Medicinal Products Act

Passed 19 December 1995
(RT[1] I 1996, 3, 56),
entered into force 1 April 1996,
amended by the following Acts:
12.02.2003 entered into force 21.03.2003 - RT I 2003, 26, 156;
18.09.2002 entered into force 24.10.2002 - RT I 2002, 82, 480;
19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387;
19.06.2002 entered into force 01.10.2002 - RT I 2002, 62, 377;
05.06.2002 entered into force 01.07.2002 - RT I 2002, 53, 336;
23.01.2002 entered into force 01.07.2002 - RT I 2002, 18, 97;
30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308;
16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608;
26.03.98 entered into force 03.05.98 - RT I 1998, 36/37, 554;
08.12.97 entered into force 01.01.98 - RT I 1997, 93, 1564;
26.06.96 entered into force 26.07.96 - RT I 1996, 49, 954.

Chapter 1
General Provisions

§ 1. Purpose of Medicinal Products Act

(1) The Medicinal Products Act determines the procedures for the manufacture, import, export and marketing of medicinal products.
(2) This Act is the basis for other legislation concerning medicinal products.

§ 2. Definitions used in Medicinal Products Act

(1) For the purposes of this Act, a medicinal product is any substance intended for the prevention, diagnosis or treatment of a disease or disease symptom, for the relief of a disease condition in a human or animal, or for the restoration or correction of vital functions in a human or animal.
(1^1) For the purposes of this Act, a medicinal product for use only in veterinary medicine (hereinafter veterinary medicinal product) is a medicinal product which is designated by the producer to be used only on animals and which shall be marked "*veterinaarseks kasutamiseks*" [for veterinary use].
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(1^2) Additives in feedingstuffs which are used mixed in feedingstuffs are not veterinary medicinal products.
(23.01.2002 entered into force 01.07.2002 - RT I 2002, 18, 97)
(2) A proprietary medicinal product is a medicinal product in the original packaging of the manufacturer which is produced for use and marketing. Proprietary medicinal products containing the same active ingredient in different quantities or different pharmaceutical forms are considered different proprietary medicinal products.
(3) A semi-medicinal product is a product which contains an active ingredient in a quantity or form which does not allow it to be considered a medicinal product or which contains no active ingredient, but the manufacturer or marketer describes areas for use of the product which are characteristic of medicinal products.

(4) An active ingredient is a substance determinable by scientific methods which is used as a medicinal product or as an ingredient in a medicinal product and is intended for use for the purposes specified in subsection (1) of this section.
(4^1) (Repealed - 23.01.2002 entered into force 01.07.2002 - RT I 2002, 18, 97)
(4^2) For the purposes of this Act, pre-mixes for medicated feedingstuffs are veterinary medicinal products which are manufactured for production of medicated feedingstuffs.
(23.01.2002 entered into force 01.07.2002 - RT I 2002, 18, 97)
(5) In this Act, proprietary medicinal products and semi-medicinal products are referred to as medicinal products, and the provisions of this Act apply to all such products unless established otherwise.
(6) For the purposes of this Act, the manufacture of medicinal products is the production, packaging or repackaging of medicinal products.
§ 3. Requirements set for medicinal products
(1) All medicinal products shall have the presumed characteristics of use and be safe for the health of the consumer when used for their intended purpose. A medicinal product for use in veterinary medicine shall also be safe for the health of the consumer of the animal product.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(2) Only medicinal products registered in the Agency of Medicines and medicinal products for which the Agency of Medicines has issued a single authorisation for import and use may be marketed and used in Estonia.
(3) In marketing a medicinal product, the product shall be accompanied by exhaustive information in Estonian concerning the composition, proportions of the ingredients and use of the medicinal product, unless otherwise established by the Minister of Social Affairs.
(4) The name and design of a medicinal product shall not be misleading with regard to its composition or general effects and shall ensure the distinguishability of the product from other medicinal products. The Agency of Medicines has the right to require additional special precautionary labelling on a product.
(5) A medicinal product must meet the requirements specified in subsections (1), (3) and (4) of this section in order to be registered.
§ 4. Relations with other Acts
(1) Acts and other legislation concerning narcotic substances extend to medicinal products which are classified as narcotic substances and are governed by this Act.
(2) (Repealed - 16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(3) Acts and other legislation concerning radioactive substances extend to radioactive medicinal products.
§ 5. Competence of the Government of the Republic, Minister of Social Affairs, Minister of Agriculture and Agency of Medicines
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(1) The Government of the Republic shall establish the requirements for issue of an activity licence for the manufacture, wholesale or retail trade of medicinal products and the procedure for application for and revocation of an activity licence.
(2) The Government of the Republic shall establish the gross margins for wholesale and retail trade of medicinal products and the procedure for their implementation.
(3) The Minister of Social Affairs shall establish the procedures for wholesale and retail trade of medicinal products, including veterinary medicinal products, registration of medicinal products,

