The Regulation is established under subsection 43 (3) of the Health Insurance Act.

**Part 1**

**GENERAL TERMS**

**§ 1. Scope of application**

The present Regulation establishes the following:
1) The procedure for drafting and amendment of the list of medicinal products (hereinafter the list of medicinal products) of the Estonian Health Insurance Fund;
2) Detailed content of the criteria provided in subsection 43 (2) of the Health Insurance Act and evaluators of compliance with the criteria.

**§ 2. Application of the Administrative Procedure Act**

Provisions of the Administrative Procedures Act are applied to the administrative procedures governed by the Regulation in the extent not provided in the Regulation.

**§ 3. Medicinal product and manufacturer of medicinal products**

Special formulae consumed on the basis of medical indications and food additives used for treating inherent metabolic disorders are considered equal to medicinal products. [RT I, 15.05.2014, 1 - entered into force 18.05.2014]

(2) A person to whom marketing authorisation of a medicinal product has been issued is equal to a manufacturer of medicinal products.

(3) A manufacturer of medicinal products is represented by an authorised person or another person under a notarized power of attorney of the manufacturer of medicinal products.
§ 4. Application of procedure for supplementing the list of medicinal products

(1) Part II of the Regulation is applied in the event of application for:
1) entry of a medicinal product with a new active ingredient and administration method into the list of medicinal products;
2) amendment of compensation amount for a medicinal product with compensation amount of 50 per cent for 75 or 100 per cent;
3) adding a new diagnosis for a medicinal product entered into the list. [RT I, 17.11.2010, 3 – entered into force 20.11.2010]

(2) Part III of the Regulation is applied in the event of application for:
1) supplementing of the list of medicinal products with a medicinal product in comparison to which a medicinal product with the same active ingredient and administration method is already listed, or for which a directive by the Minister of Social Affairs satisfying the application in regard to a medicinal product with the same active ingredient and method of administration has entered into force;
2) supplementing of the list of medicinal products with a medicinal product that (or in comparison to which a medicinal product with the same active ingredient and method of administration) has been excluded from the list of medicines due to expiry of marketing authorisation or lack of marketing or price agreement. 
[RT I, 17.11.2010, 3 – entered into force 20.11.2010]

Part 2
GENERAL PROCEDURE FOR SUPPLEMENTING THE LIST OF MEDICINAL PRODUCTS

Chapter 1
Application for entry of a medicinal product into the list of medicinal products

§ 5. Submission of an application

(1) The procedure for entering a medicinal product into the list of medicinal products begins with the submission of an application to the Minister of Social Affairs.

(2) An application for entering a medicinal product into the list of medicinal product is submitted by a manufacturer of medicinal products.

(3) An application cannot be submitted if at least 6 months have not passed from the completion of procedures regarding the same medicinal product.

(4) A manufacturer of medicinal products shall report all known circumstances of significance in regard to the processing of the application.

§ 6. Submission of an application and formal requirements

An application, together with supplementary documents, is submitted electronically in three identical copies and in format viewable with Acrobat Reader or Microsoft Office software.

[RT I, 15.05.2014, 1 - entered into force 18.05.2014]

(2) If the application or its annexes include mathematical models for reasoning the information included in the application, which cannot be used for modelling with Microsoft Office software, software for modelling the application with the necessary rights of intellectual property and other rights for the parties of the procedure shall be enclosed with the application for using the software in processing of the application.

(3) Application form is provided in an annex to the Regulation.

(4) The application and annexes thereto are in Estonian, except for copies of articles and scientific research.

(4°) The annexes to the application may be presented in English, in the case the application concerns a medicinal product necessary to treat a rare illness as defined in the Regulation (EC) No 141/2000 of the European Parliament and of the Council on Orphan Medicinal Products (OC L 18, 22.01.2000, p 1)
[RT I, 15.05.2014, 1 - entered into force 18.05.2014]

(5) The contents of annexes to an application do not constitute public information.

§ 7. Annexes to the application

(1) Annexes to an application include the following:
1) description of the area of use in Estonia on which issuing of a medicinal product on discount conditions is based (including the number of patients, treatment methods used, analysis regarding the possible retail sale volume of the medicinal product, and the predicted retail sale of the medicinal product for 3 years);
2) medical results expected from the use of the medicinal product (e.g. life-saving, symptomatic, improving the quality of life, etc.) with references to scientific publications and research, as well as copies to the referenced scientific publications and research;
3) description of the optimum duration of dosing and using the medicinal product;
4) description of side effects of the medicinal product and medical-economic evaluation to those, first of all the influence of the side effects to the quality of life; additional research necessary for the optimum use or prevention of side effects;
5) wholesale purchase prices of all packages of the medicinal product and estimated changes in the prices for 3 years;
6) pharmacoeconomic analysis of using the medicinal product according to the instruction for Baltic countries published on the website of the Ministry of Social Affairs for pharmacoeconomic evaluation of medicinal products (cost-efficiency analysis shall be presented at choosing the cost efficiency analysis, except if there is reasonable ground to waive it), relying on information provided in clauses 2 and 4 of the present section;
7) an overview of all scientific publications regarding the medicinal product;
8) a confirmation regarding the lack of additional information;
9) a copy of a document proving a right of representation;
10) other documents established by the legislation.

