Medicinal Products Act

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Amended by the following Acts:

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12.03.2008	RT I 2008, 15, 108	01.11.2008
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19.06.2008	RT I 2008, 30, 191	01.07.2008
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09.12.2008	RT I 2008, 56, 313	01.01.2009
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28.01.2010	RT I 2010, 7, 31	26.02.2010
18.03.2010	RT I 2010, 15, 77	18.04.2010
22.04.2010	RT I 2010, 22, 108	1 January 2011, shall enter into force on the date specified in the decision of the Council of the European Union concerning declaring the exception established with regard to the Republic of Estonia on the basis of article 140 (2) of the Treaty on the Functioning of the European Union, Decision No. 2010/146/EU of the Council of the European Union of 13 July 2010 invalid (OJ L 196, 28.07.2010, pp. 24-26).
09.06.2010	RT I 2010, 41, 240	01.09.2010
21.10.2010	RT I, 08.11.2010, 2	18.11.2010
20.01.2011	RT I, 02.02.2011, 2	01.03.2011

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) This Act regulates the handling of medicinal products, issue of medical prescriptions, grant of marketing authorisation in respect of medicinal products, clinical trials and advertising of medicinal products, and supervision over and liability in the area of medicinal products with the aim to guarantee the safety, high quality and efficacy of medicinal products used in Estonia and to promote the rational use of medicinal products for their intended purposes.

(2) The provisions of the Administrative Procedure Act apply to administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act.

§ 2. Medicinal product

(1) A medicinal product is any substance or combination of substances 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 alteration of vital functions in a human or animal through pharmacological, immunological or metabolic effect.

(2) The State Agency of Medicines has the right to classify the status of substances and products as medicinal products, and of products as homeopathic preparations.

§ 3. Handling of medicinal products

(1) For the purposes of this Act, handling of medicinal products shall mean the manufacture, supply, dispensing, preparation by pharmacies, import, export, placing on the market, transport, storage and withdrawing from the market of medicinal products together with relevant recording and reporting carried out concerning such activities.

(2) For the purposes of this Act, placing on the market shall mean the wholesale, retail sale or transfer by any other means of medicinal products for charge or without charge.

(3) The provisions of this Act apply to the handling of medicinal products by governmental authorities, state agencies administered by government agencies and local authorities, whereas the provisions related to supervision apply unless otherwise provided by legislation concerning such governmental authorities, state agencies administered by government agencies and local authorities.
[RT I 2008, 35, 213 – entered into force 01.01.2009]

§ 4. Proprietary medicinal products and medicinal products prepared as magistral formulae

(1) Proprietary medicinal products are medicinal products with a trade name packaged for placing on the market.

(2) Proprietary medicinal products containing the same active ingredient in different quantities or different pharmaceutical forms are considered to be different proprietary medicinal products.

(3) Medicinal products prepared as magistral formulae are medicinal products prepared in a pharmacy in accordance with a medical prescription or order form.

§ 5. Active ingredients and excipients

(1) 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 which is intended for use for the purposes specified in subsection 2 (1) of this Act.

(2) The requirements in force concerning medicinal products extend to active ingredients unless otherwise provided by this Act or legislation established on the basis thereof.

(3) Excipients are the ingredients of medicinal products which are not active ingredients.

§ 6. Veterinary medicinal products and pre-mixes of medicated feedingstuffs

(1) Veterinary medicinal products are medicinal products which are designated by the manufacturer to be used only on animals.

(2) Pre-mixes of medicated feedingstuffs are veterinary medicinal products which are manufactured for the purpose of manufacture of medicated feedingstuffs.

(3) The requirements in force concerning medicinal products extend to veterinary medicinal products and pre-mixes of medicated feedingstuffs unless otherwise provided by this Act or legislation established on the basis thereof.

(4) This Act does not apply to inactivated immunological veterinary medicinal products prepared on the basis of the pathogens of a single animal breeding establishment and used for treatment of the animals of the same establishment.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 7. Homeopathic preparation

(1) Homeopathic preparations are products prepared of scheduled homeopathic substances in adherence to the rules of the European Pharmacopoeia or a pharmacopoeia of a Member State of the European Economic Area which bear the indication "*Homöopaatiline preparaat*" [homeopathic preparation] on their package.

(2) The requirements established for medicinal products extend to homeopathic preparations unless otherwise provided by this Act or legislation established on the basis thereof.

§ 8. Herbal medicinal products, herbal preparations and herbal substances

(1) Herbal medicinal products are medicinal products which contain, as their active ingredient, one or more:

1) herbal substances;

2) herbal preparations, or

3) herbal substance in combination with one or more herbal preparations.

(2) Traditional herbal medicinal products are medicinal products which meet all the following requirements:

1) they have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner qualified to prescribe medicinal products;

2) they are exclusively for administration in accordance with a specified strength and posology;

3) they are an oral, external and/or inhalation preparation;

4) the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application for marketing authorisation, including at least 15 years in a Member State of the European Economic Area;

5) the data on the traditional use of the medicinal product are sufficient, in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

(3) Herbal substances are all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author).

(4) Herbal preparations are preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.

§ 9. Immunological medicinal products, radiopharmaceuticals, and blood products

(1) Immunological medicinal products are any medicinal product consisting of vaccines, antibodies, toxins, serums or allergen products.

(2) Radiopharmaceuticals are medicinal products which contain radioactive isotopes. This Act does not apply to veterinary medicinal products containing radioactive isotopes.

(3) Blood product is a medicinal product manufactured or produced from blood, packaged and labelled according to the requirements and containing one or several blood constituents. Whole blood, blood components and plasma-derived products are blood products.
[RT I 2005, 13, 63 – entered into force 01.05.2005]

§ 10. Defective medicinal products

A medicinal product is deemed to be defective if it does not conform to quality requirements or if its package, labelling or package leaflet is substandard, inaccurate or misleading and as such, does not meet the requirements provided by this Act or legislation established on the basis thereof.

§ 11. Dispensing chemists and pharmacists

(1) For the purposes of this Act, a dispensing chemist is a person of the pharmaceutical profession who has completed the curriculum of dispensing chemist training.

(2) For the purposes of this Act, a pharmacist is a person of who has vocational secondary education or professional higher education in the field of pharmacy.

§ 12. Competent person

For the purposes of this Act, a competent person shall mean a person appointed by the holder of an activity licence for handling of medicinal products for performance of the duties specified in § 54 of this Act who meets the requirements provided by this Act or legislation established on the basis thereof. The head of the pharmacy shall be the competent person of a pharmacy.

§ 13. General requirements for medicinal products

(1) Only the following shall be sold and used in Estonia:

1) medicinal products in respect of which a marketing authorisation has been issued by the State Agency of Medicines or the Commission (hereinafter *authorised medicinal products*) which are released for dispensing within the European Economic Area;

2) medicinal products concerning which the State Agency of Medicines has issued a single authorisation for import and use;

3) medicinal products prepared in pharmacies in adherence to the requirements provided by this Act or legislation established on the basis thereof.

(2) Clinical trials of medicinal products shall be carried out with medicinal products concerning which the State Agency of Medicines has granted corresponding authorisation.

(3) Medicinal products shall have the presumed characteristics of use and be safe for the health of the consumer when used for their intended purpose. Veterinary medicinal products shall also be safe for the health of the consumer of the animal product.

(4) Medicinal products shall be placed on the market and dispensed in packaging with Estonian text, except in exceptional cases prescribed by legislation established on the basis of this Act, and the medicinal products shall be accompanied by information in Estonian concerning the composition, content of active ingredients, and requirements for the use and storage of the medicinal product.

(5) The name of a medicinal product and the design of its packaging shall not be misleading with regard to its composition or general effects and shall ensure the distinguishability of the product from other medicinal products. A medicinal product shall be provided with additional precautionary marking at the demand of the State Agency of Medicines

(6) [Repealed – RT I 2010, 15, 77 – entered into force 18.04.2010]

§ 14. Application of other Acts

(1) This Act applies to medicinal products which are narcotic drugs or psychotropic substances in so far as the Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof or legislation established on the basis thereof do not provide otherwise.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(2) This Act applies to radiopharmaceuticals in so far as legislation concerning radioactive substances does not provide otherwise.

(3) The provisions regulating the wholesale of medicinal products provided by this Act or legislation established on the basis thereof apply to the handling of medicinal products included in the national stockpiles in so far as legislation concerning the national stockpiles does not provide otherwise.
[RT I 2005, 64, 482 – entered into force 01.01.2006]
(4) This Act applies to blood products in so far as this area is not regulated otherwise by the Blood Act or legislation established on the basis thereof.
[RT I 2005, 64, 482 – entered into force 01.01.2006]

§ 15. Duties of Government of Republic, Minister of Social Affairs and Minister of Agriculture

(1) The Government of the Republic shall establish, by a regulation, threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation. Such procedure does not apply to veterinary medicinal products.

(2) In establishing the threshold values for mark-ups and the procedure for their implementation, the Government of the Republic shall take into account the accessibility of the medicinal products to the end user arising from geographical and financial reasons, the risks involved in placing the medicinal products on the market, and the weighted average mark-up. Weighted average mark-up means the average mark-up, expressed as a percentage, of medicinal products sold in different price categories, weighted by the share of turnover in terms of sales value expressed in wholesale purchase prices in each price group. Based on the data specified in subsection (4) of this section, the Ministry of Social Affairs shall prepare an annual analysis of the weighted average mark-up.

(3) The following principles shall be considered upon establishment of threshold values for mark-ups in wholesale and retail trade of medicinal products:

1) proportionate and fixed mark-ups are applied;

2) the threshold value of mark-up per one proprietary medicinal product shall not exceed 6.40 euros;

[RT I 2010, 22, 108 – entered into force 01.01.2011]

3) the mark-up for different price groups must create equal interest for handling all medicinal products by wholesale and retail sate;

4) the weighted average mark-up in wholesale must remain between 7–10%;

5) the weighted average mark-up in retail sale must remain between 21–25%.

(4) By 1 March each year, holders of an activity licence for wholesale trade in medicinal products are required to submit to the Ministry of Social Affairs a consolidated turnover report concerning the medicinal products not subject to medical prescription and medicinal product subject to medical prescription, except veterinary medicinal products, dispensed by all their wholesalers during the preceding year. The turnover report shall set out the sales volume of medicinal products expressed in sales in packages, the turnover expressed in wholesale purchase prices (without value added tax) and the turnover from products sold to retail pharmacies expressed in pharmacy purchase prices (without value added tax). The turnover data expressed in wholesale purchase prices shall be grouped into price groups which constitute the basis for wholesale mark-ups, and the turnover data expressed in pharmacy purchase prices shall be grouped into price groups which constitute the basis for retail mark-ups.

(5) In addition to legislation specified in this Act, the Minister of Social Affairs shall establish the following by a regulation:

1) the conditions and procedure for determining a substance or product as a medicinal product;

2) the conditions and procedure for classification of proprietary medicinal products;

3) the conditions and procedure for application for marketing authorisation in respect of homeopathic preparations;

4) the rules for keeping record of medicinal products dispensed in the course of provision of health care or veterinary services, and by social welfare institutions;

5) the conditions and procedure for application for marketing authorisation for herbal medicinal products and traditional herbal medicinal products;

6) a list of herbal substances, and the conditions and procedure for handling thereof and labelling of packages.

(6) The Minster of Agriculture shall establish, by a regulation, a list of biostimulants, hormone preparations and other substances the handling of which for the purpose of use on animals is prohibited, and special circumstances under which the use of such substances is authorised for treatment of animals. The regulation shall be approved by the Minister of Social Affairs.

(7) The Minister of Agriculture shall establish, by a regulation, the conditions and procedure for the use of medicinal products and medicated feedingstuffs for the prevention and treatment of animal disease.

§ 15[1]. Fee-charging services of State Agency of Medicines

For the purposes of development and better operation of the medicinal products market, the State Agency of Medicines may provide fee-charging services relating to the control analysis and statistical analysis of medicinal products pursuant to the procedure and price list established by a regulation of the Minister of Social Affairs. The fee for the provision of a service, which is specified in the price list, shall not exceed 3,195 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

Chapter 2
HANDLING OF MEDICINAL PRODUCTS

Division 1
Manufacture of Medicinal Products

§ 16. Manufacture of medicinal products

(1) Medicinal products may be manufactured only by the holder of an activity licence for manufacture of medicinal products.

(2) The manufacture of medicinal products, including intermediate products, the sterilisation, packaging, labelling, re-packaging, re-labelling and quality control of medicinal products, and the release of batches together with related purchase, receipt, storage and dispensing of materials is deemed to be manufacture of medicinal products.

(3) For the purposes of this Act, an activity licence for manufacture of medicinal products means a licence issued for the total or partial manufacture of medicinal products including, for the manufacture of active ingredients of medicinal products or medicinal products intended for clinical trials, or for partial manufacturing activities.

(4) An activity licence for manufacture of medicinal products is not mandatory if the activities specified in subsection (2) of this section are carried out by the holder of an activity licence of general pharmacy, hospital pharmacy or veterinary pharmacy (hereinafter *activity licence for provision of pharmacy services*) either for the preparation of medicinal products as magistral formulae or officinal formulae in accordance with a medicinal prescription, or for dividing-up into packages for dispensing (hereinafter *dividing-up into packages*).

(5) An activity licence for manufacture of medicinal products is not mandatory for the manufacture of medicinal products intended for clinical trials if the packaging, labelling, re-packaging or re-labelling of the medicinal products is carried out in a hospital pharmacy, and the medicinal products are used exclusively in the hospital operated by the person who formed the hospital pharmacy.

(6) Medicinal products imported to Estonia from countries outside of the European Economic Area (hereinafter *third countries*) shall be released for the purpose of dispensing thereof only by the holder of an activity licence for manufacture of medicinal products. This requirement does not apply to the import of medicinal products carried out on the basis of subsections 21 (1), (7) and (8) of this Act.

(7) The holder of an activity licence for manufacture of medicinal products shall guarantee that the manufacture, including the packaging, labelling, re-packaging and re-labelling of the active ingredients of medicinal products, and the excipients included in the list established by the European Commission on the basis of Article 46(f) of Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp. 67–128) is carried out in compliance with good manufacturing practice for active ingredients valid within the European Union.

(8) Medicinal products shall be manufactured in accordance with good manufacturing practice. The Minister of Social Affairs shall establish, by a regulation, the rules for manufacture of medicinal products in compliance with good manufacturing practice valid within the European Union, including the requirements applicable to facilities, installations, technical equipment, staff and organisation of work. Such rules are not applicable for the manufacture of herbal substances.

(9) Based on a request by a manufacturer or exporter of medicinal products, or a competent authority of a third country, the State Agency of Medicines shall issue, within thirty days after the receipt of the request, a certificate which proves that an activity licence for manufacture of medicinal products has been issued to the manufacturer of medicinal products in Estonia. If a marketing authorisation valid in Estonia has been granted in respect of a proprietary medicinal product to be exported, the State Agency of Medicines shall append an approved summary of the product characteristics to the certificate. If no marketing authorisation valid in Estonia exists concerning a proprietary medicinal product to be exported, the manufacturer of the medicinal product is required to provide explanation to the State Agency of Medicines as to the reasons for its absence.

Division 2
Import and Export of Goods Requiring Special Authorisation by State Agency of Medicines, and Authorisation for Use

§ 17. Goods requiring special authorisation of State Agency of Medicines and import and export thereof

(1) The Minister of Social Affairs shall establish, by a regulation, a list of goods which require a special authorisation granted by the State Agency of Medicines for the import and export thereof (hereinafter *special authorisation*), which includes medicinal products, active ingredients, tissues, cells and organs of human or animal origin used for medical purposes, and tissues, cells and organs of human origin used for scientific purposes (hereinafter *goods requiring special authorisation*).

[RT I 2008, 25, 163 – entered into force 01.01.2009]

(2) For the purposes of this Act, import of goods requiring special authorisation shall mean:

1) placing such goods under the customs procedure of release for free circulation (hereinafter *import*), or

2) transport of such goods from a Member State of the European Economic Area to Estonia.

(3) For the purposes of this Act, export of goods requiring special authorisation shall mean:

1) placing such goods under export procedure (hereinafter *export*), or

2) transport of such goods from Estonia to a Member State of the European Economic Area.

(4) In all cases of import and export specified in subsections (2) and (3) of this section, the authorisation for import or export is deemed to be the special authorisation.

§ 18. Importers and exporters of goods requiring special authorisation

(1) The following have the right to import goods requiring special authorisation to Estonia and export such goods from Estonia:

1) holders of an activity licence for wholesale trade in medicinal products;

2) holders of an activity licence for manufacture of medicinal products, for the purposes of manufacturing of their own produce and within the scope thereof, whereas holders of an activity licence for manufacture of medicinal products who employ a competent person responsible for the wholesale of medicinal products also have the right to import and export medicinal products not manufactured thereby;

3) representatives of applicants for marketing authorisation - samples to be presented in the course of application for marketing authorisation;

4) holders of an activity licence for health care provision - medicinal products intended for carrying out clinical trials and medicinal products for foreign aid;

[RT I 2008, 25, 163 – entered into force 01.01.2009]

4^{1}) holders of an activity licence for the handling of cells, tissues and organs – cells, tissues and organs of human or animal origin used for medical purposes and handling;

[RT I 2008, 25, 163 – entered into force 01.01.2009]

5) educational or research institutions - medicinal products, and tissues, cells and organs of human origin used for scientific or research purposes;

[RT I 2008, 25, 163 – entered into force 01.01.2009]

6) social welfare institutions - medicinal products for foreign aid;

7) other legal persons – medicinal products for research and other purposes with the prior consent of the State Agency of Medicines.

(2) Holders of an activity licence for wholesale trade or manufacture of medicinal products have the right to import goods requiring special authorisation provided that a corresponding special condition has been entered in the licences.

(3) Only holders of an activity licence for manufacture of medicinal products are permitted to import medicinal products directly from third countries to Estonia. The specified requirement does not apply in the case of medicinal products imported on the basis of subsections 21 (1), (7) and (8) of this Act and upon import of samples to be presented in the course of application for marketing authorisation, medicinal products received as foreign aid and medicinal products used in non-clinical research.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

§ 19. Special authorisation for import and export and notification of import and export

(1) For the import or export of goods requiring special authorisation:

1) authorisation for import or export third countries shall be obtained from the State Agency of Medicines for the import or export of such goods;

2) the State Agency of Medicines shall be duly notified of conveyance of goods from Estonia to an Member State of the European Economic Area or from an Member State of the European Economic Area to Estonia, except in the case of conveyance of the goods specified in subsections (2) and (3) of this section.

(2) Authorisation of the State Agency of Medicines for import or export is required for the import or export of narcotic drugs and psychotropic substances, and medicinal products intended for clinical trials.

[RT I 2005, 24, 180 – entered into force 20.05.2005]

(3) Authorisation of the State Agency of Medicines for import or export is required for the import or export of tissues, cells and organs of human or animal origin used for medical purposes, and tissues, cells and organs of human origin used for research purposes under the conditions established on the basis of subsection (5) of this section.

[RT I 2008, 25, 163 – entered into force 01.01.2009]

(4) The State Agency of Medicines shall be notified, pursuant to the procedure provided in subsection (5) of this section, as soon as possible but not later than on the fifth working day after the goods are exported or imported.

(5) The Minister of Social Affairs shall establish, by a regulation, the conditions and procedure for the import and export, carrying for personal use and sending by post of goods requiring special authorisation of the State Agency of Medicines, and the forms of special authorisations, including the conditions under which authorisation of the State Agency of Medicines or giving notification to the State Agency of Medicines is required for the import or export of tissues, cells and organs of human or animal origin used for medical or research purposes.

