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Medicinal Products Act[1]

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Amended by the following acts

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07.12.2006	RT I 2006, 58, 439	01.01.2007
20.12.2007	RT I 2008, 3, 22	01.09.2008
12.03.2008	RT I 2008, 15, 108	01.11.2008
04.06.2008	RT I 2008, 25, 163	01.01.2009
19.06.2008	RT I 2008, 30, 191	01.07.2008
19.06.2008	RT I 2008, 35, 213	01.01.2009
09.12.2008	RT I 2008, 56, 313	01.01.2009
15.06.2009	RT I 2009, 39, 262	24.07.2009
30.09.2009	RT I 2009, 49, 331	01.01.2010, in part 22.10.2009
26.11.2009	RT I 2009, 62, 405	01.01.2010
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	01.01.2011, will enter into force on the date specified in the decision of the Council of the European Union concerning abrogation of the derogation established with regard to the Republic of Estonia under 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 (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
21.06.2012	RT I, 25.06.2012, 4	21.06.2012, in accordance with judgment no. 3-3-1-26-12 of the Administrative Chamber of the Supreme Court, the sentence part “and must not contain information not specified in the summary of the characteristics of the medicinal product” in subsection 83 (3) of the Medicinal Products Act in force on 6 June 2008 must not be applied due to a conflict with the law of the European Union.
13.06.2012	RT I, 05.07.2012, 13	21.07.2012

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application of Act

(1) This Act regulates the handling of medicinal products, issue of medical prescriptions, granting of marketing authorisations, clinical trials and advertising of medicinal products, and supervision over and responsibility in the area of medicinal products for the purpose of ensuring the safety, quality and efficacy of medicinal products used in Estonia and promoting the use of medicinal products for their intended purposes.

(2) The provisions of the Administrative Procedure Act apply to administrative proceedings provided for in this Act, taking into account 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’ means the manufacture, procuring, dispensing, preparation in pharmacies, import, export, marketing, transport, storage and withdrawing from the market of medicinal products together with relevant records and reports concerning such activities.

(2) For the purposes of this Act, ‘marketing’ means the wholesale distribution, 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 governmental authorities and local authorities, whereas the provisions related to supervision apply unless otherwise provided by legislation concerning such governmental authorities, state agencies administered by governmental authorities and local authorities.
[RT I 2008, 35, 213 - entry 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 marketing.

(2) Proprietary medicinal products containing the same active substance 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 substances and excipients

(1) An active substance 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 substances unless otherwise provided by this Act or legislation established on the basis thereof.

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

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

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

(2) Pre-mixes of medicated feedingstuffs are veterinary medicinal products that 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 - entry 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 packaging.

(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 that contain, as their active substance, 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 that meet all the following requirements:
1) they have indications exclusively appropriate to traditional herbal medicinal products that, 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 a 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 that 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 - entry into force 01.05.2005]

§ 10. Defective medicinal products

A medicinal product is deemed to be defective if it does not comply with quality requirements or if its packaging, 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. Pharmacists and assistant pharmacists

(1) For the purposes of this Act, a pharmacist is a person who has completed a pharmacy curriculum in a university.

(2) For the purposes of this Act, an assistant pharmacist is a person of who has completed a pharmacy curriculum in a vocational secondary educational institution or professional higher educational institution.

§ 12. Competent person

For the purposes of this Act, ‘competent person’ means 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 manager of the pharmacy is the competent person in a pharmacy.

§ 13. General requirements for medicinal products

(1) Only the following will 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 import authorisation and a permit for 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 must be carried out with medicinal products concerning which the State Agency of Medicines has granted corresponding authorisation.

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

(4) Medicinal products will be marketed and dispensed in packaging with Estonian text, except in exceptional events provided by legislation established under this Act, and the medicinal products must be accompanied by information in Estonian concerning the composition, content of active substances, and requirements for the use and storage of the medicinal product.

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

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

§ 14. Application of other Acts

(1) This Act applies to medicinal products that 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 - entry 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 distribution 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 - entry 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 - entry into force 01.01.2006]

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

(1) Threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation will be established by a regulation of the Government of the Republic. 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 will take into account the accessibility of the medicinal products to the end user arising from geographical and financial reasons, the risks involved in marketing the medicinal products, 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 will prepare an annual analysis of the weighted average mark-up.

(3) The following principles must 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 must not exceed 6.40 euros;
[RT I 2010, 22, 108 - entry 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 March 1 each year, holders of an activity licence for wholesale distribution of 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 must set out the sales volume of medicinal products expressed in sales in packaging, 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 must be grouped into price groups that constitute the basis for wholesale mark-ups, and the turnover data expressed in pharmacy purchase prices must be grouped into price groups that constitute the basis for retail mark-ups.

(5) In addition to legislation specified in this Act, the Minister of Social Affairs will 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 a 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 a 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 packaging.

(6) The 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 will be established by a regulation of the Minister of Agriculture. The regulation will be approved by the Minister of Social Affairs.

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

§ 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 in accordance with 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, must not exceed 3,195 euros.
[RT I 2010, 22, 108 - entry 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 procuring, 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 is required for the total or partial manufacture of medicinal products including, the manufacture of active substances of medicinal products and investigational medicinal products, and 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 in accordance with a medical prescription, officinal formulae or for dividing-up into retail packaging for dispensing (hereinafter *dividing-up into retail packaging*).

(5) An activity licence for manufacture of medicinal products is not mandatory for the manufacture of investigational medicinal products 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*) will 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 under subsections 21 (1), (7) and (8) of this Act.

(7) The holder of an activity licence for manufacture of medicinal products must ensure that the manufacture, including the packaging, labelling, re-packaging and re-labelling of the active substances of medicinal products, and the excipients included in the list established by the European Commission under 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 substances valid within the European Union.

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

(9) Based on a request by a manufacturer of medicinal products, exporter of medicinal products from a third country or a competent authority of a third country, the State Agency of Medicines will issue, within 30 days after the receipt of the request, a certificate that 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 to a third country, the State Agency of Medicines will 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 to a third country, 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 Permit for Use

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

(1) The 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 substances, 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*) will be established by a regulation of the Minister of Social Affairs.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

(2) For the purposes of this Act, import of goods requiring special authorisation means:
1) placing such goods under the customs procedure of release for free circulation (hereinafter *import from third countries*), or
2) conveyance 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 means:
1) placing such goods under export procedure (hereinafter *export to third countries*), or
2) conveyance of such goods from Estonia to a Member State of the European Economic Area.

(4) In all events of import or export specified in subsections (2) and (3) of this section, the import or export authorisation 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 distribution of 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 distribution of medicinal products also have the right to import and export medicinal products not manufactured thereby;
3) representatives of applicants for a marketing authorisation – samples to be presented in the course of application for a marketing authorisation;
4) holders of an activity licence for health care provision – investigational medicinal products and medicinal products for foreign aid;
[RT I 2008, 25, 163 - entry 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 - entry 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 - entry 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 distribution 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 event of medicinal products imported from third countries under subsections 21 (1), (7) and (8) of this Act and upon import from third countries of samples to be presented in the course of application for a marketing authorisation, medicinal products received as foreign aid and medicinal products used in non-clinical research.
[RT I 2005, 24, 180 - entry into force 20.05.2005]

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

(1) For the import or export of goods requiring special authorisation:
1) authorisation must be obtained from the State Agency of Medicines for import of such goods from third countries or export of such goods to third countries;
2) the State Agency of Medicines must be duly notified of conveyance of goods from Estonia to an Member State of the European Economic Area or from a Member State of the European Economic Area to Estonia, except in the event of conveyance of the goods specified in subsections (2) and (3) of this section.

(2) Import or export authorisation of the State Agency of Medicines is required for the import or export of narcotic drugs and psychotropic substances, and investigational medicinal products.
[RT I 2005, 24, 180 - entry 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 on the conditions established under subsection (5) of this section.
[RT I 2008, 25, 163 - entry into force 01.01.2009]

(4) The State Agency of Medicines must be notified, in accordance with 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 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 will be established by a regulation of the Minister of Social Affairs.
[RT I 2008, 25, 163 - entry 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 will 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 will prepare a list of goods requiring special authorisation, which were re-imported and submit it to the State Agency of Medicines within 30 days after the rescue team returns to Estonia.

(4) If goods requiring special authorisation are imported by a foreign rescue team, the team will carry a list of goods requiring special authorisation approved by the head of the team, which will 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 import authorisation and a permit of 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 must submit an application for the use of an unauthorised medicinal product to the State Agency of Medicines. A veterinarian must submit such application through a wholesaler of veterinary medicinal products or a pharmacy.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(3) The State Agency of Medicines will verify the information and documents submitted by the applicant and decide, within 30 days after receipt of the application, whether the use of the unauthorised medicinal product is justified. The State Agency of Medicines will 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 under 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-compliant or the efficacy of the product is not proven 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 will, based on an application of the holder of an activity licence for wholesale distribution of medicinal products, grant the licence holder an import authorisation and a permit for use.

(6) The import authorisation and permit for use of 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 events 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 events 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 under the Emergency Situation Act;
2) for national programmes.
[RT I 2009, 39, 262 - entry into force 24.07.2009]

§ 22. Application for special authorisation

(1) For obtaining special authorisation, an application for an import or export authorisation must be submitted to the State Agency of Medicines. A separate application must 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 must contain, for each consignment of medicinal products, an import authorisation of such substances granted by the competent authority of the state to which the products are to be conveyed.
[RT I 2005, 24, 180 - entry into force 20.05.2005]

(3) An application in compliance with the requirements established under subsection 19 (5) of this Act must 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 a single import authorisation and a permit for use by a doctor or veterinarian qualified to prescribe the medicinal product will be set out in the application.

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

§ 23. Permit for use

(1) Unauthorised medicinal products and medicinal products imported from third countries may be marketed and used in Estonia only based on an import authorisation and a permit for use granted by the State Agency of Medicines.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(1^1) A permit for use granted by the State Agency of Medicines is not required upon import of investigational medicinal products.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

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

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

§ 24. Granting special authorisation and permit for use

(1) The State Agency of Medicines will decide on the granting of an import or export authorisation and a permit for use within five working days after the receipt of a corresponding application and other requisite information and documents.

(2) The State Agency of Medicines may refuse to grant an import or export authorisation and a permit for use if at least one of the following circumstances exists:
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 - entry 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 consent of the State Agency of Medicines is required for the distribution of 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 on the conditions set out in the regulation established under 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 under subsection 19 (5) of this Act. Narcotic drugs or psychotropic substances, full blood and blood components must not be sent by post.
[RT I 2005, 24, 180 - entry 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 must be obtained from the State Agency of Medicines in accordance with the procedure provided in subsection 19 (5) of this Act before the performance of the acts.

Division 3
Wholesale distribution of Medicinal Products

§ 26. Wholesale distribution of medicinal products

(1) Only the holder of an activity licence for wholesale distribution of medicinal products or the holder of an activity licence for manufacture of medicinal products have the right to distribute and dispense medicinal products by way of wholesale.