1) The pharmacoeconomic analysis of using the medicinal product must not be adapted to Estonian circumstances in the case the medicinal product is for treating a rare illness as defined in subsection 6 (4) herein.

§ 8. Acceptance and checking of an application

(1) The compliance of an application with the requirements established in the Regulation is checked at the Ministry of Social Affairs. In the event of a shortcoming, a period for elimination of the shortcoming shall be assigned within 15 days. The period shall not be shorter than 10 days or longer than 60 days.

(2) The calculation of the period of the procedure shall stop from the moment of assigning a term for elimination of the shortcoming until the elimination of the shortcoming by the manufacturer of the medicinal product.

(3) An application without shortcomings is submitted to the Estonian Health Insurance Fund and the State Agency of Medicines within 15 days.

§ 9. Leaving an application unprocessed

If shortcomings are not eliminated within the assigned term, the Minister of Social Affairs leaves the application unprocessed.

§ 10. Amendment and withdrawal of an application

(1) A manufacturer of medicinal products has a right to amend an application at his own disposal, submitting a new annex to the application to replace the annex to the application provided in clauses 1 – 4 and 6 of section 1 of § 7 of the present Regulation.

[RTL 2007, 14, 210 – entered into force 12.02.2007]
(2) In the event of an amendment to the application, processing terms shall be calculated from the submission of the amendments.

(3) A manufacturer of medicinal products has a right to withdraw the application at any time before the completion of the procedure.

(4) The Ministry of Social Affairs informs the Estonian Health Insurance Fund and the State Agency of Medicines of an amendment to or withdrawal of the application.

Chapter 2
Opinion of the State Agency of Medicines and the Estonian Health Insurance Fund

§ 11. Opinion of the State Agency of Medicines

(1) The State Agency of Medicines prepares a written opinion on the application within 30 days from the arrival of the application at the State Agency of Medicines. The Ministry of Social Affairs shall be informed of the author of the opinion.

[RTL 2007, 14, 210 – entered into force 12.02.2007]

(2) In preparation of the opinion, the State Agency of Medicines may use non-staff experts. The names of the experts are not published.

(3) The State Agency of Medicines immediately submits the opinion to the Estonian Health Insurance Fund, the Ministry of Social Affairs and the manufacturer of the medicinal product.

§ 12. Criteria for the opinion of the State Agency of Medicines

(1) The State Agency of Medicines shall rely on the following criteria in its opinion:
   1) the description and prevalence of the disease on which the issuing of the medicinal product on discount conditions is based, importance of pharmacotherapy in treating of the disease;
   2) existence of other medicinal products and treatment methods for the disease on which the issuing on discount conditions is based;
   3) scientifically proven effectiveness of the medicinal product, including a comparison to other medicinal products and treatment methods;
   4) scientifically proven safety of the medicinal product, including a comparison to other medicinal products and treatment methods;
   5) optimum dosing of the medicinal product and duration of use, and a need to receive other medicinal products and treatment or diagnostic procedures during the treatment, including a comparison to other medicinal products and treatment methods;
   6) information regarding the use of the medicinal product under application and other medicinal products used for the disease on which the issuing on discount conditions is based in Estonia and in other countries;
   7) possibility and consequences of misuse and excessive use of the medicinal product;
   8) necessity and possibility of establishing limitations to prescribing of the medicinal product on discount conditions to ensure the rational use of the medicinal product.

[RT I, 17.11.2010, 3 – entered into force 20.11.2010]

(2) The State Agency of Medicines relies on the information provided in the application and other information, including epidemiological, statistical and clinical information.

§ 13. Opinion of the Estonian Health Insurance Fund

(1) The Estonian Health Insurance Fund prepares a written opinion on the application within 30 days from the arrival of the opinion of the State Agency of Medicines at the Estonian Health Insurance Fund. The Ministry of Social Affairs shall be informed of the author of the opinion.

[RTL 2007, 14, 210 – entered into force 12.02.2007]

(2) In preparation of the opinion, the Estonian Health Insurance Fund may use non-staff experts. The names of the experts are not published.

(3) The Estonian Health Insurance Fund immediately submits the opinion to the Ministry of Social Affairs and the manufacturer of the medicinal product.

