LAW OF MONGOLIA

Ulaanbaatar, 7 May 1998

DRUGS ACT

CHAPTER ONE

GENERAL PROVISIONS

Article 1. The Purpose of the Law

The purpose of the present law is to regulate relations in regard with manufacturing, importing, storing, retailing, distributing, utilizing and monitoring of drugs and bio-propagate (hereafter refers as the drug) for human being and livestock medicine. /Amended by the Law on 19 April 2002/

Article 2. The Legislation on Drugs

2.1. The legislation on drugs 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. If an international treaty, to which Mongolia is a party, is inconsistent with this Law, then the provisions of the international treaty shall prevail.

Article 3. Definitions of the Law

3.1. The following terms used in this Law shall be understood in the below mentioned meanings:

3.1.1.”Drug” means a substance used in a specific dose, which is for treating illness of humans, livestock or animals, diagnosing them and preventing them from diseases, proven by pharmaceutical and clinical analyses or experiments and which is synthetic or originated from animals, plants or minerals;

3.1.2. “Biopreparate” means aproduct, made by living organisms and their organs or cells under specific production conditions for the purpose of treating ill people and animals, diagnosing and preventing them from disease;

3.1.3. “Drug raw materials” means biologically active substances that are used for producing drugs and that originates from pure elements, or has synthetic, plants, animals origin;

3.1.4. The provision has become invalid by the Law on 19 April 2002

3.1.5. “Drug registry” means a list of drugs, which are approved to be used in treatment and diagnosis, in regard to the chemical, biological, pharmaceutical analysis or experiment and drug evaluation;

3.1.6. “Drug evaluation” means an expression on quality, safety and effectiveness of drugs, which are clearly identified in accordance with their pharmacology, pharmaceutics and clinical analysis;

3.1.7. “List of essential the drugs and medical “ equipment “ means names of the drugs, approved by the State Central Administrative Body which is primarily used in diagnosis, treatment and prevention of population ill health through health aid; Amended by the Law on 19 April 2002

3.1.8. “Pharmacopeia” means list of essential standards, which contains the methods of preparing drugs and examining the drug’s quality;

3.1.9. “Dispensing the drugs” means what is provided under the Article 3.1.7 of the Health Act;

3.1.10. “Spurious drug” means a drug whose element, dose, content and quality is altered from the official document, attached to the drug;

3.1.11. “Counterfeit drug” means a drug, which is pack-aged or similarly packaged by using boxes, packages and labels of authorized factory;

3.1.12. “Narcotic and psychotropic drug” means drugs and biopreparations, provided in the list of the International convention, which have addictive and other psychologically strong effects;

3.1.13. “Series” indicates patterns of a onetime pack-aged production of certain drug;

3.1.14. “Pharmacy” means professional organization, which is licensed to provide health organizations, veterinary hospitals and people with qualified drugs and medical equipment;

3.1.15. “Branch of a pharmacy” means a branch, which is established by the parent pharmacy which the purpose of selling drugs and medical equipment without any prescriptions.

CHAPTER 2

Article 4. State Policy Regarding Drugs

4.1. The National Drugs Policy is an integrated part of the Comprehensive Policy on Mongolian National Security.

4.2. The National Drugs Policy shall be directed to provide health organizations, veterinary hospitals and people with highly effective, qualified and registered drugs and medical equipment continually, sufficiently and equally, and to introduce appropriate usage of drugs. Amended by the Law on 19 April 2002

4.3. State Central Administrative Body hereinafter referred to as “relevant State Central Administrative Body”, handling human and livestock health matters, shall approve the list of the essential drugs. Amended by the Law on 19 April 2002

4.4. The National Drugs Policy shall be reflected in the policy of the Government, State Central and Local Administrative Bodies and implemented through their activities.

Article 5. National Drug Council is non-staff, professional and consultative organization that supports implementation of The National Drugs Policy, and its components and rules shall be approved by the Government.