[RT I 2008, 25, 163 – entered into force 01.01.2009]

§ 20. Differences upon import and export of goods requiring special authorisation

(1) Medicinal products carried for first-aid purposes on ambulance cars of emergency medical care providers, state rescue services and the Estonian Defence Forces, and on board of ships and aircraft engaged in international transportation are exempt from import and export restrictions arising from this Act.

(2) Special authorisation is not required if goods requiring special authorisation are imported and exported by rescue teams for use in rescue operations.

(3) If goods requiring special authorisation are exported by Estonian rescue teams, including during exercises, the Rescue Board shall prepare, immediately after assembling the goods requiring special authorisation to be exported, a list of such goods and submit it to the State Agency of Medicines. The Rescue Board shall prepare a list of goods requiring special authorisation which were re-imported and submit it to the State Agency of Medicines within thirty days after the rescue team returns to Estonia.

(4) If goods requiring special authorisation are imported by a foreign rescue team, the team shall carry a list of goods requiring special authorisation approved by the head of the team which shall be submitted to the State Agency of Medicines upon request. The Rescue Board is required to notify the State Agency of Medicines of the arrival of a foreign rescue team to Estonia.

(5) The provisions of subsections (2)-(4) of this section apply to the import and export by the Estonian Defence Forces of goods requiring special authorisation with the specifications arising from the organisation of the Defence Forces.

§ 21. Import and use of unauthorised medicinal products

(1) Unauthorised medicinal products may be imported and used, on the basis of a single authorisation for import and use of the State 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.

(2) A doctor qualified to prescribe the medicinal product shall submit an application for the use of an unauthorised medicinal product to the State Agency of Medicines. A veterinarian shall submit such application through a wholesaler of veterinary medicinal products or a pharmacy.

[RT I 2008, 3, 22 – entered into force 01.09.2008]

(3) The State Agency of Medicines shall verify the information and documents submitted by the applicant and decide, within thirty days after receipt of the application, whether the use of the unauthorised medicinal product is justified. The State Agency of Medicines shall inform the applicant of the decision.

(4) The use of an unauthorised medicinal product is not justified if at least one of the following circumstances exists:

1) the applicant has not submitted an application which meets the requirements of the procedure established on the basis of subsection 19 (5) of this Act;

2) the data concerning the quality of the medicinal product is insufficient, the quality of the medicinal product is non-conforming or the efficacy of the product is not certified to the knowledge of the State Agency of Medicines;

3) use of the medicinal product may be harmful to the health of humans or animals;

4) use of the medicinal product for treatment is not medically justified;

5) the applicant knowingly submits incorrect information.

(5) If in the opinion of the State Agency of Medicines, the use of an unauthorised medicinal product is justified, the State Agency of Medicines grants, based on an application of the holder of an activity licence for wholesale trade in medicinal products, authorisation for import and use of the medicinal product to the licence holder.

(6) The authorisation for import and use an unauthorised medicinal product does not release the doctor who submitted a corresponding application and the manufacturer of the medicinal product from liability for damage to health resulting from the use of the medicinal product for its intended purposes.

(7) In the absence of an authorised medicinal product with equivalent effect or if such product is not available, the State Agency of Medicines may grant, in addition to the cases specified in subsection (1) of this section, authorisation to import and use:

1) unauthorised medicinal products based on an application of a professional organisation of doctors for a diagnosis specified in the application;

2) unauthorised antidotes;

3) unauthorised medicinal products for use within the framework of national programmes.

(8) In addition to the cases specified in subsections (1) and (7) of this section, the State Agency of Medicines may also grant authorisation for the import and use of unauthorised medicinal products:
1) for use in emergencies and upon declaration of an emergency situation on the basis of the Emergency Situation Act;
2) for national programmes.
[RT I 2009, 39, 262 – entered into force 24.07.2009]

§ 22. Application for special authorisation

(1) For obtaining special authorisation, an application for an authorisation for import or export shall be submitted to the State Agency of Medicines. A separate application shall be submitted for the import or export of narcotic drugs and psychotropic substances and veterinary medicinal products.
(2) An application for the export of narcotic drugs and psychotropic substances shall contain, for each consignment of medicinal products, authorisation for the import of such substances granted by the competent authority of the state to which the products are to be conveyed.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

(3) An application in conformity to the requirements established on the basis of subsection 19 (5) of this Act shall be submitted to the State Agency of Medicines at least five working days before goods requiring special authorisation arrive at the customs frontier or the border between Estonia and an Member State of the European Economic Area.

(4) Upon import of unauthorised medicinal products, the number designated by the State Agency of Medicines to the application for grant of a single authorisation for import and use by a doctor or veterinarian qualified to prescribe the medicinal product shall be set out in the application.

(5) Upon application for the import of an unauthorised medicinal product, information concerning the quality of the product shall be presented at the demand of the State Agency of Medicines.

§ 23. Authorisation for use

(1) Unauthorised medicinal products and imported medicinal products may be placed on the market and used in Estonia only based on an authorisation for import and an authorisation for use granted by the State Agency of Medicines.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(1^1) An authorisation for use granted by the State Agency of Medicines is not required upon import of medicinal products intended for clinical trials.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(2) If necessary, the State Agency of Medicines shall enter a notation concerning the packaging of the medicinal product and information necessary for the delivery of the medicinal product on the authorisation for use.

(3) Upon application for authorisation for use, a sample package of the medicinal product and additional information concerning the place of manufacture, quality of the batch and packaging of the medicinal product shall be presented at the demand of the State Agency of Medicines.

§ 24. Grant of special authorisation and authorisation for use

(1) The State Agency of Medicines shall decide on the grant of authorisation for import or export, and authorisation for use within five working days after receipt of the corresponding application and other requisite information and documents.

(2) The State Agency of Medicines may refuse to grant authorisation for import or export, and authorisation for use if at least one of the following circumstances exist:

1) incomplete information is submitted or incorrect information is knowingly submitted upon application for authorisation;

2) the applicant has been issued a precept for compliance with the requirements provided by this Act or legislation established on the basis thereof and the obligation set out in the precept has not been complied with;

3) the State Agency of Medicines has information casting doubt on the requisite quality of the medicinal product;

3^1) the State Agency of Medicines has information casting doubt on the requisite handling of the medicinal product;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

4) the use of the medicinal product to be imported is prohibited in Estonia or it is known that the use of the medicinal product to be exported is prohibited in the importing country.

(3) Written authorisation of the State Agency of Medicines is required for the distribution in Estonia, for a charge or without charge, of goods requiring special authorisation by rescue teams or defence forces of Estonia or a foreign country.

§ 25. Medicinal products for personal use

(1) Travellers arriving to or departing from Estonia have the right to carry medicinal products to be used, for medical reasons, personally by them or on animals accompanying

them in quantities, for periods of time and under the conditions set out in the regulation established on the basis of subsection 19 (5) of this Act. Travellers are forbidden to carry full blood and blood components.

(2) Medicinal products may be sent to foreign countries and to Estonia by post in quantities permitted by the regulation established on the basis of subsection 19 (5) of this Act. Narcotic drugs or psychotropic substances, full blood and blood components shall not be sent by post. [RT I 2005, 24, 180 – entered into force 20.05.2005]

(3) Mail order sale of medicinal products as well as delivery by post or express service of medicinal products ordered through the Internet is prohibited.

(4) If the quantities of the medicinal products specified in subsections (1) and (2) of this section exceed the maximum permitted quantities set for such substances, written permission shall be obtained from the State Agency of Medicines pursuant to the procedure provided in subsection 19 (5) of this Act before the performance of the acts.

Division 3
Wholesale Trade in Medicinal Products

§ 26. Wholesale trade in medicinal products

(1) Only the holder of an activity licence for wholesale trade in medicinal products or the holder of an activity licence for manufacture of medicinal products have the right to wholesale and dispense medicinal products in quantities.

(2) The holder of an activity licence for manufacture of medicinal products who wishes to engage in the wholesale of medicinal products which are not manufactured by the holder of the activity licence is required to employ, in addition to the competent person responsible for the manufacture of medicinal products, also a competent person responsible for the wholesale of medicinal products for the performance of the duties set out in subsections 54 (4) and (5) of this Act.

(3) The import, supply, warehousing, storage, transport and export of medicinal products for the purpose of wholesale or any other manner of dispensing of medicinal products in quantities is deemed to be wholesale of medicinal products.

(4) Wholesale purchases of medicinal products shall be made and dispensed in quantities in any other manner only to persons who hold an activity licence for provision of pharmacy services, manufacture of medicinal products or wholesale of medicinal products.

(5) Holders of an activity licence for wholesale of medicinal products or manufacture of medicinal products also have the right to dispense samples of medicinal products to persons who hold marketing authorisation of medicinal products and medicinal products intended for clinical trials to persons conducting a clinical trial.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(6) The State Agency of Medicines has the right to permit holders of an activity licence for wholesale of medicinal products or manufacture of medicinal products to dispense medicinal products free of charge to hospitals and social welfare institutions which, pursuant to legislation, have no right to purchase medicinal products from wholesalers.

(7) Wholesalers have the right to dispense medicinal gases, full blood and blood components directly to health care providers, whereas medicinal gases may be dispensed directly to the consumer within the meaning of the Consumer Protection Act (RT I 2004, 13, 86; 41, 278) (hereinafter *consumer*).

(8) Holders of an activity licence for wholesale of medicinal products shall purchase medicinal products only from holders of an activity licence for manufacture of or wholesale trade in medicinal products, or from holders of an activity licence for provision of pharmacy services.

(9) The following shall be established by a regulation of the Minister of Social Affairs:

1) the conditions of and procedure for wholesale of medicinal products, including the requirements for facilities, installations, technical equipment, staff, recording, reporting and organisation of work;

2) the conditions of and procedure for repackaging of starting materials for medicinal products by holders of an activity licence for wholesale of medicinal products.

§ 27. Wholesale of medicinal products to veterinarians

(1) Veterinary medicinal products and medicinal products for human use may be sold wholesale to veterinarians holding a valid activity licence for provision of veterinary services only under the conditions and pursuant to the procedure established on the basis of clause 26 (9) 1) of this Act. A special labelling bearing the words "*Ainult veterinaarseks kasutamiseks*" [for veterinary use only] shall be attached to medicinal products for human use which are dispensed to veterinarians.

(2) The following may pay for medicinal products ordered by a veterinarian:

1) an undertaking engaged in agricultural production if the veterinarian is employed in an enterprise belonging thereto, and a confirmation to this effect signed by the head of the enterprise and the veterinarian is presented to the wholesaler of the medicinal products;

2) an undertaking engaged in veterinary practice.

(3) If, in the case specified in clause (2) 1) of this section, an order for medicinal products is sent by post or fax, or transmitted in any other manner, an order prepared in writing must be confirmed by the signature and personal seal of the veterinarian, and an order sent by electronic means must be confirmed by the digital signature of the veterinarian.

(4) The head of an agricultural enterprise is required to inform the wholesaler who supplies medicinal products to the enterprise of the termination of an employment relationship with a veterinarian or the change in veterinarians.

§ 28. Right to make wholesale purchases of medicinal products

(1) In addition to the persons specified in §§ 26 and 27 of this Act, the following persons have the right to make wholesale purchases of medicinal products: social welfare institutions, schools where classes for students with special educational needs as specified in the Basic Schools and Upper Secondary Schools Act have been opened, state authorities, research institutions and owners of ambulance crews entered in the list of persons authorised to make wholesale purchases of medicinal products, which list has been established by a regulation of the Minister of Social Affairs.

[RT I 2010, 41, 240 – entered into force 01.09.2010]

(2) A person wishing to obtain the right to make wholesale purchases of medicinal products shall submit an application to this effect to the Ministry of Social Affairs.

Division 4
Pharmacy Services

§ 29. Pharmacy services

(1) Pharmacy services shall mean the retail sale or other dispensing of medicinal products together with provision of related consultations for the appropriate and effective use of medicinal products, and provision of information to the user on the correct and safe use and preservation of medicinal products, and the preparation of medicinal products as magistral formulae and officinal formulae and dividing-up into packages of medicinal products.

(2) Pharmacy services shall be provided only by pharmacies holding a corresponding activity licence and structural units thereof, taking account of the restrictions established for different categories of pharmacies.

(3) Only dispensing chemists and pharmacists registered by the Heath Board may provide pharmacy services at a pharmacy or structural unit thereof. Pharmacy services involving veterinary medicinal products may also be provided by veterinarians who are, however, prohibited from preparing such medicinal products.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

(4) Persons acquiring the speciality of dispensing chemist or pharmacist are permitted to provide pharmacy services only within the framework of the official curriculum, based on a letter of referral for practical training and under the supervision of a dispensing chemist or pharmacist.

§ 30. Categories and structural units of pharmacies

(1) Pharmacies are divided into the following categories:

1) general pharmacy;

2) veterinary pharmacy;

3) hospital pharmacy.

(2) A general pharmacy is an enterprise formed for the purpose of provision of pharmacy services, the location of which shall be marked with the word "*Apteek*" [pharmacy], accompanied by the name of the pharmacy.

(3) A veterinary pharmacy is an enterprise formed for the purpose of provision of pharmacy services which has the right to dispense only veterinary medicinal products. The location of a veterinary pharmacy shall be marked with the word "*Veterinaarapteek*" [veterinary pharmacy].

(4) A hospital pharmacy is a structural unit of a hospital which supplies such hospital and, based on an agreement, also hospitals belonging to other operators of hospitals, social welfare institutions or holders of an activity licence for provision of emergency medical care with medicinal products and other products for medical purposes.

(5) A hospital pharmacy is required to check the conformity of the storage and recording of medicinal products at the hospitals operated by the person who formed the hospital pharmacy. In performance of the checks, a hospital pharmacy has the right to obtain necessary information and make proposals to bring the storage and recording of medicinal products into conformity with the established requirements.

(6) Hospital pharmacies have no right to engage in the retail sale of medicinal products.

(7) A pharmacy of a state agency operating as a structural unit of the state agency may be formed for performance of duties of the state. A pharmacy of a state agency shall check the conformity of storage and recording of medicinal products used for performance of duties of the state.

(8) A pharmacy of a state agency shall conform to the requirements set for hospital pharmacies, including the requirements for the head of a pharmacy, established by this Act and on the basis of this Act, taking account of the specifications arising from the nature of such pharmacy.

(9) A branch pharmacy is a structural unit of a pharmacy. One general pharmacy or veterinary pharmacy may have up to three branch pharmacies. The location of a branch of a general pharmacy shall be marked by the name of the general pharmacy accompanied by the word "*haruapteek*" [branch pharmacy].

(10) The requirements established for the corresponding category of pharmacy apply to the activities of a branch pharmacy. Branch pharmacies are entered in the activity licence of the corresponding pharmacy.

§ 31. General requirements for activities of pharmacies

(1) Only medicinal products in respect of which a marketing authorisation, or an authorisation for the import and use has been granted, and medicinal products prepared as magistral formulae or officinal formulae and medicinal products divided up into packages by the same pharmacy may be dispensed by a pharmacy, taking account of the conditions prescribed by § 32 of this Act.

(2) Pharmacies have the right to handle narcotic drugs and psychotropic substances listed in Schedules I and II and medicinal products containing such substances only with the permission of the State Agency of Medicines. Such permission is granted based on an application by a pharmacy provided that requisite conditions for handling the substances exist in the pharmacy.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

(3) A pharmacy may purchase medicinal products only from an enterprise belonging to the holder of an activity licence for manufacture of or wholesale trade in medicinal products, or from another pharmacy.

(4) A pharmacy is required to keep record of the handling of medicinal products and to submit corresponding reports to the State Agency of Medicines pursuant to the procedure established on the basis of clause (6) 3) of this section.

(5) A pharmacy is permitted to sell, in addition to medicinal products, only products for medical purposes and toiletries shall, provided it does not interfere with the sale of medicinal products. Only veterinary medicinal products, animal care products and other products used in animal-keeping shall be sold in a veterinary pharmacy.

(6) The following shall be established by a regulation of the Minister of Social Affairs:

1) the conditions and procedure for preparation, dividing-up into packages and checking of medicinal products by pharmacies, a list of medicinal products prepared as officinal formulae by pharmacies, including the procedure for labelling of medicinal products and documentation of the preparation thereof, the expected shelf-life of prepared medicinal products and the composition of medicinal products prepared as officinal formulae;

2) health protection requirements for pharmacies and their structural units;

3) the conditions of and procedure for provision of pharmacy services, including the requirements for facilities, installations, technical equipment, staff, recording, reporting and organisation of work.

(7) A regulation established on the basis of clause (6) 3) of this Act may provide different requirements for the facilities and technical equipment of general pharmacies depending on their location in a city or within the territory of a local authority which does not have the status of a city. Such regulation may prescribe different requirements for hospital pharmacies and veterinary pharmacies than those established for general pharmacies.

§ 32. Preparation of medicinal products by pharmacies

(1) A general pharmacy which is located or a pharmacy whose branch is located in a city with more than 4000 inhabitants is required to prepare non-sterile medicinal products. Veterinary pharmacies have no right to prepare medicinal products.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(2) Taking account of the specifications arising from subsection (1) of this section, a general pharmacy has the obligation to prepare medicinal products as magistral formulae according to medical prescription or order form, or based on an order from a branch pharmacy. Pharmacies which have no right to prepare sterile medicinal products must order sterile medicinal products from a pharmacy which holds such right.

(3) Pharmacies which have no obligation to prepare medicinal products are required to receive medical prescriptions for preparation of medicinal products as magistral formulae, and to order and dispense such products within a reasonable period of time. An order for the preparation of a medicinal product shall be immediately forwarded to a general pharmacy obligated to prepare medicinal products, and such pharmacy must guarantee that the product prepared as magistral formula is prepared and dispensed within a reasonable period of time.

(4) A branch of a general pharmacy has the obligation to receive medical prescriptions for preparation of medicinal products as magistral formulae and to immediately forward the order for preparation of the medicinal product to a general pharmacy and such pharmacy must guarantee that the medicinal product prepared as magistral formula is prepared and dispensed by the branch pharmacy within a reasonable period of time.

(5) Pharmacies are only permitted to prepare and divide up into packages the medicinal products prepared as officinal formulae which are included in the list established on the basis of clause 31 (6) 1) of this Act.

(6) Medicinal products prepared or divided up into packages by a general pharmacy or veterinary pharmacy shall be dispensed, on the basis of a medical prescription made up in respect of a medicinal product prepared as magistral formula or an order based on an order form, for the purpose of forward selling only to their branch pharmacies or to general pharmacies with no obligation to prepare medicinal products.

(7) Pharmacies with the right to prepare sterile medicinal products prepared by pharmacies with the right to prepare such products shall be dispensed, on the basis of a medical prescription made up in respect of a medicinal product prepared as magistral formula or an order based on an order form, for the purpose of forward selling to other pharmacies.

§ 33. Issue of prescriptions for medicinal products and dispensing of medicinal products by pharmacies

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(1) Medicinal products subject to medical prescription shall be dispensed by general pharmacies and veterinary pharmacies to consumers only on the basis of a conforming medical or veterinary prescription.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(1^1) Medicinal products subject to medical prescription shall be dispensed by general pharmacies and veterinary pharmacies on the basis of a prescription issued lawfully in a Member State of the European Union, a Member State of the European Economic Area or Switzerland (hereinafter *EU prescription*).

[RT I 2010, 7, 31 - entered into force 26.02.2010]

(1^2) In order to ensure safe use of medicinal products, an EU prescription is valid:

1) 60 days after issuing thereof unless another term of validity is indicated in the prescription;

2) if the prescription sets out the information, the composition of which shall be established by a regulation of the Minister of Social Affairs.

[RT I 2010, 7, 31 - entered into force 26.02.2010]

(2) Medicinal products subject to medical prescription shall be dispensed by general pharmacies and veterinary pharmacies based on a conforming order form to health care providers, including to self-employed health care providers, and to other persons qualified to prescribe medicinal products, and to persons whose right to purchase medicinal products subject to medical prescription arises from other legislation, and with the permission of the State Agency of Medicines, to persons who need medicinal products subject to medical prescription for carrying out duties arising from legislation.

