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Medicinal Products Act[1]

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RT I 2005, 2, 4
Entry into force 01.03.2005

Amended by the following acts

Passed	Published	Entry into force
09.02.2005	RT I 2005, 13, 63	01.05.2005
13.04.2005	RT I 2005, 24, 180	20.05.2005, in part 01.01.2006
09.11.2005	RT I 2005, 64, 482	01.01.2006
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
23.02.2011	RT I, 25.03.2011, 1	01.01.2014; date of entry into force amended to 01.07.2014 [RT I, 22.12.2013, 1]
13.06.2012	RT I, 05.07.2012, 13	21.07.2012
10.10.2012	RT I, 25.10.2012, 1	01.12.2012
14.11.2012	RT I, 05.12.2012, 1	01.04.2013, in part one month after the date of publication in Riigi Teataja
27.03.2013	RT I, 17.04.2013, 2	27.04.2013, in part 01.07.2013 and 02.07.2013
09.12.2013	RT I, 12.12.2013, 14	09.06.2014 - the judgment of the Supreme Court en banc declares subsections 1–3 of § 42[1]

		of the Medicinal Products Act unconstitutional and repeals them.
05.12.2013	RT I, 22.12.2013, 1	01.01.2014
26.02.2014	RT I, 15.03.2014, 1	25.03.2014
19.02.2014	RT I, 13.03.2014, 4	01.07.2014
21.05.2014	RT I, 06.06.2014, 1	01.07.2014
21.05.2014	RT I, 06.06.2014, 14	09.06.2014, in part 02.07.2014, 15.07.2014, 01.01.2015 and 09.06.2019; amended in part [RT I, 04.07.2017, 2]
11.06.2014	RT I, 21.06.2014, 2	01.07.2014
05.06.2014	RT I, 29.06.2014, 1	01.07.2014
19.06.2014	RT I, 12.07.2014, 1	01.01.2015
19.06.2014	RT I, 29.06.2014, 109	01.07.2014, the ministers' official titles have been replaced on the basis of subsection 4 of § 107³ of the Government of the Republic Act.
22.12.2014	RT I, 23.12.2014, 30	22.12.2014 - the judgment of the Supreme Court en banc declares subsections 1–6 of § 116# of the Medicinal Products Act unconstitutional and repeals them.
29.01.2015	RT I, 26.02.2015, 1	01.03.2015
18.02.2015	RT I, 10.03.2015, 6	20.03.2015
11.06.2015	RT I, 30.06.2015, 4	01.09.2015, on the basis of subsection 2 of § 107# of the Government of the Republic Act the words 'Ministry of Agriculture' have been replaced with the words 'Ministry of Rural Affairs.'
19.11.2015	RT I, 03.12.2015, 1	01.01.2016
09.12.2015	RT I, 30.12.2015, 1	18.01.2016
09.12.2015	RT I, 30.12.2015, 2	01.03.2016
20.04.2016	RT I, 04.05.2016, 1	14.05.2016
31.05.2017	RT I, 16.06.2017, 1	01.07.2017
14.06.2017	RT I, 04.07.2017, 2	01.01.2018
25.10.2017	RT I, 10.11.2017, 1	20.11.2017
06.12.2017	RT I, 28.12.2017, 5	01.01.2018
17.10.2018	RT I, 26.10.2018, 1	01.04.2022
07.11.2018	RT I, 10.11.2018, 1	11.11.2018
12.12.2018	RT I, 21.12.2018, 4	09.02.2019, in part 01.01.2019
20.02.2019	RT I, 13.03.2019, 2	15.03.2019
04.12.2019	RT I, 21.12.2019, 1	01.01.2020
20.04.2020	RT I, 06.05.2020, 1	07.05.2020
10.06.2020	RT I, 01.07.2020, 1	01.01.2021
14.04.2021	RT I, 21.04.2021, 1	01.05.2021
15.12.2021	RT I, 03.01.2022, 2	13.01.2022, in part on 28.01.2022, 01.02.2022 – enters into force on the day when a period of six months has passed from the publication of a notice specified in Article 82(3) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the Official Journal of the European Union, Commission Decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, pp 1–2).
13.04.2022	RT I, 29.04.2022, 1	01.07.2024, in part 01.05.2022
01.06.2022	RT I, 20.06.2022, 3	30.06.2022
01.06.2022	RT I, 20.06.2022, 4	01.07.2022
08.06.2022	RT I, 20.06.2022, 63	27.06.2022
22.02.2023	RT I, 11.03.2023, 9	01.04.2023, the words "Eesti Haigekassa" [Estonian Health Insurance Fund] and the

		word “haigekassa” [Health Insurance Fund] have been replaced in the Act by the word “Tervisekassa” [Estonian Health Insurance Fund] in the appropriate case form
20.06.2023	RT I, 30.06.2023, 1	01.07.2023; words "Ministry of Rural Affairs" replaced with words "Ministry of Regional Affairs and Agriculture" thoughout the Act on the basis of subsection 7 of § 105.19 of the Government of the Republic Act.
22.11.2023	RT I, 15.12.2023, 1	30.06.2024, in part 01.01.2024
23.11.2023	RT I, 15.12.2023, 3	25.12.2023, in part 01.06.2024 and 01.09.2024

Chapter 1
GENERAL PROVISIONS

§ 1. Scope of application of the Act

(1) This Act regulates the handling of medicinal products, issue of medical prescriptions, granting of marketing authorisations, clinical trials and advertising of veterinary medicinal products and medicinal products for human use, supervision over and responsibility in the field 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.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

(1^1) Clinical trials of medicinal products for human use are governed by Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.05.2014, pp 1–76). This Act applies to clinical trials of medicinal products for human use only in events provided by in the Act.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

(1^2) This Act also regulates compensation for damage to health or for proprietary and non-proprietary damage to a person in the case of death (hereinafter *vaccination damage*) resulting from the use of immunological medicinal products containing vaccines for human use (hereinafter *vaccine*), including compulsory insurance of vaccination damage (hereinafter *vaccination insurance*), liability upon occurrence of vaccination damage and procedure of compensation for damage.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

(1^3) This Act does not apply to veterinary medicinal products in the events Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 07.01.2019, pp 43–167) applies.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(2) The provisions of the Administrative Procedure Act apply to the administrative proceedings provided in this Act, taking account of the specificities provided in this Act and Regulations (EU) No 536/2014 and (EU) 2019/6 of the European Parliament and of the Council.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 2. Medicinal product

(1) ‘Medicinal product’ means a 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, or for the restoration or alteration of vital functions in a human through pharmacological, immunological or metabolic effect.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(1^1) Veterinary medicinal products within the meaning of point (1) of Article 4 of Regulation (EU) 2019/6 of the European Parliament and of the Council are also considered to be medicinal products.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 and brokering of medicinal products

[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(1) For the purposes of this Act, 'handling of medicinal products' means the manufacture, procuring, dispensing, preparation, import, export, distribution, transport, storage and withdrawing from the market of medicinal products together with relevant records and reports concerning such activities.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(2) For the purposes of this Act, 'distribution' 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 municipalities, including to enforcement and oversight, unless otherwise provided by legislation governing such authorities and agencies.
[RT I 2008, 35, 213 – entry into force 01.01.2009]

(4) The brokering of medicinal products means any and all acts that are related to the purchase and sale of medicinal products for human use, except the wholesale distribution of medicinal products, and consist of negotiations held independently in the name of another self-employed person or legal person. The brokering of medicinal products does not include the physical handling of medicinal products.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

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

(1) Proprietary medicinal products are medicinal products with a trade name packaged for distribution.

(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) 'Active substance' means a substance or a combination of substances determinable by scientific methods, which is intended to be used upon manufacturing a medicinal product or upon preparation in a pharmacy and which becomes the active ingredient of a medicinal product in the process of manufacturing or preparation for the purpose of having the effect specified in subsection 1 of § 2 of this Act.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(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, which are not active substances or packaging material.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

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

[Repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 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 of use, are intended and designed for use without the supervision of a person qualified to prescribe medicinal products;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
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]

§ 9^1. Advanced therapy medicinal product

'Advanced therapy medicinal product' means a medicinal product intended for gene therapy or somatic cell therapy or a tissue engineered product specified in Regulation No 1394/2007/EC of the European Parliament and of the Council on advanced therapy medicinal products (OJ L 324, 10.12.2007, p. 121).
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

§ 9^2. Hospital exemption

'Hospital exemption' means the making and use of a custom-made advanced therapy medicinal product (hereinafter *hospital-exemption medicinal product*) in Estonia on non-routine basis for an individual patient in a hospital and under the professional responsibility of a medical specialist.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 10. Defective medicinal product

A medicinal product is deemed to be defective where it does not comply with quality requirements or where 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.

§ 10^1. Falsified medicinal product

(1) A falsified medicinal product is any medicinal product whereby at least one of the following circumstances has been falsely represented:
1) the identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
2) the source, including the manufacturer, the country of manufacturing, the country of origin or the marketing authorisation holder;
3) the history, including the records and documents relating to the distribution channels used.

(2) The definition of ‘falsified medicinal product’ does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

§ 10^2. Safety features of a medicinal product and national repository of safety features of medicinal products

(1) The distribution of medicinal products for human use is subject to requirements provided in Commission Delegated Regulation (EU) 2016/161 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 09.02.2016, pp 1–27), taking account of the variations provided in this Act.

(2) Commission Delegated Regulation (EU) 2016/161 specified in subsection 1 of this section applies to the following:
1) the characteristics and technical specifications of the unique identifier that enables the authenticity of medicinal products to be verified and individual packs to be identified;
2) the modalities for the verification of the safety features;
3) the provisions on the establishment, management and accessibility of the national repository of safety features where the information on the safety features is contained;
4) the list of medicinal products and product categories subject to prescription which do not bear the medicinal product safety features;
5) the list of medicinal products and product categories not subject to prescription which bear the medicinal product safety features;
6) the procedures for the notification to the Commission by the State Agency of Medicines of non-prescription medicinal products judged at risk of falsification and prescription medicinal products not deemed at risk of falsification in accordance with the criteria set out in Article 54a(2)(b) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, pp 67–128);
7) the procedures for a rapid evaluation of and decision on the notifications referred to in clause 6 of this subsection.

(3) The safety features of a medicinal product are the unique identifier of an individual pack of the medicinal product and an anti-tampering device. The unique identifier of a medicinal product is the safety feature enabling the verification of the authenticity and the identification of an individual pack of the medicinal product. The anti-tampering device is the safety feature allowing the verification of whether the packaging of a medicinal product has been tampered with.

(4) The establisher and manager of the national repository of safety features of medicinal products is a non-profit legal person established by manufacturers of medicinal products and marketing authorisation holders as well as wholesalers and persons authorised or entitled to supply medicinal products to the public, and such legal person ensures the functioning of the national repository of safety features of medicinal products in accordance with Commission Delegated Regulation (EU) 2016/161. The economic activities of the non-profit legal person specified in this subsection may be related only to ensuring the functioning of the national repository system of safety features of medicinal products.

(5) Where a person authorised or entitled to supply medicinal products to the public has reason to believe that the packaging of a medicinal product has been tampered with, or the verification of the safety features shows that the medicinal product may not be authentic, the person must not release the product for sale or distribution and must immediately inform the State Agency of Medicines and the non-profit legal person specified in subsection 4 of this section thereof.

(6) The non-profit legal person specified in subsection 4 of this section is required to immediately inform the State Agency of Medicines of the commencement or winding up of its operations. The State Agency of Medicines certifies whether a non-profit legal person who has submitted a notice is an appropriate person in Estonia for the purposes of Commission Delegated Regulation (EU) 2016/161.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

§ 11. Pharmacists and assistant pharmacists

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

(2) For the purposes of this Act, ‘assistant pharmacist’ means 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 handling authorisation holder to perform 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.

§ 12[1]. Competent authority within meaning of Regulation (EU) 2019/6 of European Parliament and of Council

(1) The activities of a competent authority provided in Regulation (EU) 2019/6 of the European Parliament and of the Council are carried out and administrative acts are issued by the State Agency of Medicines, except in the case provided for in subsection 2 of this section.

(2) The activities of a competent authority relating to the prescription, dispensing and use of medicinal products upon the provision of veterinary service are carried out and administrative acts are issued by the Agricultural and Food Board, except in the cases provided in Article 110(1)–(4) and Article 116 of Regulation (EU) 2019/6 of the European Parliament and of the Council. The Agricultural and Food Board decides on the prohibition on the use of immunological veterinary medicinal products subject to the conditions provided in Article 110(1) of Regulation (EU) No 2019/6 of the European Parliament and of the Council.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 12[2]. Collection of data on volume of sales and on use of antimicrobial medicinal products

(1) The State Agency of Medicines is responsible for the collection of data on the volume of sales of antimicrobial medicinal products used in animals and for transfer of such data to the European Medicines Agency.

(2) The Agricultural and Food Board is responsible for the collection of data on the use of antimicrobial medicinal products used in animals and for transfer of such data to the European Medicines Agency.

(3) The collection and transfer of data specified in subsections 1 and 2 of this section are based on Articles 57 of Regulation (EU) No 2019/6 of the European Parliament and of the Council.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 13. General requirements for medicinal products

(1) Only the following may 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) unauthorised medicinal products with regard to which the State Agency of Medicines has granted an authorisation specified in subsection 1, 7, 8 or 9 of § 21 of this Act;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
2[1]) unauthorised veterinary medicinal products prescribed by a holder of a professional activity licence of a veterinarian in accordance with Articles 112–114 of Regulation (EU) No 2019/6 of the European Parliament and of the Council;
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]
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.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(4) Medicinal products must be distributed and dispensed in packaging with Estonian text and be accompanied by information in Estonian concerning the composition, content of active substances, and requirements for the use and storage of the medicinal product, except in events provided in this Act. The package leaflet of a veterinary medicinal product may be made available electronically, unless the State Agency of Medicines requires that the package leaflet must be made available on paper in the interest of protection of the health of animals or humans.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(4[1]) The State Agency of Medicines may, on the condition that appropriate measures for ensuring the safe use of the medicinal product are taken, authorise distribution of a veterinary medicinal product in packaging in a language of another member state of the European Economic Area and with labelling in Latin letters.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 and legislation established on the basis thereof, or by Regulation (EU) No 2019/6 of the European Parliament and of the Council.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 15. Tasks of the Government of the Republic, ministers in charge of the policy sector and the State Agency of Medicines

[RT I, 06.05.2020, 1 – entry into force 07.05.2020]

(1) Threshold values for mark-ups in wholesale and retail trade of medicinal products and the procedure for their implementation are 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 takes into account the accessibility of the medicinal products to the end user arising from geographical and financial reasons, the risks involved in distributing 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 prepares 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 in wholesale and retail trade;
4) the weighted average mark-up in wholesale trade must remain between 7–10%;
5) the weighted average mark-up in retail trade must remain between 21–25%.

(4) By March 1 each year, holders of a wholesale distribution authorisation 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 in charge of the policy sector establishes the following by a regulation:
1) the conditions of and procedure for determining a substance or product as a medicinal product;
2) the conditions of and procedure for classification of proprietary medicinal products;
3) the conditions of 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 the health service or veterinary service, and by social welfare institutions;
5) the conditions of and procedure for application for a marketing authorisation of herbal medicinal products and traditional herbal medicinal products;

6) a list of herbal substances, and the conditions of 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 is established by a regulation of the minister in charge of the policy sector. The regulation is approved by the minister in charge of the policy sector.

(7) [Repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(7^1) The requirements for the prescription, dispensing and use of medicinal products upon the provision of veterinary service and the form of veterinary prescriptions, procedure for the issue of blank veterinary prescriptions and the requirements for keeping of records of blank prescriptions is established by a regulation of the minister in charge of the policy sector.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(8) In an emergency, a state of emergency, an emergency situation or a state of war, the State Agency of Medicines may temporarily restrict the export and issue of medicinal products and allow for derogations from the requirements for handling medicinal products, marketing authorisations, clinical studies, presentation of information on the safety of medicinal products and information communication, provided that it is necessary for protecting human life and health and compliance with all the established requirements would not allow for the uninterrupted provision of the population and medical institutions with medicinal products. During an emergency, a state of emergency, an emergency situation or a state of war, the State Agency of Medicines may restrict the advertising of medicinal products where it is necessary for the protection of human life and health.
[RT I, 06.05.2020, 1 – entry into force 07.05.2020]

§ 15^1. Fee-charging services of the 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 and give scientific advice in accordance with the procedure and price list established by a regulation of the minister in charge of the policy sector. The fee for the provision of a service, which is specified in the price list, must not exceed 6000 euros.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 15^2. Confidentiality requirement

The State Agency of Medicines, members of the marketing authorisation committees for medicinal products and veterinary medicinal products, non-staff experts involved in processing an application for marketing authorisation, members of the ethics committee and persons involved in the work of the ethics committee keep information received in connection with processing a permit for a clinical trial of a medicinal product, permit for making and using a hospital-exemption medicinal product, an application for marketing authorisation of a hospital-exemption medicinal product and revisions to such permits confidential and preclude the availability of such information to third parties. Information is disclosed by 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.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

Chapter 2
HANDLING AND BROKERING OF MEDICINAL PRODUCTS

[RT I, 17.04.2013, 2 - entry into force 27.04.2013]

Subchapter 1
Manufacture of Medicinal Products

§ 16. Manufacture of medicinal products

(1) Medicinal products may be manufactured only by a manufacturing authorisation holder.

(2) The manufacture of medicinal products, including intermediate products, means 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.

(3) A manufacturing authorisation for the purposes of this Act must be for total or partial manufacture, including for making the active substance of a medicinal product and manufacturing a medicinal product for a clinical trial, and for partial manufacture operations, including for putting safety features of medicinal products on the packaging of the medicinal product or for replacing them.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

(4) A manufacturing authorisation is not mandatory where the activities specified in subsection 2 of this section are carried out by the holder of a general pharmacy, hospital pharmacy or veterinary pharmacy authorisation (hereinafter *pharmacy service authorisation*) 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) A manufacturing authorisation is not required for the re-packaging, re-labelling and extemporaneous and serial manufacturing of a medicinal product intended for human use, which is investigated in a clinical trial, provided that it is performed by a pharmacy service authorisation holder and the medicinal product is used in the clinical trial only in Estonia.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

(6) Medicinal products imported to Estonia from countries outside of the European Economic Area (hereinafter *third countries*) are released for the purpose of dispensing thereof only by the manufacturing authorisation holder. This requirement does not apply to the import of medicinal products carried out under subsections 1, 7 and 8 of § 21 of this Act.

(7) A manufacturing authorisation holder ensures that the active substances of a medicinal product are manufactured and distributed in accordance with the principles of good manufacturing practice and good distribution practice established on the basis of Articles 47(3) and (4) of Directive 2001/83/EC of the European Parliament and of the Council. To verify it, the manufacturing authorisation holder must carry out audits at the sites of operation of the manufacturers and distributors of the active substances for human use. An audit may be outsourced from a third party, but it does not affect the responsibility of the manufacturing authorisation holder.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

(7^1) The holder of an authorisation to manufacture medicinal products for human use ensures that the excipients of a medicinal product are manufactured in compliance with relevant good manufacturing practice. To that end, the manufacturing authorisation holder must, on the basis of a risk assessment, ascertain the appropriate good manufacturing practice, following the guidelines set out in Article 47(5) of Directive 2001/83/EC of the European Parliament and of the Council and taking into account the requirements of other relevant quality systems, the origin of the excipients, the intended field of use and previous quality mistakes, and ensure adherence to the relevant manufacturing practice. The application of the measures arising from this subsection must be documented.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(7^2) The manufacturing of medicinal products and active substances must comply with the good manufacturing practice of the European Economic Area drawn up on the basis of Article 47 of Directive 2001/83/EC of the European Parliament and of the Council and the requirements provided in Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.08.1991, pp 70–73).
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(8) In accordance with the practices specified in subsection $7^2$of this section, the minister in charge of the policy sector establishes, by a regulation, the rules for manufacture of medicinal products, including the requirements applicable to facilities, installations, technical equipment, staff and work organisation. Such rules are not applicable to the manufacture of herbal substances.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(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 issues, within 30 days after the receipt of the request, a certificate that proves that a manufacturing authorisation has been issued to the manufacturer of medicinal products in Estonia. Where 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 appends an approved summary of the product characteristics to the certificate. Where 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.

(10) The conditions and rules of re-labelling, re-packaging and extemporaneous and serial manufacturing of a medicinal product investigated in a clinical trial are established by a minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

Subchapter 1^1
Making and Use of a Hospital-exemption Medicinal Product

[RT I, 03.01.2022, 2 - entry into force 13.01.2022]

§ 16[1]. Hospital exemption criteria

By way of the hospital exemption permission to make and use a hospital-exemption medicinal product (hereinafter *hospital exemption authorisation*) may be applied for, provided that application of the authorisation meets all of the following criteria:
1) no authorised advanced therapy medicinal product is available or marketed for the same therapeutic indication and the same patient group;
2) there is no clinical trial for the same therapeutic indication and the same patient group in the European Union or the patient has not been included in the trial;
3) there is no similar hospital-exemption medicinal product in Estonia for the same therapeutic indication and the same patient group;
4) existing therapies have been exhausted and using the medicinal product for the treatment of an individual patient is medically justified;
5) there is sufficient research data on the medicinal product, which allow for assuming that the benefits of the medicinal product outweigh possible risks related to using the medicinal product;
6) the custom-made medicinal product is made in Estonia on non-routine basis for an individual patient in a hospital and under the professional responsibility of a medical specialist;
7) the making of the medicinal product complies with the good manufacturing practice of advanced therapy medicinal products;
8) pharmacovigilance and the traceability of the medicinal product meet the requirements established for hospital-exemption medicinal products.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[2]. Application for a hospital exemption authorisation

(1) An application for a hospital exemption authorisation is submitted to the State Agency of Medicines by the maker of the medicinal product jointly with a designated competent person, medical specialist in charge of the use of the medicinal product, a person in charge of pharmacovigilance and a health care provider using the medicinal product.

(2) The maker of a hospital-exemption medicinal product may be:
1) a central hospital, regional hospital or specialised hospital within the limits of the health care services provided by it;
2) a research and development institution or a company connected therewith;
3) person holding the right to handle cells or tissues or an undertaking holding a medicinal product manufacturing authorisation.

(3) The user of a hospital-exemption medicinal product may, within the limits of its specialty, be a central hospital, regional hospital or specialised hospital that provides an intensive care or emergency care service.