(2) The holder of an activity licence for manufacture of medicinal products who wishes to engage in the wholesale distribution 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 distribution of medicinal products for the performance of the duties set out in subsections 54 (4) and (5) of this Act.

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

(4) Medicinal products must be distributed and dispensed in any other manner by way of wholesale only to persons who hold an activity licence for provision of pharmacy services, manufacture of medicinal products or wholesale distribution of medicinal products.

(5) Holders of an activity licence for wholesale distribution of medicinal products or manufacture of medicinal products also have the right to dispense samples of medicinal products to marketing authorisation holders and investigational medicinal products to persons conducting a clinical trial.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(6) The State Agency of Medicines has the right to permit holders of an activity licence for wholesale distribution of medicinal products or manufacture of medicinal products to dispense medicinal products free of charge to hospitals and social welfare institutions which, in accordance with legislation, have no right to procure 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 for the purposes of the Consumer Protection Act (RT I 2004, 13, 86; 41, 278) (hereinafter *consumer*).

(8) Holders of an activity licence for wholesale distribution of medicinal products must procure medicinal products only from holders of an activity licence for manufacture of or wholesale distribution of medicinal products, or from holders of an activity licence for provision of pharmacy services.

(9) The following will be established by a regulation of the Minister of Social Affairs:
1) the conditions of and procedure for wholesale distribution of medicinal products, including the requirements for premises, 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 distribution of medicinal products.

§ 27. Wholesale distribution 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 on the conditions and in accordance with the procedure established under clause 26 (9) 1) of this Act. A special labelling bearing the words " *Ainult veterinaarseks kasutamiseks*" [for veterinary use only] must be attached to medicinal products for human use that 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 event specified in clause 1) of subsection (2) 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 - entry into force 01.09.2010]

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

Division 4
Pharmacy Services

§ 29. Pharmacy services

(1) ‘Pharmacy services’ means the following: retail sale or other dispensing of medicinal products together with related counselling for the appropriate and rational use of medicinal products as well as provision of information to the user on the correct and safe use and storage of medicinal products; the preparation of medicinal products as magistral formulae and officinal formulae and dividing-up into retail packaging.

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

(3) Only pharmacists and assistant pharmacists registered by the Heath Board may provide pharmacy services in a pharmacy or structural unit thereof. Veterinarians may also provide pharmacy services involving veterinary medicinal products, but veterinarians are not allowed to prepare medicinal products.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(4) Persons acquiring the speciality of a pharmacist or assistant 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 pharmacist or an assistant 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 must 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 must be marked with the word " *Veterinaarapteek*" [veterinary pharmacy].

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

(5) A hospital pharmacy is required to check the compliance 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 compliance 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 must check the compliance of storage and recording of medicinal products used for performance of duties of the state.

(8) A pharmacy of a state agency must comply with the requirements set for hospital pharmacies, including the requirements for the head of a pharmacy, established by this Act and under 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 must 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 import authorisation and a permit for use has been granted, and medicinal products prepared as magistral formulae or officinal formulae and medicinal products divided up into retail packaging by the same pharmacy may be dispensed by a pharmacy, taking account of the conditions provided for in § 32 of this Act.

(2) Pharmacies have the right to handle narcotic and psychotropic substances listed in Schedules I and II as well as 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 - entry into force 20.05.2005]

(3) A pharmacy is required to procure medicinal products only from an enterprise belonging to the holder of an activity licence for manufacture or wholesale distribution of 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 in accordance with the procedure established under clause 3) of subsection (6) of this section.

(5) In addition to medicinal products, a general pharmacy is permitted to sell also products for medical purposes and toiletries, including food supplements and natural products, provided it does not interfere with the sale of medicinal products. Veterinary medicinal products, animal care products and other products used in animal-keeping may be sold only in a veterinary pharmacy.

(6) The following will be established by a regulation of the Minister of Social Affairs:
1) the conditions and procedure for preparation, dividing-up into retail packaging 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 premises, installations, technical equipment, staff, recording, reporting and organisation of work.

(7) A regulation established under clause 3) of subsection (6) of this section 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 that 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 in pharmacies

(1) A general pharmacy that 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 - entry 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 that have no right to prepare sterile medicinal products must order sterile medicinal products from a pharmacy that holds such right.

(3) Pharmacies that have no obligation to prepare medicinal products are required to accept 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 must be immediately forwarded to a general pharmacy obligated to prepare medicinal products, and such pharmacy must ensure 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 accept 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 ensure that the medicinal product prepared as magistral formula is prepared and dispensed from the branch pharmacy within a reasonable period of time.

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

(6) Medicinal products prepared or divided up into retail packaging by a general pharmacy or veterinary pharmacy must 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 may dispense sterile products for resale to other pharmacies on the basis of a medical prescription drawn up in respect of a medicinal product prepared as magistral formula or an order based on an order form.

§ 33. Issue of prescriptions for medicinal products and dispensing of medicinal products from pharmacies
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(1) Medicinal products subject to medical prescription must be dispensed by general pharmacies and veterinary pharmacies to consumers only on the basis of a complying medical or veterinary prescription.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(1^1) Medicinal products subject to medical prescription must 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 - entry 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 information the composition of which is established by a regulation of the Minister of Social Affairs.
[RT I 2010, 7, 31 - entry into force 26.02.2010]

(2) Medicinal products subject to medical prescription must be dispensed by general pharmacies and veterinary pharmacies based on a compliant 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 procure 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 from a veterinary pharmacy, but they may dispense medicinal products for human use that are used for the treatment of animals from 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 must 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 will be informed of the correct and safe use and storage of the medicinal product.

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

(7) The following will 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 from pharmacies, and the form of prescriptions;
2) the conditions and procedure for the dispensing of medicinal products from pharmacies on the basis of EU prescriptions.
[RT I 2010, 7, 31 - entry into force 26.02.2010]

(8) The 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 may be established by a regulation of the Minister of Social Affairs.
[RT I 2010, 7, 31 - entry 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 must be transported and stored in a manner that 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 must verify that the medicinal products are stored in a customs warehouse, free zone or free warehouse on the conditions established by the manufacturer.
[RT I 2010, 15, 77 - entry 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 will consider, upon designating the location for performance of customs control, the existence of conditions for the preservation and compliant storage of such goods.

(5) The conditions and procedure for storage and transportation of medicinal products will be established by a regulation of the Minister of Social Affairs. 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 comply with 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*) must 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 must be stored under conditions that prevent their marketing or use for other than the intended purpose, and ensure their storage in a manner safe to humans, animals and the environment.

(3) Unusable medicinal products which, in accordance with § 8 of the Waste Act or the list established under subsection 2 (4) of the Waste Act, are defined as hazardous waste, must be collected separately from other waste according to the categories provided by the list and must be marked in accordance with the procedure established under subsection 62 (3) of the Waste Act.

(4) Unusable narcotic drugs and psychotropic substances must be stored on the conditions established for such substances.
[RT I 2005, 24, 180 - entry into force 20.05.2005]

(5) Packaging used for collecting or transporting unusable cytostatic or cytotoxic medicinal products must 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 must be destroyed in an enterprise holding a relevant licence for handling hazardous waste. For the purposes of this Act, destruction means the act of disposal or recycling of waste in the process of which the characteristics of the active substances 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 to be destroyed as non-hazardous waste must, 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 in accordance with the procedure approved under 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 must be destroyed as non-hazardous waste only in the presence of a representative of the State Agency of Medicines. In events 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 must be provided with a deed of delivery and receipt of the products which must 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 must verify the transaction by writing the date on the deed and signing the deed. The deed must be made in two original counterparts of which one will be retained by the deliverer and the other by the recipient.

(6) A handler of medicinal products must prepare a deed concerning the destruction of the medicinal products, which sets 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 must be verified by writing the date on the deed and signing the deed. If a representative of the State Agency of Medicines is present at the destruction, they must verify the destruction of the medicinal products by signing the deed of destruction, one counterpart of which will be retained by the State Agency of Medicines.

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

§ 37. Receipt of unusable medicinal products from consumers

(1) In addition to persons holding a waste permit under 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 under 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 - entry into force 20.05.2005]

(3) The procedure for receiving unusable medicinal products from consumers by general and veterinary pharmacies and for commissioning the destruction of such products will be established by a regulation of the Minister of Social Affairs.

Division 6
Activity Licence for Handling Medicinal Products

Subdivision 1
General Provisions

§ 38. Activity licence for handling medicinal products

(1) The types of activity licence for handling medicinal products (hereinafter *activity licence*) are the activity licence for manufacture of medicinal products, activity licence for wholesale distribution of medicinal products and activity licence for provision of pharmacy services. The types 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 in accordance with the procedure and on 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 on 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 a certificate approved by the State Agency of Medicines must 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 will 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 - entry 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 - entry 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 - entry 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 - entry 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 distribution or manufacture of medicinal products belonging to the holder of an activity licence must have a separate activity licence.

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

(3) In the event of wholesale distribution of 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 distribution without the right of storage, the office is deemed the place of business.

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 event 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 distribution of medicinal products may concurrently hold an activity licence for altering the labelling and outer packaging of medicinal products, for re-packaging of starting materials used for preparation 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 investigational medicinal products.
[RT I 2010, 15, 77 - entry 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 must 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 distribution of medicinal products.
[RT I, 08.11.2010, 2 - entry 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 must 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 - entry 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 must not be issued for operation in the corresponding city, new structural units of a general pharmacy must not be established, or the place of business of a general pharmacy, including a structural unit of the general pharmacy, must 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 that are not cities, activity licences of a general pharmacy for opening a pharmacy must not be issued and a structural unit of a general pharmacy must 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 must be disclosed on the website of the State Agency of Medicines.

(5) Applications for the right to open a general pharmacy or a structural unit thereof must be submitted to the State Agency of Medicines within 14 days after the disclosure of such information. The application must set out the applicant's name, address, registry code or personal identification code, contact 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 whether the applicant wishes to open a general pharmacy or a structural unit thereof. The application must be confirmed by the signature and date written in hand by the person with the right to represent the applicant.
[RT I, 25.10.2012, 1 - entry into force 01.12.2012]

(6) Upon receipt of more than one application that complies with the requirements, a person applying for the right to open a general pharmacy will be preferred. Upon receipt of more than one application for opening a general pharmacy, lots will be drawn between the applicants. If only applications for opening a structural unit of a general pharmacy are received, lots must be drawn between the representatives of the structural units. The results of drawing of lots will 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 will submit an application that complies with 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 must be drawn again between persons who submitted applications that comply with the requirements specified in subsection (5) of this section in accordance with the procedure provided for in subsection (6) of this section.
[RT I 2005, 24, 180 - entry into force 01.01.2006]

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

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

(2) The holder of an activity licence for general pharmacy or veterinary pharmacy must 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 must 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 must not, at the same time, be employed by the holder of an activity licence for wholesale distribution or manufacture of medicinal products.

