

LAW OF MONGOLIA

ON MEDICINES AND MEDICAL DEVICES

(Revised Version)

10 June 2010

Ulaanbaatar city

CHAPTER ONE GENERAL PROVISIONS

Article 1. Purpose of the Law

1.1. The purpose of the present law is to regulate relations in regard to processes of manufacturing, importing, exporting, storing, selling, distributing, using and monitoring medicines, including traditional medicines, biosubstance and diagnosis agents (hereinafter referred to as “medicines”), medical devices and bioactive products for humans and veterinary purposes.

Article 2. Legislation on medicines and medical devices

2.1. Legislation on medicines and medical devices shall consist of the Constitution, Law on Health, Law on Protection of Livestock Generation and Health, the present Law and other relevant legislative acts, enacted in conformity with these Laws.

2.2. The provisions of the international treaties, to which Mongolia is a party, shall prevail, if such treaties stipulate otherwise than this Law.

Article 3. Legal terms and definitions

3.1. Below terms used in the present law shall be interpreted as follows:

3.1.1. The term “medicines” means substances, which are originated from synthesis or animals, plants or minerals, shaped in certain form and used in a specific dose for prevention of humans, 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. The term “biosubstance” means a product, made of living organisms and their organs or cells and/or produced through laboratory methods for the purpose of treating diseases of people, livestock and animals, diagnosing and preventing them from diseases;

3.1.3. The term “traditional medicine” means a natural product produced through traditional methods and/or under specific production conditions, in accordance with traditional prescription of medicine, containing plant, animal and minerals originated agents and valuable treasure, and used in a specific dose for prevention of humans, livestock or animals from diseases and for diagnosis and treatment of diseases.

3.1.4. The term “diagnosis agents” means a product with specific dosage, size, composition, peculiarities and activity that is used for testing conducted on humans, livestock and animals and samples of environment, in order to prevent humans, livestock and animals from diseases, to diagnose and control process of such diseases;

- 3.1.5. The term “medical device” means an assistant tool that is used for preventing humans, livestock and animals from diseases, diagnosing and treating diseases, nursing and supporting structure and functions of organisms;
- 3.1.6. The term “hallucinogen” means drugs specified in the list of the United Convention on “Hallucinogen” of 1961, which have addictive effects;
- 3.1.7. The term “psychoactive drug” means a substance specified in the list of the Convention on “Psychoactive substances” of 1971, which have psychologically strong effects;
- 3.1.8. The term “orphan drug” means drugs, which are either seldom used nationally or used in treating a rare disease;
- 3.1.9. The term “medicinal raw materials” means pure elements that contain active treatment agents, synthesis and components originated from plants, animals or minerals;
- 3.1.10. The term “supplementary drug substance” means additional components necessary for manufacturing and compounding medicines;
- 3.1.11. The term “batch” means a lot number of medicinal products manufactured through one-off production line;
- 3.1.12. The term “drug evaluation” means an indication to the quality, safety and effects of a medicine, carefully determined through pharmacological and pharmaceutical analysis and clinical experiment;
- 3.1.13. The term “drug registry” means operations of permitting medicines, which have been certified to be eligible for the usage in prevention, diagnosis and treatment, on the basis of chemical, biological, pharmacological analysis and drug evaluation, to be consumed within the territory of Mongolia;
- 3.1.14. The term “list of essential drugs and medical devices” means names of medicines and medical devices approved by the central state administrative bodies in charge of health and agriculture, to be used in first priority for medical care provided to humans, livestock and animals;
- 3.1.15. The term “dispensing drugs” means the same as specified in provision 3.1.17 of the Law on Health;
- 3.1.16. The term “drug prescription” means a document, in which methods to prepare and dispense medicines for particular patients and instructions of how to use the medicines are prescribed by doctors, addressing to pharmacists and pharmaceutical chemists;
- 3.1.17. The term “proper drug use” means correct use of medicines, in accordance with instructions and recommendations of doctors and pharmacists, if necessary;
- 3.1.18. The term “drug side-effect” means an adverse or negative impact that may or actually occur on organisms upon taking drugs in an appropriate dose, for preventing humans, livestock and animals from diseases, and diagnosing and treating diseases;
- 3.1.19. The term “pharmacopoeia monograph” means a collection of standards to be strictly adhered, and which specifies the requirements to be met on medicines, quality indicators and methods of verification of the quality;
- 3.1.20. The term “pharmacopoeia” means a book containing pharmacopoeia monographs;
- 3.1.21. The term “counterfeit drug” means medicinal products manufactured in imitation, using a fake label named after the drug manufacturer for the purpose of illegal gains;
- 3.1.22. The term “medicine and medical device manufacturer” means a legal entity licensed to manufacture final products using medicinal raw materials and supplementary drug substance and in accordance with pharmaceutical technology;