(4) A hospital-exemption medicinal product may be used by a medical specialist holding relevant scientific qualifications in the specialty and clinical experience for prescribing the medicinal product to be made and who is in charge of using the medicinal product.

(5) The list of data and documents submitted when applying for a hospital exemption authorisation, the rules of submission of an application and the requirements for describing a hospital-exemption medicinal product are established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[3]. Duties of a holder of a hospital exemption authorisation

(1) The holder of a hospital exemption authorisation:
1) implements the requirements provided in clauses 1–2 and 11 of subsection 1 and clauses 2 and 3 of subsection 3 of § 44 of this Act to the appropriate extent in order to ensure the quality of the hospital-exemption medicinal product;
2) implements the requirements of the good manufacturing practice of advanced therapy medicinal products and the requirements established on the basis of subsection 8 of § 16 of this Act, subsection 3 of § 22 of the Procurement, Handling and Transplantation of Cells, Tissues and Organs Act and subsection 4 of § 8 of the Blood Act to the appropriate extent to ensure the quality of the hospital-exemption medicinal product;
3) ensures the traceability of the hospital-exemption medicinal product starting from the procurement of source and raw material and manages it for 30 years after the use of the medicinal product;
4) when using blood, cells and tissues of human origin for making a hospital-exemption medicinal product concludes a written contract with a blood bank, supplier or handler in order to agree on the parties' rights and

obligations, the rules of exchange of information and the rules of notifying of serious adverse reactions and events;
5) every three months after the issue of the authorisation submits to the State Agency of Medicines the data required on the basis of subsection 6 of this section regarding the making and using of the hospital-exemption medicinal product;
6) every three months after the issue of the authorisation submits to the State Agency of Medicines a list of the adverse reactions in using the hospital-exemption medicinal product along with a description of the adverse reactions and an assessment of a link between the adverse reaction and the medicinal product;
7) within six months from the expiry of the validity of the authorisation submits to the State Agency of Medicines a final report that contains a list of adverse reactions in using the hospital-exemption medicinal product along with a description of the adverse reactions, an assessment of a link between the adverse reaction and the medicinal product and data on the efficacy of the medicinal product;
8) follows the requirements established in the Helsinki Declaration of the World Medical Association and in other international guidelines.

(2) In using a hospital-exemption medicinal product, the provisions of § 763 of the Law of Obligations Act are applied to informing the patient and to the patient's consent. The patient's consent must be granted in writing.

(3) The holder of a hospital exemption authorisation is required to perform the duties provided in clauses 3 and 4 of subsection 1 of this section also in the event of suspension or revocation of the hospital exemption authorisation.

(4) In the event of bankruptcy or liquidation of the holder of a hospital exemption authorisation, the data collected on the basis of clause 3 of subsection 1 of this section must be handed over to the State Agency of Medicines.

(5) Where the maker and user of a hospital-exemption medicinal product are not the same person, the maker and the user agree on the division of duties in a written contract.

(6) The list of data required in a summary of making and using a hospital-exemption medicinal product is established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[4]. Issue of a hospital exemption authorisation and data given in the authorisation

(1) A hospital exemption authorisation is issued within 120 days after the all of the data and documents required under subsection 5 of § 16[2]of this Act have been submitted to the State Agency of Medicines for assessment of the quality, efficacy and pharmacovigilance of the hospital-exemption medicinal product.

(2) Before issuing a hospital exemption authorisation, the State Agency of Medicines may involve non-staff experts, the Health Board and the ethics committee in assessing the hospital-exemption medicinal product.

(3) The names of the medicinal product and active substance, the medical indication of the medicinal product, details of the manufacturer of the medicinal product, competent person of the holder of the hospital exemption authorisation, the health care provider using the medicinal product, the medical specialist in charge of using the medicinal product, the person in charge of pharmacovigilance and the terms of validity of the authorisation.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[5]. Validity of a hospital exemption authorisation

(1) A hospital exemption authorisation is valid for up to two years or for the treatment of up to ten patients.

(2) The State Agency of Medicines may renew the validity of a hospital exemption authorisation by up to two years where the hospital-exemption medicinal product is ready for the treatment of up to ten patients, the quality of the medicinal product is ensured, the ratio of the efficacy and risk emanating from the medicinal product remains favourable and the requirements for the making and use of the medicinal product have been met.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[6]. Revision of terms serving as the basis for granting a hospital exemption authorisation and refusal to revise

(1) To revise the data or terms serving as the basis for granting a hospital exemption authorisation, the applicant for the hospital exemption authorisation submits to the State Agency of Medicines an application not later than 30 days before the implementation of the planned revision.

(2) The State Agency of Medicines must be informed of a change that has occurred independently from the holder of the hospital exemption authorisation and, depending of the nature of the change, an application for the revision of the data or terms serving as the basis for granting the authorisation must be submitted.

(3) The State Agency of Medicines makes a decision to revise or refuse to revise the terms of a hospital exemption authorisation within 30 days after the submission of all of the required documents. The State Agency

of Medicines may extend the time of making a decision by up to 30 days in the case of a change that calls for more extensive assessment or collection of additional data.

(4) A change may be implemented after the receipt of an approving decision from the State Agency of Medicines.

(5) The list of data to be submitted in the event of changes in the terms serving as the basis for granting a hospital exemption authorisation is established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[7]. Suspension and revocation of a hospital exemption authorisation

(1) The State Agency of Medicines may suspend the validity of a hospital exemption authorisation in the event of a change that has occurred independently from the holder of the authorisation until a decision to revise the terms serving as the basis for granting the authorisation has been made.

(2) The State Agency of Medicines revokes a hospital exemption authorisation where:
1) the terms serving as the basis for granting the authorisation have not been met or have changed and the authorisation holder has not applied for revision or the revision applied for has not been approved by the State Agency of Medicines;
2) the authorisation holder does not meet the requirements provided in an Act or legislation established on the basis thereof;
3) new information about the medicinal product becomes evident, which, in comparison with the information submitted for applying for the authorisation, confirms lower efficacy or higher dangerousness of the medicinal product or according to which the efficacy and risk ratio of the medicinal product proves to be unfavourable, given the contemporary level;
4) an authorised medicinal product for the same therapeutic indication and the same patient group has become available.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[8]. Refusal to issue a hospital exemption authorisation and to revise terms serving as the basis for granting a hospital exemption authorisation

(1) The State Agency of Medicines refuses to grant a hospital exemption authorisation where the application does not meet the criteria of the hospital exemption authorisation or at least one of the circumstances specified in clauses 1–5 or 9 of subsection 1 of § 74 of this Act is missing.

(2) The State Agency of Medicines refuses to revise the terms of a hospital exemption authorisation where the change:
1) does not meet the terms of granting the authorisation;
2) calls for the submission of a new application for an authorisation;
3) brings about important changes in the quality, efficacy or safety of the medicinal product.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[9]. Pharmacovigilance of a hospital-exemption medicinal product

(1) The holder of a hospital exemption authorisation performs all of the duties of ensuring pharmacovigilance, which have been established to the holder of the marketing authorisation of the medicinal product in § 78[3] of this Act.

(2) The holder of a hospital exemption authorisation informs the State Agency of Medicines of a serious adverse event without any unreasonable delay, but not later than within 24 hours after learning of the adverse event.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

§ 16[10]. Traceability of a hospital-exemption medicinal product

(1) The holder of a hospital exemption authorisation performs all of the duties of ensuring the traceability of the medicinal product which have been established to a holder of an advanced therapy medicinal product under Article 15 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council and in the good manufacturing practice of advanced therapy medicinal products.

(2) The list of data retained for ensuring the traceability of a hospital-exemption medicinal product is established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

Subchapter 1[2]
Making of a Radiopharmaceutical Preparation

[RT I, 03.01.2022, 2 - entry into force 01.02.2022]

§ 16[11]. Authorisation for making a radiopharmaceutical preparation

(1) An authorisation for making a radiopharmaceutical preparation may be applied for by a central hospital or a regional hospital where radiopharmaceutical preparations are used within the medical institution.

(2) In an application for an authorisation for making a radiopharmaceutical preparation, the following documents and data are given:
1) the layout and description of the premises of the place of business;
2) a description of the technical equipment;
3) a description of preservation of preparations;
4) organisation of the quality control of preparations;
5) the persons in charge of making preparations and documents certifying their education and work experience;
6) the list of preparations made;
7) the scheme and a brief description of the processes of making preparations;
8) a description of the organisation of the maintenance of the premises and equipment;
9) a description of the organisation of validation and calibration;
10) the list of undertakings performing commissioned work and the content of the commissioned work;
11) a description of the transport of preparations;
12) a description of the quality assurance system;
13) the classification of the premises where preparations are made, the types of construction and finishing materials;
14) the schemes of movement of the staff and materials;
15) a simplified scheme and description of the ventilation system, the types of the filters;
16) a simplified scheme and description of the water system and the water quality classes where water is used in making preparations;
17) the organisation chart of the undertaking.

(3) The State Agency of Medicines decides the granting of or refusal to grant an authorisation for making a radiopharmaceutical preparation within 60 days after the submission of an application and all of the required documents and data.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 16[12]. Duties of a holder of an authorisation for making a radiopharmaceutical preparation

(1) The holder of an authorisation for making a radiopharmaceutical preparation is required to:
1) ensure the conditions for making radiopharmaceutical preparations in compliance with the requirements of this Act and legislation established on the basis thereof and with those of other legislation regulating the handling of medicinal products;
2) apply a quality system that sets out, among other things, the responsibility, processes and risk management measures;
3) appoint a person in charge of making radiopharmaceutical preparations;
4) provide the person in charge and, in their absence, their replacement with conditions and means required for the performance of their duties;
5) make certain that the manufacturers, importers and wholesalers from whom components for making radiopharmaceutical preparations are acquired have received a respective authorisation for such activity from the competent authority of their Member State of location;
6) check the genuineness and quality of components used in making radiopharmaceutical preparations;
7) keep account of making radiopharmaceutical preparations and submit to the State Agency of Medicines reports thereon in accordance with the rules provided in subsection 2 of this section.

(2) The conditions and rules of making a radiopharmaceutical preparation and a radiopharmaceutical preparation used as an investigational diagnostic medicinal product and requirements for the qualifications of a person in charge of making a radiopharmaceutical preparation are established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 16[13]. Refusal to grant an authorisation for making a radiopharmaceutical preparation

The State Agency of Medicines refuses to grant an authorisation to make a radiopharmaceutical preparation where the applicant does not or the documents or data given in the application do not meet the criteria of an authorisation for making a radiopharmaceutical preparation or an authorisation for handling medicinal products is required for the activity applied for.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 16[14]. Revision of and refusal to revise an authorisation for making a radiopharmaceutical preparation

(1) To change the date or conditions that serve as the basis for granting an authorisation for making a radiopharmaceutical preparation, an authorisation holder submits to the State Agency of Medicines an application not later than 30 days before the implementation of the planned change along with the documents and data listed in subsection 2 of § 16[11] of this Act as per substance of the change.

(2) The State Agency of Medicines refuses to change the conditions of an authorisation for making a radiopharmaceutical preparation where the grounds provided in § 16[13] of this Act exist.

(3) The State Agency of Medicines makes a decision to revise or refuse to revise the terms of an authorisation within 60 days after the submission of an application and all of the required documents and data.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 16[15]. Revocation of an authorisation for making a radiopharmaceutical preparation

The State Agency of Medicines revokes an authorisation for making a radiopharmaceutical preparation where:
1) the conditions serving as the basis for granting the authorisation have not been met or have changed and the authorisation holder has not requested a change;
2) the authorisation holder does not meet the requirements provided in an Act or legislation established on the basis thereof.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

Subchapter 2
Import and Export of Goods Requiring Special Authorisation of State Agency of Medicines, and Authorisation for Distribution of Unauthorised Medicinal Products

[RT I, 15.12.2023, 3 - entry into force 25.12.2023]

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

(1) The list of goods which require a special authorisation of the State Agency of Medicines (hereinafter *special authorisation*), which includes medicinal products, including investigational 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*) is established by a regulation of the minister in charge of the policy sector.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 Union or a member state of the European Economic Area to Estonia.
[RT I, 12.07.2014, 1 – entry into force 01.01.2015]

(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 Union or to a member state of the European Economic Area.
[RT I, 12.07.2014, 1 – entry into force 01.01.2015]

(4) In all events of import or export specified in subsections 2 and 3 of this section, the import or export authorisation or notification of the State Agency of Medicines of import or export is deemed to be the special authorisation.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(5) An active substance may be imported for the manufacture of a medicinal product for human use, provided that it has been manufactured in accordance with the good manufacturing practices of the European Economic Area or equivalent requirements.
[RT I, 17.04.2013, 2 – entry into force 02.07.2013]

(6) An active substance imported for the manufacture of a medicinal product for human use must be accompanied by a written confirmation of the competent authority of the exporting non-Community state, which confirms that the plant manufacturing the active substance is subject to requirements equivalent to the good manufacturing practices of the European Economic Area, the competent authority exercises regular, strict and transparent supervision over the plant and that, in the event of detecting the non-compliance of the active substance, the competent authority immediately informs the competent authority of the state that imported the active substance. A written confirmation does not influence the liability of the manufacturing authorisation holder.
[RT I, 17.04.2013, 2 – entry into force 02.07.2013]

(7) The written certificate specified in subsection 6 of this section is not required where the exporting state has been included in the list specified in Article 111b of Directive 2011/83/EC of the European Parliament and of the Council.
[RT I, 17.04.2013, 2 – entry into force 02.07.2013]

(8) By way of exception, the State Agency of Medicines may, for the purpose of ensuring the availability of a medicinal product, grant authorisation to import the active substance without applying the requirement set out in subsection 6 of this section where the competent authority of a member state of the European Economic Area has inspected the plant manufacturing the exported active substance and found that the manufacturing of the active substance complies with the good manufacturing practices of the European Economic Area. The period of application of the exception must not exceed the term of validity of the certificate of good manufacturing practices. The State Agency of Medicines informs the European Commission of the application of the exception.
[RT I, 17.04.2013, 2 – entry into force 02.07.2013]

§ 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 a wholesale distribution authorisation;
2) holders of a manufacturing authorisation, for the purposes of manufacturing of their own produce and within the scope thereof, whereas holders of a manufacturing authorisation 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) [repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]
4) holders of a health service provider authorisation – investigational medicinal products, unauthorised medicinal products on the basis of clause 4 of subsection 7 and clause 2 of subsection 8 of § 21 of this Act, and medicinal products for foreign aid;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
4^1) holders of an authorisation to acquire or handle cells, tissues and organs – cells, tissues and organs of human or animal origin used for medical purposes and handling;
[RT I, 26.02.2015, 1 – entry into force 01.03.2015]
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.

(1^1) Holders of a professional activity licence of a veterinarian and holders of a general pharmacy and a veterinary pharmacy authorisation also have the right to import veterinary medicinal products requiring special authorisation to Estonia.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(2) [Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3) Only a manufacturing authorisation holder is permitted to import medicinal products directly from third countries to Estonia. The specified requirement does not apply in the event of medicinal products imported under subsections 1, 7 and 8 of § 21 of this Act and upon medicinal products received as foreign aid and medicinal products used in non-clinical research.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(4) An importer or exporter of goods requiring special authorisation is the recipient or sender of goods requiring special authorisation specified in subsection 1 of this section.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 19. Special import and export authorisation

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(1) For the import or export of goods requiring special authorisation:
1) an import authorisation must be obtained from the State Agency of Medicines for import;

2) the State Agency of Medicines must be notified of conveyance of goods from Estonia to a Member State of the European Union or a Member State of the European Economic Area or from a Member State of the European Union or a Member State of the European Economic Area to Estonia, and of export of goods, except in the case of the goods specified in subsections 2 and 3^1 of this section.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(2) Import or export authorisation of the State Agency of Medicines is required for the import or export of narcotic drugs and psychotropic substances.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3) [Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3^1) In the cases provided in clause 2 of subsection 1 of this section, the notification obligation is not applied to an unauthorised medicinal product not intended for distribution in Estonia, and in the case of an investigational medicinal product and auxiliary medicinal product used in a clinical trial of a medicinal product, provided that a marketing authorisation valid in the European Economic Area has been granted in respect of the auxiliary medicinal product.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3^2) The requirements provided in clause 2 of subsection 1 of this section are applied upon import of medicinal products on the basis of clauses 1 and 2 of subsection 7 of § 21 of this Act, provided that a marketing authorisation has been granted in respect of the medicinal products in a Member State of the European Economic Area.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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.

(4^1) Upon import of goods requiring special authorisation, the recipient of the goods is required to apply for an import authorisation or notify the State Agency of Medicines. Upon export of goods requiring special authorisation, the sender of the goods is required to apply for an export authorisation or notify the State Agency of Medicines.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(5) The minister in charge of the policy sector establishes by a regulation:
1) the conditions of and procedure for the import and export of goods requiring special authorisation of the State Agency of Medicines and carrying for personal use and sending of medicinal products;
2) the conditions under which special authorisation of the State Agency of Medicines is required for the import or export of tissues, cells and organs of human or animal origin used for medical or research purposes.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

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

(1) Goods requiring special authorisation included in the medicinal products carried for first-aid purposes and used for the performance of their duties by ambulance crews, Estonian and foreign rescue teams, the Security Police Board, the armed forces of foreign states staying in the territory of the Republic of Estonia and the Defence Forces are exempt from import and export restrictions arising from this Act.

(2) Goods requiring special authorisation included in and required for restocking the medicinal products carried for first-aid purposes on board of ships and aircraft engaged in international transportation are exempt from import and export restrictions arising from this Act.

(3) An importer or exporter of the goods specified in subsection 1 of this section, except an ambulance crew and the Security Police Board, prepares a list of the goods requiring special authorisation before import or export. At the request of the State Agency of Medicines, the importer or exporter mentioned above must submit such list to the State Agency of Medicines.

(4) An authorisation of the State Agency of Medicines is required for the distribution of goods requiring special authorisation in Estonia for a charge or without charge by Estonian or foreign rescue teams, the armed forces of foreign states staying in the territory of the Republic of Estonia or the Defence Forces.

(5) As an extraordinary measure, the State Agency of Medicines may ban the export of a medicinal product where the continuous supply of the medicinal product is important from the point of view of human or animal health and where other medicinal products with the same active substance and strength are either not distributed or are distributed in an insufficient quantity in Estonia.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 21. Authorisation for distribution of unauthorised medicinal product

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(1) Unauthorised medicinal products for human use may be distributed, provided that an authorised medicinal product with suitable effect is not available or distributed according to treatment needs and the State Agency of Medicines has granted an authorisation for the distribution of an unauthorised medicinal product at the medically justified request of a doctor qualified to prescribe the medicinal product (hereinafter *authorisation for distribution of unauthorised medicinal product*).

(2) A doctor qualified to prescribe the medicinal product must submit an application for an authorisation for distribution of an unauthorised medicinal product to the State Agency of Medicines.

(3) The list of data of an application for an authorisation for distribution of an unauthorised medicinal product and the conditions of and procedure for the submission of an application are established by a regulation of the minister in charge of the policy sector.

(4) The State Agency of Medicines verifies the information and documents submitted by the applicant and decides, within 30 days after receipt of the application, whether the distribution of the unauthorised medicinal product is justified.

(5) The distribution of an unauthorised medicinal product is not justified where at least one of the following circumstances exists:
1) the applicant has not submitted an application which complies with the requirements and the procedure established on the basis of subsection 3 of this section;
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 is not medically justified or there is an alternative medicinal product with equivalent effect and a marketing authorisation, which is distributed according to treatment needs;
5) the applicant knowingly submits incorrect information.

(6) An authorisation for distribution of an unauthorised medicinal product granted by the State Agency of Medicines does not ensure the quality, safety or efficacy of such medicinal product. Grant of an authorisation for distribution of an unauthorised medicinal product does not release the applicant for the authorisation for distribution of the medicinal product or 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 authorised medicinal products with equivalent effect or where such products are not distributed according to treatment needs, the State Agency of Medicines may, in addition to the provisions of subsection 1 of this section, grant an authorisation for distribution of:
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 the use in national programmes;
4) medicinal products offered free of charge by the manufacturer of medicinal products provided that the doctor providing treatment to the patient has confirmed that the medicinal product is necessary for life-saving purposes and there are no other options for the treatment of a chronic or life-threatening illness and also provided that the illness is deemed life-threatening and all other treatment methods for which the payment obligation is assumed by the Estonian Health Insurance Fund and that are medically suitable and financially accessible to the person have been exhausted, and it is likely that the benefits of the medicinal product outweigh possible risks.

(8) In addition to the events specified in subsections 1 and 7 of this section, the State Agency of Medicines may also grant an authorisation for distribution of an unauthorised medicinal product:
1) during an emergency, an emergency situation, a state of emergency or a state of war;
2) on the basis of Article 83 of Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.04.2004, pp 1–33).

(9) The State Agency of Medicines may grant an authorisation for temporary distribution of an unauthorised medicinal product or allow the use of a medicinal product on conditions not approved by a marketing authorisation in connection with a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation. The marketing authorisation holder, manufacturer of the medicinal products and a health care professional are not liable for the consequences resulting from the use of the medicinal product where the medicinal product is used on the basis of an authorisation for temporary distribution specified above or according to the conditions not approved by a marketing authorisation.

(10) Unauthorised medicinal products in respect of which a marketing authorisation has been granted by at least one of the Member States of the European Economic Area may be imported before the receipt of an

authorisation for distribution of an unauthorised medicinal product specified in subsection 1 of this section, taking account of the requirements provided in § 19 of this Act.

(11) Unauthorised medicinal products in respect of which no marketing authorisation has been granted by any of the Member States of the European Economic Area, may be imported on the basis of an import authorisation and dispensed to persons with the right to handle medicinal products only on the basis of an authorisation for distribution of unauthorised medicinal products.

(12) Distribution of unauthorised medicinal products to other persons with the right to handle medicinal products is permitted only on the basis of an authorisation specified in subsection 1, 7, 8 or 9 of this section.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 22. Application for import and export authorisation

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(1) For obtaining import and export authorisation, an application 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 granted by the competent authority of the state to which the goods are to be conveyed.

(3) An application in compliance with the requirements of the regulation established on the basis of clause 1 of subsection 5 of § 19 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 a Member State of the European Economic Area.

(4) The number of the authorisation for distribution of an unauthorised medicinal product granted by the State Agency of Medicines or a reference to the application of a professional organisation of doctors must be indicated in the application for an import authorisation of the unauthorised medicinal product.