(5) A person employed as the competent person with a wholesaler of medicinal products must 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 must not, at the same time, be employed by the holder of an activity licence for wholesale distribution of 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 distribution or manufacture of medicinal products must not provide veterinary services.

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

(1) The holder of an activity licence for manufacture of medicinal products or wholesale distribution of medicinal products is required to:
1) ensure 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) ensure that the competent person and, in their absence, their substitute, has the conditions and means required for performing their duties;
3) ensure that medicinal products are dispensed, on the conditions and in accordance with 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 in accordance with the procedure established under clause 26 (9) 1) of this Act;
5) ensure 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 ensure the availability of the medicinal products included in a sales offer;
7) ensure 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 distribution 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 winding-up 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 in accordance with the procedure and within the term established for the operation of a handler of medicinal products of that type, and to notify the State Agency of Medicines thereof in writing;
[RT I 2010, 15, 77 - entry 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 distribution of medicinal products with no storage rights, taking account of the differences 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 a marketing authorisation in respect of a medicinal product, or if the inspection is regular;
2) ensure that medicinal products are manufactured taking account of the developments in the area of science and technology;
3) ensure 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 - entry 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) ensure 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) ensure that the competent person who, at a pharmacy, is the head of the pharmacy, and in the absence of the competent person, their substitute, has necessary conditions and means for performance of their duties, and that the staff of the pharmacy have necessary conditions and means for performing their work in adherence to the requirements;
3) ensure that medicinal products are dispensed, on the conditions and in accordance with 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 - entry 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) ensure the availability, within a reasonable period of time, of medicinal products existing in Estonia concerning which a marketing authorisation has been granted;
6) keep record of the handling of medicinal products and submit reports to the State Agency of Medicines in accordance with the procedure established under 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) ensure a sufficient choice of medicinal products or order such products within a reasonable period of time;
9) ensure, upon the sale of medicinal products concerning which a reference price has been established under 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) ensure the provision of pharmacy services only by the persons specified in subsection 29 (3) of this Act;
11) transfer, upon winding-up 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 in accordance with 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 - entry 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 must pay a state fee for application for an activity licence and submit the documents and information required in accordance with the procedure established based on subsection 47 (10) of this Act to the State Agency of Medicines.

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

(3) The following must be annexed to an application for renewal of an activity licence: an overview of the operations at the place of business during the term of validity of the activity licence, including information on the employees holding pharmaceutical qualifications (name, position, professional experience); depending on the type of the activity licence applied for, the documents submitted upon application for the activity licence or written confirmation regarding each document that the information has not changed.

Subdivision 4
Grant, Renewal and Extension of Activity Licence

§ 47. Grant, renewal and extension of activity licence

(1) Activity licences are granted, 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 events, 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 an activity licence or for the renewal or extension of an activity licence must employ a competent person who meets the established requirements.

(5) The State Agency of Medicines will make a decision to grant or renew an activity licence within 60 days after receipt of all requisite documents.

(6) Prior to making a decision to grant, 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 will be 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 will grant the applicant a reasonable term for elimination of the circumstances. The State Agency of Medicines will 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 in 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 the issue or renewal of an activity licence, the State Agency of Medicines will inspect, according to its competence, the compliance 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 - entry 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 conditions of 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 will be established by a regulation of the Minister of Social Affairs.

§ 48. Period of validity of activity licence

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

(2) The term of validity of an activity licence for manufacture of medicinal products granted to the holder of an activity licence for wholesale distribution of medicinal products must not be longer than the term for the activity licence for wholesale distribution of medicinal products.

§ 49. Refusal to grant or renew activity licence

(1) The State Agency of Medicines may refuse to grant 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 comply with the requirements provided by this Act or legislation established on the basis thereof;
4) the competent person fails to perform their duties;
5) the holder of the activity licence has not performed an obligation by the deadline or to the extent provided 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 will refuse to grant 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 in accordance with subsection 47 (6) of this Act;
4) the applicant has not eliminated, during the additional term set under subsection 47 (7) of this Act, the deficiencies that 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 in accordance with 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 will refuse to grant 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) or 2) of subsection (1) 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 an activity licence is not granted 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 will be renewed in accordance with the general procedure.

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

(6) The decision specified in subsection (5) of this section will 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 investigational medicinal products 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 distribution or manufacture of medicinal products has been issued;
3) groups of medicinal products which general pharmacies and hospital pharmacies have the right and obligation to prepare;
4) the right of the holder of an activity licence for manufacture of medicinal products or wholesale distribution of medicinal products to handle narcotic drugs and psychotropic substances;
[RT I 2005, 24, 180 - entry into force 20.05.2005]
5) a list of manufacturers and quality control undertakings performing contract work upon manufacturing medicinal products.

(2) The right specified in clause 4) of subsection (1) of this Act will not be granted to the holder of an activity licence for wholesale distribution 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 will 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) winding-up 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 comply with 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 provided 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 them under this Act;
8) it becomes evident that there are circumstances which, in accordance with 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 a decision to revoke the activity licence, a precept to the holder of the activity licence, setting a reasonable term for elimination of the circumstances that 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 terminated 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 will be sent to the holder of the activity licence within five working days after making the decision.

(7) In the event 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 suspended does not extend the period of validity of the activity licence.

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

§ 52. Amending data contained in activity licence

(1) In order to make amendments involving a change of the place of business, creation of a new structural unit, amendment of special conditions of the activity licence or change or addition of undertakings performing contract work for the holder of the activity licence for manufacture of medicinal products, the licence holder must beforehand apply to the State Agency of Medicines for amendment of the activity licence, provide reasons for the amendment, submit the documents required in accordance with the procedure established under subsection 47 (10) of this Act and pay the state fee.

(2) If the amendment involves 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 must inform the State Agency of Medicines of the amendment after it is carried out.

(3) The State Agency of Medicines must be given written notice of the amendments 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 competent person or the head of a pharmacy and appointment of a substitute must be communicated immediately.

(4) If the amendment specified in subsection (2) of this section results in the need to amend the data contained in the activity licence, the holder of the activity licence must submit, without delay but not later than within two months after the a takes place, an application together with the documents required in accordance with 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 will be reviewed and the amendment decision will be made in accordance with the general procedure within 30 days. In exceptional events, the State Agency of Medicines may extend such term to up to 60 days.

(6) If the circumstances that constituted the basis for granting an activity licence amendment, the holder of the licence must ensure the compliance of the new conditions to the requirements provided by this Act and legislation established on the basis thereof. The substitute for a competent person will 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) Amendment of the information or conditions of an activity licence will 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 may 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 will 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 manufacturing medicinal products must have appropriate qualifications and experience for the manufacturing activities and the substitute for the competent person must meet the requirements established for competent persons.

(4) The holder of an activity licence who is a self-employed person may act as a competent person provided that they meet the requirements established for competent persons.

(5) Only persons with the higher education and work experience provided for in a regulation established under subsection (6) of this section can 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 requirements for the qualifications of competent persons and a list of evidence of formal qualifications will be established by a regulation of the Minister of Social Affairs.

§ 54. Obligations of competent person

(1) A competent person appointed by the holder of an activity licence for manufacture of medicinal products must:
1) ensure that each batch of medicinal products manufactured in Estonia is manufactured and checked in accordance with 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 full qualitative analysis, a quantitative analysis of at least the active substances, and other tests to verify that the quality of the medicinal products meet the requirements of the marketing authorisation.

(2) A competent person must perform the duty specified in clause 2) of subsection (1) 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 must, regarding investigational medicinal products:
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 checked under equivalent good manufacturing practices and is checked in accordance with the supplementary documentation related to the clinical trial;
3) ensure that, unless otherwise established in the European Union, each comparator of an authorised medicinal product originating from a third country concerning which there is no indication that the batch has been manufactured under equivalent good manufacturing practices is analysed in accordance with the supplementary documentation related to the clinical trial to prove the compliant quality of the lot.

(4) A competent person appointed by the holder of an activity licence for wholesale distribution of medicinal products must ensure the compliance of the medicinal products sold by the holder of the activity licence for wholesale distribution 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) If the holder of an activity licence for wholesale distribution of medicinal products imports medicinal products, the competent person has the additional duty to verify adherence to the storage requirements during the transport of the medicinal products, compliance of the packaging of the medicinal products with requirements and with 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 compliance with 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 - entry into force 20.05.2005]

Division 8

Registration of Pharmacists and Assistant Pharmacists and Recognition of Professional Qualifications of Pharmacists

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

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

(2) Recognition of the professional qualifications of a pharmacist (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 pharmacist 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 pharmacist specified in clause 2) of subsection (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 on the conditions provided by § 53 of this Act.

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

(1) A person applying for registration as a pharmacist or assistant pharmacist (hereinafter *registration*) or applying for the recognition of professional qualifications must submit to the Health Board a corresponding application and copy of the evidence of formal qualifications.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(1^1) Before the submission of an application, a person applying for registration as a pharmacist or assistant pharmacist or applying for recognition of the professional qualifications of a pharmacist must 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 - entry into force 01.01.2007]

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

(3) The Health Board will verify the authenticity of information submitted in the evidence of formal qualifications and make the requested decision to register or recognise professional qualifications within 30 days as of submission of the documents specified in subsection (1) of this section, except in the events specified in subsection 58 (1^1) and 59 (3) of this Act.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(4) Registration or recognition of professional qualifications will be 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 will be informed thereof within ten days after the date the corresponding decision is made.

(6) Upon registration as a pharmacist or assistant pharmacist or recognition of such professional qualifications, the Health Board will issue a corresponding certificate to the applicant. The Minister of Social Affairs will establish the form of the certificates by a regulation.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

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

(1) The list of documentary evidence in proof of formal qualifications, which constitutes the basis for registration and recognition of the professional qualifications of persons who acquire the qualifications of a pharmacist in Estonia will be established by a regulation of the Minister of Social Affairs.

(2) A person applying for registration who submits evidence in proof of their formal qualifications not included in the list established under subsection (1) of this section or complying with the provisions of subsection (4) of this section, must pass a qualification examination and submit to the Health Board a document certifying

passing the examination for the purpose of having them entered in the register. The conditions of and procedure for organisation of qualification examinations will be established by a regulation of the Minister of Social Affairs.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

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

(4) Registration of a person as a pharmacist or assistant 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 qualifications for a consecutive period of at least three years.