(3) Veterinarians are permitted to dispense only veterinary medicinal products through a veterinary pharmacy but they may dispense medicinal products for human use which are used for the treatment of animals through a general pharmacy.

(4) Medicinal products subject to medical prescription which are not veterinary medicinal products but are to be used on animals must be dispensed to veterinarians based on an order form, and to consumers based on a medical prescription issued by a veterinarian. Medicinal products dispensed for veterinary use shall be marked with the words "*Ainult veterinaarseks kasutamiseks*" [for veterinary use only].

(5) Upon dispensing of a medicinal product from a pharmacy, the recipient of the medicinal product shall be informed of the correct and safe use and preservation of the medicinal product.

(6) Except in cases prescribed by law, pharmacies are prohibited to disclose information related to the issue of prescriptions for medicinal products.

(7) The following shall be established by a regulation of the Minister of Social Affairs:

1) the conditions and procedure for the issue of prescriptions for medicinal products and for the dispensing of medicinal products by pharmacies, and the format of prescriptions;

2) the conditions and procedure for the dispensing of medicinal products by pharmacies on the basis of EU prescriptions.

[RT I 2010, 7, 31 - entered into force 26.02.2010]

(8) The Minister of Social Affairs may, by a regulation, establish restrictions on medicinal products or classes of medicinal products dispensed on the basis of EU prescriptions in the interests of the protection of public health.

[RT I 2010, 7, 31 - entered into force 26.02.2010]

Division 5
Storage and Transport of Medicinal Products and Handling of Medicinal Products Withdrawn from Market

§ 34. Storage and transport of medicinal products

(1) Medicinal products shall be transported and stored in a manner which ensures the preservation of their quality and prevents them from falling into the hands of unauthorised persons or becoming a hazard to humans, animals or the environment.

(2) An importer of medicinal products shall verify that the medicinal products are stored in a customs warehouse, free zone or free warehouse under the conditions established by the manufacturer.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) Processing of medicinal products, including making alterations to the packaging or labelling thereof is prohibited in a customs warehouse, free zone or free warehouse.

(4) If medicinal products or substances used for the preparation thereof need to be detained in a customs warehouse or customs terminal for the purpose of customs control, the customs authorities shall consider, upon designating the location for performance of customs control, the existence of conditions for the preservation and conforming storage of such goods.

(5) The Minister of Social Affairs shall establish, by a regulation, the conditions and procedure for storage and transportation of medicinal products. Such procedure also applies to customs warehouses, free zones and free warehouses where medicinal products or substances used for the preparation thereof are stored.

§ 35. Unusable medicinal products

(1) All medicinal products which do not conform to quality requirements, whose shelf life has expired, the use of which is Estonia is prohibited or which cannot be used for their intended purpose due to other reasons (hereinafter *unusable medicinal products*) shall be withdrawn from the market.

(2) Persons handling medicinal products are required to separate unusable medicinal products from other goods and mark such products accordingly in a clearly understandable manner. Medicinal products withdrawn from the market shall be stored under conditions which prevent their placing on the market or use for other than the intended purpose, and guarantee their storage in a manner safe to humans, animals and the environment.

(3) Unusable medicinal products which, pursuant to § 8 of the Waste Act (RT I 2004, 9, 52; 30, 208) or the list established on the basis of subsection (2) 4) of the Waste Act, are defined

as hazardous waste, shall be collected separately from other waste according to the categories provided by the list, and shall be marked pursuant to the procedure established on the basis of subsection 62 (3) of the Waste Act.

(4) Unusable narcotic drugs and psychotropic substances shall be stored under the conditions established for such substances.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

(5) Packaging used for collecting or transporting unusable cytostatic or cytotoxic medicinal products shall be marked with a clearly distinguishable additional warning to such effect.

§ 36. Destruction of unusable medicinal products

(1) Unusable medicinal products deemed to be hazardous waste shall be destroyed in an enterprise holding a licence for handling hazardous waste for such activity. For the purposes of this Act, destruction means the act of removing or recycling of waste in the process of which the characteristics of the active ingredients of the medicinal products are changed such that the products no longer have the dangerous effects specified in § 8 of the Waste Act.

(2) The person handling medicinal products which to be destroyed as non-hazardous waste shall, directly before destruction, remove the packaging of the medicinal products, render any printed packaging material unreadable and crush any solid medicinal waste.

(3) If the categorisation as hazardous waste of narcotic drugs and psychotropic substances is not verified pursuant to the procedure approved on the basis of subsection 6 (2) of the Waste Act, such waste may be destroyed as non-hazardous waste, additionally observing the conditions specified in subsection (4) of this section.
(4) Unusable narcotic drugs and psychotropic substances shall be destroyed as non-hazardous waste only in the presence of a representative of the State Agency of Medicines. In cases where substances and products are to be destroyed by the person specified in subsection (1) of this section, the handler of the substances is required to deliver such substances in separate lots, and the substances must be destroyed immediately after their receipt.

(5) A person who receives medicinal products from the handler thereof shall be provided with a legal instrument concerning the delivery of the products which shall set out the name of the medicinal product, name of the manufacturer, batch number, quantity, name of the person who delivers the medicinal products for destroying and the name of the person receiving the medicinal products. The deliverer and recipient shall verify the transaction by entering the date on the instrument and signing it. The instrument shall be prepared in two original copies of which one shall be retained by the deliverer and the other by the recipient.

(6) A handler of medicinal products shall prepare a legal instrument concerning the destruction of the medicinal products, which shall set out the data specified in subsection (5) of this section, the name of the person who destroyed the products and the method of destruction. The fact of destruction is verified by entering the date and signing the instrument. If a representative of the State Agency of Medicines is present at the destruction, he or she shall verify the destruction of the medicinal products by signing the legal instrument for destruction, one copy of which shall be retained by the State Agency of Medicines.

(7) The legal instruments specified in subsections (5) and (6) of this section shall be preserved for a period of two years, and the instruments for withdrawal from the market of medicinal products which are narcotic drugs or psychotropic substances shall be preserved for a period of five years.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

§ 37. Receipt of unusable medicinal products from consumers

(1) In addition to persons holding a waste permit on the basis of the Waste Act, general pharmacies and, in the part of veterinary medicinal products, also veterinary pharmacies are required to receive unusable medicinal products for destruction from consumers and send such products for destruction based on the procedure established on the basis of subsection (3) of this section.

(2) Only pharmacies with the right to handle medicinal products which are narcotic drugs or psychotropic substances have the right to receive unusable medicinal products which are narcotic drugs or psychotropic substances from consumers.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

(3) The Minister of Social Affairs shall establish, by a regulation, the procedure for receiving unusable medicinal products from consumers by general and veterinary pharmacies, and for sending such products for destruction.

Division 6
Activity Licence for Handling Medicinal Products

Subdivision 1
General Provisions

§ 38. Activity licence for handling medicinal products

(1) The classes of activity licence for handling medicinal products (hereinafter *activity licence*) are the activity licence for manufacture of medicinal products, activity licence for wholesale trade in medicinal products and activity licence for provision of pharmacy services. The classes of activity licence for provision of pharmacy services are the activity licence for general pharmacy, activity licence for hospital pharmacy and activity licence for veterinary pharmacy.

(2) The requirements for hospital pharmacies apply for application for an activity licence for a pharmacy of a state agency.

(3) An activity licence grants the holder of the licence the right to operate pursuant to the procedure and under the conditions provided by this Act and legislation established on the basis thereof within a specified period of time in the area of activity, place of business and under the conditions set out in the activity licence. A licence is not transferable.

(4) Upon provision of pharmacy services, except in a hospital pharmacy and a branch thereof, a certificate in proof of the existence of an activity licence or a copy of such certificate approved by the State Agency of Medicines shall be displayed in the service hall in a visible place.

§ 39. Register of activity licences for handling of medicinal products

(1) The register of activity licences for handling of medicinal products is a national register established by the Government of the Republic by proposal of the Minister of Social Affairs. The statutes of the register of activity licences for handling of medicinal products shall be established by the Government of the Republic.

(1[1]) The purpose of the state register of activity licences for handling medicinal products is to keep account of holders of the licences, their professional activities and supervision relating to handling medicinal products, in order to obtain information for performing the functions of management and organisation of the medicinal products policy and for producing statistics regarding handling medicinal products.

[RT I, 02.02.2011, 2 – entered into force 01.03.2011]

(1[2]) The register processes the following:

1) data of applications for activity licences for handling medicinal products and data of activity licences for handling medicinal products;

2) data gathered in the course of exercising state supervision over handlers of medicinal products;

3) data of statistical reports submitted by holders of pharmacy licences;

4) data gathered in the course of exercising state supervision over defective medicinal products;

[RT I, 02.02.2011, 2 – entered into force 01.03.2011]

(1[3]) Applicants for activity licences for handling medicinal products, holders of activity licences for handling medicinal products and the State Agency of Medicines are required to submit data to the register.

[RT I, 02.02.2011, 2 – entered into force 01.03.2011]

(1[4]) The chief processor has the right to submit queries by way of cross-usage for the purpose of obtaining data to be entered in the register and to obtain data from other state registers.

[RT I, 02.02.2011, 2 – entered into force 01.03.2011]

(2) The chief processor of the register of activity licences for handling of medicinal products is the State Agency of Medicines.

§ 40. Scope of activity licence

(1) Every general pharmacy, veterinary pharmacy, hospital pharmacy and place of business for wholesale trade or manufacture of medicinal products belonging to the holder of an activity licence shall have a separate activity licence.

(2) The structural units of a pharmacy shall be entered on the activity licence of a general pharmacy, veterinary pharmacy or hospital pharmacy, correspondingly.

(3) In the case of wholesale trade in medicinal products, the place of storage of the medicinal products is deemed to be the place of business and, if the activity licence has been issued for wholesale trade without the right of storage, the place of business shall be the office.

Subdivision 2
Holder of Activity Licence

§ 41. Holder of activity licence

Authorities of executive power, local authorities, other legal persons in public law, self-employed persons and legal persons in private law, except non-profit associations, may be the holders of an activity licence.

§ 42. Restrictions related to holding of activity licence

(1) Except in the case specified in subsection (2) of this section, the holder of an activity licence is permitted to concurrently hold licences belonging to only one of the types of activity licence specified in subsection 38 (1) of this Act.

(2) The holder of an activity licence for wholesale trade in medicinal products may concurrently hold an activity licence for altering the labelling and outer packages of medicinal products, for re-packaging of starting materials used for manufacture of medicinal products and for the import of medicinal products from third countries to Estonia and release thereof. The holder of an activity licence for a hospital pharmacy may hold, concurrently with the activity licence for provision of pharmacy services, an activity licence for manufacture of full blood and blood components and for packaging, labelling, re-packaging or re-labelling of medicinal products intended for clinical trials.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) The holder of an activity licence for a general pharmacy, hospital pharmacy or veterinary pharmacy or a subsidiary thereof shall not be a shareholder or a member of a legal person in private law holding an activity licence for manufacture of medicinal products or wholesale trade in medicinal products.

[RT I, 08.11.2010, 2 – entered into force 18.11.2010]

(4) The holder of an activity licence for manufacture of medicinal products or provision of health services or a subsidiary thereof, a person qualified to prescribe medicinal products or the holder of an activity licence for provision of veterinary services shall not be a shareholder or member of a legal person in private law holding an activity licence for a general pharmacy or veterinary pharmacy. Such requirement does not apply to the holder of an activity licence for manufacture of medicinal products who has been granted the activity licence for manufacture of medicinal products in compliance with subsection (2) of this section.

[RT I, 08.11.2010, 2 – entered into force 18.11.2010]

§ 42[1]. Restrictions on issue and amendment of activity licence of general pharmacy

(1) Upon issue of an activity licence of a general pharmacy to a general pharmacy, upon amendment of an activity licence of a general pharmacy in connection with establishment of a new structural unit with the place of business in a city, or upon change of the place of business of a general pharmacy or a structural unit thereof in a city, a restriction applies that new activity licences of a general pharmacy shall not be issued for operation in the corresponding city, new structural units of a general pharmacy shall not be established, or the place of business of a general pharmacy, including a structural unit of the general pharmacy, shall not be changed if, according to the State Agency of Medicines and the Statistical Office,

there are less than 3000 inhabitants in this city per general pharmacy, including a structural unit of a general pharmacy.
(2) The restriction specified in subsection (1) of this section does not apply upon amendment of an activity licence of a general pharmacy in connection with changes in the place of business of the general pharmacy or a structural unit of the general pharmacy, provided that the new place of business is not farther away than 500 metres from the previous place of business.
(3) In settlements which are not cities, activity licences of a general pharmacy for opening a pharmacy shall not be issued and a structural unit of a general pharmacy shall not be opened at a distance closer than 1 kilometre to an already existent general pharmacy or a structural unit thereof. The specified restriction also applies if the place of business of a general pharmacy or a structural unit thereof is changed.
(4) If the basis for the restriction provided for in subsection (1) or (3) of this section has ceased to exist or a corresponding local authority has forwarded a written reasoned proposal to the State Agency of Medicines as regards the need to open a general pharmacy or a structural unit thereof in a specific region due to the relocation of population, poor quality of pharmacy services or the absence of a pharmacy, the corresponding information shall be disclosed on the website of the State Agency of Medicines.
(5) Applications for the receipt of the right to open a general pharmacy or a structural unit thereof shall be submitted to the State Agency of Medicines within fourteen days after the disclosure of such information. The application shall set out the applicant's name, address, registry code or personal identification code, details, a statement from the regional tax centre of the Tax and Customs Board certifying the absence of tax arrears with respect to the applicant and a specification whether the applicant wishes to open a general pharmacy or a structural unit thereof. The application shall be confirmed by the signature and date provided by the person with the right to represent the applicant.
(6) Upon receipt of more than one application which conforms to the requirements, a person applying for the right to open a general pharmacy shall be preferred. Upon receipt of more than one application for opening a general pharmacy, lots shall be drawn between the applicants. If only applications for opening a structural unit of a general pharmacy are received, lots shall be drawn between the representatives of the structural units. The results of drawing of lots shall be disclosed on the website of the State Agency of Medicines within three working days.
(7) A person who has obtained the right to open a general pharmacy or a structural unit thereof shall submit an application which conforms to the requirements for the receipt of an activity licence of a general pharmacy not later than within 180 days after the disclosure of the results of drawing of lots. Upon failure to submit the specified application, lots shall be drawn again between persons who submitted applications which conform to the requirements specified in subsection (5) of this section pursuant to the procedure provided for in subsection (6) of this section.
[RT I 2005, 24, 180 – entered into force 01.01.2006]

§ 43. Restrictions related to areas of activity of holder of activity licence, head of pharmacy and veterinary employed by holder of activity licence

(1) The holder of an activity licence for wholesale trade in medicinal products or manufacture of medicinal products shall not provide veterinary services.

(2) The holder of an activity licence for general pharmacy or veterinary pharmacy shall not provide health care services and veterinary services during the term of validity of the activity licence.

(3) The holder of an activity licence for hospital pharmacy shall not operate in other areas of activity except in the provision of pharmacy services, manufacture of full blood and blood components and the activities specified in subsection 22 (3) of the Health Services Organisation Act.

(4) A person employed as the head of a pharmacy shall not, at the same time, be employed by the holder of an activity licence for wholesale trade or manufacture of medicinal products.

(5) A person employed as the competent person with a wholesaler of medicinal products shall not, at the same time, be employed by the holder of an activity licence for provision of pharmacy services.

(6) A person employed as the competent person or a substitute for the competent person with a manufacturer shall not, at the same time, be employed by the holder of an activity licence for wholesale trade in medicinal products or provision of pharmacy services.

(7) A veterinarian employed by a general pharmacy, veterinary pharmacy, or the holder of an activity licence for wholesale trade or manufacture of medicinal products shall not provide veterinary services.

§ 44. Obligations of holder of activity licence for manufacture of medicinal products or wholesale trade in medicinal products

(1) The holder of an activity licence for manufacture of medicinal products or wholesale trade in medicinal products is required to:

1) guarantee the existence of conditions for handling of medicinal products in compliance with this Act and legislation established on the basis thereof, and with the requirements of other legislation regulating the handling of medicinal products;

2) guarantee that the competent person, and in the absence thereof, his or her substitute, has necessary conditions and means for performing his or her duties;

3) guarantee that medicinal products are dispensed, under the conditions and pursuant to the procedure provided by this Act, legislation established on the basis thereof and other legislation regulating the handling of medicinal products, only to persons with the right to handle such medicinal products;

4) keep record of the handling of medicinal products and submit reports to the State Agency of Medicines pursuant to the procedure established on the basis of clause 26 (9) 1) of this Act;

5) guarantee a continuous and sufficient choice of medicinal products and expedient delivery within the territory of Estonia;

6) communicate sales offers in a manner accessible to persons specified in subsection 26 (4) and 28 (1) of this Act and guarantee the availability of the medicinal products included in a sales offer;

7) guarantee equal sales and payment terms and, under equal circumstances, also equal delivery terms for holders of an activity licence for a general pharmacy who have no unfulfilled obligations towards the holder of an activity licence for wholesale trade or manufacture of medicinal products;

8) notify the State Agency of Medicines of detection of defective or counterfeit medicinal products, or ensure that State Agency of Medicines is notified thereof;

9) transfer, upon dissolution of the holder of the activity licence or termination of the activity entered in the activity licence, the medicinal products to the holder of an activity licence for handling of medicinal products or to a person who based on subsection 27 (1) or subsection 28 (1) of this Act has the right to make wholesale purchases of medicinal products, or to withdraw the medicinal products from the market pursuant to the procedure and within the term established for the operation of a handler of medicinal products of that class, and to notify the State Agency of Medicines thereof in writing;

[RT I 2010, 15, 77 – entered into force 18.04.2010]

10) notify the State Agency of Medicines of suspension of operation with a period exceeding six months, and of re-commencement of activities;

11) comply with other requirements arising from this Act, legislation established on the basis thereof and other legislation regulating the handling of medicinal products.

(2) The requirements established in subsection (1) of this section also apply to the holder of an activity licence for wholesale trade in medicinal products with no storage rights, taking account of the specifications arising from the activities thereof.

(3) In addition to the duties specified in subsection (1) of this section, the holder of an activity licence for manufacture of medicinal products is required to:

1) pay, based on an invoice, the inspection costs composed of the mission expenses of the inspector if the inspection constitutes a part of the procedure for application for marketing authorisation in respect of a medicinal product, or if the inspection is regular;

2) guarantee that medicinal products are manufactured taking account of the developments in the area of science and technology;

3) guarantee that only substances whose characteristics, purity and composition are specified in valid pharmacopoeias or by other rules are used in the manufacture of medicinal products.