5.2. The National Drug Council may have a sub-council, in charge of drug matters for humans and livestock.

5.3. The National Drug Council shall exercise the following powers:

5.3.1. To develop proposal and recommendations on is-sues of The National Drug Policy and submit them to the relevant State Central Administrative Body;

5.3.2. to develop proposals for amending the list of essential drugs;

5.3.3. to make conclusions and recommendations on production and import of the drugs; Amended by the Law on 19 April 2002

5.3.4. To make professional recommendations on altering the list of and controlling the usage of narcotics and psychotropic drugs;

5.3.5. To make conclusions on national standards of the drugs and provisions of the pharmacopeias; Amended by the Law on 19 April 2002

5.3.6. To approve making pharmacological, pharmaceutical and clinical analyses on new drugs, discuss their results and to make final decisions on whether to put them into practice or not.

Article 6. Drug Procurement Organization

6.1. Drug procurement organization shall consist of the following organizations:

6.1.1. The Drug industries;

6.1.2. Drug procurement organizations;

6.1.3. Pharmacies and their branches;

6.2. Relations with the drug procurement organizations, provided under the Article 6.1 of this Law other than to gel the permission to produce retail and import the grugs shall be regulated in accordance with the Articles 12-21 of the Health Act.

6.3. The relevant State Central Administrative Body shall organize activities to issue permission on the import and refail of the drugs for human beings and livestock, and to assure quality of drugs and medical equipment in accordance with the legislation. Amended by the Law on 30 November 2001, 19 April 2002

Article 7. Principles and Common Duties of Drug Procure

7.1. The principles of the drug procurement organization shall be to provide, equitably, health organizations, veterinary hospitals and population with drugs and medical equipment, which are registered in the State Drug Registry and with guaranteed quality.

7.2. Drug procurement organization shall the following common duties apart from those, provided under the Article 15 of the

Health Act:

7.2.1. Tis provision by the law on 19 April 2002

7.2.2. To operate its activities under conditions that meets the requirements of drug manufacturing storage and transportation.

7.2.3. To provide health organizations, veterinary hospitals and population with information on drugs, and to coordinate activities on resources, supplying and selling of the drugs;

7.3. Drug procurement organization shall have wholesale trade of the drugs to the health organizations, veterinary hospitals and pharmacies.

7.4. Pharmacies and their branches shall have retail trade of the drugs to health organizations, veterinary hospitals and population.

Article 8. Import and Export of the Drugs

8.1. Import and export of drugs, which are registered in the State Drug Registry, shall be permitted.

8.2. Permission for drug import and export shall be issued to the drug procurement organization in accordance with regulations, approved by the relevant State Central Administrative Body.

8.3. It is prohibited to import and export drugs without permission of the relevant body.

8.4. Any organizations or individuals shall negotiate with the relevant State Central Administrative Body in advance in case of importing drugs through assistance or

donation, and decide issues on the imported drug quality, storage, consumption and distribution.

8.5. The license holder of drug importing must have a contract with a foreign drug manufacturing entity.

8.6. Titles, scopes of the drugs and date to cross the state border and name of the entering border post shall be mentioned in the special permission. Amended by the Law on 30 November 2001

8.7. The drug which are use to treat rear diseases with relatively small portion shall be imported without state registration.

The government cabinet member in charge of health matters shall approve the list of the above mentioned drugs. Amended by the Law on 19 April 2002/

Article 9. Passing Drugs through the State Border

9.1. The Government shall determine the border posts in which drugs can be passed through.

9.2. It is prohibited to pass drugs through border posts, other than those approved.

9.3. Transportation the drugs for personal consumption of passenger across the state boundaries shall be regulated by the para-graph of article 32 of the Law on the Customs. Amended by the Law on 19 April 2002/

Article 10. Engaging In the Production of the Drugs

10.1. The license to manufacture the drugs for livestock shall be issued by the state central administrative organization in charge of agriculture and the license for manufacturing the drugs for human by the state central administrative organization in charge of health matters relatively. Amended by the Law on 19 April 2002/

10.2. The following basic requirements shall be met for engaging in the production of the drugs:

10.2.1. To have technology that meet with the national and international standards for producing drugs and medical equipment;

10.2.2. To have particular buildings and equipment, which meet with hygienic and sanitation standards for storing and producing drugs and medical equipment;

10.2.3. To acquire quality assurance of its products from the authorized organization in accordance with the relevant legislation and to make drugs registered in the State Drug Registry;

10.2.4. To have professional workers who are specialized in the production line according to the technology;

10.2.5. To organize monitoring activities on the processing and final products, and to facilitate making qualitative guarantees at every step in production;

10.2.6. To make a produced drug box, bundle, package and label weet with the standard requirements;

10.2.7. To make their products meet with quality requirements;

10.3. To follow specific regulations during the production, transportation and storage of oxygen and nitrogen, which are used for treatment.