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

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

(1) The qualifications of a pharmacist acquired in a Member State of the European Economic Area or Switzerland are certified by a document that grants a pharmacist 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 will 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, inform the person of the missing documents. The Health Board will 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 will immediately inform the person applying for registration of extension of the term and the reasons for the extension.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(2) The list of evidence in proof of the formal qualifications of a pharmacist 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 will be established by a regulation of the Minister of Social Affairs.
[RT I 2008, 30, 191 - entry into force 01.07.2008]

(3) If a document certifying the qualifications of a pharmacist who has acquired the qualifications in a Member State of the European Economic Area or Switzerland is not included in the list established in accordance with subsection (2) of this section, the Health Board will decide to recognise the professional qualifications of the person or have the person take an aptitude test in accordance with the provisions of the Recognition of Foreign Professional Qualifications Act.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

§ 59. Recognition of professional qualifications of persons who acquire qualifications of pharmacist 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 a pharmacist 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 pharmacist 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 their qualifications or in Switzerland, the Health Board will decide to recognise the professional qualifications of the person or oblige the person to take an aptitude test in accordance with the provisions of the Recognition of Foreign Professional Qualifications Act. Upon application for registration, the person will 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 - entry into force 01.01.2010]

(3) The Health Board will compare the qualifications of a person who acquired the qualifications of a pharmacist in a state not specified in § 58 of this Act with the qualifications required in Estonia, 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 pharmacist in a foreign

state with the qualifications required in Estonia will be established by a regulation of the Minister of Social Affairs.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(4) In order to assess the compliance of qualifications, persons who have acquired qualifications of a pharmacist in foreign states not specified in § 58 of this Act may be required to take aptitude tests. The procedure for compiling, conducting and evaluating aptitude tests will be established by a regulation of the Minister of Social Affairs.
[RT I 2008, 30, 191 - entry into force 01.07.2008]

§ 59[1]. Temporary provision of pharmacy services

A person who has acquired the qualifications of a pharmacist in a member state of the European Economic Area or in Switzerland may temporarily provide pharmacy services in Estonia without the registration obligation required in accordance with § 55 of this Act and an activity licence required under § 38 of this Act in accordance with the provisions of Chapter 3 of the Recognition of Foreign Professional Qualifications Act. A competent authority for the purposes Chapter 3 of the Recognition of Foreign Professional Qualifications Act is the Health Board.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

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

(1) The application for registration as pharmacist submitted by a person who acquired the qualifications of a pharmacist in a Member State of the European Economic Area or in Switzerland will be processed concurrently with the application for recognition of their 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 - entry into force 01.07.2008]

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

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

§ 62. Register of pharmacists and assistant pharmacists

(1) The register of pharmacists and assistant 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 will establish the statutes of the register of pharmacists and assistant pharmacists.

(2) The Health Board is the chief processor of the register of pharmacists and assistant pharmacists.
[RT I 2009, 49, 331 - entry 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 pharmacist or assistant pharmacist immediately after becoming aware of the fact and will specify the date of entry into or termination of the employment relationship.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(4) The Health Board will publish on its website the first name and surname, the number of the registration certificate and place of employment of the pharmacists and assistant pharmacists employed in a pharmacy.
[RT I 2009, 49, 331 - entry 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 retail packaging by pharmacies;
2) medicinal products imported based on a single import authorisation and a permit for 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 - entry into force 18.04.2010]

§ 64. Marketing authorisation holder

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

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

(3) A marketing authorisation holder must give written notice to the State Agency of Medicines of the commencement of the actual marketing 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.

(3^1) The State Agency of Medicines may authorise the marketing of a prescription medicinal product in packaging in the language of another member state of the European Economic Area, along with the Estonian package leaflet, provided that medicinal products with the same active substance and of the same strength are not marketed in Estonia and ensuring the continuous supply of the medicinal product is important from the point of view of human or animal health. In the event of medicinal products that are not marketed directly to patients, the State Agency of Medicines may decide not to demand an Estonian package leaflet.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(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 will submit a corresponding application together with supplementary documentation to the State Agency of Medicines and pay a state fee. All the documents provided for under clause 1) of subsection (12) of this section must be submitted.

(2) For the purpose of renewal of the marketing authorisation, a marketing authorisation holder must submit an application to the State Agency of Medicines at least nine months before the expiry of the authorisation.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(3) An applicant wishing to obtain a 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 complies with 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 a 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 substance or active substances 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 substances and the same pharmaceutical form) and bioequivalent to a medicinal product in respect of which a 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 substance are 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 are considered to be one and the same pharmaceutical form.

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

(6) The period specified in subsection (5) of this section will 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 that 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 events where the holder of the marketing authorisation of a medicinal product intended for use on agricultural animals has also applied for establishment of maximum residue limits in respect of the active substances of the medicinal product.

(8) A holder of a marketing authorisation may allow using the pharmaceutical, toxicological and clinical data accompanying their application in the assessment of an application for a marketing authorisation for another medicinal product with the same quantitative and qualitative composition of active substances and pharmaceutical form.

(9) If a medicinal product does not fully meet the similarity requirements specified in clause 2) of subsection (4) 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 must 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 must be presented.

(11) If a marketing authorisation is granted in respect of a medicinal product on the conditions specified in clause 1) of subsection (4) of this section for a therapeutic indication for which the active substance 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 will not grant a marketing authorisation with respect to a proprietary medicinal product with the same active substance for this therapeutic indication to another applicant for a marketing authorisation on the basis of the data of these trials during one year.

(12) The following will be established by a regulation of the Minister of Social Affairs:
1) types of and formal requirements for applications for marketing authorisations of medicinal products, supplementary documentation list, 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 - entry 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 distribution or manufacture of medicinal products provided that all the following conditions are fulfilled:
1) [Repealed – RT I 2005, 24, 180 – entry 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 will 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 has all the rights and obligations of the marketing authorisation holder.

§ 67. Remuneration for professional assessment of application

(1) An applicant must 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 under clause 65 (12) 1) of this Act.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(2) If an applicant for a marketing authorisation requests that Estonia participate in the decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition as a reference country, the amount of 14 000 euros will be added to the assessment fee.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(3) In the event of a repeated marketing authorisation procedure of mutual recognition and, upon renewal of a marketing authorisation in the event of decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition in which Estonia participates as a reference country, the amount of 3000 euros will be added to the assessment fee.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

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

(1) Before acceptance of an application for processing, the State Agency of Medicines will evaluate the compliance of the application and supplementary documentation submitted with the requirements established under clause 65 (12) 1) of this Act and, if necessary, set the applicant a term for elimination of deficiencies.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(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 event of failure to submit the information and documents by the due date, the State Agency of Medicines will 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 at the expense of the applicant the sites located outside of the European Union required for the attestation of the compliance of clinical trials and the manufacturing facilities of the medicinal product and active substance.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(3) Based on an application and other materials, the State Agency of Medicines will assess the compliance of the efficacy, safety and quality of the medicinal product with the requirements provided by this Act and legislation established on the basis thereof and draw up an assessment report on the medicinal product, including explanations concerning the results of pharmaceutical, pre-clinical and clinical studies of the medicinal products, the risk management system and the master file of the pharmacovigilance system, as well as reasons regarding each indication separately. The State Agency of Medicines has the right to involve non-staff experts in the assessment of an application.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(4) The State Agency of Medicines will 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 event 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 a 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 will suspend the processing of the application for a 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 a marketing authorisation in the event of suspension of the processing of the marketing authorisation under the circumstances specified in subsection (5) of this section. The State Agency of Medicines will 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 will 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 granting a marketing authorisation to the medicinal product may result in a risk to public health or, in the event 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 a marketing authorisation to recognise the assessment report will be settled in accordance with 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 must comply with the decision of the Committee for Human Medicinal Products of the European Medicines Agency, and of the Commission.
[RT I 2010, 15, 77 - entry 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 consists of up to ten members and the marketing authorisation committee for veterinary medicinal products consists of up to eight members. The members of the marketing authorisation committee for medicinal products for human use must 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 must 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 - entry 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 will be appointed by the Minister of Social Affairs.

(6) The committees are formed and the rules of procedure thereof will 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 will grant an applicant a marketing authorisation in respect of a medicinal product or inform the applicant of refusal to grant a marketing authorisation within 210 days as of the date of acceptance of the application. The time needed by the applicant for submitting additional information and documents requested by the State Agency of Medicines as well as the time needed, where necessary, for verifying the correctness of submitted information by way inspection, will not be included in the time limit specified above.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(2^1) The State Agency of Medicines will 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 submitting additional information and documents requested by the State Agency of Medicines and the time needed, where necessary, for verifying the correctness of submitted information by way inspection, will not be included in the time limit specified above.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(3) Upon processing an application for a 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 will 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 will issue a marketing authorisation in respect of a medicinal product within 30 days as of making a decision to recognise.
[RT I 2010, 15, 77 - entry 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 one or several of the following conditions:
1) supplementation of the risk management system with measures for ensuring the safe use of the medicinal product;
2) conducting a safety or efficacy survey following the receipt of the marketing authorisation;
3) performance of additional duties in connection with registration or communication of an adverse reaction;
4) the existence of a sufficient pharmacovigilance system;
5) other conditions or restrictions relating to the safe and effective use of the medicinal product.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(4^1) A marketing authorisation may be issued on the conditions specified in subsection (4) of this section only if the applicant cannot, due to objectives and verifiable reasons, submit full information about the efficacy and safety of the medicinal product in the ordinary conditions of use of the medicinal product. In such an event the renewal of the marketing authorisation is bound to annual review of the conditions.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(4^2) The State Agency of Medicines informs the European Medicines Agency about all marketing authorisations which have been issued on the conditions specified in subsection (4) of this section.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(5) The State Agency of Medicines may issue a marketing authorisation in respect of a medicinal product that 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 will notify the authorisation holder of the Member State of the European Economic Area that 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 - entry into force 18.04.2010]

(6) The State Agency of Medicines will immediately publish on its website the details of the marketing authorisation along with the package leaflet, summary of the product characteristics and a public assessment report. A public assessment report is an assessment report presented to the public in a comprehensible manner, which contains, above all, a summary of the conditions of use of the medicinal product and from which confidential information has been removed.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(7) In addition, the State Agency of Medicines will publish on its website summaries of the risk management plans of such medicinal products which have been granted marketing authorisation on the conditions specified in subsection (4) of this section.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

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

(1) A marketing authorisation in respect of a medicinal product will be issued for five years.

(2) The State Agency of Medicines will renew a marketing authorisation or inform the holder of a marketing authorisation of the refusal to renew the marketing authorisation before expiry of the marketing authorisation. The State Agency of Medicines may renew the term of validity of a marketing authorisation until an application for renewal of the marketing authorisation has been processed, but not for more than one year.

(3) A marketing authorisation issued under subsection 70 (2) of this Act will be renewed for an unspecified term after five years have passed. A marketing authorisation issued under subsection 70 (3) of this Act will be issued in the reference state after the expiry of the validity of the marketing authorisation.