3.1.23. The term “agency for procurement of medicines and medical devices” means a legal entity licensed to carry out activities of supplying pharmacies, health institutions and veterinary hospitals with medicines and medical devices at wholesale prices;

3.1.24. The term “pharmacy” means a legal entity licensed to conduct activities of supplying health institutions, veterinary hospitals and population with medicines and medical devices;

3.1.25. The term “bioactive product” means what is specified in provision 3.1.21 of the Law on Health.

CHAPTER TWO

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

Article 4. National policy on medicines

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

4.2. National policy on medicines shall be directed towards providing health organizations, veterinary hospitals and population with highly effective, quality guaranteed, nationally registered drugs on a continuous basis, ensuring availability and equal accessibility, and promoting 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, central state administrative bodies and local self governments and be implemented through their activities.

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

4.6. The Government shall determine upper limits of prices of medicines included in the list specified in provision 4.5 of this Law.

Article 5. Council of Medicines

5.1. The central state administrative bodies in charge of health and agricultural matters shall have a council (hereinafter referred to as “council of medicines”), which is responsible for medicines for humans and livestock, next to them.

5.2. Council of medicines shall be a non-staff, professional and consultative body to support implementation of the national policy on medicines, and its composition, internal rules and procedures of its members reporting on conflict of interest shall be approved by the Government members in charge of health and agriculture.

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, in the state of emergency or disaster, human and veterinary medicine councils shall have a joint meeting to settle the issue.

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

- 5.5.1. to develop proposals and recommendations in regard to national policy on medicines and submit them to respective central state administrative body;
- 5.5.2. to develop proposals and recommendations on selection of medicines and medical devices to be used in diagnosis and treatment;
- 5.5.3. to settle issues of registering and amending medicines and bioactive products, within the scope of the national policy of medicines;
- 5.5.4. to draw conclusions and give recommendations on issues in regard to manufacturing and importing medicines, medical devices and bioactive products;
- 5.5.5. to provide technical recommendations toward making amendment to the list of the hallucinogen and psychoactive drugs and controlling over use of such drugs;
- 5.5.6. to discuss on findings of pharmacological research and pre-clinical survey conducted on medicines newly developed in Mongolia and draw conclusions on whether the medicines shall be launched to public usage;
- 5.5.7. to make a decision on whether to give permission for conducting a pharmaceutical and clinical analysis on the newly imported medicines, which are registered in Mongolia for the first time.

Article 6. State regulations on manufacturing, imports, exports, trading, distribution and control of medicines, medical devices and bioactive products

6.1. The State shall provide comprehensive and integrated regulations on activities related to manufacturing, imports, exports, trading, distribution and control of medicines, medical devices and bioactive products.

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

- 6.2.1. registration and market research and surveillance on quality and safety of medicines and bioactive products;
- 6.2.2. special license to manufacture, import and sell;
- 6.2.3. imports and exports license, monitoring and regulations;
- 6.2.4. quality assurance;
- 6.2.5. certificate of satisfying the pharmaceutical industry standards of GMP;
- 6.2.6. specialized inspection on pharmacological activities;
- 6.2.7. control over side-effects of drugs;
- 6.2.8. permission and control on publicity of medicines and bioactive products;
- 6.2.9. regulations and control over prices of essential drugs;
- 6.2.10. independent and accurate information about medicines for medical officers and general public.

6.3. The regulations specified in provision 6.2 of this Law shall be executed by the state administrative body responsible for pharmaceutical aspects that operates under the central state administrative body in charge of health matters.

Article 7. Special license

7.1. The state administrative body responsible for pharmaceutical aspects shall issue the special license for manufacturing, importing and selling human medicines, medical devices, hallucinogen and psychoactive drugs and their precursors, and bioactive products.