(5) Upon import of an unauthorised medicinal product, a medicinal product in respect of which a marketing authorisation has been granted by a competent authority of a Member State of the European Economic Area must be preferred. Information concerning the quality of the medicinal product must be submitted at the request of the State Agency of Medicines. Where the requirement provided in the first sentence cannot be complied with, documents concerning the quality of the medicinal product and the reasons why a medicinal product in respect of which a marketing authorisation has been granted by a Member State of the European Economic Area cannot be preferred must be submitted together with the application.

(6) An import and export authorisation is granted for a single act of import or export and for no longer than three months. In justified cases, the State Agency of Medicines may extend the validity of an import and export authorisation of narcotic drugs and psychotropic substances for up to six months.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 23. Distribution authorisation

[Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 24. Grant of import and export authorisation

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(1) The State Agency of Medicines decides on the grant of an import or export authorisation within five working days after receipt of an application and required information and documents.

(2) Upon application for an import authorisation of an unauthorised medicinal product, additional information concerning the packaging of the medicinal product, the manufacturing site of the medicinal product and the quality of the batch must be submitted at the request of the State Agency of Medicines.

(3) Where necessary, the State Agency of Medicines enters a notation concerning the packaging of the medicinal product and information necessary for the delivery of the medicinal product on the import authorisation of the unauthorised medicinal product.

(4) The State Agency of Medicines may refuse to grant an import or export authorisation where 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 compliance notice for compliance with the requirements provided by this Act or legislation established on the basis thereof and the obligation set out in the compliance notice has not been complied with;
3) the State Agency of Medicines has information casting doubt on the quality of the medicinal product;
4) the State Agency of Medicines has information casting doubt on the requisite handling of the medicinal product;
5) 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;
6) upon application for an import authorisation of an unauthorised medicinal product, there are no documents concerning the quality of the medicinal product or the reasons why a medicinal product in respect of which a marketing authorisation has been granted by a Member State of the European Economic Area cannot be preferred are insufficient.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 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 5 of § 19 of this Act. Travellers are forbidden to carry full blood and blood components.

(2) Medicinal products may be sent to foreign countries or to Estonia in quantities permitted by the regulation established on the basis of subsection 5 of § 19 of this Act. It is prohibited to send anabolic steroids, narcotic drugs and psychotropic substances, full blood and blood components, cells and tissues for medicinal use, and advanced therapy medicinal products.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(3) [Repealed – RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(4) Where 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 5 of § 19 of this Act before the performance of the acts.

Subchapter 3
Wholesale Distribution and Brokering of Medicinal Products

[RT I, 17.04.2013, 2 - entry into force 27.04.2013]

§ 26. Wholesale distribution and brokering of medicinal products

[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(1) Only a wholesale distribution authorisation holder and a manufacturing authorisation holder have the right to distribute and dispense medicinal products by way of wholesale.

(2) A manufacturing authorisation holder who wishes to engage in the wholesale distribution of medicinal products which are not manufactured by the authorisation holder 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 4 and 5 of § 54 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.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(3^1) The exceptional delivery of a veterinary medicinal product in small quantity from one holder of a professional activity licence of a veterinarian to another is not deemed to be wholesale distribution of medicinal products. The amount of medicine necessary to immediately ensure the health or welfare of an animal, which does not exceed the amount of medicine necessary for the treatment for two months, is considered to be a small quantity. A veterinary medicinal product must be delivered in its original packaging or immediate packaging.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(4) Medicinal products must be distributed and dispensed in any other manner by way of wholesale only to persons who hold a pharmacy service authorisation, manufacture of medicinal products or wholesale distribution of medicinal products.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(5) Holders of a wholesale distribution authorisation 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]

(5^1) Wholesale distribution authorisation holders or manufacturing authorisation holders may dispense veterinary medicinal products that have the pharmaceutical form of a pre-mix of medicated feed to operators of feed who have been granted an authorisation to manufacture medicated feed or intermediate products on the basis of the Feed Act.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(6) The State Agency of Medicines may allow wholesale distribution authorisation holders and manufacturing authorisation holders 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*).

(7^1) Upon wholesale distribution of medicinal products and other dispensing of medicinal products, it must be verified that the person whom the medicinal product is distributed is authorised to engage in the respective activity in the Member State of their location.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

(8) Wholesale distribution authorisation holders may procure medicinal products only from manufacturing authorisation holders or wholesale distribution authorisation holders, or from pharmacy service authorisation holders. Medicinal products may be acquired from pharmacy service authorisation holders only in the events specified in clause 11 of § 45 of the Medicinal Products Act and for the purpose of import of medicinal products.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(8^1) The wholesale distribution of medicinal products and active ingredients for human use and the brokering of medicinal products for human use must comply with the good distribution practices established on the basis of Article 47(4) and Article 84 of Directive 2001/83/EC of the European Parliament and of the Council.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(8^2) A broker of medicinal products must ensure that brokered medicinal products have the marketing authorisation issued by the European Commission or the competent authority of a Member State.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(9) The following are established by a regulation of the minister in charge of the policy sector:
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) [repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 27. Wholesale distribution of medicinal products to veterinarians

(1) Veterinary medicinal products and medicinal products for human use may be sold wholesale to a veterinarian holding a valid professional activity licence only on the conditions and in accordance with the procedure established under clause 1 of subsection 9 of § 26 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 a veterinarian.
[RT I, 06.06.2014, 1 – entry into force 01.07.2014]

(2) The following may pay for medicinal products ordered by a veterinarian:
1) an undertaking engaged in agricultural production where 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 having a contractual relationship with the veterinarian.
[RT I, 06.06.2014, 1 – entry into force 01.07.2014]

(3) Where, 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, legal persons in public law, 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 in charge of the policy sector.
[RT I, 21.12.2018, 4 – entry into force 01.01.2019]

(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.

Subchapter 4
Pharmacy Service

§ 29. Pharmacy service

(1) 'Pharmacy service' 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) The pharmacy service must be provided only in pharmacies holding a corresponding authorisation 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 the pharmacy service in a pharmacy or structural unit thereof. Veterinarians may also provide the pharmacy service 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 the pharmacy service 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 the pharmacy service, 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 the pharmacy service, 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 emergency medical care authorisation.

(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) The structural unit of a hospital pharmacy and a veterinary pharmacy is a branch pharmacy. The structural unit of a general pharmacy is a branch pharmacy and a pharmacy bus. The location of the branch of a general pharmacy and veterinary pharmacy must be marked by the name of the general pharmacy accompanied by the word ' *haruapteek*' [branch pharmacy]. A pharmacy bus must bear the name of the general pharmacy accompanied by the word ' *apteegibuss*' [pharmacy bus].
[RT I, 06.06.2014, 14 – entry into force 15.07.2014]

(9^1) A branch pharmacy of a general pharmacy may be located in a settlement unit that is not a city. A branch pharmacy of a general pharmacy may be located in a settlement unit that is a city where there are less than 4,000 inhabitants. In a settlement unit that is a city where there are more than 4,000 inhabitants, a branch pharmacy of a general pharmacy may also be located in a city district, provided that the nearest pharmacy in the city is located at a distance of at least 10 kilometres and there is a justified need for the availability of medicinal products in the area.
[RT I, 06.05.2020, 1 – entry into force 07.05.2020]

(10) The requirements established for the corresponding pharmacy category apply to the activities of a branch pharmacy and a pharmacy bus. The structural units of a pharmacy are specified in the pharmacy service authorisation.
[RT I, 06.06.2014, 14 – entry into force 15.07.2014]

(11) The requirements provided in subsection $9^1$of this section do not apply to a branch of a general pharmacy located in the airport security check area. Also, the requirements provided in subsections 1–4 of § 32 of this Act do not apply to such general pharmacy and branch of a general pharmacy.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 31. General requirements for activities of pharmacies

(1) Only authorised medicinal products or unauthorised medicinal products in respect of which an authorisation for distribution has been granted, and medicinal products prepared as magistral formulae or officinal formulae and medicinal products divided up into retail packaging by the pharmacy may be dispensed by a pharmacy, taking account of the conditions prescribed by § 32 of this Act.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(2) [Repealed – RT I, 17.04.2013, 2 – entry into force 01.07.2013]

(3) A pharmacy is required to procure medicinal products only from an enterprise belonging to a manufacturing authorisation holder or wholesale distribution authorisation holder, 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 and prepare also products for medical purposes and toiletries, including food supplements and natural products, provided that their sale and preparation does not interfere with the sale or preparation of medicinal products. A general pharmacy service authorisation holder must inform the State Agency of Medicines about the commencement of the preparation of such products. A general pharmacy may also sell medicated feed for pets. Only veterinary medicinal products, animal care products and other products used in animal-keeping, including medicated feed may be sold in a veterinary pharmacy.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(5^1) A general pharmacy authorisation holder has the right to engage in the distance selling of medicinal products for human use and over-the-counter medicinal products for veterinary use. The distance selling of medicinal products means the retail sale of medicinal products as an information society service. Upon distance selling, the provider of the pharmacy service engaged in the distance selling of medicinal products must follow the requirements provided in this Act, the Information Society Service Act and the Law of Obligations Act.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(5^2) The State Agency of Medicines authorises the distance selling of medicinal products on the basis of an application where the requirements and conditions of the distance selling of medicinal products have been fulfilled and the state fee has been paid.
[RT I, 06.06.2014, 14 – entry into force 02.07.2014]

(5^3) The distance selling of medicinal products is permitted only on a website that contains a logo complying with the technical, electronic and cryptographic requirements specified in Article 85c(3) of Directive 2011/83/EC of the European Parliament and of the Council.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(5^4) A pharmacy service provider engaged in the distance selling of medicinal products must ensure common conditions of sale and delivery of consignments, including the size of the delivery fee based on the manner of delivery of the consignment throughout the territory of Estonia.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(5^5) Medicinal products must be delivered to the address indicated by the client within three working days after the confirmation of the order, unless the client has requested a later delivery of the medicinal products or where the adherence to the term is impossible for a reason beyond the control of the pharmacy service provider.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(5^6) The size of the delivery fee of medicinal products must not depend on the medicinal products dispensed, the price of the order or the number of the medicinal products or consignments to the client.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(5^7) A pharmacy service provider may organise the delivery of medicinal products issued by the same pharmacy. The delivery of medicinal products is subject to requirements established to the delivery of medicinal products by way of distant sale, except for the provisions of subsection $5^4$of this section.
[RT I, 06.06.2014, 14 – entry into force 09.06.2014]

(5^8) Where a corresponding right exists, a pharmacy service provider may provide the pharmacy service via video call. The State Agency of Medicines grants the right to provide the pharmacy service via video call on the basis of a corresponding application, provided that the requirements for and conditions of the provision of such service are complied with. The pharmacy service may be provided via video call without the presence of a pharmacist or assistant pharmacist only in a branch pharmacy located in a settlement unit that is not a city and has no other provider of the pharmacy service.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(6) The following are established by a regulation of the minister in charge of the policy sector:
1) the conditions of 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 the pharmacy service, including the requirements for premises, installations, technical equipment, staff, recording and reporting regarding medicinal products, organisation of work, distance selling of medicinal products and provision of the pharmacy service via video call.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(7) In a regulation established on the basis of clause 3 of subsection 6 of this section, different requirements may be established regarding the premises and technical equipment of general pharmacies depending on the pharmacies being located in a city or in a settlement unit that is not a city. In the regulation, variations from requirements established regarding general pharmacies may be established for hospital pharmacies and veterinary pharmacies.
[RT I, 04.07.2017, 2 – entry into force on the day of announcement of the results of the 2017 elections of municipal councils]

(8) The State Agency of Medicines publishes on its website the list of pharmacies engaged in the distance selling of medicinal products along with the addresses of the respective websites.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(9) The State Agency of Medicines publishes on its website the following information about the distance selling of medicinal products:
1) information about the legislation that applies to the distance selling of medicinal products, including information about the fact that the classification of proprietary medicinal products and the conditions applicable to the sale and delivery of medicinal products may differ between Member States;
2) information about the purpose of the common logo used upon distance selling of medicines in the European Economic Area;
3) information about risks related to medicinal products provided illegally by way of distance selling.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(10) The website of the State Agency of Medicines contains a hyperlink to the website of the European Medicines Agency which provides information about the distance selling of medicinal products in the European Union.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

§ 31[1]. Duty to provide the pharmacy service

[Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 32. Preparation of medicinal products in pharmacies

(1) The pharmacy service authorisation holder has the obligation to prepare non-sterile medicinal products in a general pharmacy that is located in a city that is a settlement unit with 4000 or more inhabitants. In a veterinary pharmacy, the pharmacy service authorisation holder does not have the right to prepare medicinal products.
[RT I, 06.06.2014, 14 – entry into force 09.06.2019, amended in part [RT I, 04.07.2017, 2]]

(2) Taking account of the specifications arising from subsection 1 of this section, the pharmacy service authorisation holder has the obligation to prepare medicinal products as magistral formulae on the basis of a medical prescription or an order form or for its structural unit. Where a pharmacy does not have the right to prepare sterile medicinal products, a medicinal product must be ordered to the pharmacy from a pharmacy that holds the right to prepare sterile medicinal products.
[RT I, 06.06.2014, 14 – entry into force 15.07.2014]

(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 pharmacy service authorisation holder has the obligation to accept medical prescriptions for preparation of medicinal products as magistral formulae via a structural unit of the general pharmacy and to immediately forward the order for preparation of the medicinal product to the general pharmacy and the latter must ensure that the medicinal product prepared as magistral formula is prepared and dispensed from the structural unit within a reasonable amount of time.
[RT I, 06.06.2014, 14 – entry into force 15.07.2014]

(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 1 of subsection 6 of § 31 of this Act.

(6) A pharmacy service authorisation holder may dispense from a general pharmacy and a veterinary pharmacy medicinal products prepared as magistral formula or divided up into retail packaging to its structural unit or another pharmacy for resale 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.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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.

(8) The State Agency of Medicines may permit special rules regarding the requirements for preparation of a medicinal product, preparation for administration of a medicinal product and dividing-up into retail packaging in a pharmacy, provided that other medicinal products with the same active substance and strength are either not distributed or are distributed in an insufficient quantity in Estonia.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 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]) On the basis of an electronic prescription of the European Union, medicinal products may be issued via the cross-border health record exchange platform specified in subsection 1 of § 50[7] of the Health Services Organisation Act to a person whom the prescription has been issued.
[RT I, 10.11.2018, 1 – entry into force 11.11.2018]

(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) where the prescription sets out information the composition of which is established by a regulation of the minister in charge of the policy sector.
[RT I 2010, 7, 31 – entry into force 26.02.2010]

(1^3) The issue of prescription medicinal products by way of distance selling is permitted only on the basis of a prescription issued electronically and recorded in the Prescriptions Centre.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(1^4) Doctors, dentists, midwives and nurses who have acquired a nursing specialty specified in a regulation established on the basis of subsection 2 of § 24 of the Health Services Organisation Act and nurses working together with family doctors authorised to provide a health service have the right to issue prescriptions for medicinal purposes and for the purpose of the outpatient treatment of another person treated by them.
[RT I, 20.06.2022, 3 – entry into force 30.06.2022]

(1^5) A nurse working together with a family doctor operating on the basis of the list of family doctors has the right to issue prescriptions where the nurse has completed supplementary training in clinical pharmacology, which is reflected in the health administration information system.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(1^6) As of the third year of residency, a doctor-resident has the right to issue prescriptions equal to that of a doctor who has acquired the respective speciality of specialised medical care.
[RT I, 30.12.2015, 2 – entry into force 01.03.2016]

(1^7) Nurses who have acquired a nursing specialty specified in a regulation established on the basis of subsection 2 of § 24 of the Health Services Organisation Act have the right to issue prescriptions for medicinal products in the case they have completed master's studies in health sciences at Tallinn Health Care College or Tartu Health Care College and acquired a nursing specialty as of the academic year 2019/2020 or in the case they have completed supplementary training in clinical pharmacology, which is reflected in the public register of health care professionals.
[RT I, 20.06.2022, 3 – entry into force 30.06.2022]

(1^8) A doctor, dentist, nurse or midwife who issues a prescription is responsible for the reasonableness of the prescription and for the compliance of the prescription with legislation.
[RT I, 30.12.2015, 2 – entry into force 01.03.2016]

(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.

(2^1) The delivery of medicinal products ordered by way of distance selling is permitted only from a pharmacy holding the right provided in subsection $5^2$of § 31 of this Act and from a pharmacy holding the respective right and having a place of business in a member state of the European Economic Area or Switzerland, except in the events provided in the second sentence of subsection 2 of § 25 of this Act.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(2^2) In the event of distance selling of medicinal products to a member state of the European Economic Area, the medicinal product must comply with the marketing authorisation in force in the member state of destination.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(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 is 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.

(6^1) Where the continuous supply of a medicinal product is important from the point of view of human or animal health and where other medicinal products with the same active substance and strength are either not

distributed or are distributed in an insufficient quantity in Estonia, the State Agency of Medicines may restrict the quantity of the medicinal product dispensed from a pharmacy or allow to dispense the medicinal product only in the case of an established diagnosis.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(7) The following are established by a regulation of the minister in charge of the policy sector:
1) the conditions of 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 of 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 in charge of the policy sector.
[RT I 2010, 7, 31 – entry into force 26.02.2010]

Subchapter 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) Where 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 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 of and procedure for storage and transportation of medicinal products are established by a regulation of the minister in charge of the policy sector. 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 Commission Regulation (EU) No 1357/2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (OJ L 365, 19.12.2014, pp 89–96) or the list established under subsection 5 of § 2 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 3 of § 62 of the Waste Act
[RT I, 03.12.2015, 1 – entry into force 01.01.2016]

(4) Unusable narcotic drugs and psychotropic substances must be stored until the transfer thereof to a person holding an environmental protection permit for handling hazardous waste for disposal on the conditions established in the Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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.

(6) The Defence Forces are allowed to use the expired solutions for injection and infusion included in their medicinal products carried for first-aid purposes during training and exercises.The expired solutions for injection and infusion to be used must be clearly labelled to preclude the use thereof for other purposes. The Defence Forces must indicate upon recording medicinal products the solutions for injection and infusion and the quantities thereof used for training purposes. After use for training purposes, the medicinal products must be transferred to a person entitled on the basis of the Waste Act.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 36. Referral of unusable medicinal products to waste handling and transfer thereof for handling

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(1) Unusable medicinal products deemed to be hazardous waste must be handled in an undertaking holding an environmental protection permit for such activity. For the purposes of this Act, handling as hazardous waste means the act of disposal or recovery of unusable medicinal products in the process of which the properties of the active substances of a medicinal product are changed such that the substances no longer have the hazardous properties specified in Commission Regulation (EU) No 1357/2014.

(2) Unusable medicinal products must be transferred for handling to a person entitled on the basis of the Waste Act and prepare a consignment note for hazardous waste provided in § 64 of the Waste Act and a list of the medicinal products to be transferred for handling including the following information: the name of the medicinal product, manufacturer or holder of the marketing authorisation of the medicinal product, batch number and quantity.

(3) The list of medicinal products transferred for handling appended to the consignment note for hazardous waste is preserved for three years from the preparation thereof.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 37. Receipt of unusable medicinal products from consumers

(1) In addition to persons entitled on the basis of the Waste Act, general pharmacies and, in the case of veterinary medicinal products, also veterinary pharmacies are required to receive unusable medicinal products from consumers and refer such products to waste handling. Such medicinal products must be stored in a pharmacy separately from other medicinal products removed from the market. Upon transfer of medicinal products received from consumers to a person entitled on the basis of the Waste Act, the list appended to the consignment note provided in subsection 2 of § 36 of this Act is not required.

(2) Pharmacies provide users of medicinal products with information about the possibilities of returning medicinal waste. In the sales area of a pharmacy, a collection container which is made in a way that prevents unauthorised persons to retrieve unusable medicinal products from such container may be used for the collection of unusable medicinal products. The location of a collection container must have a noticeable and legible sign.

(3) Unusable medicinal products received from consumers or placed in a collection container are handled as hazardous waste.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

Subchapter 6
Handling and Brokering Authorisation

[RT I, 17.04.2013, 2 - entry into force 27.04.2013]

Division 1
General Provisions

§ 38. Authorisation requirement

[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (date of entry into force amended – RT I, 22.12.2013, 1)]

(1) An authorisation is required for operating in the following fields of activity:
1) manufacturing of medicinal products;
2) wholesale of medicinal products;
3) provision of the pharmacy service, including the general pharmacy service, the hospital pharmacy service and the veterinary pharmacy service;
4) brokering of medicinal products.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (date of entry into force amended – RT I, 22.12.2013, 1)]

(2) The requirements for hospital pharmacies apply to the application for an authorisation as a pharmacy of a state agency.