(4) Depending on the safety information of a marketing authorisation, including the little number of patients who have used a medicinal product, the State Agency of Medicines may decide that a second limited term of validity of five years is required.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 72. Classification of medicinal products

Upon issue of a marketing authorisation in respect of a medicinal product, the State Agency of Medicines will 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 must set out information concerning the name, active substance, strength, pharmaceutical form, packaging size, shelf life, and marketing authorisation holder of the medicinal product, the manufacturer responsible for batch release, term of validity of marketing authorisation, classification of the medicinal product, restrictions to the marketing authorisation, and conditions of the marketing authorisation and the term of fulfilment of the conditions, and the frequency of periodic safety update reports.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(2) In addition to the above, a marketing authorisation issued in respect of a veterinary medicinal product must 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 must also indicate the period during which the corresponding animal products must not be used for human consumption.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(3) Along with granting a marketing authorisation, the State Agency of Medicines will also approve the summary of product characteristics, package leaflet, packaging labelling and the frequency of periodic safety update reports in accordance with subsection 78^7(2) of this Act and, in the event of a conditional marketing authorisation, also a summary of the risk management plan.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

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

(1) The State Agency of Medicines will refuse to grant 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 substances 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 granted regarding a veterinary medicinal product the active substances 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 will not be granted on the aforementioned conditions concerning a veterinary medicinal product the active substances of which are listed in Annex IV to Council Directive 2377/90/EEC. A marketing authorisation may be granted regarding a medicinal product prescribed for equidae used for human consumption provided that the active substances 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 granted if 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 - entry into force 18.04.2010]

(3) The grounds for refusal to grant or renew a marketing authorisation provided for in subsections (1) or (2) of this section do not apply in events 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 granting or refusal to grant the marketing authorisation is decided in accordance with the procedure provided for in 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 a marketing authorisation must ensure the confidentiality of the information obtained in the course of processing marketing authorisations, and must preclude the accessing of such information by third parties. Information will be 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 a 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
Amendment, Suspension and Revocation of Marketing Authorisation of Medicinal Product

[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 76. Amendment, suspension and revocation of marketing authorisation of medicinal product

(1) After granting a marketing authorisation, the State Agency of Medicines may obligate the holder of the marketing authorisation to carry out a safety survey if there are doubts about the safety of the medicinal product or an efficacy survey if there are doubts about the adequacy of previous efficacy studies.

(2) The State Agency of Medicines will inform the holder of a marking authorisation of the duty to carry out a safety or efficacy survey specified in subsection (1) of this section following the receipt of the marketing authorisation, the purpose of the survey and the time limit of carrying out and presenting the results of the survey. The holder of the marketing authorisation has the right to file written objections within 30 days as of the receipt of a notice about the duty.

(3) On the basis of the objections specified in subsection (2) of this section, the State Agency of Medicines will make a decision as to whether to cancel or approve the duty to carry out a safety or efficacy survey. In the event of approval of the duty, the State Agency of Medicines will amend the marketing authorisation, including in it the condition regarding the duty specified in subsection (1) of this section.

(4) The holder of a marketing authorisation must immediately update the risk management system, taking into account the duty to carry out a safety or efficacy survey.

(5) The State Agency of Medicines must inform the European Medicines Agency of all the marketing authorisations whereby duties have been established under subsection (1) of this section.

(6) The State Agency of Medicines may amend, suspend or revoke a marketing authorisation if at least one of the following circumstances exists:
1) the conditions serving as the basis for granting the marketing authorisation have changed or have not been fulfilled;

2) the marketing authorisation holder fails to perform the duties imposed on it by this Act or violates the requirements provided by this Act or the Advertising Act or legislation established under these Acts;
3) new information about the medicinal product becomes evident, which, in comparison with the information submitted for applying for the marketing authorisation, confirms to be less effective or more harmful or if the risk-benefit balance of the medicinal product proves to be unfavourable, given the contemporary level of medical science;
4) in the event of medicinal products administered to farm animals, the withdrawal period is insufficient to ensure the safety of the consumers of the corresponding animal products;
5) the European Commission has made a respective decision.

(7) Before a marketing authorisation is amended, suspended or revoked on the initiative of the State Agency of Medicines, the State Agency of Medicines will notify the marketing authorisation holder of the initiation of the relevant procedure and grant the marketing authorisation holder a reasonable term for provision of an opinion and objections, and determine the form of submission thereof, if necessary.

(8) If the circumstances that constituted the basis for suspension of a marketing authorisation in respect of a medicinal product have been eliminated within the term, the director general of the State Agency of Medicines will terminate the suspension of the marketing authorisation by a decision, otherwise the marketing authorisation must be revoked.

(9) The State Agency of Medicines will immediately inform the marketing authorisation holder and holders of an activity licence for handling relevant medicinal products, the European Medicines Agency, competent authorities of other Member States and the European Commission of the amendment, suspension or revocation of the marketing authorisation in respect of a medicinal product. In the event of a threat to public health, the State Agency of Medicines must also inform the persons authorised to prescribe medicinal products or the public.

(10) In the event of medicinal products whose marketing authorisation has been issued in two or more Member States, the procedure for the amendment, suspension or revocation of the marketing authorisation will be carried out as a joint procedure of the European Economic Area.

(11) If, due to assessment of information relating to pharmacovigilance, the State Agency of Medicines finds that a marketing authorisation must be urgently suspended or revoked, deliveries of medicinal products banned, new contraindications reported, indications limited or the advisable dose of a medicinal product reduced or if a marketing authorisation holder has communicated the interruption of the marketing of a medicinal product or the initiation of a marketing authorisation due to safety considerations, the State Agency of Medicines will initiate the expedited procedure of the European Economic Area. Not later than on the next working day, the State Agency of Medicines will immediately inform the marketing authorisation holder and the European Medicines Agency, competent authorities of other Member States and the European Commission of the initiation of the expedited procedure and submit to the European Agency for Evaluation of Medicinal Products relevant information which has become known to the State Agency of Medicines. In such an event, the term of validity of the marketing authorisation will be suspended until the Coordination Group of the European Medicines Agency or the European Commission has made a decision regarding the preservation, amendment, suspension, revocation of or refusal to renew the marketing authorisation, unless the procedure only concerns the marketing authorisation issued in Estonia.

(12) If a marketing authorisation in respect of a medicinal product is revoked or suspended, the marketing authorisation holder will organise the withdrawal of the medicinal product from the market and preclude putting the product back on the market.

(13) If the term of validity of a marketing authorisation in respect of a medicinal product has been suspended or revoked, the State Agency of Medicines may, in exceptional circumstances, permit during a transitory period the sale or issue of the medicinal product to patients who are already being treated with the medicinal product.

Division 5
Application for Amendments Relating to Medicinal Products

[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 77. Application for and refusal to satisfy application for variations relating to medicinal products
[RT I 2010, 15, 77 - entry into force 18.04.2010]

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

(1[1]) A marketing authorisation holder must ensure the updating of the production and control methods of a medicinal product, taking into account the development of science and technology, and the updating of the summary of product characteristics and package leaflet on the basis of the newest scientifically reasoned knowledge, including evaluation results and recommendations published in the web portal of European medicinal products.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(2) A marketing authorisation holder must pay a state fee for submission of an application, and if a medium (type IB) or a significant (type II) variation is applied for, must pay the fee for professional assessment corresponding to the type of application. The size of the payment for a type IB variation is 100 euros and, for a type II variation, 383 euros per application. If Estonia participates in the decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition of the European Economic Area as a reference country, an additional 500 euros must be paid for a type IB variation and 1000 euros for a type II variation per application.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(2[1]) The State Agency of Medicines will refuse to satisfy an application on the basis provided for in § 74 of this Act.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(3) The types of amendments of conditions that constitute the basis for granting marketing authorisations and the conditions of and procedure for application for amendments will be established by a regulation of the Minister of Social Affairs.

§ 78. Communicating information on pharmacovigilance

[Repealed – RT I, 05.07.2012, 13 – entry into force 21.07.2012]

Division 5[1]
Pharmacovigilance

[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

Subdivision 1
General Provisions

§ 78[1]. Pharmacovigilance system and pharmacovigilance system master file

(1) The pharmacovigilance system is a system used by a marketing authorisation holder and the State Agency of Medicines to fulfil pharmacovigilance tasks and responsibilities, which is designed to monitor the safety of authorised medicinal products and detect changes to their risk-benefit balance.

(2) The pharmacovigilance system master file is a detailed description of the pharmacovigilance system used by a marketing authorisation holder with respect to one or more authorised medicinal products. The pharmacovigilance system master file must be located in the European Economic Area.

§ 78[2]. Risk management system and risk management plan

(1) The risk management system is a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of these measures. The risk management system must be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.

(2) The risk management plan is a detailed description of the risk management system.

§ 78[3]. Responsibilities of marketing authorisation holder for ensuring pharmacovigilance

(1) For the purpose of ensuring continuous pharmacovigilance, a marketing authorisation holder must establish a pharmacovigilance system with regard to authorised medicinal products and ensure that entries are made in the pharmacovigilance system master file of the pharmacovigilance system with regard to its implementation.

(2) For the purpose of ensuring the functionality of the pharmacovigilance system, a marketing authorisation holder must:
1) appoint a qualified person responsible for pharmacovigilance and the person substituting for such person and communicate their names and contact details to the State Agency of Medicines;
2) register and record information about adverse reactions to which attention has been drawn by a user of the medicinal product, pharmacist, assistant pharmacist or a person authorised to prescribe the medicinal product

or that have become evident in the course of a post-authorisation safety study or that have been published in medical literature, provided that the source is not in the list monitored by the European Medicines Agency;
3) take measures to obtain accurate and verifiable data about suspected adverse reactions, in order to scientifically assess the information;
4) with the help of the pharmacovigilance system, scientifically assess the entire information and possibilities of reduction and prevention of risks and, if necessary, take appropriate measures;
5) organise regular audits of the pharmacovigilance system, enter the audit results in the pharmacovigilance system master file of the pharmacovigilance system, ensure that appropriate corrective action plan is prepared on the basis of the audit results and ensure its implementation;
6) implement the risk management system with regard to each medicinal product;
7) assess the effectiveness of the measures set out in the risk management plan or in the conditions of the marketing authorisation;
8) monitor the safety data of the medicinal product in order to decide whether any new risks have emerged due to using the medicinal product, whether the risks have changed or whether there have been changes to the risk-benefit balance of the medicinal product;
9) upon emergence of new risks or change of the risks, update the risk management system;
10) follow the recommendations and timetable of the Coordination Group and the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency;
11) upon ensuring pharmacovigilance, follow the guidelines of the European Commission and the Good Pharmacovigilance Practice.

(3) The qualified person responsible for pharmacovigilance must:
1) reside in the European Economic Area and be available to the marketing authorisation holder at all times;
2) be responsible for the functionality of the pharmacovigilance system;
3) ensure the collection, maintenance and assessment of the medicinal product safety information communicated to the marketing authorisation holder and common access thereto;
4) prepare medicinal product safety information to be communicated to the State Agency of Medicines;
5) give an immediate exhaustive response to the request of the State Agency of Medicines to submit additional information about the safety of the medicinal product, including information about the sales and the number of prescriptions of the medicinal product.

(4) A marketing authorisation holder must ensure that the competent person in charge of pharmacovigilance has completed basic medical training, in the event of veterinary medicinal products, in the field of veterinary medicine or that a person holding the given qualifications is available to the competent person for consultation at all times.

(5) A marketing authorisation holder must provide the qualified person responsible of pharmacovigilance with additional training and tools required for work.

(6) A marketing authorisation holder must inform the State Agency of Medicines, the European Medicines Agency and the competent authorities of other Member States about newly identified risks, changed risks or when changes to the risk-benefit balance have been detected.