7.2. The state administrative body responsible for agricultural aspects shall issue the special license for manufacturing, importing and selling medicines and medical devices for livestock.

Article 8. Dispensing medicines

8.1. Medical officers who hold a special license specified in provision 22.3 of the Law on Health shall carry out activities of dispensing medicines.

8.2. Accredited veterinarians who have graduated from an authorized school providing veterinary education shall dispense medicines for animal use.

Article 9. Agencies for procurement of medicines

9.1. The following bodies shall be included in the agencies for procurement of medicines:

- 9.1.1. medicine and medical device manufacturers;
- 9.1.2. medicine and medical device suppliers;
- 9.1.3. pharmacies.

9.2. Relations with regard to the agencies for procurement of medicines mentioned in provision 9.1 of this Law, except obtaining a license to manufacture, sell and import medicines and medical devices, shall be regulated by the Law on Health;

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

Article 10. Principles and common duties of the agency for procurement of medicines

10.1. The agency for procurement of medicines shall adhere to the principle of regular supply of health organizations, veterinary hospitals and population with nationally registered and quality warranted medicines and medical devices.

10.2. The agency for procurement of medicines shall undertake duties specified in Article 15 of the Law on Health.

10.3. The agency for procurement of medicines shall carry out operations of manufacturing, storing and selling medicines and medical devices in conditions that meet pharmacological technology requirements.

10.4. Structure and operations of the agency for procurement of medicines shall satisfy the national standard requirements.

Article 11. Activities prohibited in the agency for procurement of medicines

11.1. Following activities shall be prohibited in the agency for procurement of medicines:

- 11.1.1. to manufacture, import or sell medicines and medical devices without obtaining the special license specified in Article 7 of this Law;
- 11.1.2. to provide with medicines and medical devices, which are not registered in drug registry of Mongolia, of which the quality is not assured and validity expired;
- 11.1.3. to get medicines and medical devices from sources other than medicine supply organizations;
- 11.1.4. to involve any person who's not licensed to dispense medicine in the process of formulating, preparing, verifying, handing out and selling medicines;
- 11.1.5. to sell medicines and medical devices to suppliers of medicines and medical devices and citizens;
- 11.1.6. to involve health professionals in selling medicines and medical devices and offer premiums to them for selling medicines and medical devices for the purpose of increasing revenues and to participate in activities similar thereto;
- 11.1.7. to manufacture, import and sell counterfeit drugs.

11.2. Following activities shall be prohibited in hospitals:

- 11.2.1. to let an unauthorized professional dispense medicines;
- 11.2.2. to violate medicine storage and safety rules.

11.3. It shall be prohibited to store and sell medicines and medical devices in inappropriate places.

CHAPTER THREE MANUFACTURING MEDICINES AND MEDICAL DEVICES

Article 12. Requirements imposed on manufacturing medicines and medical devices

12.1. Following requirements shall be met, in order to manufacture medicines and medical devices:

- 12.1.1. to have technologies, which qualify national and international standard requirements for manufacturing medicines and medical devices;
- 12.1.2. to have premises and equipment that meet hygiene and sanitation standard requirements to suit for storing and manufacturing medicines and medical devices;
- 12.1.3. to have medicinal raw materials registered in the drug registry;
- 12.1.4. to have medicinal raw materials and supplementary substances sent to an accredited laboratory for testing prior to start of producing a particular product;
- 12.1.5. to have professional work force skilled to manage and supervise production process as per technology standards;
- 12.1.6. to ensure conditions for organization of quality control over the production process and final products, and for ensuring the quality at every production batch;
- 12.1.7. to ensure that produced medicines and medical devices, their bundles, boxes, packages and labels meet the required standards.

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

12.3. The state administrative body responsible for pharmaceutical aspects shall issue a quality certificate, which assures the medicine factory qualifies the standard requirements.

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

- 12.4.1. to produce hallucinogens and psychoactive drugs without obtaining a special license;
- 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 use raw materials without quality assurance in production of medicines and medical devices.

Article 13. Compounding medicines in pharmacies

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

13.2. Authorized pharmaceutical chemist shall compound medicines, through pharmaceutical technology, in a pharmacy that qualifies standard requirements of compounding medicines.