including veterinary medicinal products, recording and reporting regarding medicinal products and disclosure of data.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(4) The Minister of Social Affairs shall establish the rules for the manufacture, import and export of medicinal products, including veterinary medicinal products, and the procedures for related recording and reporting.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(5) The Minister of Social Affairs shall in accordance with this Act issue lists of medicinal products, including veterinary medicinal products, and rules concerning supporting documentation for applications for registration and concerning procedures for variations to the composition, packaging or labelling of a proprietary medicinal product or semi-medicinal product.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(5^1) The Minister of Social Affairs shall obtain approval from the Minister of Agriculture for the parts of legislation passed on the basis of this Act which concern medicinal products for use in veterinary medicine.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(5^2) The Minister of Agriculture shall establish, with the approval of the Minister of Social Affairs:
1) (Repealed - 30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
2) a list of biostimulants, hormone preparations and other substances prohibited to be used on farm animals;
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
3) (Repealed - 23.01.2002 entered into force 01.07.2002 - RT I 2002, 18, 97)
(5^3) The Minister of Agriculture shall establish the conditions and procedure for the use of medicinal products and medicated feedingstuffs for the prevention and treatment of animal disease.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(6) The Agency of Medicines administers and is responsible for registration of medicinal products and quality control of medicinal products.
(7) The Agency of Medicines issues marketing authorisations and import and export licences for medicinal products to manufacturers and wholesalers of medicinal products and inspects the import, export, storage and use of narcotic and psychotropic medicinal products.
(8) The function of the Agency of Medicines is to provide expert assessments regarding applications for registration of medicinal products and to inspect the chemical and pharmaceutical characteristics of medicinal products.
(9) The Agency of Medicines has the right to decide whether a product is a medicinal product and, if necessary, to classify a preparation as a narcotic or psychotropic medicinal product.
(10) The Agency of Medicines has the right to demand information from persons dealing with medicinal products concerning their professional activities, to inspect the production, storage, marketing and distribution in any other manner of all medicinal products and other products for medical purposes, and to inspect related documentation. The Agency of Medicines has the right to issue precepts for the elimination of discovered violations.

Chapter 2
Manufacture, Import and Export of Medicinal Products

§ 6. Manufacture of medicinal products

(1) Only persons who hold an activity licence issued by the Ministry of Social Affairs for the manufacture of medicinal products are permitted to manufacture medicinal products. An enterprise manufacturing medicinal products shall employ a person with professional qualifications who is responsible for quality control of medicinal products.
(2) Pharmacies have the right and the obligation to prepare medicinal products as magistral formulae only pursuant to a medical prescription or with the permission of the Agency of Medicines, pursuant to rules approved by the Minister of Social Affairs.
(3) Substances whose characteristics, purity and composition are specified in valid pharmacopoeias or by other rules shall be used in the manufacture of medicinal products.
(4) The head of an enterprise manufacturing medicinal products is responsible for compliance with the requirements specified in subsection (3) of this section and other legislation concerning medicinal products.
(5) A person may concurrently hold only one of the following activity licences: an activity licence for the manufacture, wholesale or retail trade of medicinal products.
§ 7. Import and export of medicinal products
(1) Medicinal products may be imported into the Republic of Estonia by an enterprise manufacturing medicinal products in Estonia for manufacture of the production of the enterprise or by an enterprise which holds an activity licence issued by the Ministry of Social Affairs for wholesale trade of n
(2) Medicinal products may be exported from the Republic of Estonia by an enterprise manufacturing medicinal products in Estonia, within the extent of its production, or by an enterprise which holds an activity licence issued by the Ministry of Social Affairs for wholesale trade of medicinal p
(3) A natural person arriving in or departing from Estonia may carry with him or her medicinal products for his or her personal medical use or for medical use on animals accompanying him or her.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(4) A medical institution may only import medicinal products pursuant to procedure established by the Minister of Social Affairs and upon a single permission by the Agency of Medicines.
(5) Other institutions may also import medicinal products for scientific purposes pursuant to procedure established by the Minister of Social Affairs and upon a single permission by the Agency of Medicines on the condition that the medicinal products are not used for medical purposes.
(6) Medicinal products not registered with the Agency of Medicines may be imported, on the basis of a single authorisation for import of the Agency of Medicines, at the medically justified written request of a doctor or veterinarian qualified to prescribe the medicinal product for the treatment of a person or animal treated by the doctor or veterinarian.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(7) In order to apply for the import of a medicinal product not registered with the Agency of Medicines, a doctor or veterinarian qualified to prescribe the medicinal product shall submit the following documents and information to the Agency of Medicines:
1) an application which sets out the name and place of employment of the applicant, the seat and address of the place of employment, the position and telecommunications numbers of the applicant, the date an