(3) An authorisation grants the holder 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 field of activity, place of business and on the conditions set out in the authorisation.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (date of entry into force amended – RT I, 22.12.2013, 1)]

(3^1) By way of exception, the State Agency of Medicines can, on the basis of a reasoned application of a municipality, grant the pharmacy service authorisation holder the right to open a branch pharmacy on a permanently settled small island on conditions different from those provided in this Act and regulation established on the basis of clause 3 of subsection 6 of § 31 of this Act.
[RT I, 06.06.2014, 14 – entry into force 09.06.2014]

(4) [Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(4^1) The State Agency of Medicines sends information about the manufacturing of medicinal products and active substances for human use and about wholesale distribution authorisations to the database specified in Article 111(6) of Directive 2011/83/EC of the European Parliament and of the Council.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(5) By way of exception, the State Agency of Medicines may, on the basis of a respective application of the holder of a valid general pharmacy authorisation, grant the authorisation holder for up to one week the permission to sell at mass events and in other exceptional cases outside the place of business specified in the authorisation proprietary medicinal products that may be dispensed by a pharmacy without a prescription (hereinafter *medicinal product not subject to medical prescription*).
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (date of entry into force amended – RT I, 22.12.2013, 1)]

§ 39. Authorisation register of the State Agency of Medicines

[RT I, 26.02.2015, 1 – entry into force 01.03.2015]

(1) The authorisation register of the State Agency of Medicines (hereinafter *authorisation register*) is established and its statutes are approved by a regulation of the minister in charge of the policy sector, which sets out the following:
1) the processor of the database where a processor has been appointed, and the tasks of the processors;
2) composition of data collected to the database and the procedure of entering data in the database;
3) procedure for access to data and issue of data;
4) list of data providers and data obtained from them, where data are obtained from other databases;
5) other organisational matters.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

(2) The purpose of the authorisation register is to keep account of the holders of authorisations to handle medicinal products, broker medicinal products, handle precursors of narcotic drugs, handle cells, tissues and organs, and to keep account of their professional activities as well as of exercising supervision over handling and brokering medicinal products, handling precursors of narcotic drugs, and over acquiring and handling cells, tissues and organs for the purpose of gathering information for the performance of the functions of management and organisation of the medicinal products policy and the policy of handling cells, tissues and organs and for producing pharmacy service statistics.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3) The authorisation register processes:
1) data of applications for handling and brokering authorisations and the data of the authorisations;
2) data of applications for authorisations to acquire and handle cells, tissues and organs and the data of the authorisations;
3) data gathered in the course of regulatory enforcement aimed at handlers and brokers of medicinal products;
4) data gathered in the course of regulatory enforcement aimed at acquirers and handlers of cells, tissues and organs;
5) data of the statistical reports submitted by pharmacy authorisation holders;
6) data collected on defective and counterfeit medicinal products in the course of regulatory enforcement;
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]
7) data gathered in the course of regulatory enforcement aimed at handlers of precursors of narcotic drugs.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3^1) Data entered into the authorisation register of the State Agency of Medicines is retained for ten years as of the moment of the entry of the data in the register.
[RT I, 28.12.2017, 5 – entry into force 01.01.2018]

(4) An applicant for and the holder of an authorisation to handle and broker medicinal products and to acquire and handle cells, tissues and organs as well as the State Agency of Medicines and an applicant for and the holder of a registration of drug precursors or an authorisation for handling of drug precursors are required to submit data to the register.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(5) [Repealed – RT I, 13.03.2019, 2 – entry into force 15.03.2019]

(6) The State Agency of Medicines is the controller of the authorisation register.

(7) The provisions of the General Part of the Economic Activities Code Act regulating registers apply to the authorisation register, except in the case of information relating to the handling of drug precursors in order to ensure security.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 40. Scope of authorisation

(1) Every general pharmacy, veterinary pharmacy, hospital pharmacy and place of business for wholesale distribution or manufacture of medicinal products belonging to the authorisation holder must have a separate authorisation.

(2) The structural units of a pharmacy must be entered on the authorisation 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, where the authorisation has been issued for wholesale distribution without the right of storage, the office is deemed the place of business.

Division 2
Authorisation Holder

§ 41. Authorisation holder

(1) Authorities of executive power, municipalities, 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 authorisation.
[RT I, 08.11.2010, 2 – entry into force 18.11.2010]

(2) Upon issuing a general pharmacy authorisation to a self-employed person, the self-employed person must be a pharmacist and work as the manager in at least one general pharmacy operating on the basis of an authorisation issued to the person.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

(3) Upon issuing a general pharmacy authorisation to a private legal person, more than 50 per cent of the shares of the private legal person and the dominant influence must belong to a pharmacist who works as the manager in at least one general pharmacy operating on the basis of an authorisation issued to the person.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

(4) The pharmacist specified in subsections 2 and 3 of this section may be related to the fulfilment of the conditions of issuing the authorisation of up to four general pharmacies operating in a settlement with a population of 4000 or more.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

(5) The restriction of the number of general pharmacies specified in subsection 4 of this section applies to all persons who directly or via another private legal person hold shares in a general pharmacy.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

(6) A person to whom a general pharmacy authorisation has been issued must, during the term of validity of the authorisation, comply with the terms and conditions of issue of the general pharmacy authorisation specified in this section. In the event of non-compliance with the terms and conditions of issue of a general pharmacy authorisation specified in this section, the person to whom the authorisation has been issued must bring their activities into compliance with the requirements of the authorisation within three months from the emergence of the non-compliance.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

§ 42. Restrictions related to holding of authorisation

(1) Except in the event specified in subsection 2 of this section, an authorisation is granted to an undertaking for operating only in one of the fields of activity specified in subsection 1 of § 38 of this Act.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (date of entry into force amended – RT I, 22.12.2013, 1)]

(2) A wholesale distribution authorisation holder may concurrently hold a manufacturing authorisation and vice versa.A hospital pharmacy authorisation holder may concurrently hold a manufacturing authorisation for the manufacture of full blood and blood components and to package, label, re-package or re-label investigational medicinal products.A pharmacy service authorisation holder may concurrently hold a manufacturing authorisation for the manufacture of medicinal products for other pharmacies.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3) A general pharmacy, hospital pharmacy or veterinary pharmacy authorisation holder or a subsidiary thereof must not be a shareholder or a member of a legal person in private law holding a manufacturing authorisation or wholesale distribution authorisation.
[RT I, 08.11.2010, 2 – entry into force 18.11.2010]

(4) Shareholders or members of a private legal person holding a veterinary pharmacy authorisation must not include persons holding a manufacturing authorisation or a health service authorisation or their subsidiaries or persons holding the right to prescribe medicinal products or holders of a professional activity licence of a veterinarian. Such requirement does not apply to a manufacturing authorisation holder who has been granted the manufacturing authorisation in compliance with subsection 2 of this section.
[RT I, 06.06.2014, 1 – entry into force 01.07.2014]

(5) Shareholders or members of a private legal person holding a general pharmacy authorisation must not include persons holding a wholesale distribution or manufacturing authorisation or a health service authorisation or undertakings related to these undertakings via dominant influence for the purposes of the Competition Act or persons holding the right to prescribe medicinal products or holders of a professional activity licence of a veterinarian. The State Agency of Medicines has the right to request that the Competition Authority identify an undertaking related via dominant influence.
[RT I, 06.06.2014, 1 – entry into force 01.07.2014]

§ 42[1]. Restrictions on issue and amendment of a general pharmacy authorisation

(1) [Repealed – RT I, 12.12.2013, 14 – entry into force 09.06.2014 – the judgment of the Supreme Court *en banc*declares subsections 1 to 3 of § 42[1]of the Medicinal Products Act unconstitutional and repeals them.]

(2) [Repealed – RT I, 12.12.2013, 14 – entry into force 09.06.2014 – the judgment of the Supreme Court *en banc*declares subsections 1 to 3 of § 42[1]of the Medicinal Products Act unconstitutional and repeals them.]

(3) [Repealed – RT I, 12.12.2013, 14 – entry into force 09.06.2014 – the judgment of the Supreme Court *en banc*declares subsections 1 to 3 of § 42[1]of the Medicinal Products Act unconstitutional and repeals them.]

(4) [Repealed – RT I, 06.06.2014, 14 – entry into force 09.06.2014]

(5) [Repealed – RT I, 06.06.2014, 14 – entry into force 09.06.2014]

(6) [Repealed – RT I, 06.06.2014, 14 – entry into force 09.06.2014]

(7) [Repealed – RT I, 06.06.2014, 14 – entry into force 09.06.2014]

§ 43. Restrictions related to fields of activity of an authorisation holder, head of pharmacy and veterinarians employed by an authorisation holder

(1) A wholesale distribution authorisation holder or a manufacturing authorisation holder is not allowed to provide the veterinary service, unless the manufacturing authorisation has been granted for the collection of blood from animals and the manufacture or production of blood products.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(2) A general pharmacy or veterinary pharmacy authorisation holder must not provide the health service or veterinary service during the term of validity of the authorisation.

(3) A hospital pharmacy authorisation holder must not operate in other field of activity except for the provision of the pharmacy service, manufacture of full blood and blood components and the activities specified in subsection 3 of § 22 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 a wholesale distribution authorisation holder or manufacturing authorisation holder.

(5) A person employed as the competent person with a wholesaler of medicinal products must not, at the same time, be employed by a pharmacy service authorisation holder.

(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 a wholesale distribution authorisation holder or pharmacy service authorisation holder.

(7) A veterinarian employed by a general pharmacy, veterinary pharmacy or a wholesale distribution authorisation holder or a manufacturing authorisation holder is not allowed to provide the veterinary service, unless the manufacturing authorisation has been granted for the collection of blood from animals and the manufacture or production of blood products.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 44. Obligations of a manufacturing authorisation holder and wholesale distribution authorisation holder

(1) A manufacturing authorisation holder or a wholesale distribution authorisation holder is required to:
1) apply a quality system that establishes, among other things, the responsibility, processes and risk management measures;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
2) ensure that the competent person and, in their absence, their substitute, has the conditions and means required for performing their duties;
2^1) verify that the manufacturers, importers and wholesalers from whom the active substances of the medicinal products for human use are obtained, have been authorised by the competent authority of their Member State of location to engage in the respective activity;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
2^2) upon obtaining medicinal products for human use from a wholesaler, verify that it holds a wholesale distribution authorisation and follows the good distribution practices of the European Economic Area;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
2^3) upon obtaining medicinal products from a manufacturer or importer, verify that it holds a manufacturing authorisation;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
2^4) upon obtaining medicinal products via a broker, verify that it follows the good distribution practices of the European Economic Area and other requirements established to the broker;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
2^5) verify the authenticity and quality of the active substances and excipients used for manufacturing medicinal products for human use;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
2^6) upon import of a medicinal product, verify the compliance of the packaging of the medicinal product with the marketing authorisation and, upon receipt and distribution of a medicinal product for human use, verify that the medicinal product has not been falsified, verifying the authenticity and integrity of the safety features of the medicinal product in accordance with the requirements provided in Commission Delegated Regulation (EU) 2016/161;
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]
2^7) immediately inform the State Agency of Medicines and the holder of the marketing authorisation or its representative about a medicinal product that is or may be falsified or defective, regardless of whether the medicinal product was distributed or whether the medicinal product was to be distributed in a legal chain of supply or illegally;
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]
2^8) ensure that the requirements provided in Commission Delegated Regulation (EU) 2016/161 for the safety features appearing on the packaging of medicinal products for human use;
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]
2^9) ensure the verification of the authenticity and integrity of the safety features of medicinal products for human use and decommission the unique identifier where a medicinal product is dispensed on the basis of subsection 1 of § 27 or subsection 1 of § 28 of this Act or to the persons specified in subsection 4 of this section or to persons who do not hold the right to retail sale, but hold the right to dispense medicinal products to the public, except upon dispensing to a hospital pharmacy;
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]
2^{10}) ensure payment of the vaccination insurance premium provided for in Chapter 5^1 of this Act and submission of data to the Estonian Health Insurance Fund;
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]
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 1 of subsection 9 of § 26 of this Act;
4^1) once a year, inform the State Agency of Medicines about changes in the list of active substances used for manufacturing of medicinal products for human use that are imported, manufactured and distributed, and immediately inform the State Agency of Medicines of any change relating to the activity, which may have an impact on the quality or safety of active substances;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

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

5[1]) ensure in the case of distribution of medicinal products with the same active substance priority to the acquiring and availability of such medicinal products to which a limit price has been established under the Health Insurance Act, except a wholesale distribution authorisation holder who distributes only the medicinal products of one marketing authorisation holder;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

5[2]) allow wholesale distribution of a less expensive authorised medicinal product not subject to medical prescription where the marketing authorisation holder addresses the holder concerning a distribution intention;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

6) disclose, in a manner available to the persons specified in subsection 4 of § 26, subsection 1 of § 27 and subsection 1 of § 28 of this Act, their sales offer and ensure the availability of the medicinal products specified in the sales offer;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

7) ensure equal sales and payment terms and, under equal circumstances, also equal delivery terms for general pharmacy authorisation holders who have no unfulfilled obligations towards the wholesale distribution authorisation holder or the manufacturing authorisation holder;

8) [Repealed – RT I, 17.04.2013, 2 – entry into force 27.04.2013]

9) transfer, upon winding-up of the authorisation holder or termination of the activity specified in the authorisation, the medicinal products to a handling authorisation holder or to a person who based on subsection 1 of § 27 or subsection 1 of § 28 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.

(1[1]) Clauses 2[2]to 2[6]of subsection 1 of this section do not apply where the medicinal product has been acquired from a third country, provided that it has not been imported, and is to be marketed in a third state.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

(2) The requirements established in subsection 1 of this section also apply to a wholesale distribution authorisation holder 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, a manufacturing authorisation holder is required to:

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

2) ensure that medicinal products are manufactured taking account of the developments in the field 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]

(4) In addition to the persons specified in clause 2[9]of subsection 1 of this section, the minister in charge of the policy sector may, by a regulation, establish an additional list of persons instead of whom wholesalers are required to verify the authenticity and integrity of the safety features of medicinal products and to decommission the unique identifiers of medicinal products.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

§ 45. Obligations of a pharmacy service authorisation holder

A pharmacy service authorisation holder 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;
4^1) ensure the provision of the pharmacy service in a general pharmacy located in a city that is a settlement unit having 4000 or more inhabitants, at least 40 hours a week;
[RT I, 04.07.2017, 2 – entry into force on the day of announcement of the results of the 2017 elections of municipal councils]
4^2) for the purpose of developing and increasing the competence of pharmacists and assistant pharmacists who provide the pharmacy service, ensure at its own expense their professional training to the extent of no less than 40 academic hours in two years, whereas professional training means participating in supplementary pharmacy or medical training course, seminar, conference or training day the content of which is independent of manufacturers, marketing authorisation holders or wholesalers of medicinal products and which is organised by a higher educational institution that teaches the pharmacist or assistant pharmacist curriculum, a state agency, training centre of a health service provider or a professional association of pharmacists, pharmacy operators or health care professionals;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
4^3) ensure, in the case the pharmacy service is provided via video call, the provision of the pharmacy service in a branch pharmacy specified in subsection $5^8$of § 31 of this Act for at least 24 hours per week, as well as ensure the presence of a specialist employee in the branch pharmacy for at least five hours per week;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
4^4) ensure, in the case the pharmacy service is provided via video call, a training in handling of medicinal products to the staff working in a branch pharmacy specified in subsection $5^8$of § 31 of this Act at least once a year;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
5) ensure the availability of a medicinal product distributed in Estonia on the basis of a marketing authorisation or an authorisation for distribution of an unauthorised medicinal product within a reasonable amount of time;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
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 3 of subsection 6 of § 31 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) upon the sale of medicinal products to which a limit price has been established under the Health Insurance Act and with regard to which a price agreement has been made, ensure the availability for purchase of at least one proprietary medicinal product with the same content of the active substance;
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]
10) ensure the provision of the pharmacy service only by the persons specified in subsection 3 of § 29 of this Act;
11) transfer, upon winding-up of the authorisation holder or termination of the activity specified in the authorisation, the medicinal products to a handling authorisation holder or a person specified in subsection 2 of § 33 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]
11^1) inform immediately the Health Board of entry into of an employment contract with a pharmacist or assistant pharmacist and specify the date of entry into of the employment relationship;
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]
12) comply with other requirements arising from this Act, legislation established on the basis thereof and other legislation regulating the handling of medicinal products.

§ 45^1. Provision of the pharmacy service in a pharmacy bus

The pharmacy service may be provided in a pharmacy bus only in a settlement unit that is not a city and the place of provision of the service must be at least three kilometres from an existing general pharmacy or branch pharmacy, except in the event provided in subsection 5 of § 38 of this Act. Where there is no general pharmacy or branch pharmacy in a city that is a settlement unit, the pharmacy service may be provided in a pharmacy bus also in the city.
[RT I, 04.07.2017, 2 – entry into force on the day of announcement of the results of the 2017 elections of municipal councils]

Division 3
Application for Authorisation

§ 46. Applying for authorisation

(1) The State Agency of Medicines reviews an application for an authorisation and grants or refuses to grant an authorisation within 60 days as of the receipt of the application.

(2) In addition to the information required in the General Part of the Economic Activities Code Act, an application for an authorisation must contain the following documents and data:
1) a document certifying the right of use of the premises;
2) the layout and description of the premises of the place of business;
3) a description of the technical equipment;
4) a description of storage of medicinal products;
5) organisation of the quality control of medicinal products;
6) in addition to the information listed in subsection 2 of § 19 of the Economic Activities Code, the name of the enterprise.

(2^1) The application must be submitted on the form published on the website of the State Agency of Medicines, depending on the authorisation applied for.

(3) To apply for a manufacturing authorisation, the following documents and data must be submitted in addition to the information specified in the General Part of the Economic Activities Code Act and subsection 2 of this section:
1) the list of medicinal product groups, pharmaceutical forms or medicinal products to be produced, thereby separately indicating dangerous and sensibilising substances, the list of active substances intended for the manufacturing of medicinal products for human use, which are to be imported, produced or marketed, and the groups of active substances intended for manufacturing veterinary medicinal products, which are to be manufactured;
2) the groups of medicinal products, pharmaceutical forms or medicinal products that are released upon import from non-EEA states;
3) the scheme and a brief description of the manufacturing processes;
4) a description of the sterilisation methods and stages;
5) the list of equipment to be used upon manufacturing and quality control, indicating the purpose of each device;
6) a description of the organisation of the maintenance of the premises and equipment;
7) a description of the organisation of validation and calibration;
8) the list of manufacturing and quality control enterprises that perform contract work and the substance of the contract work;
9) a description of the transport of medicinal products;
10) a description of the quality assurance system;
11) a description of the organisation of the release of output;
12) the classification of the production premises, the types of construction and finishing materials;
13) the schemes of movement of the staff and materials;
14) a notation of the existence of separate premises for handling toxic, hazardous and sensibilising substances;
15) a simplified scheme and description of the ventilation system, the types of the filters;
16) a simplified scheme and description of the water system and the water quality classes where water is used in manufacturing;
17) the organisation chart of the structure of the manufacturing enterprise.

(4) To apply for a wholesale distribution authorisation, the following documents and data must be submitted in addition to the information specified in the General Part of the Economic Activities Code Act and subsection 2 of this section:
1) the organisation chart of the structure of the wholesale enterprise;
2) the groups of medicinal products, pharmaceutical forms or medicinal products that are to be handled;
2^1) the list of active substances prescribed for the manufacture of medicinal products for human use, which are to be imported or distributed;
3) a description of the transport of medicinal products;
4) the planned total number of employees and the number of specialist employees (pharmacists, assistant pharmacists, veterinarians) per specialty;
5) a copy of the contract for storage and dispensing of medicinal products concluded with a wholesale distribution authorisation holder where the person applying for the authorisation lacks facilities for storing medicinal products.

(5) To apply for a pharmacy service authorisation, the following documents and data must be submitted in addition to the information specified in the General Part of the Economic Activities Code Act and subsection 3 of this section:
1) the planned number of specialist employees (pharmacists, assistant pharmacists, veterinarians) and the number of existing employees with special qualifications;
2) the list of other pharmacies (if any) belonging to the same person;
3) a description of the organisation of distance selling of medicinal products where the right of distance selling of medicinal products is applied for;
4) the planned travel schedule of the pharmacy bus and the places of provision of the service where the right to provide the pharmacy service in a pharmacy bus is applied for.
[RT I, 06.06.2014, 14 – entry into force 15.07.2014]

(6) To apply for a state agency pharmacy authorisation, a description of the system of supplying medicinal products to the stage agency and the documents and data specified in subsection 5 of this section must be submitted in addition to the information specified in the General Part of the Economic Activities Code Act.

(7) The State Agency of Medicines refuses to grant a brokering authorisation where the information submitted by the applicant is incorrect or insufficient, the applicant's permanent place of business is outside Estonia, the applicant does not give additional clarifications or where a handling authorisation is required for the activity applied for.
[RT I, 29.06.2014, 1 – entry into force 01.07.2014]

Division 4
Grant, Renewal and Extension of Authorisation

§ 47. Object of inspection of authorisation

An authorisation is granted where the applicant complies with the requirements of this Act and legislation established on the basis thereof and with those of other legislation regulating the handling of medicinal products.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]

§ 48. Term of validity of authorisation

[Repealed – RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]

§ 49. Refusal to issue and update authorisation

[Repealed – RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]

§ 50. Secondary conditions of authorisation

The following secondary conditions apply to an authorisation:
1) manufacturing activities for which a manufacturing authorisation has been issued, pharmaceutical forms and groups of medicinal products, including investigational medicinal products for the manufacture of which a manufacturing authorisation has been issued, and hazardous substances for the handling of which a corresponding authorisation has been issued;
2) wholesale activities and groups of medicinal products for the handling of which a wholesale distribution or manufacture authorisation 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 a manufacturing authorisation holder and a wholesale distribution authorisation holder to handle narcotic drugs and psychotropic substances;
5) the list of manufacturers and quality control enterprises performing contract work upon manufacturing medicinal products.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]
6) the right of distance selling of medicinal products of a general pharmacy authorisation holder.
[RT I, 06.06.2014, 14 – entry into force 02.07.2014]

Division 5
Termination and Suspension of Authorisation and Alteration of Information Contained therein

§ 51. Specifics of revocation of authorisation

(1) In the event of partial or full revocation of an authorisation, the State Agency of Medicines may set the authorisation holder a time limit and conditions for selling medicinal product stock and submitting reports.

(2) In the event of partial revocation of an authorisation, a new authorisation with changed data is issued.
[RT I, 25.03.2011, 1 – entry into force 01.07.2014 (entry into force amended – RT I, 22.12.2013, 1)]

§ 52. Change of data and change of authorisation data

[Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

Division 6
Brokering Authorisation

[Repealed -RT I, 29.06.2014, 1 - entry into force 01.07.2014]

§ 52[1]. Brokering authorisation

[Repealed – RT I, 29.06.2014, 1 – entry into force 01.07.2014]

Subchapter 7
Competent Person

§ 53. Requirements for a 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 1 of § 40 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 cannot be appointed a competent person where:
1) the person was formerly employed in the position of competent person at a place of business whose authorisation was revoked due to violations of legislation regulating the field of medicinal products and less than two years have passed from the revocation of the authorisation;
2) the person provides the pharmacy service in a pharmacy operating on the basis of another pharmacy service authorisation, unless the pharmacy is located in a city that is a settlement unit or in a settlement unit that is not a city and has less than 4000 inhabitants.
[RT I, 04.07.2017, 2 – entry into force on the day of announcement of the results of the 2017 elections of municipal councils]

(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) An authorisation holder 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 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 are established by a regulation of the minister in charge of the policy sector.