CHAPTER FOUR BRINGING MEDICINES AND MEDICAL DEVICES ACROSS THE BORDERS

Article 14. Bringing medicines and medical devices across the borders

14.1. The Government shall determine the border points for bringing medicines and medical devices across.

14.2. Matter of bringing medicines by travelers for personal use across the border shall be regulated under Article 227 of the Customs Law.

Article 15. Importing and exporting medicines and medical devices

15.1. The agency for procurement of medicines shall get the license for importing and exporting medicines and medical devices from the state administrative bodies responsible for pharmaceutical and agricultural aspects.

15.2. The Government members in charge of health and agricultural matters shall approve the procedures of issuing the license specified in provision 15.1 of this Law.

15.3. The import and export license documents shall specify names, types, doses and quantities of medicines and medical devices, names of manufacturers, frontier crossing-point and the date.

15.4. The state administrative bodies responsible for pharmaceutical and agricultural aspects shall issue the import license for the medicines specified in provisions 22.7.1-22.7.9 of this Law.

15.5. In case if it's inevitable to procure non-registered medicines and/or emergency medicines and medical devices from abroad, under the circumstances of disaster or emergency, the license for importing such medicines shall be issued by the decision of the Government members in charge of health and agricultural matters, on the basis of conclusions of the Council of medicines specified in Article 5 of this Law.

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

15.7. Organizations or individuals, receiving medicines and medical devices in the form of foreign aid or donation, shall have a prior consultation with the central state administrative bodies in charge of health and agricultural matters and have a solution on storage, usage and distribution of the medicines and the medical devices.

15.8. Procedures to be followed on the process of receiving and using medicines and medical devices via foreign aid and donation shall be approved by the Government members in charge of health and agricultural matters.

15.9. Followings shall be prohibited in the processes of importing and exporting medicines and medical devices:

15.9.1. bringing medicines and medical devices across other border points except the established ones;

15.9.2. importing medicines and medical devices with a label “Made in Mongolia” and a standard number;

15.9.3. importing medicines, medical devices and bioactive products by legal entities and individuals who don’t have the special license;

15.9.4. bringing medicines and medical devices with more numbers or varying specifications other than the names, types, doses and quantities of the import and export license documents, specified in provision 15.3 of this Law, across the border.

15.10. In accordance with the list approved by the Government, the central state administrative body in charge of health matters may concede a right to directly supply immunization products, medicines and medical devices through imports, on the basis of making a direct contract with internationally recognized medicine manufacturers and suppliers.

CHAPTER FIVE DISTRIBUTION OF MEDICINES

Article 16. Process of selling medicines, medical devices and bioactive products

16.1. Local administrative body shall be responsible for determining location and scope of service of pharmacies, to suit for the local peculiarities, and coordinating the services to provide medicines and medical devices.

16.2. Pharmacies may sell medicines, medical tools and devices, bioactive products, health, cosmetic and sanitary products.

16.3. Soum and bagh doctors may provide service to the population of a catchment area by medicines and medical devices bought from local pharmacies of the jurisdiction.

16.4. Veterinarians may provide service to the people with animals by medicines for animal use and veterinary devices bought from pharmacies.

16.5. Following activities shall be prohibited in pharmacies:

- 16.5.1. to hand out prescription medicines without or with invalid prescription;
- 16.5.2. to give out medicines of animal use and veterinary devices for human use;
- 16.5.3. to sell compulsory vaccination, medicines prescribed to use exclusively in hospitals, and medicines and medical devices received as grant and designed to distribute free of charge;
- 16.5.4. to dispense medicines, except traditional ones, in places other than pharmacies or branch pharmacies.

16.6. Bioactive products shall be sold at pharmacies and food stores, which qualify to standard requirements.

Article 17. Proper use of medicines

17.1. Hospitals shall have a medicine therapy coordination committee, which is responsible for proper use 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 use of medicine and potential side-effects etc.

17.3. When dispensing medicines, the pharmacist shall give advice to clients on usage and storing conditions and proper use of the medicines.

Article 18. Medicine labeling and marking

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

- 18.1.1. trade 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. day, month and year of production and expiration;
- 18.1.7. dispense conditions;
- 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 HIV".