2) the name of the medicinal product, name of the active ingredient, pharmaceutical form and strength, route of administration, the size of packaging, manufacturer of the medicinal product and the quantity to be imported;
3) medical justification of the need to use the medicinal product;
4) information needed for the delivery of the medicinal product;
5) the importer of the medicinal product, if possible.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(8) The Agency of Medicines shall verify the information and documents submitted by the applicant and decide whether import of the medicinal product not registered with the Agency of Medicines is justified or not justified within thirty calendar days as of the date of filing the documents and information specified in subsection (7) of this section with the Agency of Medicines.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(9) The Agency of Medicines shall decide that import of the medicinal product not registered with the Agency of Medicines is not justified if:
1) the applicant fails to submit documents and information specified in subsection (7) of this section;
2) the quality and efficacy of the medicinal product has not been proved;
3) use of the medicinal product may be harmful to the health of the person or animal;
4) use of the medicinal product for treatment is not medically justified;
5) the applicant knowingly submits false information.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(10) If, in the opinion of the Agency of Medicines, the import of a medicinal product not registered with the Agency of Medicines is justified, the Director General of the Agency of Medicines shall issue a single authorisation to import the medicinal product to a person who holds an activity licence for wholesale trade in the medicinal product.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(11) Persons specified in subsections (1) and (4) of this section may import medicinal products in order to conduct clinical trials of medicinal products with the consent of the Director General of the Agency of Medicines.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)

Chapter 3
Marketing and Registration of Medicinal Products

§ 8. Wholesale trade of medicinal products

(1) Only a manufacturer who holds an activity licence valid in the Republic of Estonia for the manufacture of medicinal products, within the extent of the manufacturer's production, or an enterprise which holds an activity licence issued by the Ministry of Social Affairs for wholesale trade of medicinal products may wholesale medicinal products.
(2) Medicinal products may be sold wholesale to pharmacies, enterprises manufacturing medicinal products, wholesalers who hold a corresponding activity licence and institutions in a list approved by the Minister of Social Affairs. A wholesaler of medicinal products may only procure medicinal products from an enterprise manufacturing medicinal products, another wholesaler of medicinal products or a pharmacy. Medicinal products for use in veterinary medicine may also be sold wholesale to a person holding a valid activity licence for the provision of veterinary services.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)

(3) The head of a wholesaler of medicinal products is responsible for compliance of the medicinal products sold by the enterprise with the requirements set in this Act and other legislation, for compliance with the rules concerning storage of medicinal products, recording requirements and legislation governing medicinal products.
(4) A wholesaler is required to repurchase and, in the required manner, safely dispose of substandard medicinal products distributed by the wholesaler.
§ 9. Retail trade of medicinal products
(1) Retail trade of medicinal products to the public and preparation of medicinal products as magistral formulae are permitted only in a pharmacy.
(2) A pharmacy may only procure medicinal products from enterprises specified in subsection 8 (1) of this Act or other pharmacies.
(3) A pharmacy may only sell medicinal products which meet the requirements specified in subsection 3 (2) of this Act and medicinal products prepared in the same pharmacy under the conditions specified in subsection 6 (2) of this Act. A prescription medicinal product may only be sold pursuant to a valid prescription.
(4) Upon dispensation of a medicinal product from a pharmacy, the recipient of the medicinal product shall be informed of the correct and safe use of the medicinal product.
(5) In addition to medicinal products, pharmacies may sell other products for medical purposes (toiletries, disinfectants, medical supplies, etc.) on the condition that the sale of such products does not hinder the sale of medicinal products.
(6) The procedure for the issue of prescriptions for medicinal products and for the dispensation of medicinal products by pharmacies and the format of prescriptions shall be established by the Minister of Social Affairs.
(19.06.2002 entered into force 01.10.2002 - RT I 2002, 62, 377)
§ 10. Pharmacy
(1) A pharmacy is an enterprise whose operational rules and procedures for foundation and termination shall be established by the Minister of Social Affairs.
(1^1) A veterinary pharmacy is a pharmacy which has the right to dispense only veterinary medicinal products and which has no obligation to prepare medicinal products as magistral formulae.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(2) A branch pharmacy and a pharmacy counter are subsidiaries of a pharmacy. A pharmacy has the right to open one branch pharmacy and two pharmacy counters. The head of the pharmacy is responsible for the activities of the branch pharmacy and pharmacy counter.
(3) A hospital pharmacy supplies the hospital it is founded by and, if necessary, other medical and social welfare institutions in the territory of the local government with medicinal products and other products for medical purposes, and does not have the right to engage in retail trade of medicinal products.
(4) The requirements set for branch pharmacies, pharmacy counters and hospital pharmacies and the procedures for their foundation and termination shall be established by the Minister of Social Affairs.
(5) Medicinal products may be prepared and dispensed to the public from pharmacies only by persons educated in pharmacy. Medicinal products for use in veterinary medicine may also be dispensed by persons educated in veterinary medicine.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)

