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11 June 1998
30 February 2000;
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If a whole or part of a section has been amended, the date of the amending law appears in square brackets at the end of the section. If a whole section, paragraph or clause has been deleted, the date of the deletion appears in square brackets beside the deleted section, paragraph or clause.

The *Saeima*¹ has adopted and
the President has proclaimed the following law:

On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products

Chapter I General Provisions

Section 1.

Terms Used in this Law:

1) **trade** - the import, export, transit, production, preparation, distribution, research and preparation of narcotic and psychotropic substances and medicinal products;

2) **export** - the physical movement of narcotic and psychotropic substances and medicinal products from the territory of Latvia to the territory of another state, by crossing of the customs border;

3) **import** - the physical movement of narcotic and psychotropic substances and medicinal products from the territory of another state to the territory of Latvia, crossing the customs border;

4) **distribution** - the purchase, storage supply, movement across the State border (import, export, transit), sale, or transfer for use with or without charge, of narcotic and psychotropic substances and medicinal products;

5) **the consignee of the cargo** - a natural or legal person to whom a shipment of plants, substances or medicinal products, which are included in the Registers of narcotic substances, psychotropic substances and precursors controlled in Latvia, is delivered. Such person need not be the user of the plants, substances or medicinal products received;

6) **narcotic and psychotropic medicinal products** - medicinal products, in the composition of which, are included narcotic and psychotropic substances that are permitted to be used for medical or scientific purposes in accordance with laws and other regulatory enactments regulating pharmaceutical activities;

7) **narcotic substance** – any natural or synthetic substance, which is classified in accordance with the 30 March 1961 Single Convention on Narcotic Medicinal products and with the 1972 Protocol on Amendments to the 30 March 1961 Single Convention on Narcotic

¹ The Parliament of the Republic of Latvia

Medicinal products, and included in the Registers of narcotic substances, psychotropic substances and precursors, which are controlled in Latvia;

8) **illicit trade (illicit traffic)** - any operations with narcotic and psychotropic substances and medicinal products that are not in compliance with the provisions of this Law;

9) **precursors** - substances, which may be utilised for illicit production of narcotic or psychotropic substances, which have been classified in conformity with the 20 December 1988 U. N. Convention Against Illicit Traffic in Narcotic Medicinal products and Psychotropic Substances and included in Register IV of the Registers of narcotic substances, psychotropic substances and precursors controlled in Latvia;

10) **psychotropic substance** – any natural or synthetic substance, which have been classified in accordance with the 21 February 1971 Convention on Psychotropic Substances and included in the Registers of narcotic substances, psychotropic substances and precursors controlled in Latvia;

11) **transit** - carriage of narcotic or psychotropic substances and medicinal products through the territory of Latvia, if Latvia is neither the exporter nor the importer of such substances and medicinal products; and

12) **preparation** – activity as a result of which narcotic or psychotropic substances and medicinal products may be obtained and which include purification, as well as the transformation of narcotic and psychotropic substances into other substances.

[11 June 1998; 19 June 2003]

Section 2.

The purpose of this Law is to prescribe the procedures for the trade of narcotic and psychotropic substances and medicinal products, and to prevent such substances and medicinal products entering into illicit trade, as well as to prescribe liability for violations of this Law.

[11 June 1998]

Chapter II

Classification of Narcotic and Psychotropic Substances and Medicinal products

Section 3.

(1) Plants, substances and medicinal products, which have been classified by or in accordance with international conventions, as narcotic or psychotropic substances or medicinal products, or which may be used for the illegal preparation of such substances or medicinal products, as well as any other plants, substances or medicinal products with a similar pharmacological effect, the abuse of which may endanger health, shall be included in the Registers of narcotic substances, psychotropic substances and precursors controlled in Latvia. Depending on the degree of risk from the abuse of such plants, substances and medicinal products, they shall be classified in four Registers.

(2) The Cabinet shall approve the Registers of narcotic substances, psychotropic substances and precursors controlled in Latvia on the basis of a recommendation of the Minister for Health. Register I shall include prohibited, especially dangerous narcotic substances and psychotropic substances and plants that are their equivalent. Register II shall include very dangerous narcotic substances and psychotropic substances and medicinal products that are their equivalent, which are permitted to be used for medical and scientific purposes. Register

III shall include dangerous psychotropic substances and medicinal products, which are subject to abuse. Register IV shall include precursors, which may be utilised for the preparation of illegal narcotic or psychotropic substances and the trade of which is regulated by the Law On Precursors.