18.4. On the package of blood serum, it shall specify what animal's blood, organ or tissues it was originated from, and on the package of immunization substances the nutrient medium for bacteriological research shall be specified;

18.5. Instructions of how to 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. trade and international name of the medicine;
- 18.5.3. composition, dosage and size of medicine;
- 18.5.4. instructions of usage;
- 18.5.5. contraindications;
- 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. dispense conditions.

CHAPTER SIX CREATION OF NEW MEDICINE

Article 19. Introducing new medicines for public usage

19.1. New medicines manufactured in country shall be introduced for usage upon completion of pre-clinical research and clinical experiment, and registration in the drug 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 pharmaceuticals, toxicology and pharmacology or kinetic and dynamic directions of medicine.

20.2. Pharmaceutical analysis shall determine and verify the following indicators:

- 20.2.1. quality and purification of serving agent;
- 20.2.2. special reaction to recognize drug substance and amount of quantitative component;
- 20.2.3. amount of serving agent estimated by biological method, in case if necessary;
- 20.2.4. stability and solubility of medicine;
- 20.2.5. biodigestivity;
- 20.2.6. relevant trial results.

20.3. Toxicology analysis shall provide the findings below:

- 20.3.1. should it contain pure chemical substance, results of analysis that verify the substance doesn't have a nature of showing negative impact on fetus in womb and genealogy or causing tumor, and findings of pathology and gystology analysis shall be provided;
- 20.3.2. results of experiments carried out on animals and dose and amount of chronic or startling toxicity.

20.4. Kinetic analysis of medicine shall have measured assimilation and secretion time and biodigestivity of the medicine.

20.5. Dynamic analysis of medicine shall have measured 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. drug interactions;

20.5.4. summary of identified effects.

20.6. Findings of the pre-clinical survey of new medicines shall be discussed amongst research institutes, which carry out surveys in the medical field, and academic council of medical universities and colleges, and have conclusions drawn.

Article 21. Clinical experiment

21.1. In the process of conducting clinical experiment, principles of obeying laws, respecting human rights and effective proceeding shall be adhered.

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 such experiment methodologies shall be approved by the academic council specified in provision 20.6 of this Law.

21.3. Within the methodologies specified in provision 21.2 of this Law, it shall reflect methods of clinical experiment, time, coordinator, implementer and partner organizations, number of respondents of the survey, justifications, sampling methods and external auditing.

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

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

21.6. The contract specified in provision 21.5 of this Law shall be approved by the parties involved in the clinical experiment and be verified by independent witnesses.

21.7. The clinical experimenter shall have a special form designed for informing about side-effects that may occur during the experiment and in the event of appearance of serious side-effects he/she shall inform relevant organizations and take necessary actions.

21.8. Unless it is performed differently for the purpose of preventing from risks of potential damages to health of the person to be involved in the experiment, the clinical experiment shall not 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 shall be informed to the Ethics committee specified in provision 21.4 of this Law and the academic council specified in provision 20.6 of this Law respectively.

21.11. Findings of the clinical experiment shall be submitted to the same academic council, which has approved the methodology of the experiment, for discussion and conclusion.

CHAPTER SEVEN

QUALITY AND SAFETY OF MEDICINES AND MEDICAL DEVICES

Article 22. Drug registry

22.1. Medicines, medical devices and bioactive products to be manufactured, imported and sold in Mongolia shall be registered in the national drug registry under all circumstances, except those specified in provision 22.7 of this Law.

22.2. In the event of registering medicines, medical devices and bioactive products in the drug registry, it shall base on request of the manufacturer, results of the analysis, relevant documents and conclusions drawn by the expert on those documents.

22.3. Medicines, medical devices and bioactive products shall be registered in the drug registry by each of their country of origin, manufacturer, type and dosage.

22.4. While registering medicines in the drug registry, it shall determine whether the medicine is to be available exclusively at hospitals and to be dispensed with or without prescription, and verify the instructions of usage.

22.5. Registration of medicines, which have been registered at the internationally recognized drug control institution, shall be processed on a rapid basis.

22.6. Regulations on registration of medicines, medical devices and bioactive products in the national drug registry both on a regular or rapid basis, processing time, estimation of registration fee and its spending shall be approved by the Government members in charge of health and agricultural matters.