(6) Only a person who holds an activity licence issued by the Ministry of Social Affairs for retail trade of medicinal products may work as the head of a pharmacy. A person has the right to hold one activity licence for retail trade of medicinal products. Assignment of an activity licence or transfer in any other manner is not permitted.
(7) An activity licence for retail trade of medicinal products shall be issued by the Ministry of Social Affairs for activity at a specified address to a person who has obtained an operating licence from the local government, has completed higher education in pharmacy or, in the case of veterinary medicinal products only, higher education in veterinary medicine and has at least five years of professional experience. The Agency of Medicines has the right to issue precepts pursuant to procedure established by the Minister of Social Affairs to an applicant regarding the location and operations of the pharmacy and the assortment of medicinal products.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(8) An activity licence for retail trade of medicinal products shall be revoked if the conditions which were the basis for issue of the activity licence change, the holder of the activity licence has not commenced activities within six months or the holder of the activity licence lacks full control over the activities of the pharmacy.
(9) A natural person, legal person in private law, the state, a local government or other legal person in public law may be the owner of a pharmacy.
(26.06.96 entered into force 26.07.96 - RT I 1996, 49, 954)
(10) (Repealed - 26.06.96 entered into force 26.07.96 - RT I 1996, 49, 954)
(11) The head of a pharmacy is responsible for compliance with legislation governing medicinal products in the operation of the pharmacy and shall ensure the availability of medicinal products registered in the Republic of Estonia.
(12) The local government and the Agency of Medicines shall be notified of the termination of a pharmacy two months in advance. Upon termination or change of ownership of a pharmacy, the medicinal products existing in the pharmacy may only be sold to enterprises which hold an activity licence for wholesale or retail trade of medicinal products. The sale of the stock of medicinal products of a pharmacy being terminated shall be inspected by the Agency of Medicines.
§ 11. Registration of medicinal products
(1) In order to register a medicinal product, the manufacturer of the medicinal product shall submit an application to the Agency of Medicines.
(2) Registration of a medicinal product shall be based on an application from the manufacturer of the medicinal product together with supporting documentation, expert assessments and the results of testing for the chemical and pharmaceutical characteristics of the medicinal product conducted by the Agency of Medicines.
(3) (Repealed - 30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(4) A medicinal product shall be registered within 210 days as of the date of receipt of the application, if the applicant has proved the efficacy and safety of the medicinal product upon use thereof for its intended purpose and the quality of the medicinal product meets the established requirements.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
(5) Upon registration of a medicinal product, the Agency of Medicines shall issue a marketing authorisation for the medicinal product to the applicant, valid for up to five years, and, if necessary, shall establish restrictions on trade and use of the medicinal product.

(6) Pursuant to procedure established by the Minister of Social Affairs, the Agency of Medicines may refuse to register a medicinal product by a reasoned decision.
(7) The Agency of Medicines may require additional information from the manufacturer concerning a medicinal product. Upon failure to submit such information, the Agency of Medicines may refuse to register the medicinal product or revoke the marketing authorisation.
(8) With the permission of the Agency of Medicines, the composition, packaging or labelling of a proprietary medicinal product or semi-medicinal product may be altered without new registration on the condition that the medicinal product itself or its indications are not significantly changed.
(9) The Agency of Medicines may revoke or suspend the registration and marketing authorisation of a medicinal product pursuant to procedure established by the Minister of Social Affairs if the conditions for registration and issue of the marketing authorisation have changed or are not fulfilled, the requirements set for marketing the medicinal product are ignored or the availability of the medicinal product is not ensured.
(10) Upon submission of an application for registration of a medicinal product, the applicant shall pay the costs of expertise pursuant to procedure established by the Minister of Social Affairs and the state fee.
(11) If necessary, the Agency of Medicines shall make decisions concerning the registration of diagnostic substances and tests, radioactive, immunologic and blood preparations, and contraceptive and cosmetic devices.

§ 12. Storage of medicinal products

(1) In marketing, transporting and storing medicinal products, it shall be ensured that such products do not fall into the hands of unauthorised persons or become dangerous to users of medicinal products or the environment.
(2) All medicinal products the date of expiry of which has passed or which are removed from the market for other reasons shall be safely rendered harmless to humans, animals and the environment pursuant to procedure established by the Minister of Social Affairs.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(3) Rules for storage and transport of medicinal products shall be established by the Minister of Social Affairs.