[RT I 2005, 24, 180 – entered into force 20.05.2005]

§ 45. Obligations of holder of activity licence for provision of pharmacy services

The holder of an activity licence for provision of pharmacy services is required to:

1) guarantee the existence of conditions for handling of medicinal products in compliance with this Act and legislation established on the basis thereof, and with the requirements of other legislation regulating the handling of medicinal products;

2) guarantee that the competent person who, at a pharmacy, is the head of the pharmacy, and in the absence of the competent person, his or her substitute, has necessary conditions and means for performance of his or her duties, and that the staff of the pharmacy have necessary conditions and means for performing their work in adherence to the requirements;

3) guarantee that medicinal products are dispensed, under the conditions and pursuant to the procedure provided by this Act, legislation established on the basis thereof and other legislation regulating the handling of medicinal products, only to persons with the right to handle such medicinal products;
[RT I 2005, 24, 180 – entered into force 20.05.2005]

4) employ, taking account of the volume of work and business hours of the enterprise, a sufficient number of employees with requisite qualifications;

5) guarantee the availability, within a reasonable period of time, of medicinal products existing in Estonia concerning which marketing authorisation has been granted;

6) keep record of the handling of medicinal products and submit reports to the State Agency of Medicines pursuant to the procedure established on the basis of clause 31 (6) 3) of this Act;

7) notify the State Agency of Medicines of detection of falsified medical prescriptions, and defective or counterfeit medicinal products, or ensure that State Agency of Medicines is notified thereof;

8) guarantee a sufficient choice of medicinal products or order such products within a reasonable period of time;

9) guarantee, upon the sale of medicinal products concerning which a reference price has been established on the basis of the Health Insurance Act, that at least one medicinal product whose price is lower than the reference price is offered in each reference price group;

10) guarantee the provision of pharmacy services only by the persons specified in subsection 29 (3) of this Act;

11) transfer, upon dissolution of the holder of the activity licence or termination of the activity entered in the activity licence, the medicinal products to the holder of an activity licence for handling of medicinal products or a person specified in subsection 33 (2) of this Act, or to withdraw the medicinal products from the market pursuant to the procedure and within the term established for the operation of a handler of medicinal products of that class, and to notify the State Agency of Medicines thereof in writing;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

12) comply with other requirements arising from this Act, legislation established on the basis thereof and other legislation regulating the handling of medicinal products;

Subdivision 3
Application for Activity Licence

§ 46. Documents submitted upon application for issue and renewal of activity licence

(1) An applicant shall pay a state fee for application for an activity licence and submit the documents and information required pursuant to the procedure established based on subsection 47 (10) of this Act to the State Agency of Medicines.

(2) The holder of an activity licence shall pay a state fee for application for renewal of the activity licence and submit a standard format application at least two months before the expiry of the activity licence to the State Agency of Medicines.

(3) An overview of operation at the place of business during the term of validity of the activity licence, including information on the employees of the pharmaceutical profession (name, position, professional experience) and the documents submitted upon application for the activity licence, depending on the type of activity licence applied for, containing updated information, or separate confirmation in writing for each document that the information contained in the document has not changed shall be appended to an application for renewal of an activity licence.

Subdivision 4
Issue, Renewal and Extension of Activity Licence

§ 47. Issue, renewal and extension of activity licence

(1) Activity licences are issued, renewed and extended by the State Agency of Medicines

(2) Based on an application of the holder of a valid activity licence of a general pharmacy, the State Agency of Medicines may authorise, in exceptional cases, the holder of the licence to sell pharmaceutical preparations which may be dispensed by pharmacies without a medical

prescription (hereinafter *medicinal products not subject to medical prescription*) at public events and under other extraordinary circumstances outside of the place of business entered on the activity licence during a period of up to one week.

(3) If the holder of a valid activity licence is unable, due to reasons independent of the holder, to renew the licence within the specified term, the State Agency of Medicines has the right to extend the term of validity of the activity licence for a period of one to three months based on a corresponding written reasoned application submitted by the holder of the activity licence.

(4) A person applying for the issue, renewal or extension of an activity licence shall employ a competent person who meets the established requirements.

(5) The State Agency of Medicines shall make a decision to issue or renew an activity licence within sixty days after receipt of all requisite documents.

(6) Prior to making a decision to issue, renew or extend an activity licence, the State Agency of Medicines may request, and the applicant must provide additional written explanations concerning the activities thereof, and the documents and information submitted thereby necessary for making the decision. The term for processing the application for issue or renewal the activity licence is suspended until the requested explanations are submitted.

(7) If circumstances preventing the first issue of an activity licence become evident upon processing an application, and such circumstances can be eliminated, the State Agency of Medicines shall grant the applicant a reasonable term for elimination of the circumstances. The State Agency of Medicines shall inform the applicant of the establishment of this term, indicating the circumstances preventing the licence from being issued and setting out the date by which the deficiencies must be eliminated. The term prescribed for making a decision is extended by the term set for elimination of the deficiencies unless the deficiencies are eliminated during a shorter period of time.

(8) Upon processing an application, the State Agency of Medicines has the right to verify the accuracy of information submitted upon application. Before issue or renewal of an activity licence, the State Agency of Medicines shall inspect, according to its competence, the conformity of the conditions, operations and if necessary, also of the personnel of a place of business to the established requirements.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

(9) The decision of the State Agency of Medicines to issue, renew or extend an activity licence enters into force on the date of making the decision unless a later date is indicated on the activity licence.

(10) The Minister of Social Affairs shall establish, by a regulation, the conditions and procedure for application and processing of activity licences, including a list of documents and information to be submitted upon application for an activity licence, and the information contained in an activity licence.

§ 48. Period of validity of activity licence

(1) An activity licence is issued or renewed for a period of up to five years.

(2) The term of validity of an activity licence for manufacture of medicinal products issued to the holder of an activity licence for wholesale trade in medicinal products shall not be longer than the term for the activity licence for wholesale trade in medicinal products.

§ 49. Refusal to issue or renew activity licence

(1) The State Agency of Medicines may refuse to issue or renew an activity licence if at least one of the following circumstances exists:

1) repeated or significant violations of the requirements provided by this Act or legislation established on the basis thereof, or by other legislation regulating the handling of medicinal products have been discovered in the operation of the applicant for the activity licence;

2) the operation of the applicant for the activity licence does not meet the conditions of the activity licence;

3) the place of business of the applicant for the activity licence does not conform to the requirements provided by this Act or legislation established on the basis thereof;

4) the competent person fails to perform his or her duties;

5) the holder of the activity licence has not performed an obligation by the deadline or to the extent prescribed by a precept issued by the State Agency of Medicines;

6) the holder of the activity licence does not meet the requirements provided for in this Act.

(2) The State Agency of Medicines refuses to issue or renew an activity licence if at least one of the following circumstances exists:

1) documents or information required for obtaining an activity licence under this Act are not submitted;

2) the applicant has not paid the state fee;

3) the applicant for the activity licence has not submitted additional explanations pursuant to subsection 47 (6) of this Act;

4) the applicant has not eliminated, during the additional term set on the basis of subsection 47 (7) of this Act, the deficiencies which prevent the issue of the activity licence;

5) inaccurate information was submitted upon application for the activity licence;

6) the applicant for the activity licence is declared bankrupt;

7) the applicant for the activity licence has been punished for operating without an activity licence in a field of activity for which an activity licence is required pursuant to this Act and if the terms specified in § 25 of the Penal Register Act have not expired;

8) a person formerly employed as the competent person at a place of business the activity licence of which has been revoked due to violations of legislation regulating the field of medicinal products is nominated for entry on the activity licence as the competent person, and less than two years have passed from the revocation of the activity licence.

(3) In addition to the grounds specified in subsection (2) of this section, the State Agency of Medicines shall refuse to issue an activity licence or entry of a new structural unit on an activity licence if at least one of the following circumstances exists:

1) any of the activity licences for handling of medicinal products held by the holder of the activity licence has been revoked due to violations of legislation regulating the field of medicinal products, and less than two years have passed from entry into force of the decision to revoke the licence;

2) renewal of any of the activity licences held by the holder of the activity licence has been refused on the grounds specified in clauses (1) 1) or 2) of this section, and less than two years have passed from entry into force of the decision to refuse to renew the licence.

(4) If issue of an activity licence is refused due to the existence of the circumstances specified in subsection (3) of this section, other activity licences held by the holder of the activity licence are renewed pursuant to general procedure.

(5) The decision to issue or to refuse to issue an activity licence shall be made within the term specified in subsection 47 (5) of this Act.

(6) The decision specified in subsection (5) of this section shall be communicated to the applicant in writing within three working days after the decision is made.

§ 50. Conditions of activity licence

(1) The following are the special conditions of an activity licence:

1) manufacturing activities for which an activity licence for manufacture of medicinal products has been issued, pharmaceutical forms and groups of medicinal products, including medicinal products intended for clinical trials for the manufacture of which an activity licence for manufacture of medicinal products has been issued, and hazardous substances for the handling of which a corresponding activity licence has been issued;

2) wholesale activities and groups of medicinal products for the handling of which an activity licence for wholesale trade or manufacture of medicinal products has been issued;

3) groups of medicinal products for the manufacture of which general pharmacies and hospital pharmacies have the right and obligation;

4) the right of the holder of an activity licence for manufacture of medicinal products or wholesale trade in medicinal products to handle narcotic drugs and psychotropic substances; [RT I 2005, 24, 180 – entered into force 20.05.2005]

5) a list of manufacturers and control authorities working under jobbing contracts related to the manufacture of medicinal products.

(2) The right specified in clause (1) 4) of this Act shall not be granted to the holder of an activity licence for wholesale trade or manufacture of medicinal products upon the first application for the activity licence and during the term of validity of the first activity licence.

(3) The special conditions of an activity licence shall enter into force together with the entry into force of the activity licence or at a date established by the State Agency of Medicines.

(4) The State Agency of Medicines has the right to establish, by an activity licence, the secondary conditions specified in subsection 53 (1) of the Administrative Procedure Act.

Subdivision 5
Termination and Suspension of Activity Licence and Alteration of Information Contained therein

§ 51. Grounds and consequences of termination, revocation and suspension of activity licence

(1) An activity licence terminates upon:

1) expiry of the term of validity of the activity licence;

2) death of the holder of the activity licence who is a self-employed person;

3) dissolution or termination of the holder of the activity licence who is a legal person,

4) revocation of the licence.

(2) The State Agency of Medicines revokes an activity licence based on a written application to this effect of the holder of the activity licence.

(3) The State Agency of Medicines may revoke an activity licence in part or in full if one of the following circumstances exists:

1) the holder of the activity licence fails to perform the duties imposed on the holder by this Act;

2) the holder of the activity licence does not meet requirements provided for in this Act;

3) repeated or significant violations of the requirements provided by this Act or legislation established on the basis thereof, or in other legislation regulating the handling of medicinal products are discovered at a place of business or the in the operation of the applicant for the activity licence;

4) a place of business or the operation does not conform to the conditions, including the special and secondary conditions, established by the activity licence;

5) incorrect information has been submitted upon application for the issue, renewal or extension of the activity licence and such information is of material importance to the decision on whether to issue the licence, or upon repeated failure to submit information required by the State Agency of Medicines by the prescribed term;

6) the holder of the activity licence has not performed an obligation by the deadline or to the extent prescribed by a precept issued by the State Agency of Medicines;

7) the competent person specified in the activity licence fails to perform the duties imposed to him or her on the basis of this Act;

8) it becomes evident that circumstances exist which, pursuant to this Act, constitute a basis for refusal to issue or renew an activity licence;

(4) If the facts provided for in subsection (3) of this section become evident, the State Agency of Medicines issuer may:

1) issue, before making the decision to revoke the activity licence, a precept to the holder of the activity licence, setting a reasonable term for elimination of the circumstances which constitute the basis for revocation of the licence;

2) suspend, based on a precept or without issue of a written precept, the activity licence in part or in full until the offence or its consequences are eliminated;

3) revoke the activity licence in part or in full and set the term and conditions for realisation of the stocks of medicinal products and submission of reports.

(5) Suspension of an activity licence in part or in full is revoked by a decision of the State Agency of Medicines after elimination of an offence or the consequences thereof has been established in the process of checks conducted by the State Agency of Medicines, and the decision is communicated to the holder of the activity licence.

(6) A copy of the decision of the State Agency of Medicines concerning the revocation or suspension of an activity licence shall be sent to the holder of the activity licence within five working days after making the decision.

(7) In the case of partial revocation of an activity licence, a new activity licence containing amended information is issued.

(8) The period during which an activity licence is revoked does not extend the period of validity of the activity licence.

(9) Upon revocation of an activity licence before the date of expiry set out therein, the holder of the activity licence shall return the certificate in proof of existence of the licence and copies thereof to the State Agency of Medicines within five working days.

§ 52. Change of data and alteration of data contained in activity licence

(1) The holder of an activity licence wishing to carry out changes which involve a change of places of business, creation of new structural units, alteration of special conditions of the activity licence, or change of enterprises working under jobbing contracts for the holder of the activity licence or addition of new enterprises, shall beforehand apply to the State Agency of Medicines for amendment of the activity licence, provide justification for the amendment, submit the documents required pursuant to the procedure established on the basis of subsection 47 (10) of this Act and pay the state fee.

(2) If the change concerns an alteration of the documents, information or other relevant circumstances which constitute the basis for issue of an activity licence not specified in subsection (1) of this section and the State Agency of Medicines is not notified of such change beforehand, the holder of the activity licence shall inform the State Agency of Medicines of the change after it is carried out.

(3) The State Agency of Medicines shall be given written notice of the changes specified in subsection (2) of this section without undue delay but not later than within seven days after a change takes place. Information concerning termination of an employment relationship with the head of a pharmacy and appointment of a substitute must be communicated immediately.

(4) If a change specified in subsection (2) of this section results in a need to amend the data contained in the activity licence, the holder of the activity licence shall submit, without delay but not later than within two months after the change takes place, an application together with the documents required pursuant to the procedure established based on subsection 47 (10) of this Act to the State Agency of Medicines, and pay the state fee.

(5) Applications specified in subsections (1) and (4) of this section together with requisite documents shall be reviewed and the amendment decision shall be made pursuant to general procedure within thirty days. In exceptional cases, the State Agency of Medicines may extend such term to up to sixty days.

(6) If the circumstances which constituted the basis for issue of an activity licence change, the holder of the licence shall guarantee the conformity of the new conditions to the requirements provided by this Act and legislation established on the basis thereof. The substitute for a competent person shall perform the duties of the competent person until an activity licence containing the name of a new competent person or the head of the pharmacy is issued.

(7) Alteration of the information or conditions of an activity licence does not result in amendment of the term of validity of the activity licence.

Division 7
Competent Person

§ 53. Requirements for competent person and substitute for competent person

(1) A person shall be employed as a competent person only at one of the places of business specified in subsection 40 (1) of this Act at the same time. Such requirement does not apply to places of business used for manufacture of medicinal products.

(2) A person shall not be appointed as a competent person if the person was formerly employed in the position of competent person at a place of business whose activity licence was revoked due to violations of legislation regulating the field of medicinal products, and less than two years have passed from revocation of the licence.

(3) A person appointed to act as a competent person at a place of business used for manufacture of medicinal products shall have appropriate preparation and experience for the manufacturing activities, and the substitute for the competent person shall meet the requirements set for a competent person.

(4) The holder of an activity licence who is a self-employed person may himself or herself act as the competent person provided that he or she meets the requirements set for competent persons.

(5) Only persons with the higher education and work experience prescribed by a regulation established on the basis of subsection (6) of this section shall be employed as competent persons. A competent person working in an enterprise engaged in the packaging of herbal substances may have other appropriate special education specified in such regulation.

(6) The Minister of Social Affairs shall establish, by a regulation, the requirements for the qualifications of competent persons and a list of evidence of formal qualification.

§ 54. Obligations of competent person

(1) A competent person appointed by the holder of an activity licence for manufacture of medicinal products is required to:

1) ensure that each batch of medicinal products manufactured in Estonia is manufactured and controlled in adherence to legislation in the pharmaceutical field and the documents related to the activity licence and marketing authorisation;

2) ensure that, unless otherwise established in the European Union, each batch of medicinal products imported from a third country, except unauthorised medicinal products undergo, before release for dispensing in an Member State of the European Economic Area, a complete qualitative analysis, a quantitative analysis of at least the active ingredients, and other tests to verify that the quality of the medicinal products meet the requirements of the marketing authorisation.

(2) A competent person is required to perform the duty specified in clause (1) 2) of this section with respect to medicinal products manufactured in a Member State of the European Economic Area as well as medicinal products manufactured in third countries.

(3) A competent person appointed by the holder of an activity licence for manufacture of medicinal products is required, in the part of medicinal products investigated under clinical trials, to:

1) ensure that each batch of medicinal products manufactured in Estonia is manufactured and controlled in adherence to legislation in the pharmaceutical field and the activity licence, the application for the clinical trial and supplementary documentation;

2) ensure that, unless otherwise established in the European Union, each batch of medicinal products manufactured in a third country has been manufactured and controlled under equally good manufacturing practices and is checked pursuant to the supplementary documentation related to the clinical trial;

3) ensure that, unless otherwise established in the European Union, each reference medicinal product of an authorised medicinal product originating from a third country concerning which there is no indication that the batch has been manufactured under equally good manufacturing practices is analysed pursuant to the supplementary documentation related to the clinical trial to prove the conforming quality of the lot.

(4) A competent person appointed by the holder of an activity licence for wholesale trade in medicinal products is required to ensure the conformity of the medicinal products sold by the holder of the activity licence for wholesale of medicinal products to the requirements provided by this Act and legislation established on the basis thereof, and compliance with the requirements for handling of medicinal products, recording and reporting.

(5) A competent person employed by the holder of an activity licence for wholesale trade in medicinal products has the additional duty to verify adherence to the storage requirements during the transport of the medicinal products, conformity of the packaging of the medicinal products and correspondence thereof to the marketing authorisation.

(6) A competent person employed by the holder of an activity licence for pharmacy services has the obligation to ensure that medicinal products are handled, at the pharmacy and structural units thereof, in conformity to the requirements provided by this Act, legislation established on the basis thereof and other legislation regulating the handling of medicinal products.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

Division 8
Registration of Dispensing Chemists and Pharmacists and Recognition of Professional Qualifications of Dispensing Chemists

§ 55. Registration of dispensing chemists and pharmacists and legal effect of recognition of professional qualifications of dispensing chemists

(1) Dispensing chemists and pharmacists wishing to provide pharmacy services in the Republic of Estonia must be registered in the national register of dispensing chemists and pharmacists maintained by the Health Board.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

(2) Recognition of the professional qualifications of a dispensing chemist (hereinafter *recognition of professional qualifications*) is required if:

1) the person wishes to work in the field of pharmacy outside of the Republic of Estonia;

2) the person has acquired the qualifications of a dispensing chemist in a Member State of the European Economic Area, Switzerland or another foreign state and wishes to work in the field of pharmacy in the Republic of Estonia.

(3) Recognition of professional qualifications ensures that a person with the qualifications of a dispensing chemist specified in clause (2) 2) of this section has access to activities in the field of pharmacy in the Republic of Estonia, including the research, manufacture, production

and quality control of medicinal products and ingredients thereof, provision of pharmacy services to the public and health care providers, provision of information and consultations concerning medicinal products, and employment as a competent person under the conditions provided by § 53 of this Act.

§ 56. General procedure for recognition of professional qualifications and registration as dispensing chemists and pharmacists

(1) A person applying for registration as a dispensing chemist or pharmacist (hereinafter *registration*) or applying for the recognition of professional qualifications shall submit a corresponding application to the Health Board, and a copy of the evidence of formal qualifications.
[RT I 2009, 49, 331 – entered into force 01.01.2010]
(1^1) Before the submission of an application, a person applying for registration as a dispensing chemist or pharmacist or applying for recognition of the professional qualifications of dispensing chemist is required to pay the state fee for the review of the application according to the rate provided for in the State Fees Act.
[RT I 2006, 58, 439 – entered into force 01.01.2007]

(2) The Minister of Social Affairs shall establish the list of information to be submitted in applications.

(3) The Health Board shall verify the authenticity of information submitted in the evidence of formal qualifications and shall make the requested decision to register or recognise professional qualifications within thirty days as of submission of the documents specified in subsection (1) of this section, except in the cases specified in subsection 58 (1^1) and 59 (3) of this Act.

[RT I 2009, 49, 331 – entered into force 01.01.2010]

(4) Registration or recognition of professional qualifications is denied if the applicant knowingly submits incorrect information upon application for registration or recognition.

(5) If registration or recognition of professional qualifications is denied, the applicant shall be informed thereof within ten days after the date the corresponding decision is made.