22.7. Under the following circumstances the medicines, raw materials and bioactive products shall not be registered in the national drug registry:

22.7.1. samples of medicines and bioactive products for registration;

22.7.2. donation and aid medicines;

22.7.3. medicines procured through international organizations, in accordance with Government agreement;

22.7.4. medicines, for which a trade contract could be made with only one entity, under the reason of protecting an intellectual right, and there is no body to replace the contracted entity;

22.7.5. orphan drugs;

22.7.6. medicines to be used in research and pharmacological and clinical experiments and analysis;

22.7.7. samples of medicines, medical devices and bioactive 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 emergency and the state of disaster;

22.7.11. medicines compounded in pharmacies as per 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 of medicines for human and animal use and of medical devices shall be assured in Mongolia under the relevant laws and regulations.

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

23.3. National pharmacopoeia of Mongolia and procedures of developing, approving and numbering it, forming, structure and internal operational rules of the pharmacopoeia committee shall be approved by the Government members in charge of health and agricultural matters respectively.

23.4. The central state administrative bodies in charge of health and agricultural matters shall have a non-staff pharmacopoeia committee, which is responsible for discussing draft pharmacopoeia monographs and drawing conclusions. Secretary of the pharmacopoeia committee shall be a fulltime employee.

Article 24. Control on hallucinogens and psychoactive drugs

24.1. Relations with regard to issuance, suspension and termination of a license for manufacturing, importing and selling hallucinogens and psychoactive drugs and their precursors shall be regulated by relevant laws.

24.2. List of hallucinogens and psychoactive drugs to be used in Mongolia and regulations on manufacturing, importing, storing and selling those drugs shall be approved by the Government member in charge of health matters.

Article 25. Registration and information of drug side-effects

25.1. The Government member in charge of health matters shall approve the procedure of registration and information of drug side-effects.

CHAPTER EIGHT MEDICINE INFORMATION AND PUBLICITY

Article 26. Information on medicines

26.1. Information on medicines, which are dispensed with prescription or are available exclusively at hospitals, shall be delivered to medical officers only.

26.2. Information on medicines shall be aimed at promoting proper, correct 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. Publicity of medicine

27.1. Medicines and bioactive products dispensed without prescription may be publicized through professional newspapers and public media.

27.2. Content of publicity of medicines and bioactive products shall be reviewed by the state administrative bodies in charge of health and agricultural matters.

27.3. Medicine publicity information shall be based on pharmaceutical specifications and results of clinical experiment, despite the form of the medicine.

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

27.4.1. publicize medicines through mass media for the purpose of importing and selling;

27.4.2. broadcast publicity of medicine targeting children;

27.4.3. publicize medicines available on presentation of a prescription;

27.4.4. disseminate information, which in nature gives an idea to deny doctor's advice, therapy and surgery;

27.4.5. delude the consumers that a particular medicine is rare or important, or the only one, highly active or more effective, compared to other medicines, or safe and free of side-effects and/or new and patented medicine.

27.4.6. publicize incentives for buying medicines and medical devices, or price discounts thereof.

CHAPTER NINE MISCELLANEOUS

Article 28. Involvement of non-governmental organizations in the process of supply of medicine

28.1. Specialized and non-governmental organizations shall undertake the following responsibilities in coordinating the processes of manufacturing, importing, exporting, storing, selling, using and controlling medicines and medical devices:

28.1.1. to perform public monitoring on implementation of the Law on medicines and medical devices and relevant rules and regulations and instructions enacted in conformity with the law, to demand for solution to any violation investigated and to address the issue to an authorized body for settlement;

28.1.2. to give its opinion on issues of expressing interests of agency for procurement of medicine and pharmacists to relevant state administrative body and local government and authorities of administrative units;

28.1.3. to perform some duties of government organizations on a contractual basis;

28.1.4. to organize trainings and advocacy events on professional skills and ethics of pharmacists, jointly with relevant organizations;

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

Article 29. Liabilities imposed on violators of the Law on Medicines and Medical Devices

29.1. Enforcement of this Law shall be monitored by relevant organization and/or official authorized under the legislation.