§ 13. Definition of clinical trial of medicinal product

(1) A clinical trial of a medicinal product is the use of a medicinal product in humans or the use of a veterinary medicinal product on animals in order to collect information on the effect, side effects, absorption, distribution, metabolism, excretion, efficacy and safety of the medicinal product.
(2) The publication of information concerning a clinical trial to possible trial subjects, the owner of the animal in the case of a clinical trial of a veterinary medicinal product or the performance of procedures related to the trial is deemed to be the commencement of the clinical trial.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)

§ 13[1]. Requirements for clinical trials of medicinal products

(1) Clinical trials may only be conducted with regard to medicinal products which are manufactured in compliance with the requirements of this Act and legislation established on the basis thereof and regarding which the person conducting the clinical trial has sufficient up-to-date information on its effects and side effects.
(2) The planning and conducting of a clinical trial of a medicinal product and the publication of the results thereof shall be in compliance with the quality requirements of good clinical practice.

(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)

§ 13^2. Persons who conduct clinical trials of medicinal products and their rights and obligations

(1) Clinical trials of medicinal products may be conducted by doctors, dentists and veterinarians only in their respective areas of specialisation and within the limits of their competence.

(2) Other providers of health services and manufacturers of medicinal products or representatives thereof may participate in conducting a clinical trial of a medicinal product.

(3) If several doctors, dentists or veterinarians participate in conducting a clinical trial of a medicinal product or other providers of health services and manufacturers of medicinal products or representatives thereof participate in a trial, their mutual rights and obligations shall be determined in an agreement entered into between them.

(4) If the manufacturer of a medicinal product or a representative of the manufacturer participates in the commencement, organisation or conduct of a clinical trial of a medicinal product, such person shall provide the doctor, dentist or veterinarian conducting the trial with true and exhaustive information concerning the medicinal product being investigated.

(5) A doctor, dentist or veterinarian conducting a trial and a provider of health services participating in a trial shall provide necessary assistance to a trial subject within the limits of his or her competence.

(6) A doctor or dentist conducting a trial shall ensure the availability of competent assistance of other health service providers to the trial subject if necessary. In the case of a clinical trial of a veterinary medicinal product, the veterinarian shall ensure the availability of competent assistance of other veterinarians to the trial subject.

(7) A doctor or dentist conducting a trial is required to inform the trial subject and, in the cases prescribed in this Act, the legal representative of the trial subject and a veterinarian is required to inform the owner of an animal involved in the trial of facts related to the clinical trial of the medicinal product, including possible hazards and the manner and rate of compensation for any health damage sustained in connection with the trial.

(8) A doctor, dentist or veterinarian conducting a trial is required to observe the procedure for conducting clinical trials of medicinal products.

(9) The procedure for conducting clinical trials of medicinal products shall be established by a regulation of the Minister of Social Affairs.

(10) A doctor, dentist or veterinarian conducting a trial and a manufacturer of medicinal products or a representative thereof participating in the conduct of a trial shall notify, pursuant to the procedure established by the Minister of Social Affairs, the Agency of Medicines and, in the case of a trial of a veterinary medicinal product, the Veterinary and Food Board in writing of any serious side-effects which appear in the course of the trial and amendments to the clinical trial protocol.

(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)

§ 13^3. Consent to participate in clinical trial of medicinal product

(1) Consent of the trial subject is required for a clinical trial of a medicinal product. Consent is given after having been informed of all facts relating to the clinical trial of a medicinal product and consent shall be documented. Consent may be withdrawn at any time.

(2) Consent to the participation of a person with restricted active legal capacity in a clinical trial of a medicinal product is given by the legal representative of such person, and for a minor who is 7-18 years old to participate in a trial, the consent of the minor is necessary.

(05.06.2002 entered into force 01.07.2002 - RT I 2002, 53, 336)