(7) The State Agency of Medicines may at any time request that a marketing authorisation holder submit data certifying that a favourable benefits and risks ratio of the medicinal product remains. The marketing authorisation holder is required to reply to such claim in full and without delay.

(8) The State Agency of Medicines may request from a marketing authorisation holder a copy of the pharmacovigilance system master file of the pharmacovigilance system at any time. The marketing authorisation holder must submit a copy of the document not later than on the seventh day following the submission of the request.

§ 78[4]. Duties of State Agency of Medicines upon ensuring pharmacovigilance

(1) The State Agency of Medicines must ensure the functionality of the national pharmacovigilance system and to that end the State Agency of Medicines:
1) informs persons authorised to prescribe medicinal products, pharmacists, assistant pharmacists and the public of the need to report the adverse reactions of medicinal products;
2) accepts information about adverse reactions in a web environment and on paper and take appropriate measures to obtain accurate and verifiable data about adverse reactions, in order to assess the information scientifically;
3) collects and assesses pharmacovigilance data to determine whether there are new risks, whether risks have changed or whether there are changes to the risk-benefit balance of a medicinal product;
4) takes the appropriate measures for prevention and reduction of risks relating to pharmacovigilance;
5) informs persons authorised to prescribe medicinal products, pharmacists, assistant pharmacists and the public of the emergence of risks relating to the use of medicinal products;

6) assesses the results of the risk minimisation measures specified in the risk management plan drawn up by a marketing authorisation holder and the results of the measures specified in the conditions of the marketing authorisation;
7) assesses the updating of the risk management system;
8) inspects the functionality of the pharmacovigilance systems of marketing authorisation holders in Estonia and their compliance with the requirements of quality systems, provided that the pharmacovigilance system master file of the pharmacovigilance system is located in Estonia, and participate in inspections organised by other Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council or Directive 2001/82/EC of the European Parliament and of the Council on the Community Code relating to veterinary medicinal products (OJ L 311, 28.11.2001, pp. 3-67);
9) once every two years, carries out an audit of the pharmacovigilance system and submits to the European Commission a report on the audit results;
10) participates in the joint work-sharing of the Coordination Group and Pharmacovigilance Risk Assessment Committee of the European Medicines Agency and pursue relevant cooperation with the competent authorities of other Member States;
11) at the request of the European Committee, participates in the international harmonisation and standardisation of the technical measures of pharmacovigilance, which is coordinated by the European Medicines Agency;
12) follows the recommendations of the Coordination Group and Pharmacovigilance Risk Assessment Committee of the European Medicines Agency upon implementation of risk minimisation measures and decisions of the European Committee regarding the measures to be applied due to marketing authorisations granted in the Member States.

(2) In pharmacovigilance, including upon carrying out inspections and communicating their results, the State Agency of Medicines must follow Directive 2001/83/EC of the European Parliament and of the Council or Directive 2001/82/EC of the European Parliament and of the Council, the guidelines of the European Commission and the Good Pharmacovigilance Practice.

(3) The State Agency of Medicines must inform the European Medicines Agency, the competent authorities of other Member States and the marketing authorisation holder of newly identified risks, changed risks or a change to the risk-benefit balance of a medicinal product.

(4) The State Agency of Medicines will update the assessment report if new information important from the point of view of assessment of the quality, safety or effectiveness of a medicinal product is obtained.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

Subdivision 2
Safety Information of Medicinal Product and Communication of Information

§ 78[5]. Safety information of medicinal product and communication of information

(1) For the purposes of this Act, safety information of a medicinal product includes:
1) any new information about the safety or lower-than-expected efficacy of a medicinal product;
2) restrictions imposed on a medicinal product by competent authorities in a state where the medicinal product is marketed;
3) information about the adverse reactions of a medicinal product, i.e. an adverse reaction report;
4) information about minimisation or prevention of risk, which calls for the initiation of an urgent procedure in accordance with subsection 76 (11) of this Act;
5) reports relating to the assessment of the risk-benefit balance of a medicinal product, i.e. a periodic safety update reports.

(2) A marketing authorisation holder must submit to the State Agency of Medicines the information specified in clauses 1) and 2) of subsection (1) of this section if the information may bring about the need to change the data of documents serving as the basis for the marketing authorisation. This information must cover positive as well as negative results of clinical studies or other studies of all the indications, carried out in all population groups, and data about the use of the medicinal product not in compliance with the marketing authorisation.

(3) A marketing authorisation holder must submit the information specified in clause 3) of subsection (1) of this section to the database and data-processing network (hereinafter *EudraVigilance database*) specified in Article 24 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 20.04.2004, pp. 1–33), amended by Regulation (EU) No 1235/2010 (OJ L 348, 31.12.2010, pp. 1–16). The marketing authorisation holder of a veterinary medicinal product must send the information to the State Agency of Medicines or to the EudraVigilance database.

(4) A marketing authorisation holder must electronically send the information specified in clause 5) of subsection (1) of this section to the European Medicines Agency who will make reports available to the State Agency of Medicines via the database specified in Article 25a of Regulation (EC) No. 726/2004 of the European Parliament and of the Council. The marketing authorisation holder of a veterinary medicinal product must

electronically send the information to the State Agency of Medicines. At the request of the State Agency of Medicines, the marketing authorisation holder must immediately submit a periodic safety update report.

(5) The State Agency of Medicines must send the information specified in clause 3) of subsection (1) of this section to the EudraVigilance database.

(6) The State Agency of Medicines must send the information specified in clauses 1) and 4) of subsection (1) of this section to the European Medicines Agency, competent authorities of other Member States and the European Commission.

(7) If a marketing authorisation holder intends to make public announcement about the risks relating to the use of a medicinal product, the State Agency of Medicines, the European Medicines Agency and the European Commission must be immediately informed thereof. Safety information to be given to the public must be objective and must not be misleading or contain any medicinal product advertising.

(8) The State Agency of Medicines must inform the European Medicines Agency, competent authorities of other Member States and the European Commission at least 24 hours in advance of the intention to make information about the risks relating to the use of a medicinal product public, unless the public needs to be informed immediately for the purposes of protecting public health. Information that may harm trade secrets and personal data the disclosure of which is not important from the point of view of protecting public health must be removed from the information to be made public.

(9) In the event of emergence of a threat to the life or health of humans or animals or to the environment, a marketing authorisation holder must send relevant information to persons authorised to prescribe medicinal products, coordinating the contents and the plan of submission of the information with the State Agency of Medicines in advance. The State Agency of Medicines has the right to request that the marketing authorisation holder send the information to persons authorised to prescribe medicinal products, pharmacists and assistant pharmacists if it is necessary for ensuring the safe and efficient use of the medicinal product.

(10) The State Agency of Medicines must inform the Health Board about the adverse reactions of vaccines, including about adverse reactions arising from possible medication errors.

(11) A marketing authorisation holder must pay the State Agency of Medicines a safety and quality monitoring fee of 160 euros per marketing authorisation valid in the previous calendar year. The safety and quality monitoring fee of a medicinal products serves the purpose of administration of the pharmacovigilance system, including collection, assessment and processing of safety information of medicinal products, sending the information to the databases of the European Economic Area and international monitoring centres, assessment of the non-interventional safety study protocols, and laboratory monitoring of the quality of marketed medicinal products.

(12) If Estonia participates in the decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition as a reference country or if the State Agency of Medicines regularly participates as a reference country in the work-sharing procedure of the periodic safety update report of the Coordination Group and Pharmacovigilance Risk Assessment Committee of the European Medicines Agency, the safety and quality monitoring fee of a medicinal product will be 320 euros per marketing authorisation that was valid for over six months in the previous calendar year.

(13) On the basis of a reasoned application of a marketing authorisation holder, the State Agency of Medicines may release the marketing authorisation holder from the obligation to pay the safety and quality monitoring fee of a medicinal product if the sales of the medicinal product in Estonia fall short of the quantity specified in the procedure established under subsection (14) of this section.

(14) The procedure for reporting safety information of medicinal products and calculation and payment of the safety and quality monitoring fee will be established by the Minister of Social Affairs.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 78[6]. Adverse reaction of medicinal product

(1) An adverse reaction of a medicinal product is any noxious and unintended effect arising from the use of the medicinal product in the usual manner or in a manner not specified in the conditions of the marketing authorisation, due to a medication error, in the event of the misuse or abuse of the medicinal product or upon coming into contact with the medicinal product in a working environment and whereby a causal link between the medicinal product and the adverse reaction cannot be precluded. An adverse reaction of a veterinary medicinal product also means an adverse reaction that becomes evident on a human after coming into contact with the veterinary medicinal product, including with residues in animal foodstuffs.

(2) A serious adverse reaction of a medicinal product is an adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of hospitalisation, results in long-term incapacity for work or a severe or profound disability or a congenital anomaly or a birth defect.

(3) An unexpected adverse reaction of a medicinal product means an adverse reaction which has not been described in the summary of the product characteristics or whose nature, severity or frequency is not consistent with the summary of the product characteristics.

(4) A person authorised to prescribe medicinal products is required to inform the State Agency of Medicines of all serious adverse reactions.

(5) The State Agency of Medicines has the right to impose additional duties on marketing authorisations holders, persons authorised to prescribe medicinal products, pharmacists and assistant pharmacists regarding communication of adverse reactions if it is reasoned from the point of view of pharmacovigilance.

(6) A marketing authorisation holder may be informed of an adverse reaction. The marketing authorisation holder must, in cooperation with the State Agency of Medicines and the European Medicines Agency, take measures for detection and prevention of the sending of duplicate adverse reaction reports.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 78[7]. Periodic safety update report

(1) A periodic safety update report means a report relating to the assessment of the risk-benefit balance of a medicinal product, which contains:
1) an updated summary of relevant data required for assessment of the risk-benefit balance of the medicinal product, including data obtained from studies;
2) a scientific assessment of the risk-benefit balance of the medicinal product;
3) the medical product's sales data and the number of prescriptions, including an assessment of the number of people coming into contact with the medicinal product.

(2) The frequency of submission of periodic safety update reports is proportional to the risks arising from the medicinal product and it is detailed in the conditions of the marketing authorisation.

(3) In the event of medicinal products that have received a marketing authorisation in more than one Member State or contain the same active substance or combination of active substances, periodical safety updates are assessed by way of the joint work-sharing procedure of the European Economic Area.

(4) Upon assessment of a periodic safety update report, the State Agency of Medicines must follow Directive 2011/83/EC of the European Parliament and of the Council or Directive 2001/82/EC of the European Parliament and of the Council and the Good Pharmacovigilance Practice.

(5) After the assessment of a periodic safety update report, the State Agency of Medicines must decide whether the marketing authorisation needs to be amended, suspended or revoked. In the event of joint work-sharing assessment of the European Economic Area, the position of the Coordination Group or Pharmacovigilance Risk Assessment Committee of the European Medicines Agency or a decision of the European Commission must be followed.