29.2. In case of violations of the Law on medicines and medical devices not related to manufacturing, importing, exporting, distributing and selling hallucinogens and psychoactive

drugs and counterfeit drugs, and in the absence of liability for criminal charges, the offender shall be imposed the following administrative penalties by an authorized state inspector or a judge:

29.2.1. in case of violations of articles 8 and 10 of this Law, an official shall be punished by a fine of MNT 100000-200000, a pharmacy by a fine of MNT 200000-300000, and a medicine manufacturer and an agency for procurement of medicine and medical device by a fine of MNT 300000- 500000, and the license shall be terminated in case of repeated violations;

29.2.2. in case of violation of article 11 of this Law, medicines, medical devices and illegally earned income shall be confiscated, and a citizen shall be punished by a fine of MNT 150000-250000, an official by a fine of MNT 200000-300000, a legal entity by a fine of MNT 300000-500000, and the license for dispensing medicines and carrying out professional activities shall be terminated in case of repeated violations;

29.2.3. in case of violation of provision 12.4.1 of this Law, medicines and illegally earned income shall be confiscated, and a citizen shall be punished by a fine of MNT 200000-300000, an official by a fine of MNT 400000-500000, a legal entity by a fine of MNT 1500000-3000000, the license for dispensing medicines and carrying out professional activities shall be terminated for a period of up to 5 years;

29.2.4. in case of violations of provisions 12.1, 12.2, 12.4.2, 12.4.3 and 19.1 of this Law, the manufactured products shall be confiscated for transforming into state own or abolished, if sold, the illegally earned income shall be confiscated and transformed into state revenue, and an offending official shall be punished by a fine of MNT 200000-300000 and a legal entity punished by a fine of MNT 500000-700000 and/or its license to manufacture medicines and medical devices shall be suspended for a period of 6 months to 1.5 years;

29.2.5. in case of violations of article 13 and provisions 16.2-16.6 of this Law, a citizen shall be punished by a fine of MNT 100000-150000, an official by a fine of MNT 150000-200000 and a legal entity punished by a fine of MNT 200000-250000;

29.2.6. in case of violations of provisions 15.1, 15.6, 15.7 and 15.9 of this Law, a citizen and an official shall be punished by a fine of MNT 150000-250000 and a legal entity punished by a fine of MNT 250000-300000 and medicines, medical devices shall be confiscated for transforming into state own or abolished, if sold, the illegally earned income shall be confiscated and transformed into state revenue;

29.2.7. in case of violation of provision 16.1 of this Law, an official shall be punished by a fine of MNT 150000-200000;

29.2.8. citizens who violate provisions 17.2 and 17.3 of this Law shall be punished by a fine of MNT 50000-100000, an official by a fine of MNT 100000-150000 and a legal entity punished by a fine of MNT 150000-200000;

29.2.9. in case of violations of article 18 and provisions 22.1 and 23.1, an official shall be punished by a fine of MNT 200000-300000 and a legal entity punished by a fine of MNT 300000-500000;

29.2.10. in case of violations of articles 20 and 21, a citizen shall be punished by a fine of MNT 100000-150000, an official by a fine of MNT 150000-200000 and a legal entity punished by a fine of MNT 250000-500000;

29.2.11. in case of violations of articles 26 and 27, a citizen shall be punished by a fine of MNT 200000-300000, an official by a fine of MNT 300000-500000 and a legal entity punished by a fine of MNT 1000000-1500000.

29.3. If violations determined in relation to publicizing and using hallucinogens and psychoactive drugs are considered to be a criminal case by nature, the case shall be submitted to an authorized body for further investigation.

Article 30. Entry of the Law into force

30.1. Article 6 of this Law shall enter into force and be conformed starting from the date of 01 July 2011.

**CHAIRMAN OF THE MONGOLIAN STATE IKH KHURAL
D. DEMBEREL**

LAW OF MONGOLIA

Date: 10 June 2010

Ulaanbaatar City

**REPEAL OF THE LAW
ON MEDICINES AND MEDICAL DEVICES**

Provision 1. The Law on Medicines and Medical Devices, which was endorsed on the date of 7 May 1998, shall be considered as repealed.

Provision 2. The present Law shall be conformed starting from the effective date of the Law on Medicines and Medical Devices /Revised version/.

**CHAIRMAN OF THE MONGOLIAN STATE IKH KHURAL
D. DEMBEREL**