(3) The botanical names of plants shall be indicated; for substances and medicinal products – their international non-patented names – or, if such do not exist - their chemical names. To mixtures of substances and medicinal products the composition of which has substances included in the Registers, the same control measures shall be applied as for the substances that are in the composition thereof. If a mixture of substances or the composition of a medicinal product contains substances included in several Registers, the control conditions which are applicable to the more strictly controlled substance contained in such mixture or medicinal product shall be applied, but in individual cases, the Minister for Health is entitled to regulate the procedures for the trade in the mixtures or medicinal products referred to.

[11 June 1998; 19 June 2003]

Section 4.

Medicinal products or other mixtures which contain a substance included in Registers II or III, but do not create any, or create a minimal possibility for their abuse, because the substances in their composition are not readily separable in such quantities as are subject to abuse, may be exempted, pursuant to an order of the Minister for Health, from specific control measures provided for by this Law. This order shall specify the control measures from which the medicinal products or other mixtures are exempted.

[11 June 1998; 19 June 2003]

Chapter III

Prohibited Plants, Substances and Medicinal products Included in Register I

Section 5.

It is prohibited to cultivate, produce, prepare, import, export, distribute, advertise, transport, store, transfer for a charge or free of charge, acquire and use, as well as to send through the territory of Latvia, the plants, substances and medicinal products included in Register I.

Section 6.

(1) It is prohibited to grow opium poppies, oil poppies, coca bushes and cannabis plants in Latvia. It shall be the duty of the owners or lessees of land usable for agricultural or other purposes to destroy opium poppies, oil poppies and coca bushes growing on their land.

(2) Procedures for the cultivation, for restricted industrial and horticultural purposes, of cannabis plants (the acquisition of fibres and seeds) and poppies shall be determined by the Cabinet.

Section 7.

Natural persons and legal persons may, in accordance with procedures prescribed by the Cabinet, receive a permit from the Ministry of Health for the cultivation of plants, production, importation, exportation, utilisation and storage of substances and medicinal products included in Register I, II or III in such quantities as do not exceed those necessary for medical and scientific research or for educational purposes. A person who has received such a permit shall record, in a strict accountability book to be preserved for ten years, data regarding the plants, substances and medicinal products and information regarding the destruction thereof, indicating the date when the respective activities were performed, as well as the name of the supplier and recipient. A person who has received such a permit shall submit every quarter to the State Agency for Medicines a report regarding trade in narcotic and psychotropic substances, indicating also the quantity of substances destroyed and in stock.

[11 June 1998; 19 June 2003]

Chapter IV

Licensing of Operations with Substances and Medicinal products Included in Registers II and III

Section 8.

In respect of substances and medicinal products included in Registers II and III, the same conditions shall apply as are prescribed for substances and medicinal products used in medicine and veterinary medicine, to the extent they are not in contradiction to this Law.

Section 9.

(1) The trade of substances and medicinal products included in Registers II and III may be performed only by such legal persons as have received a special permit (licence) for pharmaceutical activity in which it is indicated that activities with psychotropic substances and medicinal products or narcotic and psychotropic substances and medicinal products are permitted.

(2) Operations provided for in the licence, shall be performed only on the premises specified in the licence.

[30 March 2000]

Section 10.

The licences mentioned in Section 9 of this Law shall be issued only if the respective substances are intended for medical or scientific purposes. Substances included in Registers II and III are permitted to be used for other purposes also, if the applicant for a licence can prove that these substances will not be used illegally. An applicant for a licence has a duty to ensure that the products produced are not used wrongfully, in order that they do not cause adverse consequences and that the narcotic and psychotropic substances they contain are not easily extracted.

[19 June 2003]

Section 11.

The permit referred to in Section 7 or the licence referred to in Section 9 of this Law shall be issued only if:

1) the legal person in conformity with the requirements of regulatory enactments has appointed a qualified person in respect of the trade of narcotic and psychotropic substances and medicinal products, who is not ill with a mental illness, narcotics addiction, addition to toxic substances or alcoholism;

2) the founders and partners, as well as the officials of the legal person have not been convicted for the committing of a criminal offence, as well as have not been administratively convicted for violations, which are associated with trade in narcotic and psychotropic substances and precursors; and

3) the natural person is not ill with a mental illness, narcotics addiction, addition to toxic substances or alcoholism and has not been convicted for the committing of a criminal offence, as well as has not been administratively convicted for violations, which are associated with trade in narcotic and psychotropic substances and precursors.