§ 54. Obligations of a competent person

(1) A competent person appointed by a manufacturing authorisation holder 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 manufacturing authorisation 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 a 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;
3) ensure that the packaging of medicinal products for human use distributed in the European Economic Area bear safety features in accordance with the requirements of Commission Delegated Regulation (EU) 2016/161;
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]
4) ensure that each batch of medicinal products manufactured in a third country has been manufactured and checked under equivalent good manufacturing practices.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(2) A competent person must perform the duty specified in clauses 2 and 3 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.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(2[1]) The duty of the competent person appointed by the holder of a hospital exemption authorisation is to ensure that each batch of the hospital-exemption medicinal product has been made and checked in accordance with the terms established by legislation governing medicinal products, good manufacturing practice of advanced therapy medicinal products and terms of the hospital exemption authorisation and corresponds to the data serving as the basis for granting the authorisation.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(3) A competent person appointed by a manufacturing authorisation holder must, regarding investigational medicinal products:
1) ensure that each batch of medicinal products manufactured in Estonia is manufactured and controlled in compliance with legislation in the pharmaceutical field and the manufacturing authorisation, 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 a wholesale distribution authorisation holder must ensure the compliance of the medicinal products sold by the wholesale distribution authorisation holder with 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) Where a wholesale distribution authorisation holder imports medicinal products, the competent person has the additional duty to verify adherence to the storage requirements during the transport of the medicinal products, and compliance of the packaging of the medicinal products with requirements and with the marketing authorisation.

(6) A competent person employed by a pharmacy service authorisation holder 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]

Subchapter 8
Registration of Pharmacists and Assistant Pharmacists and Recognition of Professional Qualifications of Pharmacists

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

(1) Pharmacists and assistant pharmacists wishing to provide the pharmacy service in the Republic of Estonia must be registered in the health administration information system created on the basis of subsection 2 of § 26[4] of the Health Services Organisation Act.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(1[1]) The Health Board publishes on its website the qualifications and the information relating to the place of employment of pharmacists and assistant pharmacists employed in a pharmacy for public use to the extent provided in the statutes of the health administration information system.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(2) Recognition of the professional qualifications of a pharmacist (hereinafter *recognition of professional qualifications*) is required where:
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 the pharmacy service 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 as well as the details of the European Professional Card where the person has one. Where the evidence of formal qualifications of a person applying for registration is included in the Estonian Education Information System, a copy of the evidence of formal qualifications need not be submitted upon registration.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(1^1) A state fee is paid for the review of the registration application or application for recognition of professional qualifications according to the rate provided in the State Fees Act.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(2) The minister in charge of the policy sector establishes the list of information to be submitted in applications.

(3) Upon receipt of a registration application, the Health Board verifies the information concerning the qualifications of a person in the Estonian Education Information System. Where the information concerning the qualifications of a person has been entered in the Estonian Education Information System and the person has paid the state fee for the review of the registration application, the person is automatically registered as a pharmacist or assistant pharmacist in the health administration information system, except in the events specified in subsections 4 and 5 of § 57 of this Act.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(3^1) Where the information concerning qualifications is not included in the Estonian Education Information System or is insufficient, the applicant must submit a copy of the evidence of formal qualifications to the Health Board. The Health Board verifies the authenticity of information submitted in the evidence of formal qualifications and make the decision on registration within one month as of submission of the evidence, except in the events specified in subsection $1^1$of § 58 and subsection 3 of § 59 of this Act.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

(3^2) Upon receipt of an application for recognition of professional qualifications, the Health Board verifies the authenticity of information submitted in the evidence of formal qualifications and make the decision on recognition of professional qualifications within the term specified in subsection $3^1$of this section.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

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

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

(6) Pharmacists or assistant pharmacists are issued, at their request, a certificate of registration concerning the registration in the health administration information system. A state fee is paid for the issue of a certificate according to the rate provided in the State Fees Act. Upon recognition of professional qualifications of a pharmacist, a corresponding certificate is issued to the applicant.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

§ 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 is established by a regulation of the minister in charge of the policy sector.

(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 are established by a regulation of the minister in charge of the policy sector.
[RT I 2009, 49, 331 – entry into force 01.01.2010]

(2^1) Where the European Professional Card has been introduced in the pharmacist profession by an implementing regulation of the European Commission based on Article 4a(7) of Directive 2005/36/EC of the

European Parliament and of the Council on the recognition of professional qualifications (OJ L 255, 30.09.2005, pp 22–142) and the person applying for registration requests the European Professional Card for working outside Estonia, the application for the European Professional Card and application proceedings are regulated by §§ 21^1–21^3 of the Recognition of Foreign Professional Qualifications Act.
[RT I, 30.12.2015, 1 – entry into force 18.01.2016]

(3) The qualification examination for pharmacists is organised by the University of Tartu and the qualification examination for pharmacists is 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 where 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 the 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 issues 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 1 of § 56 of this Act and, where necessary, inform the person of the missing documents. The Health Board verifies 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. Where, in the course of registration proceedings, the need arises to assess the circumstances specified in subsection 3 of § 58 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 immediately informs 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 are established by a regulation of the minister in charge of the policy sector.
[RT I 2008, 30, 191 – entry into force 01.07.2008]

(3) Where 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 decides 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]

(4) Where the European Professional Card has been introduced in the pharmacist profession by an implementing regulation of the European Commission based on Article 4a(7) of Directive 2005/36/EC of the European Parliament and of the Council and the competent authority of a member state of the European Economic Area or Switzerland has submitted to the Estonian competent authority a request for the working of a person in Estonia, the European Professional Card is applied for and reviewed in accordance with §§ 211, 21^4 and 21^5 of the Recognition of Foreign Professional Qualifications Act.
[RT I, 30.12.2015, 1 – entry into force 18.01.2016]

§ 59. Recognition of professional qualifications of persons who acquire qualifications of a pharmacist in other foreign states

(1) Subsections 1 to 2 and 4 to 6 of § 56 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) Where 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 decides 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 submits 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 1 of § 56 of this Act.
[RT I 2009, 49, 331 – entry into force 01.01.2010]

(3) The Health Board compares 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 is established by a regulation of the minister in charge of the policy sector.
[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 is established by a regulation of the minister in charge of the policy sector.
[RT I 2008, 30, 191 – entry into force 01.07.2008]

(5) In the event specified in subsection 2 of this section, where the European Professional Card has been introduced in the pharmacist profession by an implementing regulation of the European Commission based on Article 4a(7) of Directive 2005/36/EC of the European Parliament and of the Council and the competent authority of a member state of the European Economic Area or Switzerland has submitted to the Estonian competent authority a request for the working of a person in Estonia, the European Professional Card is applied for and reviewed in accordance with §§ 21^1, $21^4$and $21^5$of the Recognition of Foreign Professional Qualifications Act.
[RT I, 30.12.2015, 1 – entry into force 18.01.2016]

§ 59^1. Temporary provision of the pharmacy service

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 the pharmacy service in Estonia in accordance with Chapters 3 and $3^1$of the Recognition of Foreign Professional Qualifications Act without having to register under § 55 of this Act. The competent authority within the meaning of Chapters 3 and $3^1$of the Recognition of Foreign Professional Qualifications Act is the Health Board.
[RT I, 30.12.2015, 1 – entry into force 18.01.2016]

§ 60. Registration of qualifications of persons who acquire qualifications of a pharmacist or assistant pharmacist in a member state of the 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 is processed concurrently with the application for recognition of their qualifications.

(2) The provisions of the Recognition of Foreign Professional Qualifications Act apply to the registration of a person who has acquired the qualifications of an assistant pharmacist in a member state of the European Economic Area or in Switzerland and wishes to provide the pharmacy service in the Republic of Estonia. The competent authority provided in subsection 2 of § 7 of the Recognition of Foreign Professional Qualifications Act is the Health Board.
[RT I, 30.12.2015, 1 – entry into force 18.01.2016]

§ 60^1. Revocation of registration

The Health Board revokes the registration of a pharmacist or assistant pharmacist in the health administration information system after the death of the pharmacist or assistant pharmacist.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

§ 60^2. Suspension of registration

The Health Board suspends the registration of a pharmacist or assistant pharmacist in the health administration information system for up to three years in the event a prohibition to engage in the profession or specialty specified in the evidence of formal qualifications or information system has been imposed by a court judgment on the pharmacist or assistant pharmacist.
[RT I, 20.06.2022, 63 – entry into force 27.06.2022]

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

The Health Board revokes a registration decision or decision to recognise professional qualifications where 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]

§ 61[1]. Implementation of an alert mechanism

The Health Board implements an alert mechanism in accordance with the procedure established in Chapter 3[2] of the Recognition of Foreign Professional Qualifications Act.
[RT I, 30.12.2015, 1 – entry into force 18.01.2016]

§ 62. Register of pharmacists and assistant pharmacists

[Repealed – RT I, 20.06.2022, 63 – entry into force 27.06.2022]

Chapter 2[1]
BEGINNER'S ALLOWANCE

[RT I, 06.06.2014, 14 - entry into force 01.01.2015]

§ 62[1]. Beginner's allowance for a pharmacist and an assistant pharmacist, application for, payment and recovery of the allowance

(1) The beginner's allowance of a pharmacist (hereinafter beginner's allowance) is a single allowance paid to a pharmacist or assistant pharmacist who commences work in a general pharmacy or a structural unit thereof.

(2) The beginner's allowance may be, within one year from commencing work as a pharmacist or assistant pharmacist, applied for by a person who:
1) has been registered as a pharmacist or assistant pharmacist with the Health Board;
2) commences work as a pharmacist or assistant pharmacist in one or several general pharmacies or branch pharmacies belonging to the same owner located in a city that is a settlement unit where there is no other general pharmacy or branch pharmacy or located in another settlement unit at least ten kilometres from a city and at least five kilometres from an existing general pharmacy or branch pharmacy;
3) works on site in a pharmacy specified in clause 2 of this subsection as a pharmacist or assistant pharmacist with the summarised working time of at least 24 hours per week.

(3) The application for the beginner's allowance is submitted to the Health Board. The Health Board decides the grant of the beginner's allowance within two months from the submission of the application. The beginner's allowance is paid to the bank account of the person within one month as of making the decision to grant beginner's allowance.

(4) The amount of the beginner's allowance is 15 000 euros in the case of the obligation to work for three years and 25 000 in the case of the obligation to work for five years.

(5) The pharmacist or assistant pharmacist who received the beginner's allowance must repay the beginner's allowance granted to them in proportion to the time left until the termination of the obligation to work specified in the decision to grant beginner's allowance in the case their continuous work on the conditions specified in subsection 2 of this section terminates before the termination of the obligation to work for three or five years. Work is deemed suspended for the period of maternity leave, paternity leave or parental leave or performance of the duty to serve in the Defence Forces and the person's obligation to work is extended by the respective period. Work is deemed continuous during the person's incapacity for work or where the length of employment of the person who received the beginner's allowance on the conditions provided in subsection 2 of this section does not interrupt the time limit of three or five years for more than three months at a time. The beginner's allowance must be repaid within five years as of the receipt of the notice of repayment of the beginner's allowance.

(6) A person is not required to repay the beginner's allowance paid to them where their operation as a pharmacist or assistant pharmacist ends in the pharmacy specified in the decision to grant the beginner's allowance and the person commences work in another pharmacy that complies with the requirements specified in clause 2 of subsection 2 of this section or where the person has extraordinarily cancelled the employment contract due to a fundamental breach of the employer's obligation or where the employer has cancelled the employment contract as the continuance of the employment relationship on the agreed conditions becomes impossible due to a decrease in the work volume or reorganisation of work or other cessation of work (lay-off).

(7) The procedure for application for, payment and recovery of the beginner's allowance is established by a regulation of the minister in charge of the policy sector.
[RT I, 15.12.2023, 1 – entry into force 01.01.2024]

Chapter 3
MARKETING AUTHORISATION OF MEDICINAL PRODUCT

Subchapter 1
Mandatory Nature of Marketing Authorisation of Medicinal Product, Marketing Authorisation Holder

§ 63. Mandatory nature of the marketing authorisation of a medicinal product

(1) For distribution 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) unauthorised medicinal products on the basis of an authorisation for distribution of an unauthorised medicinal product granted by the State Agency of Medicines;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
3) whole blood and blood components;
4) herbal substances;
5) [repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]
6) advanced therapy medicinal products that have been, by way of exception, made on the basis of a doctor's prescription and subject to doctor's professional liability for the purpose of use by a specific patient upon provision of in-patient health services in Estonia.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(3) Based on a decision of the State Agency of Medicines, a veterinary medicinal product prescribed for use on aquarium or pond animals, ornamental fish, cage birds, homing pigeons, terrarium animals, small rodents, ferrets and rabbits which are kept as pets may be distributed in Estonia, provided that such medicinal product is not subject to a veterinary prescription and that all necessary measures are in place to prevent the use of such medicinal product for other animals.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 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 designates one or several persons importing a medicinal product, which hold a respective authorisation, and gives written notice of such persons to the State Agency of Medicines without delay.

(3) The distribution of a medicinal product must correspond to the need for treatment. A marketing authorisation holder must give written notice to the State Agency of Medicines of the commencement of the actual distribution of an authorised medicinal product in Estonia and, at least two months in advance, unless there are exceptional circumstances, give notice of interrupting or terminating the distribution of the medicinal product in Estonia and the reasons thereof. Above all, the marketing authorisation holder must inform the State Agency of Medicines about the existence of the circumstances specified in clauses 1 and 3 of subsection 6 of § 76 of this Act.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

(3^1) Where a medicinal product is not distributed directly to patients or where medicinal products with the same active substance, of the same strength, in the same pharmaceutical form and of the same packaging size are not distributed in Estonia and ensuring the continuous supply of the medicinal product is important from the point of view of human health, the State Agency of Medicines may, on the condition that appropriate measures for ensuring the safe use of the medicinal product are taken, authorise the omission of some required information from the packaging and from the package leaflet of the medicinal product or authorise the distribution of the medicinal product in packaging and with a package leaflet in the language of another member state of the European Economic Area.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(3^2) The State Agency of Medicines immediately publishes a notice of the interruption of the distribution of a medicinal product on its website.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

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

Subchapter 2
Application for a Marketing Authorisation of a Medicinal Product and Processing of Applications

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

(1) A person wishing to obtain or renew a marketing authorisation in respect of a medicinal product submits 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. Where the marketing authorisation holder waives the renewal of the marketing authorisation, the marketing authorisation holder must inform the State Agency of Medicines about the reasons of the waiver, above all, the existence of the circumstances specified in clauses 1 and 3 of subsection 6 of § 76 of this Act.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

(3) An applicant wishing to obtain a marketing authorisation in respect of a medicinal product must prove by scientific methods that the medicinal product, where 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 3 to 5 of § 13 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 where 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 is not distributed 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 is 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) [Repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]

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

(9) Where a medicinal product does not fully meet the similarity requirements specified in clause 2 of subsection 4 of this section or where 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) Where 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) Where 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 does 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 are established by a regulation of the minister in charge of the policy sector:
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 authorisation for parallel import in respect of a medicinal product, the conditions of and procedure for processing of applications;
3) the conditions of 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]
4) the list of such medicinal products whereby, for the purpose of compensation or pharmacovigilance, the requirement according to which a medicinal product must have a unique identifier and an anti-tampering device is extended to prescription medicinal products and medicinal products subject to compensation.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

§ 66. Parallel import authorisation

(1) A parallel import authorisation is granted to a wholesale distribution holder or manufacturing authorisation holder, provided that all the following conditions are fulfilled:
1) [Repealed – RT I 2005, 24, 180 – entry into force 20.05.2005]
2) parallel import authorisation 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 parallel import authorisation has 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 parallel import authorisation remains valid for a period determined thereby.

(4) A parallel import authorisation holder has all the rights and obligations of a marketing authorisation holder.

§ 67. Remuneration for professional assessment of an application

(1) An applicant must pay the State Agency of Medicines a fee for the professional assessment in the amount of up to 6000 euros, depending on the type of application established under clause 1 of subsection 12 of § 65 of this Act.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(2) Where 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 is 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 is added to the assessment fee.
[RT I, 05.07.2012, 13 – entry into force 21.07.2012]

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

(1) Before acceptance of an application for processing, the State Agency of Medicines evaluates the compliance of the application and supplementary documentation submitted with the requirements established under clause 1 of subsection 12 of § 65 of this Act and, where 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 terminates 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 assesses 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 submits 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) Where 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 suspends 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 to 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 addresses 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 recognises 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 are 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 its 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 European Commission.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

§ 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 are appointed by the minister in charge of the policy sector.

(6) The committees are formed and the rules of procedure thereof are established by a regulation of the minister in charge of the policy sector.

Subchapter 3
Issue of a Marketing Authorisation of a Medicinal Product

§ 70. Issue of a marketing authorisation of a 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 grants 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, is not 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 issues a parallel import authorisation in respect of a medicinal product to an applicant for the parallel import authorisation or inform the applicant of refusal to issue the parallel import authorisation 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, is not 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 recognises or refuses 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 issues 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 where 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 notifies 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]

(5^1) For the purpose of patient safety or pharmacovigilance, the State Agency of Medicines may demand that a means of preventing the tampering of the packaging be used on the packaging. This requirement may also be applied after granting marketing authorisation.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(6) The State Agency of Medicines immediately publishes 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 publishes 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 a marketing authorisation of a medicinal product

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

(2) The State Agency of Medicines renews a marketing authorisation or informs the marketing authorisation holder of the refusal to renew the marketing authorisation before expiry of the marketing authorisation.The State Agency of Medicines may renew the period of validity of a marketing authorisation until an application for renewal of the marketing authorisation has been processed.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3) A marketing authorisation issued under subsection 2 of § 70 of this Act is renewed for an unspecified term after five years have passed. A marketing authorisation issued under subsection 3 of § 70 of this Act is 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 classifies 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 a marketing authorisation of a 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, marketing authorisation holder, manufacturer responsible for batch release, term of validity of the 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 where 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 also approves the summary of product characteristics, package leaflet, packaging labelling and the frequency of periodic safety update reports in accordance with subsection 2 of § 78^7 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 a marketing authorisation of a medicinal product

(1) The State Agency of Medicines refuses to grant or renew a marketing authorisation where 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 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) [repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]
8) [repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]
9) its qualitative and quantitative composition is not as declared in the application.

(2) [Repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(3) The grounds for refusal to grant or renew a marketing authorisation provided in subsection 1 of this section do not apply in events where the State Agency of Medicines does not recognise the assessment report of the 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 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).
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 75. Issue of an assessment report of an application for a marketing authorisation

[RT I, 03.01.2022, 2 – entry into force 13.01.2022]
An assessment report of an application for marketing authorisation may be issued to a competent authority of another Member State of the European Economic Area or to the European Medicines Agency in connection with the grant, renewal or amendment thereby of a marketing authorisation in respect of a medicinal product.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

Subchapter 4
Amendment, Suspension and Revocation of a Marketing Authorisation of a Medicinal Product

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

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

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

(2) The State Agency of Medicines informs the marking authorisation holder 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 marketing authorisation holder 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 makes 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 amends the marketing authorisation, including in it the condition regarding the duty specified in subsection 1 of this section.

(4) The marketing authorisation holder 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 where 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 where 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.

(6^1) The State Agency of Medicines may revoke a marketing authorisation where a medicinal product has not been available from the authorisation holder for three consecutive years, unless it is necessary to keep the authorisation in force for public health purposes.
[RT I, 10.11.2017, 1 – entry into force 20.11.2017]

(7) Before a marketing authorisation is amended, suspended or revoked on the initiative of the State Agency of Medicines, the State Agency of Medicines notifies 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, where necessary.

(8) Where 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 terminates the suspension of the marketing authorisation by a decision, otherwise the marketing authorisation must be revoked.

(8^1) The marketing authorisation holder must immediately inform the State Agency of Medicines about all measures taken in other member states of the European Economic Area for the interruption of the distribution of a medicinal product, withdrawal of the medicinal product from the market or termination of the marketing authorisation and the reasons thereof, above all, the existence of the circumstances specified in clauses 1 and 3 of subsection 6 of this section. The marketing authorisation holder must also immediately inform the State Agency of Medicines of the measures taken in third states for the interruption of the distribution of a medicinal product, withdrawal of the medicinal product from the market or termination of the marketing authorisation due to the existence of the circumstances specified in clauses 1 and 3 of subsection 6 of this section. Where the reason for a measure taken is the existence of the circumstances specified in clauses 1 and 3 of subsection 6 of this section, the marketing authorisation holder must also inform the European Medicines Agency.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

(9) The State Agency of Medicines immediately informs the marketing authorisation holder and holders of an authorisation to handle 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 qualified 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 is carried out as a joint procedure of the European Economic Area.

(11) Where, 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 or where a marketing authorisation holder has communicated the interruption of the distribution of a medicinal product or the initiation of the termination of a marketing authorisation due to safety considerations or waived the renewal of a marketing authorisation, the State Agency of Medicines initiates the expedited procedure of the European Economic Area. Not later than on the next working day, the State Agency of Medicines immediately informs the marketing authorisation holder and the European Medicines Agency, competent authorities of other member states of the European Economic Area and the European Commission of the initiation of the expedited procedure and submit to the European Medicines Agency relevant information which has become known to the State Agency of Medicines. In such an event, the State Agency of Medicines

may suspend the term of validity of the marketing authorisation and prohibit the sale and dispensing of the medicinal product until the Coordination Group of the European Medicines Agency or the European Commission has made a decision regarding the retention, amendment, suspension, revocation of or refusal to renew the marketing authorisation, thereby informing the European Medicines Agency, competent authorities of other member states of the European Economic Area and the European Commission not later than on the next working day about the reasons of the measures taken, unless the procedure only concerns the marketing authorisation issued in Estonia.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

(11[1]) Where, due to assessment of information relating to pharmacovigilance, the State Agency of Medicines suspects that new contraindications must be reported, indications must be limited or the advisable dose of a medicinal product must be reduced, the State Agency of Medicines informs the European Medicines Agency, competent authorities of other member states of the European Economic Area and the European Commission about the considered measure and the reasons thereof. Where the State Agency of Medicines considers it necessary to take urgent measures, the State Agency of Medicines initiates the expedited procedure of the European Economic Area.
[RT I, 15.03.2014, 1 – entry into force 25.03.2014]

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

(13) Where 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, allow during a transitory period the sale or issue of the medicinal product to patients who are already being treated with the medicinal product.

(14) Subsection 7 of this section applies to the procedure for the amendment, suspension or revocation of the marketing authorisation for a veterinary medicinal product.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

Subchapter 5
Notification of Variation Relating to Marketing Authorisation of Medicinal Product and Application for Variation

[RT I, 15.12.2023, 3 - entry into force 25.12.2023]

§ 77. Notification of variation relating to marketing authorisation of medicinal product and application for variation

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(1) In order to amend the conditions which constituted the basis for issue of the marketing authorisation, the marketing authorisation holder submits an application for variation 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.