(3) In order to involve an animal in a clinical trial of a veterinary medicinal product, the owner of the animal shall give his or her consent.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13[4]. Approval of conduct of clinical trials of medicinal products
(1) A clinical trial of a medicinal product shall not commence without the approval of the medical ethics committee for clinical trials.
(2) The medical ethics committee for clinical trials shall assess the ethics of conducting a clinical trial of a medicinal product.
(3) The Minister of Social Affairs shall establish, by a regulation, the requirements for membership of the medical ethics committee for clinical trials, the rules of procedure of the committee, the rate of the fee for the evaluation of clinical trials and the list of information to be submitted in order to obtain approval.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13[5]. Submission of application to conduct clinical trial of medicinal product
(1) In order to conduct a clinical trial of a medicinal product, a doctor, dentist or veterinarian shall submit a written application and the information and documents specified in subsection (3) of this section to the Agency of Medicines not later than two months prior to the commencement of the planned trial.
(2) Formal requirements for applications to conduct clinical trials of medicinal products shall be established by a regulation of the Minister of Social Affairs.
(3) The following information and documents shall be attached to an application to conduct a clinical trial of a medicinal product:
1) a trial protocol;
2) information concerning the pharmaceutical and chemical characteristics and pharmaco-toxicological characteristics of the medicinal product being investigated;
3) the results of previously conducted clinical trials of the medicinal product;
4) the approval of the medical ethics committee for clinical trials;
5) a copy of the insurance certificate.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13[6]. Grant of consent to clinical trial of medicinal product
(1) Consent to conduct a clinical trial of a medicinal product shall be granted by the Director General of the Agency of Medicines.
(2) Consent to conduct a clinical trial of a veterinary medicinal product shall be approved by the Veterinary and Food Board.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13[7]. Refusal to grant consent
(1) The Agency of Medicines may refuse to grant consent to the conduct of a clinical trial of a medicinal product if:
1) the applicant does not comply with the requirements for clinical trials of medicinal products;
2) the applicant submitted insufficient or false information;
3) the trial protocol is unreasonable;
4) the trial is of no scientific value;
5) the risk to the life and health of trial subjects is high.
(2) The Agency of Medicines shall notify the applicant of a refusal to grant consent in writing within sixty working days as of the receipt of the application. If the Agency of Medicines has not

notified the applicant of the refusal to grant consent or requested additional information within the specified term, consent is deemed to be granted.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13^{8}. Suspension of clinical trial of medicinal product
(1) The Agency of Medicines or the Veterinary and Food Board shall suspend a commenced clinical trial of a medicinal product if facts specified in subsection 13^{7} (1) of this Act become evident in the course of the trial.
(2) The person conducting the clinical trial is required to suspend the trial immediately after the receipt of the corresponding decision of the Agency of Medicines or the Veterinary and Food Board.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13^{9}. Liability of persons conducting clinical trials of medicinal products
(1) A doctor, dentist or veterinarian conducting a clinical trial of a medicinal product shall be liable for a violation of his or her obligations only if circumstances depending on the doctor, dentist or veterinarian occur.
(2) If a doctor, dentist or veterinarian who conducts a clinical trial of a medicinal product is acting upon conducting the clinical trial of the medicinal product on the basis of an employment contract or another contract entered into with a third person, the third person shall be solidarily liable together with the doctor, dentist or veterinarian.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
§ 13^{10}. Supervision over clinical trials of medicinal products
(1) The Agency of Medicines has the right upon advance notice to inspect the conduct of a clinical trial of a medicinal product and compliance with the trial protocol and the procedure for the conduct of clinical trials and for notification of side-effects.
(2) The Agency of Medicines has the right to inspect the work of the medical ethics committee for clinical trials and compliance with the rules of procedure of the committee.
(3) The Agency of Medicines is entitled to receive information concerning a clinical trial of a medicinal product and the conduct thereof from persons conducting the clinical trial of the medicinal product and providers of health services and manufacturers of medicinal products or representatives thereof participating in the conduct of the trial.
(30.06.2001 entered into force 01.07.2001 - RT I 2001, 53, 308)
Chapter 4
State Supervision
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 14. Control
(1) The Ministry of Social Affairs, the Agency of Medicines and the Veterinary and Food Board shall monitor compliance with this Act and legislation issued on the basis thereof, pursuant to their competence.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)
(2) Employees of the Agency of Medicines have the right to inspect enterprises which manufacture, store, market, use or investigate medicinal products, to take samples free of charge for control analysis and to perform investigations within the scope of their official duties.
(2^{1}) Officials of the Veterinary and Food Board shall exercise supervision over the use of medicinal products and medicated feedingstuffs by veterinarians and breeders producing animal products.
(16.06.1999 entered into force 01.01.2000 - RT I 1999, 58, 608)