[11 June 1998; 30 March 2000; 19 June 2003]

Section 12.

(1) The procedures for the reregistration and cancellation of the special permits (licences) referred to in Section 9 of this Law shall be determined by the Cabinet.

(2) Licenced legal persons shall notify changes in the nomenclature, methods of production, substances produced and the form and composition of medicinal products of the substances included in Registers II and III according to the procedures specified in regulatory enactments to the Pharmaceutical Activities Licensing Commission.

[30 March 2000; 19 June 2003]

Section 13.

Operations of a licensed legal person with substances or medicinal products included in Registers II and III may be performed in the territory of Latvia only by such natural or legal persons as have a licence or permit issued for the relevant activities.

Section 14.

(1) A decision regarding a refusal to issue or reregister a special permit (licence) and regarding the suspension of operation or cancelling of a special permit (licence) shall be taken by the Pharmaceutical Activity Licensing Commission.

(2) The State Agency for Medicines shall maintain and up-date a database of and according to the procedures specified in regulatory enactments shall provide information regarding undertakings that have received the special permit (licence) referred to in Section 9.

[19 June 2003]

Section 15.

A decision regarding the suspension or cancellation of a licence shall not release the person from administrative or criminal liability for violation of this Law.

Chapter V
Control of Production, Importation and
Exportation of Substances and Medicinal products Included in Registers II and III

Section 16.

(1) The State Agency of Medicines shall perform an analysis of the estimated consumption of narcotic and psychotropic substances and medicinal products and on the basis thereof prepare and submit an annual consumption quota of narcotic and psychotropic substances and medicinal products to the U.N. International Narcotics Control Board for approval.

(2) The State Agency of Medicines shall compile, and submit to the U.N. International Narcotics Control Board, quarterly and annual statistical reports regarding the trade of narcotic and psychotropic substances.

(3) The State Agency of Medicines shall provide notice to the U.N. International Narcotics Control Board regarding such purchases or operations as may divert narcotic and psychotropic substances and medicinal products into illicit trade.

[11 June 1998]

Section 17.

Only such legal persons as have the licence specified in Section 9 of this Law may enter into the international trade of substances and medicinal products included in Registers II and III.

Section 18.

Importation and exportation of substances and medicinal products included in Registers II and III may be performed only with a single-use permit issued by the State Agency of Medicines, which is in compliance with the requirements of the Commission on Narcotic Medicinal products of the U.N. Economic and Social Council.

[11 June 1998]

Section 19.

(1) The intended activities, the relevant licence number, the importer and exporter, their addresses, information regarding the consignee of the cargo, the international non-patented name of each substance or the name given in the schedules and tables of international conventions, the form of medicinal products and their patented name where such exists, the quantity of the substances and medicinal products, the mode of transportation or shipment, and the place and time of crossing the customs border shall be set out in applications for import or export permits.

(2) Together with an export application, an import permit issued by a competent authority of the importing state shall be submitted, if such is provided for by the laws of the respective state.

Section 20.

An import or export permit shall include the same information which is mentioned in the relevant application, and the period of validity of the permit. An import permit shall specify whether the import shipment consists of a single cargo or several cargoes. An export permit shall set out, if necessary, the number and the date of issueance of the relevant import permit, thereby confirming the import permit for the substances or medicinal products.

Section 21.

(1) It is required that each shipment be accompanied by four certified copies of the import or export permit.

(2) One copy of the import permit the client shall send to the exporter; the second copy shall be submitted to the customs office of importation together with a customs declaration, and shall be sent, with endorsements of the customs authorities regarding the actual amount of imported substances or medicinal products, to the State Agency of Medicines; the third copy shall be attached to the shipment; and the fourth copy of the permit after the performance of the import transaction shall indicate the actual amount of imported substances and medicinal products, date and shall be submitted to the State Agency of Medicines.

