossing point for medicines and medical devices to cross the state border.

The issue of importing drugs for personal use by passengers shall be regulated in accordance with Article 227 of the Customs Law.

Article 15. Import and export of medicines and medical devices

15.1. An organization supplying drugs and medical devices shall obtain a license for import and export of drugs and medical devices from the state central administrative body in charge of drugs and the state central administrative body in charge of agriculture.

/ This part was amended according to the law dated August 17, 2012 /

The member of the Government in charge of health and agriculture shall approve the procedure for issuing licenses specified in 15.1 of this Law.

15.3. Import and export license documents shall specify the name, form, dosage, quantity, name of the manufacturer, time of entry across the state border and border crossing point of drugs and medical devices.

15.4. The state central administrative body in charge of drugs and the state central administrative body in charge of agriculture shall issue import licenses for drugs specified in Articles 22.7.1-22.7.9 of this Law.

/ This part was amended according to the law dated August 17, 2012 /

15.5. Import licenses shall be issued by the decision of the Government member in charge of health and agriculture based on the conclusion of the Drug Council specified in Article 5 of this Law in case of unavoidable import of drugs and emergency drugs and medical devices that are not registered in the disaster and emergency situation. .

15.6. An importer of drugs and medical devices shall enter into a trade agreement with a foreign pharmaceutical company or its official distributor, and an exporter shall enter into a trade agreement with a purchasing organization.

15.7. In case organizations and citizens receive medicines and medical devices from abroad with assistance and donations, the issues of storage, use and distribution of medicines and medical devices shall be resolved in advance in consultation with the state central administrative body in charge of health and agriculture.

15.8. The member of the Government in charge of health and agriculture shall approve the procedure for receiving and using medicines and medical devices with assistance and donations.

15.9. The following shall be prohibited for importing and exporting medicines and medical devices:

15.9.1. To introduce drugs and medical devices through a port other than the border crossing point designated for the introduction of drugs and medical devices;

15.9.2. To import drugs and medical devices with label “Made in Mongolia” and standard number;

15.9.3. To import drugs, medical devices and biologically active products by unlicensed legal entities and individuals.

15.9.4. To allow drugs or medical devices to cross the state border in excess of the name, form, dose and quantity specified in the import and export license specified in 15.3 of this Law.

15.10. In accordance with the list approved by the Government, the state central administrative body in charge of health may enter into a direct contract with an internationally recognized pharmaceutical company or supplier and grant the right to directly import immunization preparations, drugs and medical devices.

CHAPTER FIVE
DRUG DISTRIBUTION

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

The local administrative body shall be responsible for determining the location and scope of the pharmacy in accordance with the local specifics and coordinating the supply of medicines and medical devices.

16.2 A pharmacy may provide drugs, medical devices, instruments, devices and biologically active products, health, beauty and hygiene products.

16.3. Soum bagh anthropologists may serve the population within the scope of their service with drugs and medical devices obtained from local pharmacies in accordance with the contract.

16.4 A veterinarian may serve a person with livestock with veterinary drugs and medical devices obtained from a drug supply organization.

16.5. The following is prohibited in the operation of a pharmacy:

16.5.1. To dispense prescription drugs without a prescription or with an invalid prescription;

16.5.2. To provide medicines and medical devices for animal use for human consumption;

16.5.3. To sell compulsory immunization preparations, grants and medical devices provided for use in hospital conditions and intended for free provision;

16.5.4. To use drugs other than traditional medicines in places other than pharmacies and their branches.

16.6. Biologically active products shall be sold in pharmacies and grocery stores that meet the standard requirements.

Article 17. Rational use of drugs

17.1. The drug treatment coordination committee shall be responsible for the rational use of drugs in the hospital.

17.2. The doctor shall write the prescription of the drug under an international name in accordance with the standard and explain to the client the method of use, duration and side effects.

17.3. The pharmaceutical specialist shall advise the citizens on the method of use, storage conditions and rational use when dispensing drugs from the pharmacy.

Article 18. Labeling and labeling of drugs

The labeling and marking on drug packaging shall contain the following information:

18.1.1. Drug trade and international names and forms;

18.1.2. Dose, amount and quantity;

18.1.3. Name of the manufacturer;

18.1.4. Serial number;

18.1.5. Method of application;

18.1.6. Date of manufacture and validity period;

Conditions for issuance;

18.1.8. Storage conditions;

18.1.9. Mongolian drug registration number.

18.2. There shall be an inscription “For livestock” on the packaging of drugs registered as veterinary drugs.

18.3. On the packaging of blood, blood products and preparations of human tissues and organs shall be written “Does not contain antibodies against human immunodeficiency virus”.

18.4. The blood serum package shall indicate which animal's blood and organs were extracted, and the culture medium in which the bacteria were grown on the immunization preparation.