Subdivision 3
Non-interventional Post-authorisation Safety Study

§ 78[8]. Non-interventional post-authorisation safety study marketing

(1) A post-authorisation non-interventional safety study (hereinafter *non-interventional safety study*) means a study of the properties of a medicinal product, which does not interfere with treatment or medical observation and has been initiated and is managed or funded by the marketing authorisation holder on its own initiative or for the purpose of fulfilment of the conditions of the marketing authorisation. The purpose of a non-interventional safety study is to identify the risk factors relating to a medicinal product, their nature and scope, confirm the medicinal product's risk profile or assess the effectiveness of the risk management system.

(2) A non-interventional safety study must not promote the use of a medicinal product.

(3) The time spent and the expenses incurred may be compensated to the health care professionals who participate in a non-interventional safety study.

(4) A non-interventional safety study must not be commenced before approval has been obtained from the State Agency of Medicines. If a study is carried out in multiple Member States, the marketing authorisation holder must, before the survey is commenced, obtain approval from the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency, except in the event of a veterinary medicinal product study.

(5) To obtain the approval, a marketing authorisation holder must submit the protocol of the non-interventional safety study to the State Agency of Medicines or to the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency who must send a written notice of the approval of or refusal to approve the plan within 60 days after the submission of the study protocol. In the event of a veterinary medicinal product, the State Agency of Medicines will coordinate the notice with the Ministry of Agriculture beforehand.

(6) The approval of a non-interventional safety study must be refused if at least one of the following circumstances exists:
1) the study promotes the use of the medicinal product;
2) the study does not allow for the attainment of the established study objectives;
3) the study is a clinical trial.

(7) If a non-interventional safety study has been approved by the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency, the marketing authorisation holder must, before commencement of the survey in Estonia, send the study plan to the State Agency of Medicines.

(8) Before commencement of a non-interventional safety study in Estonia, the approval of the medical ethics committee for clinical trials is required in accordance with § 93 of this Act, except in the event of a veterinary medicinal product survey.

(9) A non-interventional safety study is carried out in accordance with Directive 2001/83/EC of the European Parliament and of the Council and with the Good Pharmacovigilance Practice.

(10) For the purpose of amendment of the protocol of a non-interventional safety study, the marketing authorisation holder must submit essential amendments to the protocol to the State Agency of Medicines or to the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency for approval. The State Agency of Medicines or the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency will inform the marketing authorisation holder of the approval of or refusal to approve the amendments. Before implementation of the amendments in Estonia, the marketing authorisation holder must submit the approval of the Pharmacovigilance Risk Assessment Committee of the European Medicines Agency.

(11) At the request of the State Agency of Medicines, a marketing authorisation holder must submit an interim report of a non-interventional safety study in the course of the study. Within twelve months after the completion of the study, the marketing authorisation holder must electronically submit to the State Agency of Medicines the final study report.

(12) A marketing authorisation holder must assess data obtained from a non-interventional safety study and, if necessary, submit an application for the amendment of the marketing authorisation.

(13) On the basis of the results of a non-interventional safety study, the State Agency of Medicines may demand the amendment, suspension or revocation of a marketing authorisation.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

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 will 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) The register of medicinal products contains details of the marketing authorisation of a medicinal product, a public assessment report along with a summary of the risk management plan, a summary of the product characteristics, package leaflet and the labelling of the packaging. The register of medicinal products is linked to the European web portal of medicinal products.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(4) All data entered in the register of medicinal products is public. Data contained in the register will 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, packaging 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 will be established by the Government of the Republic.

(3) A medicinal product code is designated by the Coding Centre for each packaging size of an authorised medicinal product after a marketing authorisation has been issued concerning the medicinal product, for each packaging 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 - entry 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 procedure for designation and use of medicinal product codes will be established by a regulation of the Minister of Social Affairs.
[RT I 2005, 24, 180 - entry 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 on 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.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(2) The Digital Prescription Centre and the statutes thereof will be established by a regulation of the Government of the Republic.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(3) The chief processor of the Digital Prescription Centre is the Estonian Health Insurance Fund. It is not permitted to delegate the functions of the chief processor or to appoint an authorised processor.
[RT I, 05.12.2012, 1 - entry into force 01.04.2013]

(4) The following persons submit information to the Digital Prescription Centre:
[RT I 2008, 3, 22 - entry into force 01.09.2008]
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;
[RT I 2008, 3, 22 - entry into force 01.09.2008]
7) the Health Board.
[RT I 2009, 49, 331 - entry 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 - entry 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 will 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.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(7) Persons qualified to issue prescriptions are required to issue prescriptions in electronic form, the prescriptions will be saved in the Digital Prescription Centre and, therefore, all the prescribed data fields will 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.

[RT I 2008, 3, 22 - entry into force 01.09.2008]

(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.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(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 person.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(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.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(11) A person providing pharmacy services is required to enter information concerning a prescription issued on paper in the Digital Prescription Centre immediately after the receipt of the prescription. If the Digital Prescription Centre is not accessible, the data will be entered within a reasonable amount of time.
[RT I, 05.12.2012, 1 - entry into force 06.01.2013]

(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.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

(13) The Digital Prescription Centre will release information free of charge if the information is necessary for the performance of public duties arising from law.
[RT I 2008, 3, 22 - entry into force 01.09.2008]

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

Division 1
Advertising Medicinal Products

§ 82. Classes of advertising medicinal products

(1) The classes of advertising medicinal products are:
1) advertising medicinal products to the general public;
2) advertising medicinal products to persons qualified to prescribe them, to pharmacists and assistant pharmacists.

(2) The following are not deemed to be the advertising of medicinal products:
1) information specified in subsections 70 (6) and (7) of this Act without any alterations or supplements and medicinal product safety information given under subsections 78^5(7), (8) and (9) of this Act;
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]
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, pharmacists and assistant pharmacists.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(3) Advertising of medicinal products to persons qualified to prescribe them, to pharmacists and assistant pharmacists means 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 general 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 - entry into force 18.04.2010]

(6) The requirements established for advertising directed to persons qualified to prescribe veterinary medicinal products, to pharmacists and assistant pharmacists apply to the advertising of veterinary medicinal products.

(7) Unless otherwise provided by this Act, the requirements of the Advertising Act apply to the 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 compliance of the advertising with the requirements provided by this Act or legislation established on the basis thereof.

(3) The advertising of a medicinal product must meet the general requirements provided for in the Advertising Act and 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 - entry into force 18.04.2010]

(4) The advertising of a medicinal product must facilitate rational use of the medicinal product by presenting information in an objective and unexaggerated way. The advertising must 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 that are generally known or also characteristic to other medicinal products.

(5) Each time the name of the medicinal product is mentioned, it must be accompanied by the name of its active substance set out in a clearly distinguishable and legible form.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(6) By 1 February each year, a holder of a marketing authorisation in respect of a medicinal product must submit the State Agency of Medicines a report concerning support awarded under subsections 86 (2) and (5) of this Act to pharmacists, 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 will establish the standard form 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 advertising to the general public for the period of two years after the end of advertising to the general public, and to provide such materials and documents at the request of the State Agency of Medicines.

(9) The direct offering of medicinal products for the purposes of the Media Services Act is prohibited.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 84. Advertising of medicinal products to general public

(1) It is prohibited to advertise to the general public medicinal products which are available on medical prescription only.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

(2) Advertising of medicinal products to the general public must 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 - entry into force 01.11.2008]

(3) Advertising of medicinal products to the general public must:
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, and unambiguous, ensure the distinguishability of the medicinal product from other medicinal products and must 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 packaging. Consult a doctor or pharmacist if complaints persist or adverse reactions occur.];
4) the text *"Ainult veterinaarseks kasutamiseks"*[For veterinary use only] must be added to the text specified in clause 3) of this subsection in the event of a veterinary medicinal product.

(4) In printed advertising, the warning specified in clauses 3) and 4) of subsection (3) 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 - entry into force 18.04.2010]

(5) In addition to the above, the following requirements must be adhered to in transmission of television advertising of medicinal products:
1) a clearly legible notice *"Ravimireklaam"*[Advertising of medicinal product] must 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) of subsection (3) of this section must be displayed as all screen text on a single colour background within a reasonable period of time, and must be read out at the same time at the speed of ordinary speech;
[RT I 2010, 15, 77 - entry 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] must 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) of subsection (3) of this section must 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 - entry 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 ensured, are unaccompanied by adverse reactions 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 - entry 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 – entry 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 – entry into force 18.04.2010]

(10) The prohibition on advertising of medicinal products which are available on medical prescription only does not apply to vaccination campaigns approved beforehand by the State Agency of Medicines and the Health Board.
[RT I 2010, 15, 77 - entry into force 18.04.2010]

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

(1) References taken from scientific works to be used in advertising of medicinal products to persons qualified to prescribe them, and to pharmacists and assistant pharmacists must be presented without amendments and be supplied with references to the source documents. The marketing authorisation holder must 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 must 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 – entry into force 18.04.2010]

(4) Only an authorised representative of a marketing authorisation holder in possession of complete information about the properties of the medicinal product is permitted to advertise the medicinal product by means of personal communication or at events. The information presented must be accurate, up-to-date and sufficiently complete to enable the persons qualified to prescribe medicinal products, pharmacists and assistant pharmacists to form their own opinion of the benefit and risks of the medicinal product.
[RT I 2010, 15, 77 - entry 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 must not exceed 300. Each sample of a medicinal product must be marked with the words *"Mitte müügiks"*[Not for sale], the packaging must comply with the marketing authorisation and each sample must be accompanied by a copy of the summary of product characteristic. Samples of medicinal products must 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 must 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 must be recorded in an instrument made up in two original copies, one of which must be given to the person receiving the sample and the other must remain with the person supplying the sample, and the person receiving the sample must certify receipt of the sample by their signature. A marketing authorisation holder must keep written record of the supplying of samples. Doctors must keep written record of the receipt of samples and dispensing thereof for use.

(9) A leaflet containing advertising of a medicinal product must 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 substance(s);
3) pharmaceutical form;
4) content of active substance(s);
5) packaging size;
[RT I 2010, 15, 77 - entry 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) adverse reactions;
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 substance(s);
3) one or several therapeutic indications (at least one must 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, pharmacists and assistant 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 must be recorded. Advertising of medicinal products subject to medical prescription over the Internet must include the summary of product characteristics.
[RT I 2010, 15, 77 - entry 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, pharmacists and assistant pharmacists, and such persons are prohibited from accepting such gifts or services from marketing authorisation holders or their representatives, except in the events provided in subsection (2) of this section. Receipt of all pecuniary gifts is prohibited, except in the event provided for in subsection (2) of this section. Gifts must be relevant to the corresponding professional practice of the persons and must 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 - entry 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 events where such support is provided for participation in medical or pharmaceutical events organised by a research institution or professional organisation. Such support must be granted exclusively under conditions which must be made public and which must 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 must not extend to other persons except those qualified to prescribe medicinal products, pharmacists and assistant pharmacists.