(3) The head of an enterprise under inspection is required to provide an inspector with necessary information.
(4) In the course of the inspection of an enterprise which manufactures or in any other manner deals with medicinal products, it shall be ascertained whether the enterprise is operating under conditions which do not jeopardise product quality and whether the head of the enterprise or pharmacy has actual control over all activities.
§ 15. Compensation for damage and suspension of activity licence
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
(1) (Repealed - 19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
(2) Everyone who uses information obtained due to their official duties concerning the business or professional secrets of an enterprise dealing with medicinal products or a pharmacy in the interests of themselves or a third person shall compensate for any damage caused, pursuant to procedure provided by law.
(3) Upon violation of this Act or legislation based on this Act, the Minister of Social Affairs may on a reasoned proposal of the Agency of Medicines suspend an activity licence for the manufacture, wholesale or retail trade of medicinal products for up to three months.
(4) Upon violation of this Act or legislation based on this Act, the Minister of Social Affairs may on a reasoned proposal of the Agency of Medicines revoke an activity licence for the manufacture, wholesale or retail trade of medicinal products. An application for a new activity licence may be submitted after two years.
Chapter 4^1
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
Liability
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^1. Violation of requirements for dispensation of medicinal products
(1) Dispensation of medicinal products which are not registered by the state, knowing dispensation of wrong medicinal products or violation of other requirements for the dispensation of medicinal products by an employee of a pharmacy is punishable by a fine of up to 200 fine units.
(2) The same act, if committed by a legal person, is punishable by a fine of up to 30 000 kroons.
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^2. Violation of requirements for handling of medicinal products
(1) Violation of the requirements for the manufacture, preparation in a pharmacy, retail sale, wholesale, transport, import, export, storage and removal from the market of medicinal products, and the procurement, production and distribution of medicinal products which are not registered by the state or medicinal products for which the Agency of Medicines has not issued a single authorisation for import and use is punishable by a fine of up to 200 fine units.
(12.02.2003 entered into force 21.03.2003 - RT I 2003, 26, 156)
(2) The same act, if committed by a legal person which holds an activity licence, is punishable by a fine of up to 40 000 kroons.
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^3. Violation of requirements for recording and reporting regarding medicinal products
(1) Violation of the requirements for recording and reporting regarding medicinal products or the manufacture, import or export thereof is punishable by a fine of up to 100 fine units.
(12.02.2003 entered into force 21.03.2003 - RT I 2003, 26, 156)

(2) The same act, if committed by a legal person which holds an activity licence, is punishable by a fine of up to 30 000 kroons.
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^4. Violation of requirements for advertising of medicinal products
(1) Violation of the requirements for the advertising of medicinal products directed at persons who are qualified to prescribe medicinal products is punishable by a fine of up to 100 fine units.
(2) The same act, if committed by a legal person, is
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^5. Violation of requirements for conduct of clinical trials
Violation of the requirements for the conduct of permitted clinical trials of medicinal products is punishable by a fine of up to 200 fine units.
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^6. Violation of requirements for use of veterinary medicinal products and medicated feedingstuffs
(1) Violation of the requirements for the use of veterinary medicinal products and medicated feedingstuffs is punishable by a fine of up to 200 fine units.
(2) The same act, if committed by a legal person, is punishable by a fine of up to 30 000 kroons.
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387)
§ 15^7. Proceedings
(1) The provisions of the General Part of the Penal Code (RT I 2001, 61, 364; 2002, 86, 504; 105, 612; 2003, 4, 22) and the Code of Misdemeanour Procedure (RT I 2002, 50, 313; 110, 654; 2003, 26, 156) apply to the misdemeanours provided for in §§ 15^1-15^6 of this Act.
(2) A court in the case of misdemeanours provided for in §§ 15^1–15^2 and the Customs Board in the case of misdemeanours provided for in § 15^2 may apply confiscation of a substance or object which was the direct object of the commission of the misdemeanour pursuant to the provisions of § 83 of the Penal Code.
(3) The Agency of Medicines is the extra-judicial body which conducts proceedings in matters of misdemeanours provided for in §§ 15^1-15^5 of this Act.
(4) The Customs Board is the extra-judicial body which conducts proceedings in matters of misdemeanours provided for in §§ 15^2 and 15^3 of this Act.
(5) The Veterinary and Food Board is the extra-judicial body which conducts proceedings in matters of misdemeanours provided for in § 15^6 of this Act.
(19.06.2002 entered into force 01.09.2002 - RT I 2002, 63, 387; 18.09.2002 entered into force 24.10.2002 - RT I 2002, 82, 480)
Chapter 5
Special Provisions
§ 16. Advertising of medicinal products
(1) For the purposes of this Act, advertising directed at persons who are qualified to prescribe medicinal products is considered advertising of medicinal product.
(2) Requirements for and restrictions on advertising of medicinal products directed to the public are provided for in the Advertising Act (RT I 1997, 52, 835; 1999, 27, 388; 30, 415; 2001, 23, 127; 50, 284; 2002, 13, 81; 53, 336; 61, 375; 63, 387).
(3) Only medicinal products registered in Estonia may be advertised. A medicinal product may only be advertised by the manufacturer of the medicinal product pursuant to procedure established by the Minister of Social Affairs. Offering samples of a medicinal product is considered advertising the medicinal product.