Instructions for use of the drug shall be in Mongolian and shall contain the following information:

18.5.1. Name and official address of the manufacturer;

18.5.2. Drug trade and international names;

18.5.3. Drug composition, dosage and amount;

18.5.4. Applicable provisions;

18.5.5. Prohibition provisions;

Side effects;

18.5.7. Interaction with other drugs;

18.5.8. Method of application;

18.5.9. Validity period;

18.5.10. Storage conditions and warnings;

Terms of issuance.

CHAPTER SIX
DEVELOPING A NEW DRUG

Article 19. Introduction of new drugs

19.1. Newly developed domestic drugs shall be included in pre-clinical research and clinical trials and released for use after registration in the drug registry.

Issuance of a patent for a new drug shall be regulated by relevant legislation.

Article 20. Pre-clinical research

Pre-clinical research shall be conducted in the field of pharmacology, toxicology, pharmacology or drug kinetics and dynamics.

20.2. The following indicators shall be established and confirmed by the pharmacological examination:

20.2.1. Quality and purity of the active substance;

20.2.2. The specific reaction and quantitative content of the drug substance;

20.2.3. If necessary, the amount of biologically determined active substance;

Drug stability and solubility;

20.2.5.bioengineering;

20.2.6. Relevant test report.

20.3. The following conclusions shall be drawn from the toxicology study:

20.3.1. If it contains chemically pure substances, the results of pathological and histological examinations confirming that it does not affect the embryo, cause cancer, or affect the genetic gene;

20.3.2. Dosage, amount and results of animal tests for chronic and acute poisoning.

20.4. Drug kinetics study shall determine the time of drug absorption, excretion and bioavailability.

20.5. The following indicators shall be determined by the study of drug dynamics:

20.5.1. Main indications for drug use and therapeutic dose;

20.5.2. Effects on other organ systems;

Drug interactions;

20.5.4. The amount for which the service was determined.

20.6. The results of the pre-clinical research of a new drug shall be discussed by a research organization conducting research and analysis in the field of medicine and the academic council of a medical education university.

Article 21. Clinical trials

21.1 The principles of the rule of law, respect for human rights and efficiency shall be followed in conducting clinical trials.

21.2. If the drug is found to be safe and highly therapeutic by previous clinical research, clinical trials shall be conducted using scientifically based and approved methods and the test methodology shall be approved by the Academic Council specified in Article 20.6 of this Law.

21.3. The methodology specified in 21.2 of this Law shall include the clinical trial method, duration, supervisor, implementing and partner organizations, number of participants, grounds, selection method and external control.

21.4. Permission to conduct clinical trials shall be issued by the Ethics Committee under the state central administrative body in charge of health based on the conclusion of the relevant academic council.

21.5. The clinical experimenter shall have a clear understanding of the purpose, method, and possible positive and negative consequences of the test and conclude a contract, and the model contract shall be approved by the member of the Government in charge of health.

21.6. The agreement specified in 21.5 of this Law shall be signed by the parties to the clinical trial and certified by an independent witness.

21.7. The clinical trial provider shall have a special sheet to report possible side effects during the test, and in case of serious side effects, notify the relevant authority and take necessary measures.

21.8. It is prohibited to conduct the test other than the approved methodology, except to eliminate the risk to the health of the participants in the clinical trial.

21.9. Expenses related to clinical trials shall be borne by the experimenter.

21.10. The Ethical Committee specified in Article 21.4 of this Law and the Academic Council specified in Article 20.6 of this Law shall be notified of the completion of clinical trials and their early termination.

21.11. The results of clinical trials shall be discussed at the meeting of the academic council that approved the methodology for conducting clinical trials and a conclusion shall be made.

CHAPTER SEVEN
QUALITY AND SAFETY OF MEDICINE AND MEDICAL EQUIPMENT

Article 22. Drug registration

22.1. Production, import, sale, drugs, drug raw materials and biologically active products in Mongolia shall be registered in the state registry, except for the cases specified in 22.7 of this Law.

22.2. Registration of drugs, drug raw materials and biologically active products shall be based on the manufacturer's request, test results, relevant documents and expert opinion.

22.3. Drugs, drug raw materials and biologically active products shall be registered in the state registry by country of origin, manufacturer, form and dose.

22.4. When registering a drug in the drug registry, the conditions for its use in a hospital setting, with or without a prescription shall be determined, and the instructions for use shall be confirmed.

22.5. Drugs registered by an internationally recognized drug regulatory authority shall be registered in an expedited manner.

The member of the Government in charge of health and agriculture shall approve the procedure for registration of drugs, drug raw materials and biologically active products in the state registration, registration by expedited procedure, setting deadlines and registration fees.

