REPUBLIC OF LITHUANIA REPUBLIC OF LITHUANIA LAW ON THE CONTROL OF NARCOTIC AND PSYCHOTROPIC SUBSTANCES

January 8, 1998. No. VIII-602 Vilnius

CHAPTER ONE

GENERAL PROVISIONS

ARTICLE 1. Objective of the Law

This Law shall establish the principles of the classification of narcotic and psychotropic substances, for lawful circulation of these substances when they are used for health care, veterinary and scientific purposes and circulation control, in accordance with the requirements of international agreements.

ARTICLE 2. The Basic Definitions in This Law

- 1. Narcotic and Psychotropic Substances means the biological and synthetic substances included in the lists of controlled substances, approved by the Ministry of Health, the harmful effects or misuse whereof, give rise to serious deterioration of human health, marked by mental and physical dependence on them, or pose danger to human health.
- 2. **Preparation** means a drug product of any physical form, which has been accorded a certain drug form included in which can be found therapeutic doses of one or more narcotic or psychotropic drug substances.
- 3. **Lawful circulation** production, processing, acquisition, wholesale or retail trade, keeping, internal transportation, import or export of narcotic or psychotropic substances in seeking to utilise these for health care, veterinary, law protection, science and science instruction purposes without violating any laws, and requirements of other legal acts.
- 4. **License (permit)** means a document, issued according to the procedure established by the Government of the Republic of Lithuania and granting the right to acquire, keep, transport internally within the state, manufacture, process, import and export and also, use in wholesale or retail trade.
- 5. **Import** means the bringing in of narcotic and psychotropic substances into the customs area of the Republic of Lithuania.
- 6. **Export** means the transporting out of the customs area of the Republic of Lithuania of narcotic and psychotropic substances.
- 7. **Transit** means the transporting of narcotic and psychotropic substances across the customs territory of the Republic of Lithuania under, customs supervision..

ARTICLE 3. The Names of Narcotic and Psychotropic Substances

Narcotic and psychotropic substances shall be included in the lists of controlled substances, approved by the Ministry of Health, under their international names, and in the absence thereof, under their chemical names. Included also, may be another common use name, which is more familiar to users.

ARTICLE 4. The Principles in Classification of Narcotic and Psychotropic Substances

- 1. Narcotic and psychotropic substances shall be classified according to their harmful effect upon human health, when they are being misused, and according to whether they can be used for health care purposes. Based upon Republic of Lithuania international agreements, the Ministry of Health shall classify and include narcotic and psychotropic substances in the lists according to the control regimen applied to them.
 - 2. Three lists of narcotic and psychotropic substances shall be compiled:
- 1) the first list shall be comprised of plants, narcotic and psychotropic substances the use whereof is prohibited in health care, because they bring about harmful consequences to human health, when they are being misused (further List I);
- 2) the second list shall be comprised of plants, narcotic and psychotropic substances, used for health care purposes, which are very dangerous to human health due to the harmful consequences arising when these substances are being misused (further List II);
- 3) the third list shall be comprised of plants and psychotropic substances used for health care purposes, which are dangerous to human health due to the harmful consequences of the misuse of these substances. (further List III).

ARTICLE 5. The Classification of Preparations

Preparations shall be classified according to the narcotic and psychotropic substances present in them. Preparations shall be applied the control regimen of the substances present in them. If different control regimens are applied to substances present there, the preparation shall be applied that control regimen, which corresponds to the strictest control regimen applied to a substance within its composition.

ARTICLE 6. Advertisement of Narcotic and Psychotropic Substances

- 1. Advertisement of narcotic and psychotropic substances shall be prohibited.
- 2. Information regarding drugs that are narcotic and psychotropic substances shall be provided to health care, pharmaceutical and veterinary specialists and consumers, according to the procedure established by the Ministry of Health.

CHAPTER TWO

THE REQUIREMENTS OF ACTIVITY INVOLVING THE SUBSTANCES INCLUDED IN LIST I

ARTICLE 7. Plants That Are Prohibited

It shall be prohibited to grow opium and corn poppies, cannabis and coca trees in Republic of Lithuania territory.