(4) Manufacturer of a medicinal product is liable for the correctness of information provided in advertising of medicinal products. If advertising of a medicinal product contains false, harmfully exaggerated or misleading information concerning the effect or other characteristics of the medicinal product which contradicts the information submitted upon registration, the Agency of Medicines may revoke the marketing authorisation of the corresponding proprietary medicinal product.
(5) Advertising of a medicinal product shall be based on the summary of product characteristics. The summary of product characteristics shall be approved at the time of registration of a proprietary medicinal product pursuant to procedure established by the Minister of Social Affairs. The manufacturer of a medicinal product is liable for preparing and updating the summary of product characteristics.
(6) Advertising of a medicinal product shall facilitate rational use of the medicinal product by presenting information in an objective and unexaggerated way.
(26.03.98 entered into force 03.05.98 - RT I 1998, 36/37, 554)
Chapter 6
Implementing Provisions
§ 17. Amendments to earlier legislation
(1) The Criminal Code (RT 1992, 20, 228; RT I 2001, 73, 452; 85, 510; 87, 526) is amended as follows:
1) in subsection 76 (2), the words "a psychotropic, strong or toxic substance" are substituted by the words "a psychotropic substance, non-narcotic medicinal product or toxic substance";
2) in § 210, the word "strong" is substituted by the words "non-narcotic medicinal product", and the words "narcotic or" are repealed.
(2) The Code of Administrative Offences (RT 1992, 29, 396; 2001, 74, 453; 87, 524 and 526; 97, 605; 102, 677; 2002, 18, 98) is amended as follows:
1) in subsection 38 (4), the words "state activity licence" are substituted by the words "activity licence";
2) subsection (5) is added to § 38 worded as follows:
"(5) For the procurement, production, sale, distribution or advertising of medicinal products which are not registered by the state by a person who holds an activity license or for violation of rules for the manufacture, import, export, purchase, sale and advertising of medicinal products, a fine up to the extent of one hundred days' wages shall be imposed.";
3) the words "subsection 38 (4)" are added to the lists in subsections 137 (1) and (2);
4) subsection 205 (1) is amended after the words "subsection 37(2)" and is worded as follows:
"administrative offences set out in subsections 38 (1), (2), (3) and (5), subsection 53 (1), §§ 58, 581, 60, 132 (with regard to medicinal products), § 134 (with regard to medicinal products), § 135, clauses 169 1) and 2) (with regard to medicinal products) and § 179";
5) clause 205 (2) 3) is amended and worded as follows:
"3) the Director General and Deputy Director General of the Agency of Medicines under subsections 38 (3) and (5), § 132 (with regard to medicinal products), § 134 (with regard to medicinal products), § 135 (with regard to medicinal products) and clauses 169 1) and 2) (with regard to medicinal products).";
6) the words "subsections 135 (1) and (2)" are substituted by the number "135" in the list in subsection 205 (3).
(3) Subclause 53 is added to clause 8) of Appendix 1 to the State Fees Act (RT I 1997, 80, 1344; 2001, 55, 331; 56, 332; 64, 367; 65, 377; 85, 512; 88, 531; 91, 543; 93, 565; 2002, 1, 1; 9, 45;

13, 78; 79; 81; 18, 97; 23, 131; 24, 135; 27, 151; 153; 30, 178; 35, 214; 44, 281; 47, 297; 51, 316; 57, 358; 58, 361; 61, 375; 62, 377; 82, 477; 90, 519; 102, 599; 105, 610; 2003, 4, 20; 13, 68; 15, 84; 85; 20, 118; 21, 128; 23, 146; 25, 153; 154; 26, 156; 160) worded as follows:
"53) for submission of an application for registration of a medicinal product to the Agency of Medicines, 1 000 kroons".
(4) Subsection 22 (4) of the Public Health Act (RT I 1995, 57, 978; 1996, 3, 56; 49, 953; 1997, 37/38, 569; 1999, 30, 415; 88, 804; 2001, 23, 128; 2002, 13, 81; 32, 187; 53, 336; 61, 375; 63, 387; 90, 521; 2003, 26, 156; 160) is repealed as of the entry into force of the Public Service Act (RT I 1995, 16, 228; 1999, 7, 112; 10, 155; 16, 271; 276; 2000, 25, 144; 145; 28, 167; 102, 672; 2001, 7, 17; 18; 17, 78; 24, 133; 42, 233; 47, 260; 2002, 21, 117; 62, 377; 110, 656; 2003, 4, 22; 13, 67; 69; 20, 116).
§ 18. Entry into force of Act
This Act enters into force on 1 April 1996.
[1] RT = *Riigi Teataja* = *State Gazette*