22.7. Drugs, drug raw materials and biologically active products shall not be registered in the state registry in the following cases:

22.7.1. Registration sample of drugs and biologically active products;

Donations and relief medicines;

22.7.3. Medicines purchased through international organizations in accordance with government agreements;

22.7.4. A drug that can be concluded with only one person for the purpose of protecting intellectual property rights and there is no substitute for it;

22.7.5. Orphan medicine;

22.7.6. Drugs to be used for research, analysis and clinical trials;

22.7.7. Samples of medicines, medical devices and biologically active products to participate in the exhibition;

22.7.8. Drug excipients;

22.7.9. Raw materials of traditional medicine;

22.7.10. Medicines to be used in case of disaster or emergency situation;

22.7.11. Preparations prepared in a pharmacy according to a doctor's prescription;

22.7.12. Medicines for personal use of passengers.

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

23.1. Quality assurance of medicines and medical devices to be used for human and veterinary purposes in Mongolia shall be certified in accordance with relevant legislation.

23.2. The quality of the drug shall be confirmed on the basis of pharmacopoeia and equivalent documents.

23.3. The Government member in charge of health and agriculture shall approve the National Pharmacopoeia of Mongolia, the procedure for its development, approval and numbering, the composition and working procedures of the Pharmacopoeia Committee.

23.4. A non-staff pharmacopoeia committee shall be established under the state central administrative body in charge of health and agriculture to discuss the draft pharmacopoeial article and issue a conclusion, and the secretary of the committee shall be a full-time employee.

Article 24. Control of narcotic and psychotropic drugs

24.1. Relations related to issuance, suspension and revocation of licenses for production, import and sale of narcotic drugs and psychotropic substances and their precursors shall be regulated by relevant laws.

The member of the Government in charge of health shall approve the list of narcotic and psychotropic drugs to be used in Mongolia and the procedure for regulating their production, import, storage and trade.

Article 25. Registration and information on drug side effects

The member of the Government in charge of health shall approve the procedure for registration and reporting of adverse drug reactions.

CHAPTER EIGHT
DRUG INFORMATION AND ADVERTISING

Article 26. Drug information

26.1. Information on prescription and hospital use drugs shall be provided only to medical professionals.

26.2. Drug information shall be aimed at rational, appropriate and effective use of drugs and protection of consumers' interests.

26.3. Drug information shall be true, correct and objective and shall be independent from the manufacturer and supplier.

Article 27. Drug advertising

Non-prescription drugs and biologically active products may be advertised in professional publications and mass media.

27.2. The state central administrative body in charge of drugs and agriculture shall monitor the content of advertisements of drugs and biologically active products.

/ This part was amended according to the law dated August 17, 2012 /

27.3. Drug advertisement information shall be based on pharmacological indicators and clinical research results regardless of the drug form.

27.4. In addition to those specified in Article 13 of the Law on Advertising, the following shall be prohibited in drug advertising:

27.4.1. To advertise drugs in the mass media for the purpose of importing and selling drugs;

27.4.2. To conduct drug advertisement for children;

27.4.3. To advertise prescription drugs;

27.4.4. To provide information that may lead to the denial of medical advice, treatment or surgery;

27.4.5. To mislead consumers that drugs are rare, important, unique, highly active, more effective than other drugs, safe, without side effects, new drugs or patented;

27.4.6. To advertise to the public on incentives or discounts for the purchase of medicines and medical devices.

CHAPTER NINE
MISCELLANEOUS

Article 28. Participation of non-governmental organizations in drug supply activities

Non-governmental and professional organizations shall play the following roles in regulating the production, import, export, storage, sale, use and control of medicines and medical devices:

28.1.1. To monitor the implementation of the Law on Medicines and Medical Devices, relevant regulations and instructions issued in accordance with them, to demand the elimination of revealed violations, and to submit the issue to the competent authority for resolution;

28.1.2. To submit his / her opinion on the issue of representing the interests of the drug supply organization and the drug specialist to the relevant central state administrative body and the management of the administrative and territorial unit;

/ This part was amended according to the law dated August 17, 2012 /

28.1.3 perform some functions of the state organization by contract;

28.1.4. To organize ethics, professional training and advertisement of pharmaceutical specialists in cooperation with relevant organizations;

28.1.5. To conduct research and analysis on issues related to drug production, supply and services, and to implement projects.

Article 29. Liability for violators of the law

29.1. If the actions of an official violating this Law are not of a criminal nature, he / she shall be subject to liability specified in the Civil Service Law.

A person or legal entity that violates this Law shall be subject to liability specified in the Criminal Code or the Law on Violations.

/ This article was amended according to the law dated December 04, 2015 /

Article 30. Entry into force of the law

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

CHAIRMAN OF THE PARLIAMENT OF MONGOLIA D. DEMBEREL