(6) Upon registration as a dispensing chemist or pharmacist or recognition of such professional qualifications, the Health Board shall issue a corresponding certificate to the applicant. The Minister of Social Affairs shall establish the format of the certificates by a regulation.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

§ 57. Registration and recognition of professional qualifications of persons who acquire qualifications of dispensing chemist in Estonia

(1) The Minister of Social Affairs shall establish, by a regulation, the list of evidence in proof of formal qualification which constitute the basis for registration and recognition of the professional qualifications of persons who acquire the qualifications of a dispensing chemist in Estonia.

(2) A person applying for registration who presents evidence in proof of his or her formal qualification not included in the list established on the basis of subsection (1) of this section, or who conforms to the provisions of subsection (4) of this section, shall pass a qualification examination and present, for entry in the register, the document certifying his or her passing the examination to the Health Board. The Minister of Social Affairs shall establish, by a regulation, the conditions and procedure for organisation of qualification examinations.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

(3) The qualification examination for dispensing chemists shall be organised by the University of Tartu and the qualification examination for pharmacists shall be organised by the Tallinn Health Care College.
[RT I 2008, 30, 191 – entered into force 01.07.2008]

(4) Registration of a person as a dispensing chemist or pharmacist may be denied if during the last five years, the person has not worked in the profession indicated in the evidence in proof of formal qualification for a consecutive period of at least three years.

(5) Subsection (4) of this section does not apply to cases where the person applying for registration acquired the education of a dispensing chemist or pharmacist less than three years ago.

§ 58. Recognition of professional qualifications of persons who acquire qualifications of dispensing chemist in Member States of European Economic Area or in Switzerland

(1) The qualifications of a dispensing chemist acquired in a Member State of the European Economic Area or Switzerland shall be certified by a document which grants a dispensing chemist the right to work in the field of pharmacy in the speciality set out in the document in the corresponding Member State of the European Economic Area or in Switzerland.

(1^1) The Heath Board shall issue to a person applying for registration a confirmation regarding receipt of the registration application within one month after submission of the documents specified in subsection 56 (1) of this Act and, if necessary, shall inform the person of the missing documents. The Health Board shall verify the authenticity of information submitted in documents certifying the qualifications and make a decision to register or recognise the qualifications within two months as of submission of all the requisite documents. If, in the course of registration proceedings, the need arises to assess the circumstances specified in subsection 58 (3) of this Act, the Health Board has the right to extend the term for making the decision for up to three months and the Board shall immediately inform the person applying for registration of extension of the term and the reasons for the extension.

[RT I 2009, 49, 331 – entered into force 01.01.2010]

(2) The Minister of Social Affairs shall establish, by a regulation, the list of evidence in proof of the formal qualification of dispensing chemist acquired in a Member State of the European Economic Area or in Switzerland and the procedure for the assessment of the correspondence of the qualifications.

[RT I 2008, 30, 191 – entered into force 01.07.2008]

(3) If a document certifying the qualifications of a dispensing chemist who has acquired the qualifications in a Member State of the European Economic Area or Switzerland is not included in the list established pursuant to subsection (2) of this section, the Health Board shall decide to recognise the professional qualifications of the person or oblige the person to take an aptitude test pursuant to the provisions of the Recognition of Foreign Professional Qualifications Act.

[RT I 2009, 49, 331 – entered into force 01.01.2010]

§ 59. Recognition of professional qualifications of persons who acquire qualifications of dispensing chemist in other foreign states

(1) Subsections 56 (1)-(2) and (4)-(6) of this Act also apply to the procedure for recognition of professional qualifications of persons who have acquired qualifications of dispensing chemist in a foreign state not specified in § 58 of this Act.

(2) If the qualifications of a person who has acquired the qualifications of a dispensing chemist in a foreign state not specified in § 58 of this Act have been recognised beforehand by a Member State of the European Economic Area or Switzerland and the person has acquired a professional experience of three years in the field of pharmacy in a Member State of the European Economic Area which has recognised his or her qualifications or in Switzerland, the Health Board shall decide to recognise the professional qualifications of the person or oblige the person to take an aptitude test pursuant to the provisions of the Recognition of Foreign Professional Qualifications Act. Upon application for registration, the person shall submit a document certifying the person's required period of professional experience and the right of the person to work in the field of pharmacy in a member state of the European Economic Area or in Switzerland in addition the documents required in subsection 56 (1) of this Act.

[RT I 2009, 49, 331 – entered into force 01.01.2010]

(3) The Health Board shall compare the qualifications of a person who acquired the qualifications of a dispensing chemist in a state not specified in § 58 of this Act with the qualifications required in Estonia, shall verify the authenticity of information submitted in documents certifying the qualifications and make a decision to recognise the qualifications within three months as of submission of the requisite documents. The procedure for the comparison of the qualifications of a person who acquired the qualifications of a dispensing chemist in a foreign state with the qualifications required in Estonia shall be established by a regulation established by the Minister of Social Affairs.

[RT I 2009, 49, 331 – entered into force 01.01.2010]

(4) In order to assess the compliance of qualifications, persons who have acquired qualifications of a dispensing chemist in foreign states not specified in § 58 of this Act may be required to take aptitude tests. The Minister of Social Affairs shall establish, by a regulation, the procedure for compiling, conducting and evaluating aptitude tests.

[RT I 2008, 30, 191 – entered into force 01.07.2008]

§ 59[1]. Temporary provision of pharmacy services

A person who has acquired the qualifications of a dispensing chemist in a member state of the European Economic Area or in Switzerland may temporarily provide pharmacy services in Estonia without the registration obligation required pursuant to § 55 of this Act and an activity licence required pursuant to § 38 of this Act pursuant to the provisions of Chapter 3 of the Recognition of Foreign Professional Qualifications Act. A competent authority within the meaning of Chapter 3 of the Recognition of Foreign Professional Qualifications Act is the Health Board.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

§ 60. Registration of qualifications of persons who acquire qualifications of dispensing chemist or pharmacist in Member States of European Economic Area or in Switzerland

(1) The application for registration as dispensing chemist submitted by a person who acquired the qualifications of a dispensing chemist in a Member State of the European Economic Area or in Switzerland shall be processed concurrently with the application for recognition of his or her qualifications.

(2) The provisions of the Recognition of Foreign Professional Qualifications Act apply to registration of persons wishing to provide pharmacy services in the Republic of Estonia who acquired the qualifications of a pharmacist in a Member State of the European Economic Area, in Switzerland or other foreign state.

[RT I 2008, 30, 191 – entered into force 01.07.2008]

§ 61. Revocation of registration decisions and decisions to recognise professional qualifications

The Health Board shall revoke a registration decision or decision to recognise professional qualifications if the dispensing chemist or pharmacist applying for registration or recognition of professional qualifications has knowingly submitted incorrect information.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

§ 62. Register of dispensing chemists and pharmacists

(1) The register of dispensing chemists and pharmacists is a national register established by the Government of the Republic by proposal of the Minister of Social Affairs. The Government of the Republic shall establish the statutes of the register of dispensing chemists and pharmacists.

(2) The Health Board is the chief processor of the register of dispensing chemists and pharmacists.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

(3) The holder of an activity licence for the provision of pharmacy services is required to inform the Health Board of entry into or termination of an employment contract with a dispensing chemist or pharmacist immediately after becoming aware of the fact and shall specify the date of entry into or termination of the employment relationship.

[RT I 2009, 49, 331 – entered into force 01.01.2010]
(4) The Health Board shall publish on its website the first name and surname, the number of the registration certificate and place of employment of the dispensing chemists and pharmacists employed in a pharmacy.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

Chapter 3
MARKETING AUTHORISATION OF MEDICINAL PRODUCT

Division 1
Mandatory Nature of Marketing Authorisation of Medicinal Product; Marketing Authorisation Holder

§ 63. Mandatory nature of marketing authorisation of medicinal product

(1) For marketing of a medicinal product in Estonia, a marketing authorisation concerning the medicinal product valid in Estonia is required.

(2) This requirement does not apply to:

1) medicinal products prepared as magistral and officinal formulae and medicinal products divided up into packages by pharmacies;

2) medicinal products imported based on a single authorisation for import and use granted by the State Agency of Medicines;

3) whole blood and blood components;

4) herbal substances;

5) medicinal products prescribed for use on aquarium fish, cage birds, terrarium animals, small rodents and ferrets and rabbits kept as pets provided that the use of such medicinal products on any other animal species is precluded.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 64. Marketing authorisation holder

(1) The person to whom marketing authorisation is granted is a marketing authorisation holder. A marketing authorisation holder shall be a person whose residence or seat is located in a Member State of the European Economic Area.

(2) A marketing authorisation holder shall designate one or several persons holding appropriate activity licences who will import the medicinal product, and give written notice of such persons to the State Agency of Medicines without delay.

(3) A marketing authorisation holder shall give written notice to the State Agency of Medicines of the commencement of the actual placing on the market of an authorised medicinal product in Estonia, and give at least two months prior notice if the marketing of the medicinal product in Estonia is to be terminated or supply thereof is to be suspended.

(4) The existence of a marketing authorisation in respect of a medicinal product does not release the marketing authorisation holder of liability related to the medicinal product.

Division 2
Application for Marketing Authorisation of Medicinal Product and Processing of Applications

§ 65. Application for marketing authorisation in respect of medicinal product

(1) A person wishing to obtain or renew a marketing authorisation in respect of a medicinal product shall submit a corresponding application together with supplementary documentation to the State Agency of Medicines and pay a state fee. All the documents provided for on the basis of clause (12) 1) of this section must be submitted.

(2) A marketing authorisation holder desiring the renewal of the authorisation shall submit an application to this effect to the State Agency of Medicines at least 180 days before the expiry of the authorisation.

(3) An applicant wishing to obtain marketing authorisation in respect of a medicinal product must prove by scientific methods that the medicinal product, if used for its intended purpose, is safe and effective according to the requirements of modern medical science, that the quality of the medicinal product conforms to the requirements provided by this Act and legislation issued on the basis thereof and that the conditions provided in subsections 13 (3)-(5) of this Act are fulfilled.

(4) An applicant for marketing authorisation need not provide data in proof of the efficacy and safety of the medicinal product if the applicant certifies that at least one of the following circumstances exist:

1) the active ingredient or active ingredients of the medicinal product have a well-established medicinal use, they have been used in a Member State of the European Economic Area for at least ten years and they have recognised efficacy and acceptable level of safety

which can be demonstrated by detailed references to published scientific literature appended to the application;

2) the medicinal product is similar (with the same quantitative and qualitative composition of active ingredients and the same pharmaceutical form) and bioequivalent to a medicinal product in respect of which marketing authorisation was granted in Estonia or another Member State of the European Economic Area at least eight years ago. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active ingredient shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form.

(5) A medicinal product in respect of which marketing authorisation is granted based on clause (4) 2) of this section shall not be placed on the market earlier than ten years after the grant, in Estonia or a Member State of the European Economic Area, of marketing authorisation in respect of the medicinal product which data are referred to upon application for marketing authorisation. The different strengths, pharmaceutical forms, routes of administration and package sizes shall be deemed to be one medicinal product upon the calculation of this period and the period shall be determined on the basis of the earliest marketing authorisation.

(6) The period specified in subsection (5) of this section shall be extended to eleven years for medicinal products concerning which the authorisation holder has applied for and obtained, during the first eight years of validity of the authorisation, a new therapeutic indication which is held to bring a significant clinical benefit in comparison with the existing therapies.

(7) The period specified in subsection (5) of this section may be extended to up to thirteen years for veterinary medicinal products in cases where the holder of marketing authorisation of the medicinal product intended for use on agricultural animals has also applied for establishment of maximum residue limits in respect of the active ingredients of the medicinal product.

(8) A holder of a marketing authorisation may allow to use the pharmaceutical, toxicological and clinical data accompanying his or her application in the assessment of an application for marketing authorisation for another medicinal product with the same quantitative and qualitative composition of active ingredients and pharmaceutical form.

(9) If a medicinal product does not fully meet the similarity requirements specified in clause (4) 2) of this section or if a different therapeutic indication, route of administration or dosage is applied for a medicinal product, the relevant additional data concerning the efficacy and safety of the medicinal product shall be presented.

(10) If the starting material or manufacturing process of a biological medicinal product differs from the medicinal product referred to, the relevant additional data concerning the efficacy and safety of the medicinal product shall be presented.

(11) If a marketing authorisation is granted in respect of a medicinal product on the conditions specified in clause (4) 1) of this section for a therapeutic indication for which the active ingredient of the medicinal product has not been prescribed in Estonia so far and for the obtaining of which the applicant has carried out significant pre-clinical, clinical trials, the State Agency of Medicines shall not grant a marketing authorisation with respect to a proprietary medicinal product with the same active ingredient for this therapeutic indication to another applicant for marketing authorisation on the basis of the data of these trials during one year.

(12) The following shall be established by a regulation of the Minister of Social Affairs:

1) types of and formal requirements for applications for marketing authorisation of medicinal products, a list of supplementary documentation, requirements for supplementary

documentation, amount of remuneration payable for professional assessment of applications set out by types of application, and the procedure for calculation and payment of remuneration;

2) a list of documents subject to submission for licence for parallel import in respect of a medicinal product, the conditions and procedure for processing of applications;

3) the conditions and procedure for application for grant and renewal of marketing authorisations in respect of medicinal products, processing of applications and recognition of assessments provided by a competent authority of a Member State of the European Economic Area.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 66. Licence for parallel import

(1) A licence for parallel import is granted to a holder of an activity licence for wholesale trade or manufacture of medicinal products provided that all the following conditions are fulfilled:

1) [Repealed – RT I 2005, 24, 180 – entered into force 20.05.2005]

2) licence for parallel import is applied for in respect of a medicinal product which by its clinical effect is identical to a medicinal product imported into Estonia by an undertaking appointed by the marketing authorisation holder;

3) the medicinal product concerning which the application is submitted is imported into Estonia from a Member State of the European Economic Area;

4) a marketing authorisation valid in a Member State of the European Economic Area has been granted in respect of the medicinal product concerning which the application is submitted;

5) the same person holds the marketing authorisation in Estonia and another Member State of the European Economic Area, or belongs to the same group of manufacturers of medicinal products.

(2) A licence for parallel import shall have validity equal to the validity, in Estonia, of the marketing authorisation in respect of a medicinal product imported directly, or the validity, in a source country, of the marketing authorisation in respect of a medicinal product imported parallel.

(3) Upon suspension or termination of the sale in Estonia due to economic reasons of a proprietary medicinal product concerning which a first marketing authorisation was issued, the State Agency of Medicines may decide that the licence for parallel import remains valid for a period determined thereby.

(4) The holder of a licence for parallel import shall have all the rights and obligations of the marketing authorisation holder.

§ 67. Remuneration for professional assessment of application

(1) An applicant shall pay the State Agency of Medicines a fee for the professional assessment of the application in the amount of 195 to 1275 euros, depending on the type of application established on the basis of clause 65 (12) 1) of this Act.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(2) An applicant for marketing authorisation who orders an assessment report on the professional assessment of the application to be prepared in English by the State Agency of

Medicines, and requests that Estonia participates in the decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition as a reference country, shall pay the amount of 6390 euros in addition to the assessment fee.
[RT I 2008, 56, 313 – entered into force 01.01.2009]
(3) In the case of a marketing authorisation procedure of mutual recognition and, upon renewal of marketing authorisations, in the case of decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition in which Estonia participates as a reference country, the amount of 1275 euros shall be paid in addition to the assessment fee.
[RT I 2008, 56, 313 – entered into force 01.01.2009]

§ 68. Processing of applications for marketing authorisation of medicinal product

(1) Before acceptance of an application for processing, the State Agency of Medicines shall evaluate the conformity of the application and supplementary documentation submitted with the requirements established on the basis of clause 65 (12) 1) of this Act and, if necessary, set the applicant a term for elimination of deficiencies.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(2) After acceptance of an application for processing, the State Agency of Medicines may request additional information and documents concerning the medicinal product from the applicant and set a reasonable term for submission thereof. The requested information must be submitted to the State Agency of Medicines in written form. In the case of failure to submit the information and documents by the due date, the State Agency of Medicines shall terminate the processing of the application and inform the applicant thereof in writing.

(2^1) After acceptance of an application for processing, the State Agency of Medicines may, in the event of justified need, inspect the sites located outside of the European Union required for the attestation of the conformity of clinical trials and the manufacturing facilities of the medicinal product and active ingredient at the expense of the applicant.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) Based on an application and other materials, the State Agency of Medicines shall assess the conformity of the efficacy, safety and quality of the medicinal product with the requirements provided by this Act and legislation established on the basis thereof. The State Agency of Medicines has the right to involve non-staff experts in the assessment of an application.

(4) The State Agency of Medicines shall submit the assessment of the efficacy, safety and quality of the medicinal product to the marketing authorisation committee for medicinal products for human use, and in the case of a veterinary medicinal product, to the marketing authorisation committee for veterinary medicinal products for obtaining an opinion.

(5) If it becomes known to the State Agency of Medicines that a competent authority of another Member State of the European Economic Area has commenced examining an application for marketing authorisation in respect of a medicinal product concerning which the Agency is currently processing an application, or that such competent authority has granted marketing authorisation in respect of such medicinal product, the State Agency of Medicines shall suspend the processing of the application for marketing authorisation until an assessment report is obtained from the competent authority.

(6) The provisions of subsections (2)-(4) of this section do not apply to the processing of an application for marketing authorisation in the case of suspension of the processing of the marketing authorisation under the circumstances specified in subsection (5) of this section. The State Agency of Medicines shall address the competent authority specified in subsection

(5) of this section in issues related to the assessment report prepared by the competent authority.

(7) The State Agency of Medicines shall recognise the assessment provided by the competent authority of a Member State of the European Economic Area concerning the efficacy, safety and quality of a medicinal product, unless additional information leads the Agency to believe that grant of marketing authorisation to the medicinal product may result in a risk to public health, or in the case of a veterinary medicinal product, to the health of animals or humans.

(8) Any disagreements arising from the failure by the State Agency of Medicines or competent authorities of other Member States participating in the processing of an application for marketing authorisation to recognise the assessment report shall be settled pursuant to the procedure provided by Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use (OJ L 311, 28 11 2001, pp 67–128).In making a final decision, the State Agency of Medicines shall comply with the decision of the Committee for Human Medicinal Products of the European Agency for the Evaluation of Medicinal Products, and of the Commission.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 69. Marketing authorisation committee for medicinal products for human use and marketing authorisation committee for veterinary medicinal products

(1) The marketing authorisation committee for medicinal products for human use and the marketing authorisation committee for veterinary medicinal products are advisory committees of the director general of the State Agency of Medicines whose opinion, however, is not binding on the director general of the State Agency of Medicines upon making a decision.

(2) The function of the committees specified in subsection (1) of this section is to provide consultations to the director general of the State Agency of Medicines in issues relating to the processing of marketing authorisations in respect of medicinal products.

(3) The marketing authorisation committee for medicinal products for human use shall consist of up to ten members and the marketing authorisation committee for veterinary medicinal products shall consist of up to eight members. The members of the marketing authorisation committee for medicinal products for human use shall have an academic degree in medicine or pharmacy acquired in a university, and academic or clinical experience in the field of pharmacotherapy, pharmacology or pharmacy. The members of the marketing authorisation committee for veterinary medicinal products shall have an academic degree in veterinary medicine, medicine or pharmacy acquired in a university, and extensive academic or clinical experience in the field of pharmacotherapy, pharmacology or pharmacy.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(4) The authorities of the committees are valid for three years.

(5) The members of the marketing authorisation committee for medicinal products for human use and the marketing authorisation committee for veterinary medicinal products shall be appointed by the Minister of Social Affairs.

(6) The committees are formed and the rules of procedure thereof shall be established by a regulation of the Minister of Social Affairs.