(3) One copy of the export permit the client shall be sent to the customs office of exportation together with a customs declaration and shall be sent, with endorsements of the customs authorities regarding the actual amount of exported substances or medicinal products, to the State Agency of Medicines; the second copy shall be attached to the shipment; the third copy shall be sent to the importation state competent institution; and the fourth copy of the permit after the performance of the export transaction shall indicate the actual amount of exported substances and medicinal products, date and shall be submitted to the State Agency of Medicines.

[11 June 1998; 19 June 2003]

Section 22.

As soon as an imported shipment has arrived in the territory of Latvia, or the period of validity mentioned in the import permit has expired, the State Agency of Medicines shall send to the competent authority of the exporting state the export permit issued by that state, indicating the actual quantity of the imported substances or medicinal products.

[11 June 1998]

Section 23.

If the actual quantity of the exported narcotic and psychotropic substances or medicinal products is less than the quantity mentioned in the export permit, the State Agency of Medicines shall record this in a copy of the export permit, which shall be sent to the competent authority of the importing state.

[11 June 1998]

Section 24.

In commercial documents (invoices, cargo manifests, customs, transport and other accompanying documents) there shall be set out the names of substances and medicinal products in conformity with the schedules and tables of the U. N. conventions, the quantity of substances and medicinal products to be exported from or imported into the territory of Latvia, the exporter and the importer, their addresses, the consignee of the cargo and their address.

Section 25.

If only a bank or a post-box number is set out in the place for the address of the consignee of the cargo, export from or import into the territory of Latvia of substances and medicinal products included in Registers II or III is prohibited.

Section 26.

Export of substances and medicinal products included in Registers II and III to a consignment warehouse is prohibited, except in cases when such form of delivery has been approved in the import permit issued by the competent authority of the importing state. It is also prohibited to import such substances and medicinal products to a consignment warehouse in the territory of Latvia.

Section 27.

The competent authorities (institutions and the border guard force) shall have a duty to impound those shipments, which cross the customs border in either direction, which do not have relevant import, export or transit permits, and to require that the legality of the shipments be verified. In case of failure to do so, the cargo shall be confiscated.

[11 June 1998]

Section 28.

The Cabinet shall determine the customs stations through which the import, export and transit of substances and medicinal products included in Registers II and III shall be permitted.

Section 29.

Transit carriage of substances and medicinal products included in Registers II and III through the territory of Latvia may be performed only if a transit permit issued by the State Agency of Medicines has been received, irrespective of whether the cargo is or is not unloaded from the means of transport which is carrying it.

[11 June 1998]

Section 30.

(1) Transit carriage of substances and medicinal products included in Registers II and III shall be performed in accordance with the route specified in the attached export permit and shall be delivered, accompanied by armed guards, to the destination specified in the permit.

(2) Transit regulations for such substances and medicinal products shall be determined by the Cabinet.

[11 June 1998]

Section 31.

No one shall change the composition, content or packaging of a transit cargo of substances and medicinal products included in Registers II and III, conveyed through the territory of Latvia, if a permit from the State Agency of Medicines has not been received. The provisions of this Section shall not restrict the lawful activities of competent authorities (institutions and the border guard force).

[11 June 1998]

Section 32.

In respect of free ports and free trade zones, the same control and supervision measures shall be applied as have been prescribed for other parts of the territory of Latvia.

Section 33.

Commercial carriers have the duty to carry out appropriate precautionary measures, in order to prevent the use of their means of transport for the illicit carriage of plants, substances and medicinal products mentioned in this Law. Upon arrival in the territory of Latvia, they have the duty to inform the Drug Control Office of the Ministry of the Interior, without delay, regarding circumstances which create suspicion that the means of transport has been used illegally.

Section 34.

Legal persons who have received a licence mentioned in Section 9 of this Law may send the substances and medicinal products specified in this Law by registered postal shipments, if such are packaged in boxes, indicating their value and requesting confirmation of delivery.

Chapter VI

Distribution of Substances and Medicinal products Included in Registers II and III

Section 35.

The substances and medicinal products included in Registers II and III may be purchased for professional activities in accordance with the provisions of this Law only from such legal persons to whom a licence specified in Section 9 of this Law has been issued.

Section 36.

The substances and medicinal products included in Registers II and III may be dispensed to patients only pursuant to a prescription in which instructions for their therapeutic use are indicated. The procedures for writing and preserving prescriptions shall be determined by the Cabinet. If the dispenser of the medicinal products does not personally know the submitter of the prescription, they have the right to request that a personal identification document be presented.