10.4. The relevant State Central Administrative Bodies shall jointly approve the specific regulation, which is provided under article 10.3 of this Law.

Article 11. Prohibitions for Engaging In the Production of Medical

11.1. The following activities shall be prohibited in the production of the dugs:

11.1.1. To produce drugs which are not registered in the State Drug Registry;

11.1.2. To produce spurious and counterfeit drugs;

11.1.3. To produce narcotics and psychotropic drugs without special permission;

11.1.4. To produce drugs for human together with drugs for animal in the same production line.

11.1.5. To produce drugs and medical equipment by using raw and other materials, which do not have quality assurance.

Article 12. Dispensing the Drugs

12.1. A person who has the license mentioned in article 22.3 of the Health Act shall dispense the drugs.

12.2. It is prohibited to dispense, prepare, monitor and retail the drugs by anybody except pharmacists, druggists and veterinaries who have the license.

12.3. The veterinaries who graduated and granted the accreditation to practice by the profession shall dispense the drugs. Amended by the Law on 19 April 2002/

Article 13. Pharmacy

13.1. Activities to provide health organizations, veterinary hospitals and population with drugs and medical equipment shall be operated though pharmacies and their branches.

13.2. The State Central Administrative Body handling health issues shall approve and enforce the list of drugs for sale with and without a prescription.

13.3. The Local Administrative Body shall have the responsibilities to place pharmacies at suitable locations and to coordinate activities on drugs and medical equipment service.

13.4. Persons and veterinarians in “bag” administrative units may get the drugs from pharmacies or their branches and serve the population.

13.5. A pharmacy and its branches may retail medical equipments and tools, sanitary substances personal hygene products, medical diet products, nutrition for dislдren and cosmetic products. Amended by the Law on 19 April 2002

Article 14. Prohibitions on the Activities of Article

Pharmacies and Its Branches Its Branches Its Branches Its Branches Its Branches

14.1. Prohibitions on the activities of pharmacies and their branches are as follows:

14.1.1. To serve drugs and medical equipment, which are not registered in the State Drug Registry and do not have quality assurance;

14.1.2. To sell drugs for livestock to people;

14.1.3. To dispense drugs without prescription, which are sold by prescription;

14.1.4. To dispense drugs and medical equipment, excluding traditional medicine, in a place other than a pharmacy and its branches;

14.1.5. To dispense drugs by an unauthorized person;

14.1.6. To retail the drugs which were prescribed to use exclusively in the hospitals or the drugs supplied by grants with purpose to dispense free of charge. Amended by the Law on 19 April 2002

CHAPTER THREE

STATE DRUG REGISTRY, QUALITY ASSURANCE

Article 15. State Drug Registry

15.1. Drugs, which are produced and imported by authorized organizations, shall be registered in the State Drug Registry.

15.2. The relevant State Central Administrative Body shall approve and enforce the Regulation on Registering Drugs in the State Drug Registry.

Article 16. Quality Assurance and Supervision of the Drugs Article

16.1. Quality assurance on drugs for human and livestock in Mongolia shall be made in accordance with the relevant legislation.

16.2. Quality assurance test of the drugs shall be based on the state standards, pharmacopeias and other normative-technical documents.

16.3. The relevant State Central and Local Administrative Bodies and Professional Inspection Agencies shall supervise activities on producing, importing, supplying, transporting, distributing, using, informing and advertising the drugs in accordance with the legisla-tion.

Article 16'. The monitoring of the narcotic and psychotropic drugs.

16'.1. The list of the narcotic and psychotropic drugs and the procedure to use them in Mongolia shall be approved by the Government Cabinet member in charge of health matters of Mongolia.

16'.2. The state central administrative organization in charge of health matters shall issue licenses for manufacturing and trading the narcotic and psychotropic drugs and their preparatory elements.