(1[2]) An application for variation to the conditions which constituted the basis for issue of the marketing authorisation is submitted together with the documents constituting the basis for the variation. An application for variation to the conditions of a marketing authorisation is processed according to the requirements and procedure provided in Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334, 12.12.2008, pp 7–24), amended by Commission Regulation (EU) No 712/2012 (OJ L 209, 04.08.2012, pp 4–14), and consistent with the guidelines prepared by the European Commission, unless otherwise provided by this Act.

(1[3]) Type IA and IB variations classified in Commission Regulation (EC) No 1234/2008 are considered notification of variation for the purposes of the same Regulation.

(2) A marketing authorisation holder must pay a state fee for submission of an application and a fee to the State Agency of Medicines for the professional assessment in the amount of up to 1800 euros, depending on the type of application established under subsection 3 of this section.

(2^1) The State Agency of Medicines refuses to satisfy an application on the bases provided in § 74 of this Act.

(2^2) A marketing authorisation holder must pay the State Agency of Medicines an annual fee for the management of a marketing authorisation of a veterinary medicinal product in the amount of 1395 euros per marketing authorisation of a veterinary medicinal product valid in the previous calendar year.

(3) The conditions of and procedure for notification of a variation relating to a marketing authorisation, application for variation, professional assessment and calculation of the fee and the amount of the fee per application type and the amount of the annual fee for the management of a marketing authorisation of a veterinary medicinal product are established by a regulation of the minister in charge of the policy sector.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 78. Communicating information on pharmacovigilance

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

Subchapter 5^1
Pharmacovigilance

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

Division 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 a 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, where 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 Directive 2001/83/EC of the Parliament and of the Council, Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ L 159, 20.6.2012, pp 5–25), and the Good Pharmacovigilance Practice.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 or that a person holding the given qualifications is available to the competent person for consultation at all times.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 the 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 qualified 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 qualified 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;
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]
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, Commission Implementing Regulation (EU) No 520/2012 and the Good Pharmacovigilance Practice.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 updates the assessment report where 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]

Division 2
Safety Information of a Medicinal Product and Communication of Information

§ 78[5]. Safety information of a 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 distributed;
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 11 of § 76 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 where 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 20.04.2004, pp 1–33), amended by Regulation (EU) 2019/5 (OJ L 4, 07.01.2019, pp 24–42).
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 makes 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.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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) Where 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 qualified 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 qualified to prescribe medicinal products, pharmacists and assistant pharmacists where 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 320 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.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(12) Where Estonia participates in the decentralised marketing authorisation procedure or marketing authorisation procedure of mutual recognition of the European Economic Area as a reference country or where the State Agency of Medicines participates in the work-sharing procedure of European medicines agencies as an assessor of the data specified in clause 3 of subsection 1 of § $78^4$of this Act, the safety and quality monitoring fee of a medicinal product is 600 euros per marketing authorisation that was valid for over six months in the previous calendar year.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(12^1) A marketing authorisation holder must pay the State Agency of Medicines a safety and quality monitoring fee of a veterinary medicinal product in the amount of 1395 euros per marketing authorisation of a veterinary medicinal product valid in the previous calendar year.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 where 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 the amount, calculation and payment of the safety and quality monitoring fee is established by the minister in charge of the policy sector.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 78^6. Adverse reaction of a 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.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 qualified 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 qualified to prescribe medicinal products, pharmacists and assistant pharmacists regarding communication of adverse reactions where 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 2001/83/EC of the European Parliament and of the Council, Commission Implementing Regulation (EU) No 520/2012 and the Good Pharmacovigilance Practice.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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.

Division 3
Non-interventional Post-authorisation Safety Study

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

(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, provided that such obligation is prescribed by the conditions of the marketing authorisation. Where 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.

[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 coordinates the notice with the Ministry of Regional Affairs and Agriculture beforehand.
[RT I, 30.06.2023, 1 – entry into force 01.07.2023; words "Ministry of Rural Affairs" replaced with words "Ministry of Regional Affairs and Agriculture" thoughout the Act on the basis of subsection 7 of § 105.19 of the Government of the Republic Act.]

(6) The approval of a non-interventional safety study must be refused where 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) Where 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-interfering safety survey in Estonia, the assessment of the Clinical Trial Ethics Committee is required in accordance with § 99^2 of this Act, except in the event of a veterinary medicinal product trial.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

(9) A non-interventional safety study is carried out in accordance with Directive 2001/83/EC of the European Parliament and of the Council, Commission Implementing Regulation (EU) No 520/2012 and with the Good Pharmacovigilance Practice.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 informs 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, where 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]

Subchapter 6
Register of Medicinal Products, Packaging Code and Digital Prescription Centre

[RT I, 04.05.2016, 1 - entry into force 14.05.2016]

§ 79. Register of medicinal products

(1) The register of medicinal products is established and its statutes are approved by a regulation of the minister in charge of the policy sector, which sets out the following:
1) the processor of the database where a processor has been appointed, and the tasks of the processors;
2) composition of data collected to the database and the procedure of entering data in the database;
3) procedure for access to data and issue of data;
4) list of data providers and data obtained from them, where data are obtained from other databases;

5) other organisational matters.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

(2) The purpose of keeping the register of medicinal products is to:
1) via a unique code attributed to each packaging size in information systems and information exchange in health care, identify medicinal products distributed in Estonia and such food for particular nutritional uses and food supplements for which the payment obligations are assumed by the Estonian Health Insurance Fund;
2) give the public information about the medicinal products and other products specified in clause 1 of this subsection;
3) keep account of the medicinal products and other products specified in clause 1 of this subsection.

(2^1) Data entered in the register of medicinal products is retained for an unspecified time.
[RT I, 28.12.2017, 5 – entry into force 01.01.2018]

(3) The register of medicinal products processes data on medicinal products that hold a marketing authorisation valid in Estonia, medicinal products distributed in Estonia without a marketing authorisation and veterinary medicinal products not subject to the marketing authorisation requirement as well as on such food for particular nutritional uses food supplements for which the Estonian Health Insurance Fund assumes the obligation to pay. The register of medicinal products is connected to the European online portal of medicinal products.

(4) The controllers of the register of medicinal products are the State Agency of Medicines and the Estonian Health Insurance Fund.
[RT I, 28.12.2017, 5 – entry into force 01.01.2018]

(5) The data is published on the website of the State Agency of Medicines, except on the prices of preparations established by a price agreement, which are subject to access restrictions. All the data is available via the X-road.
[RT I, 04.05.2016, 1 – entry into force 14.05.2016]

§ 80. Packaging code

[RT I, 04.05.2016, 1 – entry into force 14.05.2016]

(1) A packaging code is a unique combination of numbers for the purpose of identifying the medicinal products and other products specified in subsection 3 of § 79 of this Act.

(2) The use of a packaging code is mandatory for all marketing authorisation holders and handling authorisation holders.

(3) The register of medicinal products attributes a packaging code to each packaging size. To a medicinal product with a marketing authorisation, a packaging code is given after the granting of the marketing authorisation; to a medicinal product without a marketing authorisation, a packaging code is given upon the first granting of a special authorisation; to a food for particular nutritional purposes and to a food supplement for which the payment obligation is taken over by the Estonian Health Insurance Fund, on the basis of a notification by the Estonian Health Insurance Fund or the Ministry of Social Affairs; and to a veterinary medicinal product not subject to the marketing authorisation requirement, on the basis of a notification by the distributor.

(4) The procedure for coding medicinal products and other products contained in the register of medicinal products and for use of packaging codes is established by a regulation of the minister in charge of the policy sector.
[RT I, 04.05.2016, 1 – entry into force 14.05.2016]

§ 81. Digital Prescription Centre

(1) The Digital Prescription Centre is a database established for the purpose of writing and processing prescriptions and medical device cards as well as for providing insured persons with benefits for medicinal products and medical devices on the conditions provided in the Health Insurance Act, in order to ensure the 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]

(1^2) The Digital Prescription Centre processes the following data:
1) data related to writing and issuing prescriptions;
2) data related to writing and issuing medical device cards;
3) personal data related to the insurance cover and validity thereof.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

(2) The Digital Prescription Centre is established and its statutes are approved by a regulation of the minister in charge of the policy sector, which sets out the following:
1) composition of data collected to the database and the procedure of entering data in the database;
11) the processor of the database, provided that a processor has been appointed, and the tasks of the processors;

[RT I, 21.04.2021, 1 – entry into force 01.05.2021]
2) procedure for access to data and issue of data;
3) list of data providers and data obtained from them;
4) other organisational matters.
[RT I, 13.03.2019, 2 – entry into force 15.03.2019]

(3) The controller of the Digital Prescription Centre is the Estonian Health Insurance Fund.
[RT I, 21.04.2021, 1 – entry into force 01.05.2021]

(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) [Repealed – RT I, 28.12.2017, 5 – entry into force 01.01.2018]
5) the Estonian 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]

(4^1) The data of a prescription-entitled person are transmitted from the Health Information System and the data of a legal representative are transmitted from the population register to the Digital Prescription Centre.
[RT I, 03.01.2022, 2 – entry into force 13.01.2022]

(5) Persons providing the pharmacy service 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 are 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 are saved in the Digital Prescription Centre and, therefore, all the prescribed data fields are completed in the Digital Prescription Centre. A prescription may be issued on paper where 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 provider of the pharmacy service is required to enter information concerning a prescription issued on paper in the Digital Prescription Centre immediately after the receipt of the prescription. Where a paper prescription has been issued to a person insured in a member state of the European Union, European Economic Area or Switzerland who certifies their insurance cover using a valid European health insurance card or its replacement certificate or a duly formalised certificate (E112, E123, S2 or DA1) issued by the competent authority of the country of insurance, the provider of the pharmacy service must enter the details of the document certifying the insurance cover in the Digital Prescription Centre. Where the Digital Prescription Centre is not accessible, the data is entered within a reasonable amount of time.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(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 releases information free of charge where 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

Subchapter 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 6 and 7 of § 70 of this Act without any alterations or supplements and medicinal product safety information given under subsections 7, 8 and 9 of § $78^5$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 for the purpose of increasing the sales of a medicinal product, containing a recommendation for contacting a doctor and direct or indirect reference to a specific medicinal product.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(6) [Repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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) [Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(3) The advertising of a medicinal product must meet the general requirements provided in the Advertising Act and be in full compliance with the information specified in the summary of product characteristics of the medicinal product. Where 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) [Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(7) [Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(8) The person placing, producing and publicising advertising is required to store the advertising materials and documents related to publicising of advertising for the period of two years after the end of publicising thereof, and to provide such materials and documents at the request of the State Agency of Medicines.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 where complaints persist or adverse reactions occur.].
4) [repealed – RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(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 municipalities;
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, and, for promotional purposes, to sell or give away items connected to medicinal products or to organise raffles or lotteries related 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 in connection with the purchase of a medicinal product. The prohibition to supply samples of medicinal products does not apply to pharmacists and assistant pharmacists on the conditions provided in subsection 7 of § 85 of this Act.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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]

(11) immunological veterinary medicinal products may be advertised to professional keepers of animals in the case the advertising of medicinal products includes an express invitation to the professional keepers of animals to consult a veterinarian about the immunological veterinary medicinal product.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

§ 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 person placing advertising 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.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(2) Upon advertising of a medicinal product, the up-to-date summary of product characteristics of the medicinal product must be available. Upon advertising of a medicinal product through personal communication, the summary of product characteristics of the medicinal product must be available on site.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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) Only a marketing authorisation holder or an authorised person of the holder may provide a sample of a medicinal product. One person may be provided with up to five samples of medicinal products each no larger than the smallest presentation on the market, and the number of samples provided per year must not exceed 300 within two years as of the provision of the first sample or approval of a new indication of the medicinal product. New strength or size of the packaging of the same active substance without a new indication does not

give the right to provide new samples. Each sample of a medicinal product must be marked with the words "Mitte müügiks" [Not for sale], the package must conform to the marketing authorisation and each sample must be accompanied by a copy of the summary of product characteristic. It is prohibited to sell samples of medicinal products and to transfer them for non-medical purposes.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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 subject to medical prescription must only be supplied to a person qualified to prescribe them, based on a signed request of the person.A sample of a medicinal product not subject to medical prescription, which has little value, may be provided to a pharmacist or assistant pharmacist on the conditions provided in subsection 1 of § 86 of this Act.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(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.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(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 where 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 marketing authorisation holder, and the contact details of the marketing authorisation holder or an authorised person of the holder.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(11) Advertising of medicinal products subject to medical prescription over the Internet is permitted only where 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]

Subchapter 2

Inducement Designed to Promote Prescription or Sales

§ 86. Inducement designed to promote prescription or sales

(1) Marketing authorisation holders, their authorised persons and third persons 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, except in the events provided in subsection 2 of this section. Receipt of all pecuniary gifts is prohibited, except in the event provided 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, 15.12.2023, 3 – entry into force 25.12.2023]

(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 marketing authorisation holder 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) Where a marketing authorisation holder or an authorised person of such holder organises a scientific event intended for persons qualified to prescribe medicinal products, dispensing chemists 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.Information provided concerning medicinal products at such events must comply with the requirements set for advertising of medicinal products.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(7) All support granted to persons qualified to prescribe medicinal products, pharmacists or assistant 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 authorised person or branch of the marketing authorisation holder.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(8) All contracts concluded between a marketing authorisation holder or an authorised person of the holder and a person holding the right to prescribe medicinal products, pharmacist or assistant pharmacist on the basis of which the person, pharmacist or assistant pharmacist receives pecuniary or non-pecuniary compensations not related to a clinical trial approved by the State Agency of Medicines and the Clinical Trials Ethics Committee, are submitted to the State Agency of Medicines at its request and constitute public information.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(9) A marketing authorisation holder or an authorised person of the holder is prohibited to give and a wholesale distribution authorisation holder 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.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

Chapter 5
CLINICAL TRIAL

[RT I, 03.01.2022, 2 - entry into force 01.02.2022]

§ 87. Clinical trials of medicinal products

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 88. Requirements for clinical trials of medicinal products

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

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

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

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

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 91. Consent to participate in clinical trial of medicinal product

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 92. Medical ethics committee for clinical trials

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 93. Approval of clinical trials by committee

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 94. Payment for evaluation of clinical trial

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

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

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 96. Granting authorisation to conduct clinical trial of medicinal product

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

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

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 971. Application for amendment of conditions for conducting clinical trial of medicinal product

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

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

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

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

[Repealed – RT I, 03.01.2022, 2 – entry into force 01.02.2022]

Subchapter 1
Clinical Trial of a Medicinal Product for Human Use

§ 99[1]. General requirements for a clinical trial of a medicinal product for human use

(1) Regulation (EU) No 536/2014 of the European Parliament and of the Council regulates the performance of a clinical trial of a medicinal product for human use (hereinafter *clinical trial of a medicinal product*).

(2) The immediate packaging and outer packaging of the investigational medicinal product is labelled in Estonian in accordance with Articles 66 and 67 of Regulation (EU) No 536/2014 of the European Parliament and of the Council. Where a medicinal product is meant for use only in a health care institution or it is administered by a health care professional, the labelling may be in English.

(3) In accordance with Regulation (EU) No 536/2014 of the European Parliament and of the Council, the duties imposed on a Member State are performed in Estonia by the State Agency of Medicines, unless provided otherwise in this Act. For the purposes of Article 83(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council, the State Agency of Medicines is the national contact point of which the European Commission is notified and that participates in the work of the Clinical Trials Coordination and Advisory Group.

(4) Persons who assess the dossier of a clinical trial of a medicinal product is assessed and its compliance submit to the State Agency of Medicines annually by 31 May a declaration of interests wherein they certify that they do not have a conflict of interests or financial or other interests that could affect their impartiality.

(5) A clinical trial of a medicinal product is free of charge for a subject thereof. A subject of a clinical trial is prohibited to charge a fee for the investigational medicinal product, auxiliary medicinal product, medical device used for administering the medicinal product and a procedure specifically demanded in the protocol.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.1 applies as of 01.02.2022]

§ 99[2]. Clinical Trials Ethics Committee

(1) The Clinical Trials Ethics Committee (hereinafter *ethics committee*) is an independent body of researchers and representatives of various specialties that assesses a clinical trial of a medicinal product for the purpose of ensuring the safeguarding, safety and well-being of the subjects of the trial.

(2) The ethics committee assesses aspects covered by the second part of the clinical trial assessment report and is involved in assessing the first part of the assessment report, adheres to the requirements and time limits prescribed by Regulation (EU) No 536/2014 of the European Parliament and of the Council and draws up the second part of the assessment report in English for the State Agency of Medicines.

(3) In its activities, the ethics committee follows the established ethical rules and international conventions and the principles established by Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 04.05.2016, pp 1–88) and special laws.

(4) The ethics committee assesses the size of the ethical risks of a clinical trial and the background of the trial organiser, seeking a balance between the protection of fundamental rights and the practicality of the trial.

(5) The ethics committee operates under the aegis of the State Agency of Medicines.

(6) The rules of procedure, number of members, rules of membership and the time limit of the powers of the members are established by a regulation of the minister in charge of the policy sector.

(7) The State Agency of Medicines decides the composition of the members of the ethics committee, taking into account the member’s qualifications and experience in assessing clinical trials of medicinal products.

(8) The composition of the ethics committee and the experts involved in the work of the committee are published on the website of the State Agency of Medicines.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.2 applies as of 01.02.2022]

§ 99[3]. Authorisation procedure for a clinical trial of a medicinal product

(1) An application dossier of a clinical trial of a medicinal product is submitted in English in accordance with the rules established in Regulation (EU) No 536/2014 of the European Parliament and of the Council, except for the information specified in Part L of Annex I to the same Regulation or other information aimed at a subject, which is given in Estonian.

(2) The application dossier of a clinical trial conducted in Estonia is assessed by the State Agency of Medicines in accordance with the requirements and within the time limit established by Regulation (EU) No 536/2014 of the European Parliament and of the Council, cooperating for that purpose with the competent authorities of other

Member States and involving in the assessment experts of the respective field and the ethics committee; the State Agency of Medicines also draws up the first part of the assessment report.

(3) When Estonia becomes a reporting Member State in the authorisation procedure of a clinical trial of a medicinal product, the State Agency of Medicines performs the functions of a reporting Member State and coordinates cooperation between relevant Member States within the scope of the prescribed time limit and duties.

(4) In making a decision on a clinical trial of a medicinal product, the State Agency of Medicines takes into account the conclusions drawn in the second part of the assessment report prepared by the ethics committee.

(5) The State Agency of Medicines may issue the first part of the assessment report of a clinical trial of a medicinal product to the competent authority of another contracting state of the European Economic Area or to the European Medicines Agency.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.3 applies as of 01.02.2022]

§ 99[4]. Duties of the sponsor and investigator of a clinical trial of a medicinal product

(1) A clinical trial of a medicinal product may be carried out by a doctor or dentist registered in the Health Board within the limits of their competence.

(2) In every place of a clinical trial of a medicinal product, the principal investigator is appointed from among investigators and the principal investigator ensures the compliance of the clinical trial of the medicinal product at the place of the trial with the requirements provided in Regulation (EU) No 536/2014 of the European Parliament and of the Council and acts as a contact person in communicating with the State Agency of Medicines.

(3) The sponsor must submit an Estonian summary of the results of a clinical trial of a medicinal product aimed at an ordinary user to the database specified in Article 81 of Regulation (EU) No 536/2014 of the European Parliament and of the Council in accordance with Article 37(4) of the same Regulation.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.4 applies as of 01.02.2022]

§ 99[5]. Variations in giving informed consent

(1) A subject in a clinical trial or, where a subject is unable to give informed consent, their legal representative must, before giving informed consent to participate in the clinical trial, talk to a member of the trial team who is a doctor, nurse or pharmacist and has thorough knowledge of all aspects related to the clinical trial of the medicinal product and the investigational medicinal product and is able to provide the subject with an all-encompassing overview thereof.

(2) In a clinical trial of a medicinal product, which complies with Article 30(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council, it is permitted to obtain informed consent by simplified means provided in Article 30(2) of the same Regulation.

(3) The legal representative of an incapacitated subject gives informed consent to the participation of the incapacitated subject in a clinical trial of a medicinal product, taking into account the presumable intent of the incapacitated subject. The incapacitated subject must, to a reasonable extent, be informed of the circumstances of the trial and decisions made. Informed consent to the participation of a person of 7–17 years of age to participate in a trial must be obtained from a capacitated subject as well as their legal representative, taking into account the intent of the capacitated subject.

(4) Where the decision of the legal representative clearly harms the interests of an incapacitated subject, it cannot be relied on.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.5 applies as of 01.02.2022]

§ 99[6]. Decision of a clinical trial of a medicinal product and revision thereof and a decision to suspend and revoke a clinical trial authorisation

(1) On a clinical trial of a medicinal product or substantial modification thereof, the State Agency of Medicines makes a decision:
1) to grant an authorisation;
2) to grant an authorisation on certain conditions, or
3) to refuse to grant an authorisation.

(2) Where the State Agency of Medicines has reason to believe that requirements provided in Regulation (EU) No 536/2014 of the European Parliament or of the Council or requirements provided in this Act are not complied with, the State Agency of Medicines may, by its decision:

1) suspend the authorisation of a clinical trial of a medicinal product;
2) revoke the authorisation of a clinical trial of a medicinal product;
3) demand that the sponsor modify any aspect of a clinical trial of a medicinal product.

(3) The State Agency of Medicines notifies of decisions specified in subsections 1 and 2 of this section in accordance with the rules provided in Regulation (EU) No 536/2014 of the European Parliament and of the Council.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.6 applies as of 01.02.2022]

§ 99[7]. Fee for specialised assessment of a clinical trial of a medicinal product

(1) When applying for authorisation for a clinical trial of a medicinal product or substantial modification thereof, the sponsor pays the State Agency of Medicines a specialised assessment fee.

(2) The sponsor pays the State Agency of Medicines a fee of 330 to 7,860 euros for a specialised assessment of an application for a clinical trial of a medicinal product based on the application type at the rate provided in a regulation established on the basis of subsection 5 of this section. The fee is set based on the costs of assessing the application and the making of an assessment by the ethics committee.