ARTICLE 8. The Lawful Circulation of the Substances Included in the List

- 1. It shall be prohibited to use for health care purposes, the substances included in the list.
- 2. It shall be prohibited to acquire, keep, transport within state territory, manufacture, process, import, export, use for scientific experimentation, the substances included in List I, without a license (permit) issued in accordance with the procedure established by the Republic of Lithuania Government.
- 3. The Ministry of Health shall issue licenses according to Government established procedure, to acquire, keep, transport within State territory, manufacture, process, import, export and use for scientific experiments or law protection institutions, the required minimal amounts of the substances included in List I.
- 4. The Ministry of Health shall establish the procedure of the lawful use for scientific purposes, of the substances included in List I.

CHAPTER III

THE REQUIREMENTS OF ACTIVITY INVOLVING THE SUBSTANCES INCLUDED IN LISTS II AND III

ARTICLE 9. General Requirements of the Lawful Use of Substances Included in Lists II and III

The activities involving the substances included in Lists II and III shall be applied the circulation requirements of other substances and preparations employed for health care and veterinary purposes, provided this Law shall not establish otherwise.

ARTICLE 10. The licensing of Activities Involving the Substances Included in Lists II or III

- 1. The substances included in Lists II and III may only be manufactured, imported into the Republic of Lithuania, exported from the Republic of Lithuania, engaged in wholesale or retail trade thereof in the Republic of Lithuania, by legal persons prepared for that activity, individual enterprises, having a licence for that activity, and only within the buildings and premises for the use of which a special license has been issued.
- 2. Issuance of licenses for the production, import into the Republic of Lithuania and export from the Republic of Lithuania of the substances included in Lists II and III and engaging in wholesale and retail trade thereof, interruption of the validity of these licenses, cancellation of interruption, procedure and conditions of re-

registration and procedure of issuing licenses for the use of buildings or premises shall be established by the licensing regulations. The Government of the Republic of Lithuania shall confirm the regulations and establish the conditions of licensed activity.

- 3. Legal persons and individual enterprises may acquire and keep the narcotic and psychotropic substances included in Lists II and III, if they possess a licence to engage in pharmaceutical activity and a license for this activity, issued in accordance with the procedure established by the Government of the Republic of Lithuania.
- 4. The Ministry of Health or an institution authorised by it, shall issue the licenses to manufacture, import into the Republic of Lithuania and export from the Republic of Lithuania the substances included in Lists II and III and engage in wholesale and retail trade thereof, interrupt the validity of these licenses, annul the validity and control licensed activity.
- 5. A legal person or an individual enterprise may appeal to the Ministry of Health the decision regarding non issuance of license, interruption of its validity or annulment thereof, within a period of 30 calendar days. The Ministry shall examine the appeal within 30 days. A legal person or individual enterprise, if they are dissatisfied with the decision of the Ministry of Health, or if the Ministry of Health has failed to examine the appeal within the stipulated term, shall have the right to appeal to court.
- 6. Having annulled the validity of a license, the remnants of the substances included on Lists II and III, held by a legal person or individual enterprise, shall be transferred to persons, holding a license to engage in activity with narcotic and psychotropic substances.

ARTICLE 11. Production of the Substances Included in Lists II and III

Licenses for production of the substances included in Lists I and II shall be issued only upon presentation of all of the documents regarding production and technological extraction processes, the projected amounts of production of the intermediate substances and composition thereof. The manufacturer must ensure that the production amounts indicated in the licence will not be exceeded.

ARTICLE 12. Trade in Substances Included in Lists II and III

- 1. Trade in substances included in Lists II and III shall be possible if they are properly packaged and marked.
- 2. The Ministry of Health shall determine the specific requirements of the packaging and marking of the substances included in Lists II and III.
- 3. It shall be prohibited to trade in substances included in Lists II and III, packed in packaging that does not have the written names of substances, or if the markings appearing on the packaging are inaccurate.
- 4. The names of substances, their amount, manner of use and warning concerning the required safety measures, must be indicated on the label.