16'.3. The procedure to issue, suspend and invalidate the li-cense mentioned in article 16'.2 of the present law shall be regulated by the provisions of the Law on Issuing Special Licenses to Business Entities. /Amended by the Law on 19 April 2002/

Article 17. Drug Information and Advertisement Article

17.1. Drug information shall be true, correct and independent from producers and suppliers.

17.2. The professional organization shall organize and implement activities to provide health organizations, veterinary hospitals and people with information on drugs after having permission from the relevant State Central Administrative Body.

17.3. The following things are prohibited in drug advertisement:

17.3.1. To advertise drugs that is issued by prescription in order to sell them;

17.3.2. To advertise drugs that is issued by prescription in order to sell them;

17.3.3. To advertise narcotics and psychotropic drugs through mass media;

17.3.4. To mislead in advertising the drug quality;

17.3.5. To advertise drugs that is used only in hospitals with the purpose of selling them in pharmacies.

Article 18. Producing New Drugs Raw Materials

18.1. The state central administrative responsible organization shall establish and enforce the regulations to register newly created drugs and medical products in Mongolia and evaluate them, certify the quality of them in accordance with the legislation. /Amended by the Law on 19 April 2002/

18.2. New drugs produced in Mongolia and foreign drugs that are to be used for the first time shall be sold after making pharmaceutical analysis and upon registration.

18.3. To Issue on licensing new drugs raw materials shall be regulated in accordance with the relevant legislation.

18.4. In the case of adverse effects caused by using new the drugs and drugs raw materials, the guilty person shall face penalties in accordance with the relevant legislation.

CHAPTER FOUR

MISCELLANEOUS

Article 19. Liability for Offenders of Legislation on Drugs

19.1. In case of a violation of the Legislation on Drugs, other than importing and exporting narcotics and psychotropic drugs, the state inspector or judge who has special authorization in accordance with Legislation, shall impose the following administrative penalties on the guilty person for the offence, if the offence is not punishable under the Penal Code.

19.1.1. In case of the violation of the Article 7.2.2 of this Law, the organization shall be imposed a fine of MNT 100,000- official translation 200,000 and illegal revenues shall be confiscated. If it is repeated again, the permission to operate shall be cancelled;
19.1.2. In case of the violation of the Article 8.1 and 8.3 of this Law, drugs and illegal revenues shall be confiscated and citi-zens, official and business entities shall be imposed fines of MNT 30,000-40,000, 40,000-60,000 and 150,000-250,000 respectively;

19.1.3. In case of the violation of the Article 8.4 and 8.5 of this Law, citizens, officials and business entities shall be imposed fines of MNT 10,000-20,000, 20,000-30,000 and 100,000- 150,000 respectively;

19.1.4. In case of the violation of the Article 9.2 of this Law, illegal revenues shall be confiscated and the offending citizen, official and business entities shall be imposed fines of MNT 25,000-30,000, 40,000-50,000 and 150,000-200,000 respectively;

19.1.5. In case of the violation of the Article 10.1, 10.2 and 11 of this Law, produced goods shall be confiscated and put into state property /income or eliminated. Legal revenues shall be confiscated and put into state income/ revenue. If the goods are sold

the offending organization shall be imposed a fine of MNT 150,000- 200,000 or the permission to engage in the production of drugs and medical equipments shall be cancelled for the period of 6 months to 1 year and 6 months.

19.1.6. In case of the violation of the Article 14 of this Law, officials and business entities shall be imposed a fine of MNT 10,000-15,000 and 100,000-150,000 respectively and the permission to engage in the Pharmacy business shall be cancelled if it is repeated again;

19.1.7. In case of the violation of the Article 17.3 of this Law, citizen, official and business entities shall be imposed fines of MNT 5,000-20,000, 10,000-25,000 and 100,000-150,000 respectively;

19.2. If any violation related to the advertisement and usage of narcotics and psychotropic drugs is considered as a crime, then it shall be transferred to the authorized organization.

Article 20. Promulgation of the Law

Article 20. This Law shall come into force from 1 July 1998. Chairman of the State Great

Hural of Mongolia R. Gonchigdorji