Division 3
Issue of Marketing Authorisation for Medicinal Product

§ 70. Issue of marketing authorisation for medicinal product

(1) Marketing authorisations in respect of medicinal products are issued and renewed by the State Agency of Medicines.

(2) The State Agency of Medicines shall issue an applicant a marketing authorisation in respect of a medicinal product or inform an applicant of refusal to issue a marketing authorisation within 210 days as of the date of acceptance of the application, and in case of refusal to renew a marketing authorisation, within 90 days as of the date of acceptance of the application. The time needed by the applicant for marketing authorisation to submit additional information and documents required by the State Agency of Medicines, and the time needed, where necessary, to verify the correctness of submitted information through inspection shall not be included in the term specified above.

(2^1) The State Agency of Medicines shall issue a licence for parallel import in respect of a medicinal product to an applicant for the licence for parallel import or inform the applicant of refusal to issue the licence for parallel import within 30 days as of the date of receipt of the application. The time needed by the applicant for the marketing authorisation to submit additional information and documents required by the State Agency of Medicines, and the time needed, where necessary, to verify the correctness of submitted information through inspection shall not be included in the term specified above.
[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) Upon processing of an application for marketing authorisation on the basis of an assessment report provided by a competent authority of another Member State of the European Economic Area, the State Agency of Medicines shall recognise or refuse to recognise the decision of the Member State of the European Economic Area concerning the issue of a marketing authorisation in respect of the medicinal product and the summary of product characteristics within 90 days after the date of receipt of the assessment report. The State Agency of Medicines shall issue a marketing authorisation in respect of a medicinal product within 30 days as of making a recognition decision.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(4) The State Agency of Medicines may make the issue of a marketing authorisation in respect of a medicinal product conditional on the market authorisation holder conducting further research for clarifying the characteristics of the medicinal product or forwarding additional safety information.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(5) The State Agency of Medicines may issue a marketing authorisation in respect of a medicinal product which is significant in terms of public health or animal health concerning which no marketing authorisation valid in Estonia exists and no application has been submitted for issue thereof, provided that a marketing authorisation has been issued for such medicinal product by another Member State of the European Economic Area. The State Agency of Medicines shall notify the authorisation holder of the Member State of the European Economic Area which issued the marketing authorisation in respect of the medicinal product of the Agency's intention to issue a marketing authorisation of the same product.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 71. Term of validity of marketing authorisation of medicinal product

A marketing authorisation in respect of a medicinal product shall be issued for five years. After five years, the marketing authorisation in respect of a medicinal product shall be renewed for an unlimited period. The State Agency of Medicines may decide, based on safety information concerning the medicinal product, that another five-year renewal period is necessary.

§ 72. Classification of medicinal products

Upon issue of marketing authorisation in respect of a medicinal product, the State Agency of Medicines shall classify the medicinal product as a medicinal product not subject to medical prescription, a medicinal product subject to medical prescription or a medicinal product subject to restricted use.

§ 73. Information entered on marketing authorisation for medicinal product

(1) A marketing authorisation issued in respect of a medicinal product shall set out information concerning the name, active ingredient, shelf life, pharmaceutical form, strength and marketing authorisation holder of the medicinal product, the manufacturer responsible for batch release, term of validity of marketing authorisation, package size, restrictions to the marketing authorisation, classification of the medicinal product and conditions imposed on the marketing authorisation holder upon issue of the marketing authorisation thereto.

(2) In addition to the above, a marketing authorisation issued in respect of a veterinary medicinal product shall set out the animal species for which the use of medicinal product is prescribed, and if the marketing authorisation is issued in respect of a veterinary medicinal product subject to use on food-producing animals, the authorisation shall also indicate the period during which the corresponding animal products must not be used for human consumption.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) At the time of grant of a marketing authorisation, the State Agency of Medicines shall also approve the summary of product characteristics, package leaflet and draft for the design of the package of the medicinal product.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 74. Refusal to issue or renew marketing authorisation of medicinal product

(1) The State Agency of Medicines refuses to issue or renew a marketing authorisation if at least one of the following circumstances exists:

1) the medicinal product is harmful to humans, animals or the environment under normal conditions of use;

2) the safety of the medicinal product is insufficiently proved by the applicant;

3) the therapeutic efficacy of the medicinal product is lacking or is insufficiently substantiated by the applicant;

4) the quality of the of the medicinal product applicant is not as declared in the application or does not comply with the requirements provided for in this Act and legislation established on the basis thereof;

5) the risk-benefit balance is not deemed to be favourable considering the level of modern medical science;

6) the use of an immunological medicinal product is contrary to the national principles of infection control;

7) the use of a veterinary medicinal product is contrary to the national principles of disease control;

8) the active ingredients of a medicinal product to be used on food-producing animals are not listed in Annex I, II or III to Council Directive 2377/90/EEC laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.08.1990, pp. 1 – 8).

9) its qualitative and quantitative composition is not as declared in the application.

(2) A marketing authorisation may be issued for a veterinary medicinal product the active ingredients of which are not listed in Annex I, II or III to Council Directive 2377/90/EEC provided that the veterinary medicinal product is prescribed for administration to individually identified equidae and the animal products derived from such animals are not used for human consumption. A marketing authorisation shall not be issued under the above conditions concerning a veterinary medicinal product the active ingredients of which are listed in Annex IV to Council Directive 2377/90/EEC. A marketing authorisation may be issued for a medicinal product prescribed for equidae used for human consumption provided that the active ingredients in the medicinal product are listed in Commission Regulation (EC) No 1950/2006 establishing a list of substances essential for the treatment of equidae. A marketing authorisation may be issued provided that the animal products derived from treated equidae and used for human consumption are subject to a withdrawal period of at least six months before consumption.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) The grounds for refusal to grant or renew a marketing authorisation prescribed by subsections (1) or (2) of this section do not apply in cases where the State Agency of Medicines fails to recognise the evaluation report of a competent authority of another Member State of the European Economic Area, and the grant of or refusal to grant the marketing authorisation is decided pursuant to the procedure prescribed by Directive 2001/83/EC of the European Parliament and of the Council on the Community Code relating to medicinal products for human use (OJ L 311, 28 11 2001, pp 67–128).

§ 75. Confidentiality requirement

(1) The State Agency of Medicines, the members of the marketing authorisation committee for medicinal products for human use and the marketing authorisation committee for veterinary medicinal products, and the non-staff experts involved in the processing of applications for marketing authorisation shall guarantee the confidentiality of the information obtained in the course of processing marketing authorisations, and shall preclude the access of third persons to such information. Information is disclosed based on a decision of the director general of the State Agency of Medicines if it is necessary for the protection of human or animal health or the environment.

(2) An assessment report of an application for marketing authorisation may be issued to a competent authority of another Member State of the European Economic Area in connection with the grant, renewal or amendment thereby of a marketing authorisation in respect of a medicinal product.

Division 4
Suspension and Revocation of Marketing Authorisation of Medicinal Product

§ 76. Suspension and revocation of marketing authorisation of medicinal product

(1) The State Agency of Medicines may suspend or revoke a marketing authorisation in respect of a medicinal product if one of the following circumstances exists:

1) the conditions which constituted the basis for issue of the marketing authorisation have changed or are not fulfilled;

2) the marketing authorisation holder fails to perform the duties imposed thereon by this Act, or violates the requirements provided by this Act or the Advertising Act and legislation established on the basis thereof;

[RT I 2008, 15, 108 – entered into force 01.11.2008]

3) new information becomes known concerning the medicinal product which, compared to the data submitted upon application for the marketing authorisation, show that the medicinal product is less effective or more dangerous;

4) the withdrawal period determined for medicinal products to be administered to food-producing animals is insufficient to guarantee the safety of the consumers of the corresponding animal products.

(2) The State Agency of Medicines shall revoke a marketing authorisation if, during three consecutive years, the medicinal product is not available from the marketing authorisation holder unless the State Agency of Medicines decides that the marketing authorisation should remain valid in the interests of public health.

(3) Before a marketing authorisation is suspended or revoked on the initiative of the State Agency of Medicines, the State Agency of Medicines shall notify the marketing authorisation holder of the initiation of the relevant procedure and provide a reasonable term to the authorisation holder for provision of an opinion and objections, and determine the form of submission thereof, as necessary.

(4) A marketing authorisation may be suspended or revoked without observing the procedure provided in subsection (3) of this section if, in the opinion of the State Agency of Medicines, delay is likely to result in a threat to human or animal health, or to the environment.

(5) The State Agency of Medicines shall immediately inform the marketing authorisation holder and all relevant holders of an activity licence for handling medicinal products of the revocation or suspension of the marketing authorisation in respect of a medicinal product and, in the case of danger to public health also the persons qualified to prescribe medicinal products and the public shall be informed.

(6) Upon revocation or suspension of a marketing authorisation in respect of a medicinal product, the holder of the marketing authorisation for such product shall arrange, based on a corresponding decision of the State Agency of Medicines, for the removal of the medicinal product from the market and prevent the further release for use of that product.

(7) If the circumstances which constituted the basis for suspension of a marketing authorisation in respect of a medicinal product are eliminated during the due term, the director general of the State Agency of Medicines shall terminate the suspension of the marketing authorisation by a decision, otherwise the marketing authorisation in respect of the medicinal product shall be revoked.

Division 5
Application for Amendments Related to Medicinal Products and Forwarding of Information Concerning Safety of Medicinal Products

§ 77. Application and refusal to satisfy application for variations related to medicinal products

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(1) A marketing authorisation holder who wishes the amendment of the conditions which constituted the basis for issue of the marketing authorisation shall submit an application to this effect to the State Agency of Medicines.

(2) A marketing authorisation holder shall pay a state fee for submission of an application, and if a significant (type II) variation is applied for, shall pay the fee for professional assessment corresponding to the type of application. The size of the payment for a type II variation shall be 383 euros. If Estonia participates in the decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition of the European Union as a reference country, an additional 510 euros shall be paid for a type II variation.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

(2^1) The State Agency of Medicines shall refuse to satisfy an application on the basis provided for in § 74 of this Act.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) The Minister of Social Affairs shall establish, by a regulation, the types of amendments of conditions which constitute the basis for grant of marketing authorisation, and the conditions and procedure for application for amendments.

§ 78. Communication of information concerning safety of medicinal products

(1) A marketing authorisation holder shall appoint, for dealing with safety issues of medicinal products, a competent person to who shall:

1) ensure that safety information concerning medicinal products to be forwarded to the marketing authorisation holder is collected, assessed and is accessible;

2) prepare information to be submitted to the State Agency of Medicines concerning the safety of medicinal products;

3) guarantee that immediate and exhaustive response is given to the State Agency of Medicines in matters of requests for additional information concerning the safety of medicinal products, including information related to the sale of medicinal products and issue of medicinal prescriptions in respect of medicinal products.

(2) A person engaged in issues of safety of medicinal products need not reside in Estonia.

(3) A marketing authorisation holder shall inform the State Agency of Medicines of safety updates concerning medicinal products or lower efficacy of medicinal products than expected and also of all the prohibitions and restrictions established on medicinal products by the competent authorities of the state where the medicinal products are placed on the market and, based on an invoice submitted by the State Agency of Medicines, pay a fee for monitoring the safety and quality of medicinal products by 1 March each year.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3^1) In order to enable the assessment of the risk-benefit balance of a medicinal product, the State Agency of Medicines may require from the marketing authorisation holder submission of information proving the continuation of the favourable risk-benefit balance of the medicinal product at any time.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(4) The fee for monitoring the safety and quality of medicinal products is a fee determined for the administration of the pharmacovigilance system, including for the collection of safety information concerning medicinal products, processing of urgent notices concerning the safety of medicinal products, review of periodic safety update, analysing signals concerning the safety of medicinal products and forwarding such information to international monitoring centres, and laboratory surveillance of the quality of medicinal products.

(5) The size of the fee for monitoring the safety and quality of medicinal products shall be 160 euros per marketing authorisation which, during the previous calendar year, was in force for a period longer than six months. Based on a reasoned request of a marketing authorisation holder, the State Agency of Medicines has the right to release the authorisation holder from payment of the fee for monitoring the safety and quality of a medicinal product if the medicinal product is sold in Estonia in quantities which remain below the quantity established pursuant to the procedure specified in subsection (7) of this section.

(6) In the case of danger to the life or health of humans or animals, or to the environment, the marketing authorisation holder shall communicate the relevant information to persons qualified to prescribe medicinal products after obtaining the approval of the State Agency of Medicines concerning the content of the information to be forwarded.

(7) The Minister of Social Affairs shall establish, by a regulation, the procedure for communication of information concerning the safety of medicinal products, and the procedure for calculation and payment of the fee for monitoring the safety and quality of medicinal products.

Division 6
Register of Medicinal Products, Coding Centre, Medicinal Product Code and Digital Prescription Centre

§ 79. Register of medicinal products

(1) The register of medicinal products is a state register established by the Government of the Republic at the proposal of the Minister of Social Affairs for registration of medicinal products in respect of which a marketing authorisation is valid in Estonia. The statutes for maintenance of the register of medicinal products shall be established by the Government of the Republic.

(2) The State Agency of Medicinal Products is the chief processor and authorised processor of the register of medicinal products.

(3) Information contained in the marketing authorisation with respect of a medicinal product and the summary of product characteristics are entered in the register of medicinal products concerning a medicinal product.

(4) All data entered in the register of medicinal products are public. Data contained in the register shall be published on the website of the authorised processor.

§ 80. Medicinal product code and Coding Centre

(1) The medicinal product code is a unique combination of digits allowing the identification of the name, package and pharmaceutical form of a medicinal product.

(2) The Coding Centre is a state register at the State Agency of Medicines established by the Government of the Republic at the proposal of the Minister of Social Affairs. The statutes for maintenance of the Coding Centre shall be established by the Government of the Republic.

(3) A medicinal product code is designated by the Coding Centre for each package size of an authorised medicinal product after a marketing authorisation has been issued concerning the medicinal product, for each package size of an imported unauthorised medicinal product after special authorisation has been issued for the first time in respect of the medicinal product, for medicinal products prepared as officinal formulae or magistral formulae by pharmacies, for medical devices transferred to the Health Insurance Fund with the payment obligation and for infant formulae or follow-on formulae and nutrients which do not contain a source of phenylalanine on the basis of an application of the Health Insurance Fund, persons providing pharmacy services or the marketing authorisation holder.

[RT I 2008, 3, 22 – entered into force 01.09.2008]

(4) Use of medicinal product codes is mandatory to all marketing authorisation holders and holders of an activity licence for handling medicinal products.

(5) The Minister of Social Affairs shall establish, by a regulation, the procedure for designation and use of medicinal product codes.
[RT I 2005, 24, 180 – entered into force 20.05.2005]

§ 81. Digital Prescription Centre

(1) The Digital Prescription Centre is a database established in order to issue and process prescriptions and medical device cards and to ensure insured persons with benefit for medicinal products and for medical devices under the conditions provided for in the Health Insurance Act, and the purpose of the database is to ensure protection of the health of persons using medicinal products subject to medical prescription and supervision over the correctness and justification of dispensing medicinal products, and to create possibilities for the state to collect statistics on medicinal products.
(2) The Digital Prescription Centre and the statutes thereof shall be established by a regulation of the Government of the Republic.
(3) The chief processor of the Digital Prescription Centre is the Ministry of Social Affairs. The authorised processor of the Digital Prescription Centre is the Estonian Health Insurance Fund.
(4) The following persons submit information to the Digital Prescription Centre:
1) persons qualified to issue prescriptions in the Republic of Estonia;
2) persons qualified to issue medical device cards in the Republic of Estonia;
3) persons who have dispensed medicinal products or medical devices on the basis of a prescription or a medical device card;
4) the Ministry of Social Affairs;
5) the Health Insurance Fund;
6) the State Agency of Medicines;
7) the Health Board.
[RT I 2009, 49, 331 – entered into force 01.01.2010]
(5) Persons providing pharmacy services are required to process prescriptions, except EU prescriptions, through the Digital Prescription Centre and save the information related to the sale of a medicinal product, including data on the person purchasing a medicinal product subject to medical prescription.

[RT I 2010, 7, 31 - entered into force 26.02.2010]
(6) Persons qualified to issue medical device cards are required to issue the medical device cards in electronic form and the cards shall be saved in the Digital Prescription Centre. Persons dispensing medical devices are required to process medical device cards through the Digital Prescription Centre and add the information related to the sale of a medical device which is also saved in the Digital Prescription Centre.
(7) Persons qualified to issue prescriptions are required to issue the prescriptions in electronic form, the prescriptions shall be saved in the Digital Prescription Centre and, therefor, all the prescribed data fields shall be completed in the Digital Prescription Centre. A prescription may be issued on paper if the Digital Prescription Centre cannot be used due to objective reasons.
(8) A person qualified to issue prescriptions has access to the personal data stored in the Digital Prescription Centre in connection with the performance of a contract for the provision of health services.
(9) A person who has dispensed medicinal products or medical devices on the basis of prescriptions or medical device cards has the right to see in the Digital Prescription Centre the medicinal products or medical devices subject to medical prescription which have not been purchased by the persons.
(10) A person regarding whom information is processed in the Digital Prescription Centre has the right to prohibit the access of a health care provider to the personal data stored in the Digital Prescription Centre.
(11) A person providing pharmacy services is required to enter information concerning a prescription issued on paper in the Digital Prescription Centre within three working days after the receipt of the prescription.
(12) A person regarding whom information is processed in the Digital Prescription Centre has access to the personal data stored in the Digital Prescription Centre.
(13) The Digital Prescription Centre shall release information free of charge if the information is necessary for the performance of public duties arising from law.
[RT I 2008, 3, 22 – entered into force 01.09.2008]

Chapter 4
ADVERTISING OF MEDICINAL PRODUCTS AND INDUCEMENT DESIGNED TO PROMOTE SALES AND PRESCRIPTION

Division 1
Advertising of Medicinal Products

§ 82. Classes of advertising of medicinal products

(1) The classes of advertising of medicinal products are:

1) advertising of medicinal products to the general public;

2) advertising of medicinal products to persons qualified to prescribe them, to dispensing chemists or pharmacists.

(2) The following are not deemed to be advertising of medicinal products:

1) summaries of product characteristics approved by the State Agency of Medicines, labelling of packaging and information leaflets without any amendments or comments thereto;

2) answers of a non-promotional nature to specific questions about a particular medicinal product;

3) statements relating to human health or diseases provided there is no reference, even indirect, to medicinal products;

4) copies of scientific articles published in pre-reviewed medical or pharmaceutical journals without any amendments or comments thereto forwarded to persons qualified to prescribe medicinal products, dispensing chemists and pharmacists.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(3) Advertising of medicinal products to persons qualified to prescribe them, to dispensing chemists or pharmacists shall mean advertising communicated in one of the following manners:

1) by personal communication with the persons mentioned above;

2) during meetings mainly attended by such persons where the names of the participants are recorded;

3) sending by post to the persons above, including by sending printed matter to a specific person;

4) publishing in pre-reviewed medical or pharmaceutical journals;

5) on websites accessed by the persons above.

(4) Advertising of medicinal products communicated in another manner than specified in subsection (3) of this section is deemed to be advertising of medicinal products to the public.

(5) The following is also deemed to be advertising of medicinal products:

1) the supply of samples;

2) information ordered or published by a holder of a marketing authorisation in respect of a medicinal product containing a recommendation for contacting a doctor and direct or indirect reference to a specific medicinal product.
[RT I 2010, 15, 77 - entered into force 18.04.2010]

(6) The requirements established for advertising directed to persons qualified to prescribe veterinary medicinal products, to dispensing chemists or pharmacists apply to advertising of veterinary medicinal products.

(7) Unless otherwise provided by this Act, the requirements of the Advertising Act extend to advertising of medicinal products.