- 5. It shall be prohibited to sell substances included in Lists II and III, if due to unsuitable marking or unsuitable label (illegible inscription, damaged label etc.), because there are no accompanying documents or these are incomplete, it is possible to misunderstand the danger posed to health or their prescribed use (manner of use).
- 6. Persons engaged in wholesale marketing of the substances included in Lists II and III must register all of the sales facts in a special journal of a Ministry of Health approved form.
- 7. Persons engaged in the wholesale marketing of substances included in Lists II and III must register, in accordance with the procedure established by the Ministry of Health, those who shall acquire these substances (natural person's surname, first name, legal person's or individual enterprise's name, code, address), while the persons acquiring these, must submit the stipulated documents of registration.
- 8. The persons engaged in the wholesale marketing of the substances included in Lists II and III, must keep the documents according to which they have sold these substances, according to the procedure and terms stipulated by the Ministry of Health.
- 9. Persons engaged in the wholesale marketing of the substances included in Lists II and III must submit the data of sales fact registration to an institution authorised by the Ministry of Health. The Ministry of Health or an institution authorised by it and law protection institutions shall have the right at any time to request that persons engaged in wholesale marketing of the substances included on Lists II and III, submit data regarding the sale of these materials.
- 10. It shall be prohibited to sell the substances included in Lists II and III to persons not having a license for activity linked with narcotic and psychotropic substances.

ARTICLE 13. The Register

- 1. An institution authorised by the Ministry of Health shall administer the register of licenses which have been issued for production, import into the Republic of Lithuania, export from the Republic of Lithuania, engage in wholesale and retail marketing of substances included in Lists II and III and record the data on interruption and annulment of the validity of licenses.
- 2. An institution authorised by the Ministry of Health shall annually establish the Republic of Lithuania's need of the substances included in Lists II and III, administer the records of the production, import, export, wholesale and retail marketing, submit according to the established procedure, the requirement and lawful use of narcotic and psychotropic substances namely, accounting to the United Nations International Committee on Control of Narcotics.

ARTICLE 14. Conditions of Import, Export, and Transit of the Substances Included in Lists II and III

1. The Government of the Republic of Lithuania guided by the international agreements of the Republic of Lithuania shall establish the conditions and implementation of import into the Republic of Lithuania, export from the Republic of

Lithuania and transit across the territory of Lithuania of the substances included in Lists II and III.

- 2. It shall be prohibited to store the substances included in Lists II and III in customs warehouses as well as temporarily keep them in import or export terminals. The customs procedures applied to temporary import, temporary import for processing, and processing under customs supervision may not be applied to these substances.
- 3. Special permission of the Ministry of Health or its authorised institution shall be required in every individual instance of import or export of the substances included in Lists II and III.
- 4. Should the requirements of this Law or other legal acts, be violated in the course of importing, exporting or while in transit, the substances included in Lists II and III, the customs service shall apply all of the measures stipulated by laws, including interception and confiscation of these substances.

ARTICLE 15. Transportation Within the Territory of the Republic of Lithuania of Substances Included in Lists II and III

Persons, transporting the substances included in Lists II and III, within the territory of the Republic of Lithuania, must have accompanying freight documents and ensure the safety of said substances. Should a suspicion arise regarding possible unlawful use of substances included in Lists II and III, the person transporting the freight must bring this to the immediate attention of law protection institutions.

ARTICLE 16. Sending of Substances Included in Lists II and III

It shall be prohibited to send through the post, substances included in Lists II and III.

CHAPTER FOUR

ACQUISITION AND KEEPING OF SUBSTANCES INCLUDED IN LISTS II AND III

ARTICLE 17. Procedure of Ordering, Acquisition and Distribution of Substances Included in Lists II and III in Pharmacies and Health Care Institutions

- 1. The substances included in Lists II and III may be ordered for health care and veterinary science purposes only. The Ministry of Health shall establish the procedure of ordering (prescribing) such medicines.
- 2. A person having submitted a valid prescription for health care or veterinary purposes shall have the right to acquire at pharmacies the prepared substances included in Lists II and III.
- 3. The Ministry of Health together with the State Veterinary Service shall establish the procedure for acquisition and distribution at pharmacies, of substances included on Lists II and III, for health care or veterinary purposes.