(3) The State Agency of Medicines exempts the sponsor from the obligation to pay the specialised assessment fee where all of the following criteria are met:
1) the sponsor has submitted a respective application;
2) the sponsor of the clinical trial of the medicinal product is a health service provider holding a valid activity licence, an independent research institution or a professional organisation of doctors;
3) a person or institution specified in clause 2 of this subsection does not receive any financial or other remuneration from the manufacturer of the medicinal product or from a representative thereof.

(4) The sponsor is exempt from the specialised assessment fee where the investigational medicinal product has been declared an orphan medicinal product for the purposes of Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products (OJ L 18, 22.01.2000, pp 1–5).

(5) The fee for a specialised assessment of an application for a clinical trial of a medicinal product per application type and the rules of calculation and terms of payment of the fee are established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, § 99.7 applies as of 01.02.2022]

Subchapter 2
Clinical Trial of a Veterinary Medicinal Product

[RT I, 03.01.2022, 2 - entry into force 28.01.2022]

§ 99[8]. General requirements for a clinical trial of a veterinary medicinal product

(1) For the purposes of Article 4(17) of Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 07.01.2019, pp 43–167), ‘clinical trial of a veterinary medicinal product’ means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof.

(2) A clinical trial of a veterinary medicinal product may be conducted only on the basis of an authorisation granted by the State Agency of Medicines in accordance with subsection 1 of § 99[11] of this Act, taking into account the requirements established in Regulation (EU) 2019/6 of the European Parliament and of the Council.

(3) The disclosure of information on the trial to the owner of an animal or a trial-related operation is deemed the start of a clinical trial of a veterinary medicinal product.

(4) Only veterinary medicinal products manufactured in accordance with the requirements of Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.08.1991, pp 70–73) and on the effects and adverse reactions of which the person conducting the trial has sufficiently relevant information may be clinically investigated. The investigational medicinal product must be labelled in accordance with the requirements established on the basis of subsection 8 of this section.

(5) In planning and conducting a clinical trial of a veterinary medicinal product and publishing the results thereof, the good clinical practice of veterinary medicinal products and other international guidelines are followed.

(6) The manner of recruitment of potential subjects of a clinical trial of a veterinary medicinal product must be coordinated with the State Agency of Medicines in advance. The information disclosed in recruitment must clearly state that it is a scientific study for which the owner of the animal is not remunerated.

(7) Written informed consent of the animal owner is required for participation in a clinical trial of a veterinary medicinal product. Before granting consent and involving an animal in a trial, the animal owner is informed of all of the circumstances of the trial. The consent may be withdrawn at any time.

(8) The rules of application for an authorisation for a clinical trial of a veterinary medicinal product, rules of organisation of a trial, requirements for recruitment and informing the animal owner, requirements for a veterinary medicinal product used in a trial and the labelling of the product and the rules of collection and retention of trial data are established by a regulation of the minister in charge of the policy sector.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 99[9]. Requirements for the sponsor and investigator of a veterinary medicinal product and for the manufacturer of an investigational medicinal product

(1) The sponsor of a clinical trial of a veterinary medicinal product is a person who is responsible for the initiation, management and financing of a clinical trial of a veterinary medicinal product. The place of residence or seat of the sponsor of a clinical trial of a veterinary medicinal product must be in the European Economic Area.

(2) A clinical trial of a veterinary medicinal product may be conducted by a veterinarian (hereinafter *investigator*) within the limits of their competence.

(3) Other persons may participate in conducting a clinical trial of a veterinary medicinal product where they have the education, training and experience necessary for performing their functions.

(4) In each trial centre, a principal investigator must be appointed from among the investigators who coordinates the conduct of the clinical trial of the veterinary medicinal product in the trial centre and ensures the exchange of information with the State Agency of Medicines and the sponsor.

(5) The sponsor ensures that the investigator receives correct and exhaustive information on the investigational veterinary medicinal product.

(6) The manufacturer of the medicinal product and the sponsor ensure an efficient and functioning mechanisms for the registration and monitoring of the recalling of medicinal products used in a clinical trial of a veterinary medicinal product. In the event of detection of a defect of a veterinary medicinal product, all trial centres and contracting states of the European Economic Area where the investigational medicinal product has been taken must be identified as soon as possible. The manufacturer of a medicinal product must register each defect detected in the medicinal product and notify the sponsor and the State Agency of Medicines thereof and, in the case of a medicinal product with a marketing authorisation, notify the authorisation holder thereof as well.

(7) The sponsor ensures the interruption of blinding applied to an investigational medicinal product, which is necessary for recalling the veterinary medicinal product from use.

(8) The investigator provides an animal involved in a clinical trial of a veterinary medicinal product with aid within the limits of their competence and ensures, where necessary, the availability of the competent aid by other veterinarians.

(9) The investigator and the sponsor report any adverse events and adverse reactions detected in the course of a clinical trial of a veterinary medicinal product in accordance with the rules established on the basis of clause 1 of subsection 10 of this section and also report changes in the protocol or trial in accordance with the rules established on the basis of clause 2 of subsection 10.

(10) By a regulation, the minister in charge of the policy sector establishes:
1) the rules of reporting adverse events and adverse reactions that have become evident in the course of a clinical trial of a veterinary medicinal product;
2) the rules of application for a modification of a clinical trial of a veterinary medicinal product.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 99[10]. Application for an authorisation for a clinical trial of a veterinary medicinal product and the specialised assessment fee

(1) To obtain an authorisation for a clinical trial of a veterinary medicinal product, the sponsor submits to the State Agency of Medicines an application corresponding to the rules established on the basis of subsection 8 of § 99[8] of this Act and the required documents not later than 60 days before the start of the clinical trial of the veterinary medicinal product.

(2) The sponsor pays the State Agency of Medicines a fee of 766 euros for a specialised assessment of the clinical trial of the medicinal product.

(3) The State Agency of Medicines exempts the sponsor from the obligation to pay the specialised assessment fee, provided that all of the following criteria are met:
1) the sponsor has submitted a respective application;
2) the sponsor of the clinical trial of the veterinary medicinal product is a veterinarian holding a valid professional activity licence, an independent research institution or a professional organisation of veterinarians;
3) a person or institution specified in clause 2 of this subsection does not receive any remuneration or other benefits from the manufacturer of the veterinary medicinal product or a representative thereof.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 99[11]. Granting and refusal to grant an authorisation for a clinical trial of a veterinary medicinal product

(1) The State Agency of Medicines grants an authorisation to conduct a clinical trial of a veterinary medicinal product.

(2) The State Agency of Medicines makes a decision to grant an authorisation for a clinical trial of a veterinary medicinal product within 60 days after the submission of documents in the event of a first-phase trial and within 30 days after the submission of documents in the event of a second-phase trial. In the event of using gene therapy, cell therapy, an immunological medicinal product and a genetically modified organism, the State Agency of Medicines makes a decision within 60 days after the submission of the required documents.

(3) The State Agency of Medicines may refuse to grant an authorisation for a clinical trial of a veterinary medicinal product where at least one of the following circumstances exists:
1) the applicant or a person participating in conducting the trial has failed to comply with the requirements for a clinical trial of a veterinary medicinal product;
2) the data or documents submitted by the applicant are incomplete;
3) the protocol is impractical;
4) the trial lack scientific value;
5) the risk to the life and health of the animal participating in the trial is high;
6) a release of genetically modified organisms into the environment may pose a threat to the environment;
7) there is no appropriate withdrawal period as regards the introduction of the food-producing animals or products obtained from them to the food chain.

(4) Where the State Agency of Medicines has not refused to grant an applicant the authorisation or demanded the submission of the missing data within the time limit provided in subsection 2 of this section, the authorisation is deemed granted.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 99[12]. Modification of and refusal to modify a clinical trial of a veterinary medicinal product and the specialised assessment fee

(1) To modify a clinical trial of a veterinary medicinal product, the sponsor submits to the State Agency of Medicines an application compliant with the rules established on the basis of clause 2 of subsection 10 of § 99[9] of this Act and other data and documents prescribed by the same rules not later than 30 days before the planned introduction of the modification.

(2) When applying for the modification of a clinical trial of a veterinary medicinal product, the sponsor must pay the State Agency of Medicines a fee of 100 euros for the specialised assessment of the application. The sponsor is exempted from the fee where all of the criteria specified in subsection 3 of § 99[10] of this Act are met.

(3) The State Agency of Medicines makes a decision to modify a clinical trial of a veterinary medicinal product within 30 days after the submission of all of the required documents. Where the State Agency of Medicines has not communicated any refusal to make the requested modification or demanded the data missing from the application, the authorisation is deemed granted.

(4) The State Agency of Medicines refuses to modify a clinical trial of a medicinal product on the grounds specified in subsection 3 of § 99[11] of this Act.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 99[13]. Suspension and revocation of an authorisation for a clinical trial of a veterinary medicinal product and end of a trial

(1) The State Agency of Medicines suspends or revokes an authorisation for a clinical trial of a veterinary medicinal product without delay where any circumstance specified in subsection 3 of § 99[11] of this Act has become evident in the course of the trial, except in the event specified in subsection 2 of this section.

(2) Where the continuance of a clinical trial of a veterinary medicinal product does not result in a threat to the life or health of the animals involved in the trial, the State Agency of Medicines informs the sponsor of the intent to suspend or revoke the authorisation for the clinical trial of the veterinary medicinal product. The sponsor of the clinical trial of the veterinary medicinal product has the right to submit their opinion to the State Agency of Medicines within seven days after receiving the notice.

(3) The sponsor of a clinical trial of a veterinary medicinal product is required to suspend or end the trial right after the receipt of the decision of the State Agency of Medicines.

(4) Where the sponsor of a clinical trial of a veterinary medicinal product suspends a trial, the State Agency of Medicines must be notified thereof in writing within 15 calendar days and an explanation on the suspension of the trial must be submitted.

(5) Where a clinical trial of a veterinary medicinal product is ended as planned, the principal investigator or sponsor notifies the State Agency of Medicines thereof within 90 calendar days.

(6) Where the data of a clinical trial of a veterinary medicinal product are not submitted in an application for a marketing authorisation, the sponsor must submit to the State Agency of Medicines a clinical study report regardless of the result thereof within one year after the end of the trial.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

Chapter 5[1]
COMPENSATION FOR VACCINATION DAMAGE

[RT I, 29.04.2022, 1 - entry into force 01.05.2022]

Division 1
General Provisions

[RT I, 29.04.2022, 1 - entry into force 01.05.2022]

§ 99[14]. General principles of vaccination insurance

(1) Vaccination insurance is a compulsory insurance the purpose of which is to ensure, on the conditions and pursuant to the procedure provided for in this Chapter, compensation for vaccination damage occurred as a result of vaccination to an entitled person if the patient dies or serious damage to health is caused to the patient which persists for at least four months as a result of vaccination performed in Estonia.

(2) For the purposes of this Chapter, an entitled person is a patient or a successor of the patient who has the right to demand compensation for damage.

(3) For the purposes of this Chapter, a distributor is a holder of an authorisation for wholesale distribution or manufacturing of medicinal products or another person who manufactures in or imports to Estonia vaccines for distribution and use in Estonia.

(4) Upon the occurrence of an insured event, the obligation to compensate for damage rests on the Estonian Health Insurance Fund on the bases and to the extent provided in this Act.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

§ 99[15]. Insurance obligation

(1) A distributor is required to pay the vaccination insurance premium for each vaccine dose distributed for use. Vaccine doses are calculated on the basis of the number of vaccine doses in a package as at the time of distribution entered in the register of medicinal products concerning a vaccine package. If a range of vaccine doses has been entered in the register of medicinal products concerning a vaccine package, the vaccine doses shall be calculated on the basis of the smallest number of vaccine doses in a package as at the time of distribution entered in the register of medicinal products concerning a vaccine package.

(2) The taxation period shall be one quarter of distribution of vaccines for use in Estonia. A distributor is required to transfer the vaccination insurance premium subject to payment for the previous quarter to the bank account of the Estonian Health Insurance Fund by the last day of the first calendar month of the following quarter.

(3) A distributor is required to submit to the Estonian Health Insurance Fund information concerning the vaccine doses distributed during the previous quarter by the last day of the first calendar month of the following quarter. The information shall be submitted to the Estonian Health Insurance Fund in a format which can be reproduced in writing, indicating the number and names of vaccine doses distributed.

(4) Upon delay in the payment of the vaccination insurance premium, the Health Insurance Fund shall have the right to demand from the distributor a penalty for late payment to the extent provided for in § 113 of the Law of Obligations Act.

(5) The amount of the vaccination insurance premium for the distributor shall be the rate of insurance premium established on the basis of subsection 8 of this section per vaccine dose multiplied by the number of vaccine doses distributed by the distributor during the previous quarter.

(6) The distributor may add the amount of the vaccination insurance premium after the application of the threshold value of mark-up pursuant to § 15 of this Act.

(7) The rate of vaccination insurance premium shall be calculated on the basis of the total amount of expected indemnities for the following calendar year and the procedure expenses of the Estonian Health Insurance Fund and the State Agency of Medicine divided by the number of vaccine doses expected to be administered in the same calendar year.

(8) The rate of vaccination insurance premium for the following calendar year shall be established by a regulation of the Government of the Republic not later than by 1 December of the current calendar year.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99[16]. Insured event

The Estonian Health Insurance Fund is required to compensate for proprietary and non-proprietary damage to the extent provided for in this Chapter to an entitled person if as a result of vaccination performed in Estonia a serious damage to health is caused to the patient which persists for at least four months or the patient dies and if:
1) there is at least a likely causal link between vaccination and damage to health or death of the patient, or
2) there is a causal link between vaccination and damage to health or death of the patient, and the distributor is liable for the damage caused to the entitled person on the basis of the Law of Obligations Act.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

Division 2
Bases for Compensation for Damage

[RT I, 29.04.2022, 1 - entry into force 01.05.2022]

§ 99[17]. Bases for compensation for damage

(1) Upon the occurrence of an insured event provided for in § 99[16] of this Act, the entitled person shall submit an application for compensation for vaccination damage to the Estonian Health Insurance Fund.

(2) If the Estonian Health Insurance Fund has compensated for vaccination damage, the claim for compensation of damage against the manufacturer belonging to the entitled person and the distributor shall transfer to the Estonian Health Insurance Fund to the extent of damage compensated.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99[18]. Extent of damage subject to compensation

(1) The Estonian Health Insurance Fund shall compensate for proprietary and non-proprietary damage incurred as a result of an insured event to the entitled person only on the conditions and to the extent provided for in this Act.

(2) The extent of compensation for damage to an entitled person by the Estonian Health Insurance Fund shall be reduced by the extent in which the manufacturer of the vaccine has compensated for damage.

(3) Compensation for damage on the basis of this Act shall not restrict the right of the entitled person to file a claim against the manufacturer or distributor of the vaccine on the basis of the Law of Obligations Act to the extent in which the Estonian Health Insurance Fund has not compensated for damage.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99[19]. Sum insured and insurance indemnities

(1) The sum insured of vaccination insurance shall be 100,000 euros for one insured event.

(2) An entitled person shall be compensated for proprietary and non-proprietary damage by a one-off indemnity for vaccination damage as follows:
1) 2,000 euros in the case of serious damage to health with mild degree of severity;
2) 10,000 euros in the case of serious damage to health with moderate degree of severity;
3) 25,000 euros in the case of serious damage to health;
4) 50,000 euros in the case of severe damage to health;

5) 100,000 euros in the case of permanent or life-threatening damage to health or death.

(3) The characteristics of the degrees of severity of damage to health specified in subsection 2 of this section shall be established by a regulation of the minister in charge of the policy sector.

(4) The sum insured and indemnities specified in subsections 1 and 2 of this section shall be increased every year from the first day of the current year by the increase of the consumer price index published by Statistics Estonia for the previous year. If the consumer price index does not increase or reduces, the existing sum insured and indemnities shall remain in force. Compensation for damage shall be based on the sum insured and indemnities of the year of the occurrence of the insured event.

(5) The Estonian Health Insurance Fund shall publish the indexed sum insured and indemnities of vaccination insurance on its website in January each year.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

Division 3
Proceedings for Compensation for Damage

[RT I, 29.04.2022, 1 - entry into force 01.05.2022]

§ 99[20]. General principles of proceedings for compensation for damage

(1) Proceedings for the compensation for damage shall commence if the entitled person submits an application to the Estonian Health Insurance Fund. An application must be submitted within a year after the occurrence of an insured event. If an application has not been submitted within the specified term, the Estonian Health Insurance Fund shall be released from the obligation to compensate for damage.

(2) Upon submission of an application specified in subsection 1 of this section, the entitled person shall be required to:
1) submit to the Estonian Health Insurance Fund all the information and documents in Estonian necessary for proving the right to receive compensation, in particular general data and relevant health data of the person;
2) immediately notify the Estonian Health Insurance Fund of circumstances affecting the right to receive compensation for vaccination damage and the payment of compensation, and changes to such circumstances.

(3) Employees of the Estonian Health Insurance Fund and State Agency of Medicines shall have the right to access personal data in the health information system for processing the applications for compensation for vaccination damage. The consent of a person to the State Agency of Medicines shall be given upon the submission of an application through the Estonian Health Insurance Fund.

(4) The extent of access to personal data in the health information system specified in subsection 3 of this section shall be established by a regulation of the minister in charge of the policy sector.

(5) The Estonian Health Insurance Fund shall forward to the State Agency of Medicines within 30 days of the receipt of a proper application all the relevant information and documents, in order to determine whether at least a likely causal link between vaccination and damage to health or death of the patient can be identified in the specific case. The State Agency of Medicines shall provide an assessment on a likely causal link, certain causal link or the likely absence of a causal link within 90 calendar days after the receipt of relevant information and documents from the Estonian Health Insurance Fund.

(6) In order to perform the obligations provided for in this Chapter, the Estonian Health Insurance Fund and the State Agency of Medicines shall have the right to check the accuracy of the information and documents submitted during application from databases belonging to the state information system or other data providers who process data necessary for the payment of compensation for vaccination damage, unless access to data is restricted by a specific Act.

(7) The Estonian Health Insurance Fund and the State Agency of Medicines shall have the right to use experts for identifying the justification of the information constituting the basis for serious damage to health and the causal link.

(8) The Estonian Health Insurance Fund and the State Agency of Medicines shall enter into a cooperation agreement for the payment of a fee for the preparation of an assessment on the causal link specified in subsection 5 of this section.

(9) The Estonian Health Insurance Fund shall make a decision on compensation for damage or refusal to compensate for damage within 30 calendar days after the receipt of the assessment specified in subsection 5 of this section from the State Agency of Medicines.

(10) Compensation for vaccination damage shall be paid within 30 calendar days after making of the decision on compensation for damage.

(11) Compensation for vaccination damage shall be transferred to the bank account of the entitled person entered in the database of the Estonian Health Insurance Fund or the bank account indicated by the person in the application for compensation for vaccination damage.

(12) An entitled person shall indicate in the application for compensation for vaccination damage the preference of the person regarding the manner of notification of acts or decisions.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99[21]. Postponement of making of decision on compensation for damage

The decision on compensation for damage may be postponed for up to three calendar months if additional information concerning the insured event or involvement of additional experts in the field is required for making the decision. In this case the entitled person shall be notified of the postponement of making the decision and the reasons for the postponement.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99[22]. Bases for refusal to pay compensation

The Estonian Health Insurance Fund shall have the right to refuse to pay compensation for vaccination damage if the following circumstances exist:
1) there is no insured event;
2) the patient has intentionally caused the occurrence of the insured event;
3) the patient has failed or fails to comply with the medically justified treatment prescribed by the doctor after the occurrence of the insured event and, therefore, recovery is hindered;
4) the patient fails to visit the doctor at the prescribed time after the insured event without good reason;
5) the entitled person has submitted incorrect information concerning the insured event to the Estonian Health Insurance Fund;
6) the patient refuses to participate in an expert assessment or medical examination ordered by the Estonian Health Insurance Fund.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99[23]. Right of recourse

(1) The Estonian Health Insurance Fund shall have the right to exercise right of recourse against the manufacturer who produced the vaccine. The Estonian Health Insurance Fund may waive the right of recourse against the manufacturer who produced the vaccine if the likely costs related to the right of recourse exceed the costs incurred for the payment of compensation for vaccination damage.

(2) The Estonian Health Insurance Fund shall have the right of recourse against the person who received compensation for vaccination damage if:
1) it becomes evident after the payment of compensation that the entitled person did not have the right to receive compensation;
2) it becomes evident after the payment of compensation that the entitled person was compensated for damage in full by the manufacturer.

(3) The Estonian Health Insurance Fund shall have the right of recourse against the distributor to the extent of damage compensated to the entitled person if the distributor failed to pay the vaccination insurance premium in part or in full by the prescribed time.

(4) The Estonian Health Insurance Fund shall decide on the right of recourse by a precept in administrative proceedings commenced on its own initiative.

(5) A reasonable term shall be set for compliance with the precept. By agreement with the person who received compensation for vaccination damage or on the basis of a reasoned request from the person, a decision on repayment in instalments may be made taking into account the size of the reclaimed amount and possibilities of the person.

(6) A warning shall be issued together with the precept concerning the commencement of compulsory enforcement in case of failure to perform the obligation to comply with the right of recourse.

(7) A precept shall set out at least the following:
1) the name and address of the recipient of the precept;
2) the bases for calculation and the size of the reclaimed amount;
3) the term for compliance with the precept;
4) the warning provided for in subsection 6 of this section;
5) the reference to contestation of the precept.