§ 83. General requirements for advertising of medicinal products

(1) Only medicinal products concerning which a marketing authorisation is valid in Estonia may be advertised.

(2) Only the holder of a marketing authorisation in respect of a medicinal product has the right to advertise the medicinal product or order the advertising of such product. The person communicating advertising of a medicinal product must verify whether the person ordering such advertising has the right to advertise the medicinal product. The holder of the marketing authorisation in respect of a medicinal product is liable for the correctness of the information communicated in the advertising and for the conformity of the advertising with the requirements provided by this Act or legislation established on the basis thereof.

(3) Advertising of a medicinal product shall meet the general requirements provided for in the Advertising Act and shall be in full compliance with the information specified in the summary of product characteristics of the medicinal product. If a homeopathic medicinal

product does not have the summary of product characteristics, only the information included in the package leaflet of the homeopathic medicinal product may be used in advertising of the medicinal product.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(4) Advertising of a medicinal product shall facilitate rational use of the medicinal product by presenting information in an objective and unexaggerated way. The advertising shall not be misleading and must not exaggerate the properties of the medicinal product. A clear separation must be made, in advertising, between the properties exclusively connected to the advertised medicinal product and the properties which are generally known or also characteristic to other medicinal products.

(5) Each time the name of the medicinal product is mentioned, it shall be accompanied by the name of its active ingredient set out in a clearly distinguishable and legible form.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(6) By 1 February each year, a holder of a marketing authorisation in respect of a medicinal product shall submit the State Agency of Medicines a report concerning support awarded on the basis of subsections 86 (2) and (5) of this Act to dispensing chemists, pharmacists, doctors and their associations for participation in medical or pharmaceutical events or for organisation of such events, and concerning the meetings and patient information events organised, samples distributed and discounts made based on subsection 86 (6) of this Act during the previous year. A report on advertising of medicinal products submitted by a marketing authorisation holder is public information.

(7) The Minister of Social Affairs shall establish the standard format of and procedure for submitting the report specified in subsection (6) of this section.

(8) The holder of a marketing authorisation in respect of a medicinal product is required to store the advertising materials concerning the medicinal product, and documents related to communication of advertising for the period of two years after the end of communication thereof, and to provide such materials and documents at the request of the State Agency of Medicines.

§ 84. Advertising of medicinal products to general public

(1) It is prohibited to advertise medicinal products subject to medical prescription to the general public.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(2) Advertising of medicinal products to the general public shall not:

1) make any reference to the treatment of tuberculosis, sexually-transmitted diseases or any other serious infectious diseases, cancer and other tumoral diseases, chronic insomnia, diabetes and other metabolic illnesses;

2) use a child in the role of a character presenting the characteristics of a medicinal product.

[RT I 2008, 15, 108 – entered into force 01.11.2008]

(3) Advertising of medicinal products to the general public shall:

1) be set out in such a way that it is clear that the message is advertising and that the product is a medicinal product;

2) be up-to-date, understandable, unambiguous, ensure the distinguishability of the medicinal product from other medicinal products and shall contain sufficient information for the correct and safe use of the medicinal product;

3) include the text *"Tähelepanu! Tegemist on ravimiga. Enne tarvitamist lugege tähelepanelikult pakendis olevat infolehte. Kaebuste püsimise korral või ravimi kõrvaltoimete tekkimisel pidage nõu arsti või apteekriga."* [Attention! This is a medicinal product. Before using the product, carefully read the information leaflet contained in the package. Consult a doctor or pharmacist if complaints persist or side effects occur.];

4) the text *"Ainult veterinaarseks kasutamiseks"* [For veterinary use only] shall be added to the text specified in clause 3) of this subsection in the case of a veterinary medicinal product.

(4) In printed advertising, the warning specified in clauses (3) 3) and 4) of this section must be set out in a font size which ensures that the warning is clearly legible and visible.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(5) In addition to the above, the following requirements shall be adhered to in transmission of television advertising of medicinal products:

1) a clearly legible notice *"Ravimireklaam"* [Advertising of medicinal product] shall be displayed in the upper left corner of the screen during the entire time of transmission of the advertising;

2) at the end of advertising a medicinal product, the message provided in clause (3) 3) of this section shall be displayed as all screen text on a single colour background within a reasonable period of time, and shall be read out at the same time at the speed of ordinary speech;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

3) it is prohibited to transmit advertising of medicinal products before and during children's programs.

(6) The following additional requirements must be adhered to upon advertising medicinal products over the radio:

1) the sentence *"Järgneb ravimireklaam."* [The following is advertising of a medicinal product] shall be read out before advertising of a medicinal product;

2) it is prohibited to transmit advertising of medicinal products before and during children's programs;

3) at the end of advertising of a medicinal product, the message contained in clause (3) 3) of this section shall be read out.

(7) It is prohibited to use material in advertising of medicinal products to the public which:

1) contains symbols of the state or local authorities;

2) refers to a recommendation by scientists, health professionals or persons who, because of their celebrity, could encourage the consumption of the advertised medicinal products;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

3) contains complicated terminology from specialised fields or unfounded opinions or assessments of the manufacturer concerning the properties or effectiveness of the medicinal products;

4) gives the impression that a medical consultation or surgical operation is unnecessary, by offering a diagnosis or by other comparable means;

5) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another treatment or medicinal product;

6) suggests that the health of the subject can be enhanced only by taking the medicine;

7) suggests that the health of the subject could be affected by not taking the medicine;

8) is directed exclusively or principally at children;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

9) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;

10) suggests that the efficacy or safety of the medicinal product is due to the fact that it is natural;

11) could, by description or detailed representation of a case history, lead to an erroneous self-diagnosis;

12) refers, in improper, misleading or alarming terms, to claims of recovery.

13) uses, in improper or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.

14) [Repealed – RT I 2010, 15, 77 – entered into force 18.04.2010]

(8) It is prohibited to supply samples of medicinal products to persons not qualified to prescribe medicinal products, to sell or give away, as a means of sales promotion, items connected to medicinal products or to organise raffles or lotteries connected to medicinal products for such persons, and to offer such persons other medicinal products, goods or services free of charge or at a discount rate together with the purchase of a medicinal product.

(9) [Repealed – RT I 2010, 15, 77 – entered into force 18.04.2010]

(10) The prohibition on advertising of medicinal products subject to medical prescription shall not apply to vaccination campaigns approved beforehand by the State Agency of Medicines and the Health Board.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 85. Advertising of medicinal products to persons qualified to prescribe them, dispensing chemists and pharmacists

(1) Quotations taken from scientific works to be used in advertising of medicinal products to persons qualified to prescribe them, and to dispensing chemists and pharmacists shall be presented without amendments and be supplied with references to the source documents. The marketing authorisation holder shall ensure that when so requested, a copy of the source document of a quotation is made available within three days after receipt of a corresponding request.

(2) Upon advertising of a medicinal product, the marketing authorisation holder shall ensure that an updated summary of product characteristics of the medicinal product is available. Upon advertising of a medicinal product through personal communication, the summary of product characteristics of the medicinal product must be available on site.

(3) [Repealed – RT I 2010, 15, 77 – entered into force 18.04.2010]

(4) Only an authorised representative of a holder of a marketing authorisation in respect of a medicinal product in possession of complete information concerning the medicinal product is permitted to advertise the medicinal product by means of personal communication or at events. The information presented shall be accurate, up-to-date and sufficiently complete to enable the persons qualified to prescribe medicinal products, dispensing chemists and pharmacists to form their own opinion of the benefit and risks of the medicinal product.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

(5) One person may be provided with five samples of authorised medicinal products no larger than the smallest presentation on the market, and the amount of samples provided per year shall not exceed 300. Each sample of a medicinal product shall be marked with the words *"Mitte müügiks"* [Not for sale], the package shall conform to the marketing authorisation and each sample shall be accompanied by a copy of the summary of product characteristic. Samples of medicinal products shall not be sold or transferred for non-medical purposes.

(6) No samples of medicinal products containing narcotic drugs and psychotropic substances, and antibiotics may be supplied to any person.

(7) Samples of medicinal products shall only be supplied to a person qualified to prescribe them, based on a signed written request of the person.

(8) The time, place and names of the person supplying a sample of a medicinal product and the person receiving the sample shall be recorded in an instrument made up in two original copies, one of which shall be given to the person receiving the sample and the other shall remain with the person supplying the sample, and the person receiving the sample shall certify receipt of the sample by his or her signature. A marketing authorisation holder shall keep written record of the supplying of samples. Doctors shall keep written record of the receipt of samples and dispensing thereof for use.

(9) A leaflet containing advertising of a medicinal product shall include the summary of product characteristics, or at least the following information needed for issue of medical prescription:

1) name of the proprietary medicinal product;

2) international non-proprietary name(s) of the active ingredient(s);

3) pharmaceutical form;

4) content of active ingredient(s);

5) package size;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

6) name and address of the manufacturer of the medicinal product or marketing authorisation holder, contact data of representation in Estonia;

7) therapeutic indication(s) permitted by marketing authorisation;

8) posology;

9) contra-indications;

10) precautions and special warnings (including on use during pregnancy and lactation, dangerous interactions with other medicinal products);

11) side effects;

12) classification of the medicinal product.

(10) Printed matter handed over in the course of personal communication or posted, a shorter version of the advertising of a medicinal product may be presented which, however, must contain at least the following data:

1) name of the proprietary medicinal product;

2) international non-proprietary name(s) of the active ingredient(s);

3) one or several therapeutic indications (at least one shall be given if the advertising is directed to the treatment of a specific disease) permitted by the marketing authorisation;

4) name and address of the manufacturer of the medicinal product or marketing authorisation holder, contact data of representation in Estonia;

5) whether the proprietary medicinal product is included in the list of medicinal products subject to medical prescription or the list of medicinal products not subject to medical prescription;

6) a message that additional information can be obtained from the representative of the marketing authorisation holder, and the address of the representation.

(11) Advertising of medicinal products subject to medical prescription over the Internet is permitted only if access to the information is limited to persons qualified to prescribe medicinal products, dispensing chemists and pharmacists. For such purpose, the person publishing the advertising is required to register the users, verify the inclusion in the group of persons specified above and issue a personal code to each user. Such acts shall be recorded. Advertising of medicinal products subject to medical prescription over the Internet shall include the summary of product characteristics.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

Division 2
Inducement Designed to Promote Prescription or Sales

§ 86. Inducement designed to promote prescription or sales

(1) Holders of marketing authorisations in respect of medicinal products are prohibited to give gifts and provide services the value of which exceeds 6.40 euros to persons qualified to prescribe medicinal products, dispensing chemists and pharmacists, and such persons are prohibited from accepting such gifts or services from marketing authorisation holders or their representatives, except in the cases provided in subsection (2) of this section. Receipt of all pecuniary gifts is prohibited, except in the case provided for in subsection (2) of this section. Gifts shall be relevant to the corresponding professional practice of the persons and shall not be connected to the sale or prescription of specific medicinal products or medicinal products manufactured by a specific manufacturer.

[RT I 2010, 22, 108 – entered into force 01.01.2011]

(2) Provision of pecuniary gifts the value of which exceeds the limit specified in subsection (1) of this section (hereinafter *support*) is only permitted in cases where such support is provided for participation in medical or pharmaceutical events organised by a research institution or professional organisation. Such support shall be granted exclusively under conditions which shall be made public and which shall not be connected to the sale or prescription of specific medicinal products or medicinal products manufactured by a specific

manufacturer, and the parties are required to enter into a written contract to such effect, precluding any inducement of the sale or prescription of medicinal products.

(3) Holders of marketing authorisations in respect of medicinal products have the right to support participation in medical or pharmaceutical events by compensating for the fee for participating in the scientific part of the event and, to a reasonable extent, also for accommodation and transport costs. Compensation of such costs shall not extend to other persons except those qualified to prescribe medicinal products, dispensing chemists and pharmacists.

(4) It is prohibited to organise raffles and lotteries connected to medicinal products for persons qualified to prescribe medicinal products, dispensing chemists and pharmacists.

(5) A holder of a marketing authorisation in respect of a medicinal product has the right to support a medical or pharmaceutical event organised by a research institution or professional organisation, provided that a contract is concluded between the authorisation holder and the organiser of the event, precluding any influence that the marketing authorisation holder might have over the programme.

(6) If a holder of a marketing authorisation in respect of a medicinal product organises a scientific event intended for persons qualified to prescribe medicinal products, dispensing chemists or pharmacists, hospitality offered at such events, including entertainment, shall remain within reasonable limits, be strictly limited to the main scientific objective of the event and must not be extended to persons other than those mentioned above. Information provided concerning medicinal products at events organised by a holder of a marketing authorisation in respect of a medicinal product shall conform to the requirements set for advertising of medicinal products.

(7) All support granted to persons qualified to prescribe medicinal products, dispensing chemists or pharmacists as well as the expenses made in connection to the events specified in subsections (5) and (6) of this section shall be recorded in the documentation of the Estonian representative or branch of the marketing authorisation holder, and the State Agency of Medicines shall be informed of the expenses made in connection to the events specified in subsections (5) and (6) of this section pursuant to the procedure provided in subsection 83 (7) of this Act.

(8) All contracts concluded between a marketing authorisation holder and a person qualified to prescribe medicinal products, a dispensing chemist or pharmacist whereby such person, dispensing chemist or pharmacist is given compensation, whether pecuniary or not, which is not related to a clinical trial approved by the State Agency of Medicines, must be submitted to the State Agency of Medicines on request and is deemed to be public information.

(9) A marketing authorisation holder is prohibited to give and a holder of an activity licence for wholesale of medicinal products and persons employed thereby are prohibited to receive any compensation, whether pecuniary or not, for giving preference, upon retail sale, to specific medicinal products or medicinal products manufactured by a specific manufacturer. Recommendations made with respect of medicinal products in a pharmacy shall be based on medical criteria only.

Chapter 5
CLINICAL TRIALS OF MEDICINAL PRODUCTS

§ 87. Clinical trials of medicinal products

(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) Trials of medicinal products in the course of which the treatment and monitoring of trial subjects is to remain unchanged, no new medicinal product is introduced and information is collected on the characteristics of a medicinal product in the course of everyday medical practice are not deemed to be clinical trials of medicinal products. The approval requirement for clinical trials of medicinal products established by this Act does not apply to the trials mentioned above, except in the part of approval of the medical ethics committee. All research and programmes for the purpose of commencement of new treatment or alteration of treatment are deemed to be clinical trials.

(3) The publication of information concerning a clinical trial of medicinal products to possible trial subjects, or to the owners of the animal which is the subject 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.

§ 88. Requirements for clinical trials of medicinal products

(1) Only medicinal products manufactured in compliance with good manufacturing practices and regarding which the person conducting the clinical trial has sufficient up-to-date information on its effects and side effects may be investigated by way of clinical trial. Investigated medicinal products shall be labelled pursuant to the requirements established on the basis of subsection (4) of this Act.

(2) The sponsor of a clinical trial of a medicinal product or the representative thereof must be a resident of, or have a seat in a Member State of the European Economic Area.

(3) The planning and conduct of a clinical trial of a medicinal product and the publication of the results thereof shall be in compliance with good clinical practice.

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

§ 89. Persons conducting clinical trials of medicinal products and other participants in clinical trials of medicinal products

(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 health care professionals not specified in subsection (1) of this section, dispensing chemists, pharmacists, health care providers, pharmacy service providers, manufacturers of medicinal products and their representatives may participate in the conduct of clinical trials of medicinal products.

(3) If several doctors, dentists, veterinarians or persons specified in subsection (2) of this section participate in the conduct of a clinical trial of a medicinal product, their rights and obligations with respect to each other shall be determined by a contract conducted between them.

§ 90. Obligations of persons conducting clinical trials and other participants in clinical trials of medicinal products

(1) 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.

(2) The manufacturer of a medicinal product and sponsor of the clinical trial shall guarantee a functional and effective system for registering and monitoring the withdrawal of the medicinal product used in the clinical trial. The manufacturer of a medicinal product shall register each defect established in a medicinal product and inform the State Agency of Medicines thereof. If a defect is discovered in a medicinal product, all research centres and Member States of the European Economic Area to which the investigated medicinal product has been imported must be identified as soon as possible.

(3) The sponsor of a clinical trial of a medicinal product shall guarantee the existence of a procedure for unblinding necessary for withdrawal of the medicinal product from use.

(4) If an authorised medicinal product is investigated, the manufacturer is required to inform, in cooperation with the sponsor, marketing authorisation holders of each established defect of the medicinal product.

(5) A doctor, dentist or veterinarian conducting a trial and health care provider 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 care 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 investigating a medicinal product 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 clinical 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 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 Ministry of Agriculture in writing of any serious adverse-events which appear in the course of the trial and amendments to the clinical trial protocol and alterations in the course of the trial.

(9) The sponsor of a clinical trial of a medicinal product shall guarantee the trial subjects health insurance protection in the event of damage to health related to the trial.

(10) A person conducting clinical trials of medicinal products is required to submit, not less frequently than once a year, reports to the medical ethics committee for clinical trials concerning ongoing clinical trials approved by the committee.

(11) A person conducting clinical trials of medicinal products is required to inform the medical ethics committee for clinical trials and the State Agency of Medicines of termination of a clinical trial.

[RT I 2010, 15, 77 - entered into force 18.04.2010]

§ 91. 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 in writing after having been informed of all facts relating to the clinical trial of a medicinal product. 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, taking account of his or her presumed will, by the legal representative of such person, in so far as the person is unable to consider the pros and cons responsibly. The person conducting the clinical trial shall not adhere to the decision of the legal representative if his or her decision clearly violates the interests of the person with restricted active legal capacity. The person with restricted active legal capacity shall be informed, to a reasonable extent, of the circumstances of the clinical trial and the decisions made. For a minor who is 7-17 years old to participate in a trial, the consent of the minor is necessary.

(3) A person unable to provide informed consent may be the subject of a trial only if the investigated medicinal product is likely to bring direct benefit to the person and the objective of the trial cannot be achieved by way of a trial whose subjects are able to give informed consent.

(4) 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.

§ 92. Medical ethics committee for clinical trials

(1) A medical ethics committee for clinical trials (hereinafter *committee*) is an independent body, consisting of scientists and representatives of different fields, which provides evaluation as to the ethics of the conduct of clinical trials of medicinal products with the aim to guarantee the protection of the rights, safety and well-being of trial subjects.

(2) The work of a committee shall be guided by this Act and legislation established on the basis thereof, other relevant legislation, good clinical practice, the Helsinki declaration of the World Medical Association and the statutes of the committee.

(3) A committee is formed by the head of a medical research institution.

(4) A committee shall have at least seven members. A committee shall have at least one member whose main activity is not scientific research, and at least one member independent of the research centre.

(5) A committee may involve experts in its work.

(6) By 1 February each calendar year, a committee shall submit the State Agency of Medicines a list of all applications for clinical trials of medicinal products received by the committee during the preceding year and of the decisions of the committee.

(7) The State Agency of Medicines has the right to examine the rules of procedure of the committee and to check compliance of the committee with such rules.

(8) The Minister of Social Affairs shall establish, by a regulation, the rules of procedure of a committee, a list of data to be submitted for obtaining approval, procedure for adoption of resolutions and the format of an application for approval.

§ 93. Approval of clinical trials by committee

(1) A clinical trial of a medicinal product shall not commence without the approval of a committee.

(2) In order to obtain approval, an applicant shall submit a written application to this effect to a committee together with data specified on the basis of subsection 92 (8) of this Act.

(3) A committee shall make one of the following decisions:

1) approves the clinical trial;

2) demands the making of alterations in the conduct of the clinical trial of the medicinal product;

3) refuses approval;

4) revokes or suspends an earlier approval.

(4) If a clinical trial is conducted by several centres, a mutual decision shall be made irrespective of the number of the ethics committees involved.