- 4. The Ministry of Health shall establish the procedure of acquisition, prescription, issuance and record keeping of the substances, at health care institutions,
- 5. The substances included in Lists II and III shall be distributed for medicinal and veterinary purposes by those having the right to this activity:
 - 1) pharmaceutical specialists in retail marketing enterprises (pharmacies);
- 2) pharmaceutical specialists in wholesale marketing and manufacturing enterprises;
 - 3) specialists in health care institutions;
 - 4) Veterinary and pharmaceutical specialists in veterinary service institutions.
- 6. The requirements of health care and veterinary specialists, having the right to acquire, distribute the substances included on Lists II and III to perform their professional duties shall be established by the Ministry of Health along with the State Veterinary Service.

ARTICLE 18. Prescriptions of Substances Included in Lists II and III

- 1. Materials included in List II shall be prescribed on special prescription blanks. The Ministry of Health shall establish the form of special prescription blanks, their completion, record keeping and storing procedure.
- 2. Materials included in List III shall be prescribed in accordance with the procedure established by the Ministry of Health.
- 3. The sale of substances included in Lists II and III, according to an inappropriately completed prescription shall be prohibited.

ARTICLE 19. Medical First Aid Kits on International Travel Transport Means

The substances included in Lists II and III which are contained in medical kits on international transport means for rendering necessary medical assistance, shall be stored according to the procedure established by the Ministry of Health.

ARTICLE 20. Passenger Rights

Passengers travelling across the Lithuanian border, may carry with them for personal consumption in connection with health care, accompanied by copies of the medicines prescribed for them, a supply of the substances included on List II, to cover a course of treatment of 7 days or less and of substances included on List III, to cover a treatment course of 30 days or less.

ARTICLE 21. Keeping of Substances Included on Lists II and III

- 1. The Ministries of Internal Affairs and Health shall establish the requirements of the premises where substances included in Lists II and III, shall be manufactured and the wholesale and retail trade shall be engaged in.
- 2. The Ministry of Health shall establish the reserve quantities of substances included in Lists II and III, the procedure for keeping them in enterprises (pharmacies) for retail trade of medicines, enterprises for the wholesale trade in medicines,

enterprises of medicine production, institutions of health care and veterinary service, laboratories of medicine control and scientific institutions.

- 3. A person who has been prescribed for the care of his health, some of the substances included in Lists II and III, may keep no greater amount of these materials, than it was possible to acquire at the pharmacy, according to the prescription.
- 4.Persons who are keeping some substances included on Lists II and III, must protect them from any influence, which may alter their characteristics. The safety of these materials must be ensured totally and their packaging may not be damaged.

CHAPTER FIVE

RECORDS AND CONTROL OF NARCOTIC AND PSYCHOTROPIC SUBSTANCE CIRCULATION

ARTICLE 22. The Entities of Record Administration and Control of Narcotic and Psychotropic Substances Implementation

An institution authorised by the Ministry of Health Protection and other institutions authorised by the Government shall administer the records and control of narcotic and psychotropic substance circulation.

ARTICLE 23. The Record-Keeping of the Circulation of Narcotic and Psychotropic Materials

- 1. Guided by international agreements of the Republic of Lithuania the Ministry of Health, shall establish the procedure of record-keeping of narcotic and psychotropic substance circulation.
- 2. The procedure for maintaining the records of narcotic and psychotropic substance inventorying and accounting of material values and the procedure of creating the balance of retail and wholesale enterprises and production enterprises shall be established by the Ministry of Health, guided by the provisions of the Law on the Principles of Accounting.

Article 24. Records of Narcotic and Psychotropic Substance Circulation

An institution authorised by the Ministry of Health shall administer the records of narcotic and psychotropic substance circulation in the Republic of Lithuania and submit the accounting to the International Committee on Control of Narcotics Circulation.

CHAPTER SIX

FINAL PROVISIONS

ARTICLE 25. Liability

The person who shall be in violation of the requirements of this Law shall be liable in accordance with the procedure established by Republic of Lithuania laws.

Article 26. Proposal to the Government

The Ministry of Health shall prepare legislation in connection with this Law within three months of the coming into force of the Law on the Control of Narcotic and Psychotropic Substances.

I promulgate this Law passed by the Seimas of the Republic of Lithuania.

PRESIDENT OF THE REPUBLIC

ALGIRDAS BRAZAUSKAS