[11 June 1998]

Section 37.

The procedures for the receipt, purchase, distribution, dispensation, storage and inventory of medicinal products included in Registers II and III by drug wholesalers, drug manufacturing undertakings, pharmacies and medical treatment institutions shall be determined by the Cabinet.

Section 38.

The Minister for Health shall determine the quantity of the medicinal products included in Registers II and III, which are necessary for the provision of medical first aid.

[11 June 1998; 30 March 2000; 19 June 2003]

Section 39.

(1) Natural persons may acquire and store only such quantities of medicinal products included in Registers II and III as are necessary for a course of medical treatment. The medicinal products shall be prescribed and supplied according to the procedures specified in regulatory enactments.

(2) Natural persons who cross the State border may export or import medicinal products included in Registers II and III for personal use without a special permit if the medicinal products included in Register II are intended for a course of medical treatment, which is not longer than 14 days, but the medicinal products included in Register III are intended for a course of medical treatment, which is not longer than 30 days. The need to use such medicinal products shall be certified by the person by presenting a prescription, a duplicate or copy of the prescription or other documents that certify such facts.

(3) Natural persons are not entitled to send and receive medicinal products included in Registers II and III utilising inland and international postal parcels.

[19 June 2003]

Section 40.

The Ministry of Health shall issue permits to use substances and medicinal products included in Registers II and III for the capture of animals, as well as approve regulations for their use.

[11 June 1998; 19 June 2003]

Chapter VII Special Provisions

Section 41.

If a cargo contains substances or medicinal products included in Register II, only the name, surname and address of the consignor and the consignee may appear on the outer packaging of the parcel intended for shipment. Shipments shall be sealed with the seal of the consignor.

Section 42.

The substances and medicinal products included in Registers II and III may not be advertised in the mass media, as well as may not be used in any other form of advertising, which is intended for non-specialists, to popularise them. This shall not apply to preparations containing substances included in Registers II or III, which, nevertheless, are exempted, pursuant to an order of the Minister for Welfare, from specific control measures provided for by this Law. In advertising of such preparations, it is prohibited to mention the substances included in Registers II or III which these preparations contain.

[11 June 1998]

Chapter VIII Control of Compliance with this Law and Liability for its Violation

Section 43. [11 June 1998]

Section 44.

(1) The State Pharmaceutical Inspection shall supervise and control legal persons and natural persons who perform activities with substances and medicinal products included in Registers II and III, shall evaluate the conformity of the distribution of substances and medicinal products included in Registers II and III with the requirements of regulatory enactments and, in accordance with regulatory enactments, shall suspend the distribution of substances and medicinal products included in Registers II and III or the pharmaceutical activities of natural persons until the final determination of the circumstances.

(2) The Medical Care and Disability Expert Examination Quality Control Inspection shall control the necessity for the utilisation of the medicinal products included in Registers II or III to ensure the medical treatment process.

[11 June 1998; 30 March 2000; 19 June 2003]

Section 45.

For violations of this Law, persons shall be subject to liability as prescribed by law.

Transitional Provisions

1. The permits (licences) referred to in Section 9 of this Law, which have been issued up to the day of the coming into force of this Law, shall preserve their specified term of validity.

2. Up to the day when the Cabinet regulations, which determine the procedures by which the special permits (licences) for pharmaceutical activities are issued, reregistered and cancelled, also for activity with narcotic and psychotropic substances and medicinal products have come into force, the procedures for the issue of the special permits (licences) referred to in Section 9 shall be determined by the Minister for Welfare.

[30 March 2000]

This Law has been adopted by the *Saeima* on 9 May 1996.

Acting for the President,
Chairperson of the *Saeima*

I. Kreituse

Rīga, 23 May 1996

**Transitional Provisions Regarding Amendments
to the Law On Procedures for the Legal Trade
of Narcotic and Psychotropic Substances and Medicinal Products**

Transitional Provision
(regarding amending law of 30 March 2000)

With the coming into force of this Law, Cabinet Regulation No. 6, Amendments to the Law On Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products (*Latvijas Republikas Saeimas un Ministru Kabineta Ziņotājs*, 2000, No. 3) issued in accordance with Article 81 of the Constitution of the Republic of Latvia is repealed.