(4) It is prohibited to organise raffles and lotteries connected to medicinal products for persons qualified to prescribe medicinal products, pharmacists and assistant 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, pharmacists or pharmacists, hospitality offered at such events, including entertainment, must 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 must comply with the requirements set for advertising of medicinal products.

(7) All support granted to persons qualified to prescribe medicinal products, pharmacists or pharmacists as well as the expenses made in connection to the events specified in subsections (5) and (6) of this section must be recorded in the documentation of the Estonian representative or branch of the marketing authorisation holder, and the State Agency of Medicines must be informed of the expenses made in connection to the events specified in subsections (5) and (6) of this section in accordance with 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 pharmacist or assistant pharmacist whereby such person, pharmacist or assistant 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 distribution 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 must 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, adverse reactions, 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. The State Agency of Medicines must be informed of the trial. All trials, surveys and programmes for the purpose of commencement of new treatment or alteration of treatment are deemed to be clinical trials.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

(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 adverse reactions may be investigated by way of clinical trial. Investigated medicinal products must be labelled pursuant to the requirements established under 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 must be in compliance with good clinical practice.

(4) The conditions and procedure for conducting clinical trials of medicinal products must 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, pharmacists, 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 must 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 must 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 must ensure 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 must 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 must ensure 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 must provide necessary assistance to a trial subject within the limits of their competence.

(6) A doctor or dentist conducting a trial must ensure the availability of competent assistance of other health care providers to the trial subject if necessary. In the event of a clinical trial of a veterinary medicinal product, the veterinarian must 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 events 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 must notify, in accordance with the procedure established by the Minister of Social Affairs, the Agency of Medicines and, in the event 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 must ensure 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 - entry 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 their 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 must not adhere to the decision of the legal representative if their decision clearly violates the interests of the person with restricted active legal capacity. The person with restricted active legal capacity must 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 consent of the owner of the animal is required.

§ 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 ensure the protection of the rights, safety and well-being of trial subjects.

(2) The work of a committee is regulated 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 must have at least seven members. A committee must 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 must submit to 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 rules of procedure of a committee, a list of data to be submitted for obtaining approval, procedure for adoption of resolutions and the form of an application for approval will be established by a regulation of the Minister of Social Affairs.

§ 93. Approval of clinical trials by committee

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

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

(3) A committee will make one of the following decisions:
1) approve the clinical trial;
2) demand the making of alterations in the conduct of the clinical trial of the medicinal product;
3) refuse approval;
4) revoke or suspend an earlier approval.

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

(5) A committee will deliberate the matter, make a decision and issue the decision in writing within 60 days and, in the event of clinical trial involving medicinal products for gene therapy or somatic cell therapy, immunological medicinal products or medicinal products containing genetically modified organisms, within 90 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 time limit for granting approval will be extended by 90 days, of which the applicant will be given written notice. A committee will 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 will 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 must pay the committee an amount of up to 383 euros for evaluation of the clinical trial.
[RT I 2010, 22, 108 - entry into force 01.01.2011]

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

(3) A committee will 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 must submit a written application compliant with the procedure established under subsection 88 (4) of this Act and other information and documents provided 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 must 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 - entry 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 - entry 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. Granting authorisation to conduct clinical trial of medicinal product

(1) Authorisation to conduct a clinical trial of a medicinal product is granted by the State Agency of Medicines. Authorisation to conduct 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 to conduct a clinical trial of a medicinal product within 60 days after receipt of all requisite documents in the event of I phase trials and within 30 days after receipt of all requisite documents in the event 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, the authorisation is deemed to be granted.
[RT I 2008, 56, 313 - entry into force 01.01.2009]

(3) In the event 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 will decide the granting of the authorisation for a clinical trial within 90 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 time limit for granting approval will be extended by 90 days, of which the applicant will be given written notice. Such clinical trials must not be commenced before obtaining written consent of the State Agency of Medicines.

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

The State Agency of Medicines may refuse to grant authorisation to conduct a clinical trial of a medicinal product 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 conducting clinical trial of medicinal product

(1) In order to amend the conditions for conducting a clinical trial of a medicinal product, the sponsor of the trial or a representative thereof must submit an application compliant with the procedure established under subsection 88 (4) of this Act and other information and documents provided by the same procedure to the State Agency of Medicines at least 30 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 must 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 - entry into force 01.01.2011]

(3) The State Agency of Medicines makes the decision to grant an authorisation for amendment of the conditions for conducting a clinical trial of a medicinal product within 30 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 time limit, authorisation is deemed to be granted taking account of the specifications specified in subsection 96 (3).

(4) The State Agency of Medicines will 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 - entry into force 01.01.2009]

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

(1) The State Agency of Medicines will 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 event 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 will 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 is liable for the compliance 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 is liable for a violation of their 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 under an employment contract or another contract entered into with a third person, the third person will 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 is 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 - entry into force 01.01.2010]

(2) The Health Board exercises 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 - entry into force 01.01.2010]

(3) [Repealed – RT I 2009, 49, 331 – entry into force 01.01.2010]

(4) The Veterinary and Food Board exercises supervision over the use of medicinal products and medicated feedingstuffs by veterinarians and breeders producing animal products.

(5) The Competition Board exercises supervision over compliance with the requirement specified in clause 44 (1) 7) of this Act in accordance with the procedure provided for in this Act and the Competition Act.

(6) The Tax and Customs Board checks, for goods requiring special import or export authorisation of the State Agency of Medicines, the existence and compliance of the import or export authorisation or written permit in accordance with the procedure provided for in 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 comply with 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 provided 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 1) of subsection (7) of this section is terminated by a corresponding consent granted by the State Agency of Medicines unless the circumstances described in clause 2) of subsection (7) of this section 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 will, within 90 days, issue a certificate to the holder of the activity licence concerning the compliance of the enterprise with good manufacturing practices if inspection results confirm the compliance.

§ 101. Rights and obligations of officials exercising supervision

(1) For performance of their duties, an official exercising supervision (hereinafter *supervisory official*) has the right 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, examine relevant documents, including documents containing sensitive personal data, in the process of supervision, and obtain or make copies thereof or, if a misdemeanour is suspected, take the documents with them;
[RT I 2010, 15, 77 - entry 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 their 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 that 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 must 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 must be prepared in two original copies of which one will remain with the person who prepares the precept and the other will 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 will 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 in accordance with 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 - entry 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 intra-agency appeal 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 will review an intra-agency appeal and make a decision within 14 days as of the date on which the appeal is filed. The supervisory official against whose precept or decision the appeal has been filed must not participate in the review of the appeal.

(3) The filing of an intra-agency appeal will not release the person who filed the appeal 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 appeal.

(4) The director general of the supervisory agency has the right to revoke, in part or in whole, a precept that 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 - entry 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 - entry into force 01.01.2011]

§ 106. Violation of requirements related to marketing authorisation

(1) Violation of the requirements related to a marketing authorisation as well as the procurement or distribution of a medicinal product with regard to which the State Agency of Medicines has not issued any import authorisation or permit for use 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 - entry 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 - entry 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 - entry 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 - entry 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 - entry 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 - entry 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 - entry into force 01.01.2010]

(3) Extra-judicial proceedings concerning the misdemeanours provided for in §§ 104-108, 110 and 111 of this Act will 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 will be conducted by the Health Board.
[RT I 2009, 49, 331 - entry 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, will be conducted by the Health Protection Inspectorate.
[RT I 2009, 49, 331 - entry into force 01.01.2010]

(6) Extra-judicial proceedings concerning the misdemeanours provided for in §§ 104-106 and § 111 of this Act will be conducted by police authorities and the Tax and Customs Board.
[RT I 2009, 62, 405 - entry into force 01.01.2010]

(7) Extra-judicial proceedings concerning the misdemeanours provided for in § 109 and § 111 of this Act will 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 distribution of medicinal products who has not entered the name of the responsible person on the licence must inform the State Agency of Medicines of the name of the responsible person and their substitute by 1 May 2005.

(3) The holder of an activity licence for wholesale distribution of medicinal products who alters the labelling or outer packaging of a medicinal product, including investigational medicinal products, or imports medicinal products form third countries, must 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 must 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 pharmacists and assistant pharmacists

(1) The Health Board will commence the registration of the persons specified in §§ 55-57 and § 60 of this Act as pharmacists or assistant pharmacists beginning from 1 July 2005.

(2) The requirement provided by this Act according to which pharmacy services must be provided only by pharmacists and assistant 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 - entry into force 01.01.2010]

§ 115. Pharmacy counters

(1) Pharmacy counters established under the Medicinal Products Act in force before the entry into force of this Act (hereinafter *pharmacy counters*) must be wound up or 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 their winding-up or transformation.

(3) The area of a pharmacy counter must 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 comply with 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 a 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.

§ 116^{1}. Pharmacovigilance

(1) The duty to create and make available the pharmacovigilance system master file of the pharmacovigilance system, which has been established in subsections 78^{3}(1) and (3) of this Act, applies to marketing authorisations issued before 21 July 2012 as of the date of renewal of the marketing authorisation or as of 21 July 2014, whichever date comes earlier.

(2) In the event of marketing authorisations issued before 21 July 2012, the implementation of the risk management system under clause 78^{3}(2) 6) of this Act is not required with regard to each medicinal product. The State Agency of Medicines may impose on a marketing authorisation holder the duty to implement the risk management system on a medicinal product and submit to the State Agency of Medicines its detailed description if there is reason to suspect the existence of risks which may influence the risk-benefit balance of the medicinal product which received the marketing authorisation, giving the marketing authorisation holder the chance to submit written objections within 30 days before making a decision. Upon establishment of the duty, the conditions of the marketing authorisation will be amended in accordance with clause 70 (4) 1) of this Act.

(3) The duty provided for in § 78^{8}of this Act applies only to surveys and trials commenced after 21 July 2012.

(4) The State Agency of Medicines will draw up a report on the audit of the pharmacovigilance system and submit it to the European Commission not later than by 21 September 2013 and thereafter once every two years.
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]

§ 117.–§ 121.[Omitted from this text.]

§ 122. Entry into force of Act

(1) This Act will enter into force on 1 March 2005.

(2) Subsections 8 (2), 16 (6) and 65 (5) of this Act will enter into force on 30 October 2005.

(3) Clause 15 (5) 5) of this Act will enter into force on 1 October 2005.

(4) Subsection 18 (2) of this Act will enter into force in respect of holders of activity licences for wholesale distribution of and manufacture of medicinal products on 1 July 2005.

(5) Subsections 42 (3) and (4) of this Act will enter into force on 1 February 2006.

(5[1]) Section 42[1] of this Act will enter into force on 1 January 2006.

(6) Section 43 of this Act will 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 will enter into force on 1 July 2005.

(8) Subsection 80 (4) of this Act will enter into force on 1 October 2005.

(9) Section 81 of this Act will enter into force on 1 January 2006.
[RT I 2005, 24, 180 - entry into force 20.05.2005]

[1]Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, pp. 74–99)
[RT I, 05.07.2012, 13 - entry into force 21.07.2012]