(8) If a person fails to repay the reclaimed amount within the term prescribed in the precept, the Estonian Health Insurance Fund shall have the right to issue a precept for compulsory enforcement pursuant to the procedure provided for in the Code of Enforcement Procedure. If the Estonian Health Insurance Fund issues a precept to a person who received compensation for vaccination damage concerning the commencement of compulsory enforcement upon failure to perform the obligation to comply with the right of recourse but there is no information concerning the address of the person or the person does not live at the address known and the actual location of the person is unknown and the precept cannot be delivered in the manner provided for in subsection 12 of § $99^{20}$of this Act, the conclusion of the precept shall be published in the publication *Ametlikud Teadaanded.*
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 99^{24}. Challenge proceedings

An entitled person shall have the right to file a challenge against an administrative act issued by the Estonian Health Insurance Fund on the basis of this Chapter. The Estonian Health Insurance Fund shall adjudicate a challenge within 90 days from the filing thereof.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

Chapter 6
REGULATORY ENFORCEMENT AND ADMINISTRATIVE OVERSIGHT

[RT I, 13.03.2014, 4 - entry into force 01.07.2014]

§ 100. Regulatory enforcement and administrative oversight

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(1) Regulatory enforcement of and administrative oversight over the performance of this Act and legislation established on the basis thereof is carried out by the State Agency of Medicines and, according to their competence, by the Health Board, the Agriculture and Food Board, Competition Authority and the Tax and Customs Board.
[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(2) The Health Board enforces and oversees compliance with the requirements provided by this Act and legislation established on the basis thereof by health care providers and health care professionals, except by pharmacists and assistant pharmacists who provide the pharmacy service.
[RT I, 06.06.2014, 14 – entry into force 09.06.2014]

(3) The Agriculture and Food Board enforces and oversees compliance with the requirements for the prescription, dispensing and use of medicinal products upon the provision of veterinary service and compliance of owners and keepers of food-producing animals with the requirements for the use of medicinal products and the requirements for keeping records of the use of medicinal products.
[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(4) The Competition Authority enforces and oversees the compliance with the requirement specified in clause 7 of subsection 1 of § 44 of this Act in accordance with the procedure set out in this Act and in the Competition Act.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(5) In the case of goods requiring special authorisation by the State Agency of Medicines, the Tax and Customs Board verifies the existence of import or export authorisation or written authorisation and the compliance of the authorisation with the goods in accordance with the procedure established in this Act and in the Customs Act.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 101. Special measures of regulatory enforcement

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]
A law enforcement authority may, for the purpose of regulatory enforcement provided in this Act, take special measures of regulatory enforcement provided in §§ 30, 31, 32, 50, 51 and 52 of the Law Enforcement Act on the grounds and in accordance with the procedure provided in the Law Enforcement Act.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 101[1]. Specifics of regulatory enforcement

(1) In enforcement, the State Agency of Medicines has, by its compliance notice, the right to:
1) suspend the sale and dispensing of a medicinal product, among other things, in a place of temporary storage of goods, customs warehouse, free zone or free warehouse for the purposes of the Customs Act where the State Agency of Medicines has reason to believe that the medicinal product may have been falsified or 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, where necessary, demand the withdrawal from the market of a medicinal product where 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 or falsified, the medicinal product lacks a valid marketing authorisation, or where facts confirming the harmfulness of the medicinal product to the life or health of humans or animals or to the environment become evident;
3) ban the advertising of the medicinal product and demand that the person placing, producing or publicising advertising publish a statement with the text prescribed by the State Agency of Medicines in the same form as the advertising and on an equal surface ensuring the same attention;
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]
4) suspend and terminate a clinical study of a medicinal product and demand that the sponsor modify the conditions of the trial;
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]
4[1]) suspend and terminate a clinical study of a veterinary medicinal product and demand that the sponsor modify the conditions of the trial;
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]
5) demand that the marketing authorisation holder or the wholesaler inform the public or health care professionals about risks relating to a medicinal product;
6) order a non-profit legal person specified in subsection 4 of § 10[2]of this Act to allow, within a reasonable time, a marketing authorisation holder to distribute a medicinal product with safety features, provided that it is necessary on public health considerations, there is a threat to the availability of the medicinal product and a medicinal product with an equivalent active substance is not distributed.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

(2) In regulatory enforcement and administrative oversight, the State Agency of Medicines has the right to carry out mystery shopping without giving the person any advance notice.

(3) For enforcement purposes the State Agency of Medicines has the right to enter the facilities to be inspected, including the seat of the holder of the marketing authorisation or its representative, the place of quality control of the manufacturer of the medicinal product, the place of temporary storage of the goods, a customs warehouse, a free zone, a free warehouse, the site of operation of a non-profit legal person specified in subsection 4 of § 10[2]of this Act, and the site of operation of the manufacturer and importer of the excipient of the medicinal product for human use.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

(4) The State Agency of Medicines has the right to demand and obtain free samples and certified reference materials for control analysis of the quality of medicinal products and the quality of substances used for making medicinal products.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(5) The suspension of the sale or dispensing of a medicinal product specified in clause 1 of subsection 1 of this section is lifted by a respective permit of the State Agency of Medicines, unless the circumstances described in clause 2 of subsection 1 become evident.

(6) After conducting a general inspection of an enterprise, the State Agency of Medicines, within 90 days, issues a certificate to the inspected enterprise concerning the compliance of the enterprise with good manufacturing or distribution practices of the European Economic Area, provided that the inspection results confirm such compliance. The State Agency of Medicines enters the certificate in the database specified in Article 111(6) of Directive 2001/83/EC of the European Parliament and of the Council.

(7) In connection with a marketing authorisation or in the event of suspicion that the requirements established in accordance with the guidelines drawn up by the European Commission on the basis of Directive 2001/83/EC of the European Parliament and of the Council, the State Agency of Medicines may engage in regulatory enforcement towards the manufacturer of a medicinal product and towards the manufacturer, importer and distributor of an active substance and excipient of a medicinal product for human use who is located in the European Economic Area or outside it. Regulatory enforcement can also be initiated at the request of a Member State, the European Commission, the Council of the European Union or the European Medicines Agency.
[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(8) The State Agency of Medicines assesses serious adverse reactions to an investigational medicinal product, which have become evident in the course of a clinical trial, in cooperation with the European Medicines Agency and the competent authorities of other Member States and assesses adverse events and adverse reactions that have become evident in the course of a clinical trial of a veterinary medicinal product.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, applicable as of 01.02.2022]

(9) The State Agency of Medicines conducts inspections of compliance with requirements for a clinical trial of a medicinal product and manufacturing and import requirements of investigational medicinal products in accordance with Regulation (EU) No 536/2014 of the European Parliament and of the Council.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, applicable as of 01.02.2022]

(10) The State Agency of Medicines regularly inspects the operations specified in subsection 5 of § 16 of this Act when handling a medicinal product investigated in a clinical trial and the compliance of the handling operations with requirements established on the basis of subsection 10 of § 16.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022, applicable as of 01.02.2022]

(11) The State Agency of Medicines exercises supervision and, where necessary, conducts inspections of compliance with requirements for a clinical trial of a medicinal product.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 102. Rate of non-compliance levy

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(1) Where a compliance notice is not complied with, a law enforcement agency has the right to impose substitutional performance and a non-compliance levy in accordance with the procedure established in the Substitutional Performance and Non-Compliance Levies Act. The maximum limit of a non-compliance levy is 9600 euros.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

(2) Upon failure to comply with a precept issued in the event of failure to perform the obligation provided for in clause 2^{10} of subsection 1 of § 44 of this Act, the upper limit for a penalty payment shall be 100,000 euros.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 103. Contestation of compliance notice

[Repealed – RT I, 13.03.2014, 4 – entry into force 01.07.2014]

Chapter 7
LIABILITY

§ 104. Non-compliance with requirements for handling of medicinal products

(1) The sanction for non-compliance with the requirements for handling medicinal products or the brokering requirements provided in subsection 8^2 of § 26 of this Act is a fine of up to 300 fine units.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

(2) The sanction for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 105. Non-compliance with requirements for recording and reporting regarding medicinal products

(1) The sanction for non-compliance with the requirements for recording and reporting regarding medicinal products is a fine of up to 300 fine units.

(2) The sanction for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 106. Non-compliance with requirements related to marketing authorisation

(1) Violation of the requirements related to a marketing authorisation as well as the acquiring or distribution of an unauthorised medicinal product or a medicinal product without a special authorisation of the State Agency of Medicines
is punishable by a fine of up to 300 fine units.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(2) The sanction for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 107. Non-compliance with requirements for advertising of medicinal products and prohibition on inducement designed to promote sales

(1) The placing, producing or publicising of advertising which violates the requirements for advertising of medicinal products or violation of the prohibition on inducement designed to promote prescription or sales of medicinal products provided in § 86 of this Act
is punishable by a fine of up to 300 fine units.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(2) The sanction for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 108. Non-compliance with the requirements of a clinical trial of a medicinal product

[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

(1) The sanction for non-compliance with the requirements of a clinical trial of a medicinal product, including provisions governing the submission of data to be published via the database specified in Article 81 of Regulation (EU) No 536/2014 of the Parliament and of the Council or provisions governing the safety of a trial subject is a fine of up to 300 fine units.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

(2) The sanction for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 108[1]. Non-compliance with the requirements for a clinical trial of a veterinary medicinal product

(1) The sanction for the non-compliance with the requirements for a clinical trial of a veterinary medicinal product is a fine of up to 300 fine units.

(2) The sanction for the same act committed by a legal person is a fine of up to 32,000 euros.
[RT I, 03.01.2022, 2 – entry into force 28.01.2022]

§ 109. Violation of requirements for prescription, dispensing and use of medicinal products upon provision of veterinary service and requirements for delivery of veterinary medicinal products in small quantities

[RT I, 20.06.2022, 4 – entry into force 01.07.2022]

(1) Violation of the requirements for the prescription, dispensing and use of medicinal products upon the provision of veterinary service and the requirements for the delivery of veterinary medicinal products in small quantities from one holder of a professional activity licence of a veterinarian to another
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, 20.06.2022, 4 – entry into force 01.07.2022]

§ 110. Non-compliance with requirements for issue of medical prescriptions

(1) The sanction for non-compliance with the requirements for the issue of medical prescriptions is a fine of up to 200 fine units.

(2) The sanction for the same act committed by a legal person is a fine of up to 32 000 euros.
[RT I 2010, 22, 108 – entry into force 01.01.2011]

§ 111. Interference with regulatory enforcement

[Repealed – RT I, 12.07.2014, 1 – entry into force 01.01.2015]

§ 112. Proceedings

(1) The State Agency of Medicines conducts out-of-court proceedings in the misdemeanour cases provided in §§ 104–108 and 110 of this Act.

(2) The State Agency of Medicines conducts out-of-court proceedings in the misdemeanour cases provided in §§ 104, 105 and 110 of this Act in the event of an offence committed by a health service provider.

(3) The State Agency of Medicines conducts out-of-court proceedings in the misdemeanour cases provided in § 104 of this Act in the event of a violation of the provisions of health protection.

(4) The Tax and Customs Board is the out-of-court proceedings authority in matters concerning the misdemeanours provided in §§ 104–106 of this Act.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

(5) The Agriculture and Food Board is the out-of-court proceedings authority in the misdemeanour cases provided in § 109 of this Act.
[RT I, 01.07.2020, 1 – entry into force 01.01.2021]

(6) The court and the Tax and Customs Board may, in accordance with §§ 104–106 of the Penal Code, confiscate the substance or thing that constituted the direct object of commitment of the misdemeanours specified in § 83 of this Act.
[RT I, 15.12.2023, 3 – entry into force 25.12.2023]

Chapter 8
IMPLEMENTING PROVISIONS

§ 113. Validity of authorisations granted by the State Agency of Medicines and obligations of a holder of authorisation to handle medicinal products and a marketing authorisation holder

(1) Handling authorisations and special authorisations issued before the entry into force of this Act remain in force until the date of expiry specified therein.

(2) A manufacturing authorisation holder or wholesale distribution authorisation holder who has not entered the name of the responsible person on the authorisation must inform the State Agency of Medicines of the name of the responsible person and their substitute by 1 May 2005.

(3) A wholesale distribution authorisation holder who changes the labelling or outer packaging of a medicinal product, including investigational medicinal products, or imports medicinal products from third countries, must apply for a manufacturing authorisation by 1 July 2005, or terminate such activities.

(4) The holder of a marketing authorisation for the sale of authorised medicinal products must appoint, by 1 July 2005, the person specified in subsection 2 of § 64 of this Act and inform the State Agency of Medicines of the appointment.

§ 114. Registration of pharmacists and assistant pharmacists

(1) The Health Board commences 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 in this Act according to which the pharmacy service 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 a pharmacy service authorisation is submitted after 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 15 square metres as a minimum where the pharmacy counter is located at a distance further than 15 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.

§ 115[1]. Implementation of subsection 4 of § 3

Persons who commenced the operations specified in subsection 4 of § 3 of this Act before the subsection 4 of § 3 entered into force must, for the purpose of obtaining an authorisation, submit to the State Agency of Medicines the required data and documents within two months after the entry into force of subsection 4 of § 3.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

§ 115[2]. Implementation of requirements of good distribution practices, requirements for logos of websites engaged in distance selling of medicinal products and requirements for safety features of packaging of medicinal products

(1) The provisions set out in subsection 7 of § 16, subsection 8[1]of § 26, clauses 2[2]and 2[4]of subsection 1 of § 44 and subsection 9 of § 100 of this Act apply as of the establishment of these practices by the European Commission.

(2) The logo requirement provided in subsection 5[3]of § 31 of this Act and the provisions of clause 2 of subsection 9 of § 31 and subsection 10 of § 31 of this Act apply as of the establishment of the requirements by the European Commission.

(3) The provisions of clause 2[6]of subsection 1 of § 44, clause 3 of subsection 1 of § 54 and subsection 5[1]of § 70 of this Act regarding safety features of packaging of medicinal products apply as of the establishment of the requirements by the European Commission.
[RT I, 17.04.2013, 2 – entry into force 27.04.2013]

§ 115[3]. Implementation of requirements of Commission Delegated Regulation (EU) 2016/161

(1) Medicinal products which have been released for sale or distribution without the safety features for the purposes of Commission delegated Regulation (EU) 2016/161 before 9 February 2019 and which are not repackaged or relabelled thereafter, may be placed on the market, distributed and supplied until their expiry date.

(2) The State Agency of Medicines must immediately but not later than by 9 February 2019 be informed of the commencement of the activity provided in Article 37(a) of Commission delegated Regulation (EU) 2016/161.
[RT I, 21.12.2018, 4 – entry into force 01.01.2019]

§ 116. Temporary application of clause 3 of subsection 4 of § 65

Upon application of clause 3 of subsection 4 of § 65 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 where 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 1 and 3 of § 78[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 6 of subsection 2 of § 78[3]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 where 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 are amended in accordance with clause 1 of subsection 4 of § 70 of this Act.

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

(4) The State Agency of Medicines draws up a report on the audit of the pharmacovigilance system and submits 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]

§ 116[2]. Transition period for termination of operations of branch pharmacies

(1) A branch pharmacy located in a city as a settlement unit of 4000 or more inhabitants, which has been founded before the 9 June 2014 may operate as a branch pharmacy until 1 April 2020 without changing the place of business.
[RT I, 21.12.2018, 4 – entry into force 09.02.2019]

(2) Where a branch pharmacy no longer meets the criterion specified in subsection 9[1] of § 30 of this Act as a result of the reorganisation of the administrative territory of a municipality, the branch pharmacy may operate without changing the place of business for up to five years following the emergence of the non-conformity.
[RT I, 04.07.2017, 2 – entry into force on the day of announcement of the results of the 2017 elections of municipal councils]

§ 116[3]. Implementation of subsection 5 of § 42

General pharmacy authorisations issued before 9 June 2014, which do not comply with the conditions provided in subsection 5 § 42, must be brought into compliance with the established requirements by 1 April 2020.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

§ 116[4]. Implementation of clause 2 of subsection 2 of § 53

Competent persons appointed by a general pharmacy authorisation holder who provide the pharmacy service in a city or a rural town having 4000 or more inhabitants and who simultaneously provide the pharmacy service in a pharmacy operating on the basis of another pharmacy service authorisation may act as the competent persons appointed by the general pharmacy authorisation holder until 1 July 2015.
[RT I, 06.06.2014, 14 – entry into force 09.06.2014]

§ 116[5]. Issue and amendment of general pharmacy authorisation between 9 June 2014 and 9 June 2015

(1) [Repealed – RT I, 23.12.2014, 30 – entry into force 22.12.2014 – the judgment of the Supreme Court *en banc* declares subsections 1–6 of § 116[5] of the Medicinal Products Act unconstitutional and repeals them.]

(2) [Repealed – RT I, 23.12.2014, 30 – entry into force 22.12.2014 – the judgment of the Supreme Court *en banc* declares subsections 1–6 of § 116[5] of the Medicinal Products Act unconstitutional and repeals them.]

(3) [Repealed – RT I, 23.12.2014, 30 – entry into force 22.12.2014 – the judgment of the Supreme Court *en banc* declares subsections 1–6 of § 116[5] of the Medicinal Products Act unconstitutional and repeals them.]

(4) [Repealed – RT I, 23.12.2014, 30 – entry into force 22.12.2014 – the judgment of the Supreme Court *en banc* declares subsections 1–6 of § 116[5] of the Medicinal Products Act unconstitutional and repeals them.]

(5) [Repealed – RT I, 23.12.2014, 30 – entry into force 22.12.2014 – the judgment of the Supreme Court *en banc* declares subsections 1–6 of § 116[5] of the Medicinal Products Act unconstitutional and repeals them.]

(6) [Repealed – RT I, 23.12.2014, 30 – entry into force 22.12.2014 – the judgment of the Supreme Court *en banc* declares subsections 1–6 of § 116[5] of the Medicinal Products Act unconstitutional and repeals them.]

(7) A person who obtained the right to open a general pharmacy or a structural unit thereof as a result of lot-drawing on the basis of § 42[1] of this Act in force until 9 June 2014 has the right to submit an application for an authorisation and the authorisation is issued on the basis of the provisions of § 42[1] of this Act in force until 9 June 2014.
[RT I, 06.06.2014, 14 – entry into force 09.06.2014]

§ 116[6]. Implementation of duty to provide the pharmacy service

[Repealed – RT I, 15.12.2023, 3 – entry into force 25.12.2023]

§ 116[7]. Implementation of § 41

[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

(1) Applications for a general pharmacy authorisation submitted before the entry into force of subsections 2 to 6 of § 41 of this Act are reviewed and decided based on the wording of the Act in force at the time of submission of the application.

(2) The general pharmacy authorisations specified in subsection 1 of this section and general pharmacy authorisations issued before the entry into force of subsections 2 to 6 of § 41 of this Act, which do not comply with the conditions specified in subsections 2 to 5 of § 41 of this Act must be brought into compliance with the established requirements by 1 of April 2020.
[RT I, 10.03.2015, 6 – entry into force 20.03.2015]

§ 116[8]. Application for an authorisation for making a radiopharmaceutical preparation

The maker of a radiopharmaceutical preparation must start applying for an authorisation for making a radiopharmaceutical preparation provided in § 16[11] of this Act not later than on 1 April 2022.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 116[9]. Variation of the requirements for a clinical trial stemming from the implementation of Regulation (EU) No 536/2014 of the European Parliament and of the Council

Where an application for a clinical trial of a medicinal product has been submitted within 18 months after the publication of a notice specified in Article 82(3) of Regulation (EU) No 536/2014 of the European Parliament and of the Council, § 87–99 of this Act is applied to the clinical trial over a period of three years from the implementation of the same Regulation to the entry into force of this version.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 116[10]. Implementation of §§ 99[1]–99[7] and subsections 8–10 of § 101[1]

Sections 99[1]–99[7] and subsections 8–10 of § 101[1] of this Act apply as of the day when a period of six months has passed from the publication of a notice specified in Article 82(3) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the Official Journal of the European Union.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022]

§ 116[11]. Application of retroactive insurance cover in case of vaccination insurance

(1) The Estonian Health Insurance Fund shall, on the conditions and pursuant to the procedure provided for in Chapter 5[1] of this Act, compensate an entitled person for damage resulting from the use of vaccines used for immunisation in case of an epidemic provided for in § 9 of the Communicable Diseases Prevention and Control Act from the beginning of administration thereof in Estonia.

(2) In the case provided for in subsection 1 of this section, an entitled person shall have the right to submit an application for compensation of vaccination damage to the Estonian Health Insurance Fund by 1 May 2023. If an application has not been submitted by the specified term, the Estonian Health Insurance Fund shall be released from the obligation to compensate for damage on the basis of retroactive insurance cover.

(3) The vaccination insurance premium for retroactive insurance cover specified in subsection 1 of this section shall be paid to the Estonian Health Insurance Fund by the Republic of Estonia.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 116[12]. Application of insurance obligation in case of vaccination insurance

(1) In the case of vaccines not specified in subsection 1 of § 116[11] of this Act, the insurance obligation of the distributor shall be applied as of 1 January 2023.

(2) In the case of vaccines specified in subsection 1 of this section, the Estonian Health Insurance Fund shall compensate for the damage incurred as a result of an insured event if the insured event occurs after 1 January 2023.
[RT I, 29.04.2022, 1 – entry into force 01.05.2022]

§ 116[13]. Assessment of effect of beginner's allowance

The Ministry of Social Affairs analyses the achievement of the objective and the effect of the implementation of the beginner's allowance of a pharmacist and submits, where necessary, proposals for amendment of the regulation by 1 January 2028 at the latest.
[RT I, 15.12.2023, 1 – entry into force 01.01.2024]

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

§ 122. Entry into force of the Act

(1) This Act enters into force on 1 March 2005.

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

(3) Clause 5 of subsection 5 of § 15 of this Act enters into force on 1 October 2005.

(4) Subsection 2 of § 18 of this Act enters into force in respect of wholesale distribution authorisation holders and manufacturing authorisation holders on 1 July 2005.

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

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

(6) Section 43 of this Act enters into force in respect of holders of handling authorisations 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 3 of § 80 of this Act enters into force on 1 July 2005.

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

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

[1]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), amended by Directives 2002/98/EC (OJ L 33, 08.02.2003, pp 30–40), 2003/63/EC (OJ L 159, 27.06.2003, pp 46–94), 2004/24/EC (OJ L 136, 30.04.2004, pp 85–90), 2004/27/EC (OJ L 136, 30.04.2004, pp 34–57), 2008/29/EC (OJ L 81, 20.03.2008, pp 51–52), 2009/53/EC (OJ L 168, 30.06.2009, pp 33–34), 2009/120/EC (OJ L 242, 15.09.2009, pp 3–12), 2010/84/EU (OJ L 348, 31.12.2010, pp 74–99), 2011/62/EU (OJ L 174, 01.07.2011, pp 74–87) and 2012/26/EU (OJ L 299, 27.10.2012, pp 1–4) and Regulations (EC) No 1901/2006 (OJ L 378, 27.12.2006, pp 1–19), (EC) No 1394/2007 (OJ L 324, 10.12.2007, pp 121–137), (EU) 2017/745 (OJ L 117, 05.05.2017, pp 1–175), (EU) 2019/5 (OJ L 4, 07.01.2019, pp 24–42) and (EU) 2019/1243 (OJ L 198, 25.07.2019, pp 241–344). [RT I, 03.01.2022, 2 – entry into force 01.02.2022]