(5) A committee shall deliberate the matter, make a decision and issue the decision in writing within sixty days and, in the case of clinical trial involving medicinal products for gene therapy or somatic cell therapy, immunological medicinal products or medicinal products containing genetically modified organisms, within ninety days after receipt of the requisite documents. If a committee deems it necessary to obtain the opinion of a research organisation or other non-committee body concerning the clinical trial of the medicinal products listed above, the term for grant of approval shall be extended by ninety days, of which the applicant shall be given written notice. A committee shall provide a reasoned explanation if approval is refused.

(6) If the applicant for approval disagrees with the decision of a committee, the applicant has the right to submit additional documents to the committee which made the decision and make alterations to the planned trial on the basis of which the committee shall make a new decision. An applicant for approval has no right to address another ethics committee.

§ 94. Payment for evaluation of clinical trial

(1) A person conducting a clinical trial shall pay the committee an amount of up to 383 euros for evaluation of the clinical trial.

[RT I 2010, 22, 108 – entered into force 01.01.2011]

(2) The size of the payment shall be decided by the head of the research institution who formed a committee and release from payment shall be decided by a committee.

(3) A committee shall decide on the manner in which the payment for evaluation of a clinical trial will be used.

§ 95. Submission of application for conduct of clinical trial of medicinal product to State Agency of Medicines

(1) In order to conduct a clinical trial of a medicinal product, the sponsor of the trial or representative thereof shall submit a written application conforming to the procedure established on the basis of subsection 88 (4) of this Act and other information and documents prescribed by the same procedure to the State Agency of Medicines at least two months before the beginning of the planned trial.

(2) An applicant for a clinical trial of a medicinal product shall pay a state fee for application for the clinical trial of the medicinal product and the State Agency of Medicines a fee for the professional assessment of the application in the amount of 383 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

(3) An applicant is released of payment of the state fee if all the following conditions are complied with:

1) the applicant has submitted a corresponding application to the State Agency of Medicines;

2) the clinical trial of the medicinal product is sponsored by the Faculty of Medicine of the University of Tartu, the National Institute for Health Development, a doctor or dentist registered at the Health Board, or a health care provider or veterinary holding a valid activity licence;
[RT I 2009, 49, 331 – entered into force 01.01.2010]

3) the person specified in clause 2) of this subsection does not receive any remuneration or other compensation from the manufacturer of the medicinal product or representative thereof for conducting the trial.

§ 96. Grant of authorisation for conduct of clinical trial of medicinal products

(1) Authorisation for the conduct of a clinical trial of a medicinal product is granted by the State Agency of Medicines. Authorisation for the conduct of a clinical trial of a veterinary medicinal product is granted in agreement with the Ministry of Agriculture.

(2) The State Agency of Medicines makes the decision to grant an authorisation for the conduct of a clinical trial of a medicinal product within sixty days after receipt of all requisite documents in the case of I phase trials and within thirty days after receipt of all requisite documents in the case of II-IV phase trials. If the State Agency of Medicines has not notified the applicant of the refusal to grant authorisation or requested additional information within the specified term, authorisation is deemed to be granted.
[RT I 2008, 56, 313 – entered into force 01.01.2009]

(3) In the case of a clinical trial involving the use of medicinal products for gene therapy or somatic cell therapy, immunological medicinal products or medicinal products containing genetically modified organisms, the State Agency of Medicines shall decide on the grant of authorisation for a clinical trial within ninety days after receipt of the application. If the State Agency of Medicines deems it necessary to obtain the opinion of a scientific body or other body outside of the Agency concerning the clinical trial of the medicinal products listed above, the term for grant of approval shall be extended by ninety days, of which the applicant shall be given written notice. Such clinical trials shall not be commenced before obtaining written authorisation of the State Agency of Medicines.

§ 97. Refusal to grant authorisation for conduct of clinical trial of medicinal products

The State Agency of Medicines may refuse to grant authorisation for the conduct of a clinical trial of a medicinal product upon existence if at least one of the following circumstances exists:

1) the applicant does not comply with the requirements for clinical trials of medicinal products;

2) the information or documents submitted by the applicant are incomplete or inaccurate;

3) the trial protocol is unreasonable;

4) the trial is of no scientific value or is likely to influence the use of medicinal products in the course of health care provision in an unreasonable direction;

5) the risk to the life and health of trial subjects is high.

§ 97[1]. Application for amendment of conditions for conduct of clinical trial of medicinal products

(1) In order to amend the conditions for the conduct a clinical trial of a medicinal product, the sponsor of the trial or a representative thereof shall submit an application conforming to the procedure established on the basis of subsection 88 (4) of this Act and other information and documents prescribed by the same procedure to the State Agency of Medicines at least thirty days before introduction of the planned amendments.
(2) Upon application for amendment of the conditions for the conduct of a clinical trial of a medicinal product, the applicant shall pay the fee for assessment of the application in the amount of 63 euros to the State Agency of Medicines. The applicant is released from payment of the fee if all the conditions specified in subsection 95 (3) are complied with.
[RT I 2010, 22, 108 – entered into force 01.01.2011]
(3) The State Agency of Medicines makes the decision to grant an authorisation for amendment of the conditions for the conduct of a clinical trial of a medicinal product within thirty days after receipt of all requisite documents. If the State Agency of Medicines has not notified the applicant of the refusal to grant authorisation or requested additional information within the specified term, authorisation is deemed to be granted taking account of the specifications specified in subsection 96 (3).
(4) The State Agency of Medicines shall refuse to grant an authorisation for amendment of the conditions for the conduct of a clinical trial of a medicinal product on the bases specified in § 97.
[RT I 2008, 56, 313 – entered into force 01.01.2009]

§ 98. Suspension and termination or clinical trials of medicinal products

(1) The State Agency of Medicines shall immediately suspend or terminate, at the initiative of the Agency or on proposal of the Ministry of Agriculture, a clinical trial of a medicinal product if any of the circumstances specified in § 97 of this Act become evident, except in the case specified in subsection (2) of this section.

(2) If continuing the trial does not pose a risk to the life and health of trial subjects, the State Agency of Medicines shall notify the person conducting the trial of the intention to suspend or terminate the trial.

(3) The person conducting a trial is required to submit, within seven days after receipt of the notice specified in subsection (2) of this section, the person's opinion of the suspension of termination of the trial.

(4) The person conducting a trial is required to suspend or terminate the trial immediately after receiving a corresponding decision of the State Agency of Medicines.

§ 99. Liability of persons conducting clinical trials of medicinal products

(1) The sponsor of a clinical trial of a medicinal product shall be liable for the conformity of all aspects of the clinical trial and the conduct thereof.

(2) 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.

(3) 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 jointly and severally liable together with the doctor, dentist or veterinarian.

Chapter 6
STATE SUPERVISION

§ 100. Supervisory agency and competence of supervisory agency

(1) State supervision over compliance with the requirements provided by this Act and legislation established on the basis thereof shall be exercised by the State Agency of Medicines and, according to their competence, the Health Board, the Veterinary and Food Board, the Competition Board and the Tax and Customs Board.
[RT I 2009, 49, 331 – entered into force 01.01.2010]
(2) The Health Board shall exercise supervision over compliance with the requirements provided by this Act and legislation established on the basis thereof by health care providers and health care professionals.
[RT I 2009, 49, 331 – entered into force 01.01.2010]
(3) [Repealed – RT I 2009, 49, 331 – entered into force 01.01.2010]

(4) The Veterinary and Food Board shall exercise supervision over the use of medicinal products and medicated feedingstuffs by veterinarians and breeders producing animal products.

(5) The Competition Board shall exercise supervision over compliance with the requirement specified in clause 44 (1) 7) of this Act pursuant to the procedure prescribed by this Act and the Competition Act.

(6) The Tax and Customs Board shall check, for goods requiring special import or export authorisation of the State Agency of Medicines, the existence and conformity of the import or export authorisation or written permit pursuant to the procedure prescribed by this Act and the Customs Act.

(7) Upon exercise of supervision, the State Agency of Medicines has the right, by a precept, to:

1) suspend the sale or dispensing of a medicinal product if the State Agency of Medicines has reason to believe that the medicinal product is liable to pose a risk to the life or health of humans or animals, or to the environment;

2) terminate the sale or dispensing of a medicinal product and, if necessary, demand the withdrawal from the market of a medicinal product if the medicinal product does not conform

to the conditions based on which the marketing authorisation was granted, the medicinal product is not handled in adherence to applicable requirements, the medicinal product is defective, the medicinal product is unauthorised, or if facts in proof of hazards of the medicinal product to the life or health of humans or animals, or to the environment the become evident;

3) prohibit the advertising of the medicinal product, and to impose an obligation on the marketing authorisation holder and the person communicating the advertising to publish a statement with the text prescribed by the State Agency of Medicines,

4) suspend or terminate the clinical trial of the medicinal product;

5) impose an obligation on the marketing authorisation holder or wholesaler to inform the public or health care professionals of the dangers related to the medicinal product.

(8) Suspension of the sale or dispensing of a medicinal product specified in clause (7) 1) of this section is suspended by a corresponding authorisation granted by the State Agency of Medicines unless the circumstances described in clause (7) 2) become evident.

(9) After conducting a general inspection of an enterprise belonging to the holder of an activity licence for manufacture of medicinal products or a part of such enterprise, the State Agency of Medicines shall, within ninety days, issue a certificate to the holder of the activity licence concerning the conformity of the enterprise with good manufacturing practices if inspection results confirm the conformity.

§ 101. Rights and obligations of officials exercising supervision

(1) An official exercising supervision (hereinafter *supervisory official*) has the right, for performance of his or her duties, to:

1) check adherence with the requirements provided by this Act and legislation established on the basis thereof, including, if necessary, without giving prior notice;

2) make purchases for monitoring compliance and obtain free samples for control analysis, as necessary;

3) enter, for exercise of supervision, the facilities being inspected;

4) obtain information necessary for the exercise of supervision from natural persons and representatives of legal persons, to examine relevant documents, including documents containing sensitive personal data, in the process of supervision, and to obtain or make copies thereof or, if a misdemeanour is suspected, to take the documents with him or her;

[RT I 2010, 15, 77 - entered into force 18.04.2010]

5) make a proposal to the State Agency of Medicines, upon establishment of the violations specified in clauses 51 (3) 1)-4) of this Act, to suspend the validity of the activity licence in part or in whole, or to revoke the activity licence;

6) issue, within the limits of his or her competence, precepts to terminate a violation of the requirements of this Act or legislation established on the basis thereof or breach of the conditions of the activity licence, to eliminate the consequences of the violation or breach, to make good the damage caused by the violation or breach or to perform other acts.

(2) Supervisory officials are required to present identification for the performance of their duties.

(3) Supervisory officials are required to maintain the confidentiality of business secrets which become known to them unless keeping the secret is liable to pose a risk to the life or health of humans or animals, or to the environment.

§ 102. Precept of supervisory official and application of coercive measures

(1) A precept shall contain the following information:

1) the name and position of the person who prepares the precept and the name and address of the supervisory agency;

2) the date and place of making the precept;

3) the name, and residence or seat of the recipient of the precept;

4) the circumstances which are the basis for the issue of the precept or a reference to the document in which the circumstances are set out, and reference to legal grounds;

5) the conclusion of the precept in which the obligations of the obligated subject arising from the precept and the term for performance of the obligations are set out;

6) a reference to the possibility of administrative coercive measures being applied upon failure to perform the obligations set out in the precept;

7) the procedure and term for contesting the precept;

8) the signature of the person who prepares the precept.

(2) A precept shall be prepared in two original copies of which one shall remain with the person who prepares the precept and the other shall be given to the obligated subject. If it is necessary to inform a third party of the precept, a copy of the precept certified by the person who prepared the precept shall be delivered to the third party by post or by electronic means.

(3) Upon failure to comply with a precept, a supervisory official may impose substitutive enforcement and a penalty payment pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act. The upper limit for a penalty payment is 1600 euros.

[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 103. Contestation of precept

(1) Upon disagreement with a precept of a supervisory official, the recipient of the precept has the right to file a written challenge with the director general of the supervisory agency within ten working days as of the date on which the recipient of the precept became or should have become aware of the contested precept.

(2) The director general of the supervisory agency shall review a challenge and make a decision within fourteen days as of the date on which the challenge is filed. The supervisory official against whose precept or act the challenge is filed shall not participate in the review of the challenge.

(3) The filing of the challenge shall not release the person who filed the challenge from the duty to comply with the precept. The director general of the supervisory agency may suspend compliance with a contested precept if the circumstances specified in § 81 of the Administrative Procedure Act occur until a decision is made on the challenge.

(4) The director general of the supervisory agency has the right to revoke, in part or in whole, a precept which is contrary to this Act or legislation established on the basis thereof by a reasoned directive.

Chapter 7
LIABILITY

§ 104. Violation of requirements for handling of medicinal products

(1) Violation of the requirements for handling of medicinal products is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 105. Violation of requirements for recording and reporting regarding medicinal products

(1) Violation of the requirements for requirements for recording and reporting regarding medicinal products is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 106. Violation of requirements related to marketing authorisation

(1) Violation of the requirements related to a marketing authorisation granted in respect of a medicinal product, or the acquiring or distribution of a medicinal product no authorised by the State Agency of Medicines is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 107. Violation of requirements for advertising of medicinal products and prohibition on inducement designed to promote sales

(1) Violation of the requirements for advertising of medicinal products is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 108. Violation of requirements for clinical trials of medicinal products and violation of requirements for trial specified in subsection 87 (2)

(1) Violation of the requirements for clinical trials of medicinal products or violation of the requirements for the trial specified in subsection 87 (2) of this Act is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.

[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 109. 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 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 110. Violation of requirements for issue of medical prescriptions

(1) Violation of the requirements for the issue of medical prescriptions 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 32 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 111. Interference with exercise of state supervision

Interference with the exercise of state supervision, refusal to submit documents or information necessary for inspection or failure to submit these on time, submission of incorrect information, or submission of documents or information such that it prevents the exercise of supervision, if committed by a legal person, is punishable by a fine of up to 16 000 euros.
[RT I 2010, 22, 108 – entered into force 01.01.2011]

§ 112. Proceedings

(1) The provisions of the General Part of the Penal Code and of the Code of Misdemeanour Procedure apply to the misdemeanours provided for in §§ 104-111 of this Act.

(2) The courts, police authorities and the Tax and Customs Board may, pursuant to the provisions of § 83 of the Penal Code, apply confiscation of a substance or object which was the direct object of the commission of a misdemeanour provided for in §§ 104-106 of this Act.
[RT I 2009, 62, 405 – entered into force 01.01.2010]

(3) Extra-judicial proceedings concerning the misdemeanours provided for in §§ 104-108, 110 and 111 of this Act shall be conducted by the State Agency of Medicines.

(4) Extra-judicial proceedings concerning the misdemeanours provided for in §§ 104, 105, 110 and 111 of this Act committed by health care providers shall be conducted by the Health Board.
[RT I 2009, 49, 331 – entered into force 01.01.2010]
(5) Extra-judicial proceedings concerning the misdemeanours provided for in §§ 104 and 111 of this Act which involve a violation of health protection norms shall be conducted by the Health Protection Inspectorate.
[RT I 2009, 49, 331 – entered into force 01.01.2010]
(6) Extra-judicial proceedings concerning the misdemeanours provided for in §§ 104-106 and § 111 of this Act shall be conducted by police authorities and the Tax and Customs Board.
[RT I 2009, 62, 405 – entered into force 01.01.2010]

(7) Extra-judicial proceedings concerning the misdemeanours provided for in § 109 and § 111 of this Act shall be conducted by the Veterinary and Food Board.

Chapter 8
IMPLEMENTING PROVISIONS

§ 113. Validity of authorisations granted by State Agency of Medicines and obligations of holder of activity licence for handling of medicinal products and marketing authorisation holder

(1) Activity licences for handling of medicinal products and special authorisations issued prior to the entry into force of this Act remain valid until the term of expiry specified therein.

(2) The holder of an activity licence for manufacture of or wholesale trade in medicinal products who has not entered the name of the responsible person on the licence shall inform the State Agency of Medicines of the name of the responsible person and his or her substitute by 1 May 2005.

(3) The holder of an activity licence for wholesale trade in medicinal products who alters the labelling or outer package of a medicinal product, including medicinal products intended for clinical trials, or imports medicinal products form third countries, shall apply for an activity licence for the manufacture of medicinal products by 1 July 2005, or to terminate such activities.

(4) A holder of a marketing authorisation for the sale of authorised medicinal products shall appoint, by 1 July 2005, the person specified in subsection 64 (2) of this Act and inform the State Agency of Medicines of the appointment.

§ 114. Registration of dispensing chemists and pharmacists

(1) The Health Board shall commence the registration of the persons specified in §§ 55-57 and § 60 of this Act as dispensing chemists or pharmacists beginning from 1 July 2005.
(2) The requirement provided by this Act according to which pharmacy services shall be provided only by dispensing chemists and pharmacists registered at the Health Board applies to pharmacies concerning the activities of which an application for the grant or renewal of an activity licence for provision of pharmacy services is submitted later than on 1 October 2005.
[RT I 2009, 49, 331 – entered into force 01.01.2010]

§ 115. Pharmacy counters

(1) Pharmacy counters established on the basis of the Medicinal Products Act in force before the entry into force of this Act (hereinafter *pharmacy counters*) shall be undergo dissolution or be transformed into branch pharmacies or general pharmacies by 1 March 2006.

(2) The provisions of this Act and legislation established on the basis thereof, except in the part of the conditions specified in subsection (3) of this section, apply to pharmacy counters until the time they undergo dissolution or are transformed.

(3) The area of a pharmacy counter shall be at least 25 square metres. Based on a decision of the State Agency of Medicines, a pharmacy counter located in a rural region may be permitted to have an area of fifteen square metres as a minimum if the pharmacy counter is located at a distance further than fifteen kilometres from a pharmacy, branch pharmacy or another pharmacy counter, or the location is poorly served by public transport. A pharmacy

counter located in a rural region is permitted to sell medicinal products not subject to medical prescription as well as medicinal product subject to medical prescription, and a pharmacy counter located in a city is permitted to sell only medicinal products not subject to medical prescription.

(4) A transformed place of business and its operation must conform to the requirements provided by this Act and legislation established on the basis thereof.

§ 116. Temporary application of clause 65 (4) 3)

Upon application of clause 65 (4) 3) of this Act, an applicant for marketing authorisation in respect of a medicinal product need not submit, until 29 October 2005, information concerning the efficacy and safety of the medicinal product if the applicant is able to prove that the medicinal product is identical in its nature and bioequivalent to a medicinal product concerning which marketing authorisation was granted at least six years ago in Estonia or a Member State of the European Economic Area.

§§ 117-121. [Omitted from this text]

§ 122. Entry into force of Act

(1) This Act shall enter into force on 1 March 2005.

(2) Subsections 8 (2), 16 (6) and 65 (5) of this Act shall enter into force on 30 October 2005.

(3) Clause 15 (5) 5) of this Act shall enter into force on 1 October 2005.

(4) Subsection 18 (2) of this Act shall enter into force in respect of holders of activity licences for wholesale trade in and manufacture of medicinal products on 1 July 2005.

(5) Subsections 42 (3) and (4) of this Act shall enter into force on 1 February 2006.

(5^1) Section 42^1 of this Act shall enter into force on 1 January 2006.

(6) Section 43 of this Act shall enter into force in respect of holders of activity licences for handling of medicinal products which are valid at the time of entry into force of this Act, and with respect to the persons performing the duties specified in § 43 at the time of entry into force of this Act on 1 September 2005.

(7) Subsection 80 (3) of this Act shall enter into force on 1 July 2005.

(8) Subsection 80 (4) of this Act shall enter into force on 1 October 2005.

(9) Section 81 of this Act shall enter into force on 1 January 2006.

[RT I 2005, 24, 180 – entered into force 20.05.2005]