§ 14. Criteria for the opinion of the Estonian Health Insurance Fund

(1) The Estonian Health Insurance Fund shall rely on the following criteria in its opinion:
   1) information regarding the facilitation and use of the medicinal product under application and other medicinal products used for the disease on which the issuing on discount conditions is based in Estonia and in other countries;
2) economic justification of using the medicinal product, including a comparison to a disease on which the issuing of other medicinal products and treatment methods on discount conditions is based;
3) possibility and economic consequences of misuse and excessive use of the medicinal product;
4) necessity and possibility of establishing limitations to prescribing of the medicinal product on discount conditions to ensure the economically reasonable use of the medicinal product;
5) estimated retail sale volume of the medicinal product;
6) correspondence of listing of the medicinal product to the financial means of medical insurance, incl. considering the cost of the medicinal product under application in other countries of the European Union, primarily in the Republic of Latvia, the Republic of Lithuania, the Republic of Slovakia and the principle provided in section 3 of § 25 of the Health Insurance Act;

(2) The Estonian Health Insurance Fund relies on the information provided in the application and other information, including epidemiological, statistical and clinical information.

Chapter 3
PROCESSING OF AN APPLICATION BY THE COMMITTEE

§ 15. Committee for Medicinal Products

(1) The Committee for Medicinal Products (hereinafter the committee) is a committee with advisory rights formed by a directive of the Ministry of Social Affairs.

(2) The Committee has up to 8 members. The Minister of Social Affairs appoints the members of the committee by a directive. The following institutions make proposals for appointment of members of the committee:
1) the Estonian Medical Association in regard to one member and a substitute member thereof;
2) the Estonian Family Doctors Association in regard to one member and a substitute member thereof;
3) Department of Health of Tartu University in regard to one member and a substitute member thereof;
4) the Estonian Chamber of Disabled People in regard to one member and a substitute member thereof;
5) the Estonian Patients Advocacy Council in regard to one member and a substitute member thereof;
6) the Ministry of Social Affairs in regard to one member and a substitute member thereof;
7) the State Agency of Medicines in regard to one member and a substitute member thereof;
8) the Estonian Health Insurance Fund in regard to one member and a substitute member thereof.

(3) A person having prepared the opinion of the Estonian Health Insurance Fund or the State Agency of Medicines may be a member of the committee.

(4) The work procedures of the committee are established by a directive of the Minister of Social Affairs. (5) If necessary, the committee may include professional experts in the work of the committee.

§ 16. Submission of opinion and objections

(1) The Ministry of Social Affairs shall submit the opinions of the State Agency of Medicines and the Estonian Health Insurance Fund to the committee.

(2) A manufacturer of medicinal products may submit a written opinion in regard to the opinion of the State Agency of Medicines and the Estonian Health Insurance Fund within 15 days from the submission of the opinion of the State Agency of Medicines and the Estonian Health Insurance Fund.

(3) If the manufacturer of medicinal products has substantive objections to the opinion of the State Agency of Medicines or the Estonian Health Insurance Fund that have not been submitted before, the Ministry of Social Affairs may request the submission of additional opinion from the State Agency of Medicines and the Estonian Health Insurance Fund in regard to the objections of the manufacturer of medicinal products within 15 days. The Ministry of Social Affairs shall inform the parties of the procedure thereof, and the period of processing the application shall be suspended until the arrival of the additional opinion of the State Agency of Medicines and the Estonian Health Insurance Fund.

§ 17. Summoning and appearance to a meeting of the committee

(1) The manufacturer of medicinal products may be summoned to a meeting of the committee.

(2) The Ministry of Social Affairs shall issue an invitation to a committee meeting to parties of the procedure according to section 2 of § 17 of the Administrative Procedures Act by delivery according to the procedures
established in section 7 of chapter 1 of the Administrative Procedures Act at least 15 days before the meeting
takes place.

(3) A legal person invited to a committee meeting shall authorise a representative, who can attend upon an
invitation.

(4) If a person cannot attend the meeting upon an invitation for a significant reason, he/she shall immediately
inform the committee thereof.

(5) If a manufacturer of medicinal products or a party of the procedure or another invited person does not attend
the meeting for a significant reason, the committee meeting may take place without him/her.

§ 18. Opinion of the committee

(1) In providing of an opinion, the committee shall rely on the criteria established in section 2 of § 43 of the
Health Insurance Act and section 1 of § 12 and section 1 of § 14 of the present Regulation.
[RT I, 17.11.2010, 3 – entered into force 20.11.2010]

(2) The opinion of the committee shall be in writing and with justifications. The opinion of the committee may
be conditional.

(3) The justification needs to include considerations for not accepting the opinion and objections of the
manufacturer of medicinal products and a third person.

(4) If the following of the committee’s opinion would cause an increase in the expenses of the Estonian Health
Insurance Fund or a redistribution of financial means, the opinion shall include the financial calculations
showing the covering of additional costs or a method of redistribution of financial means within the prescribed
expenses for compensation of medicinal products in the budget of the Estonian Health Insurance Fund.

(5) The committee shall immediately submit an opinion to the manufacturer of medicinal products and the
Minister of Social Affairs.

Chapter 4
Solving of an application and supplementing
of the list of medicinal products

§ 19. Solving of an application

(1) The Minister of Social Affairs solves the application and issues the relevant directive by delivering it to
the parties of the procedure according to the procedure provided in section 7 of chapter 1 of the Administrative
Procedures Act within 180 days from the submission of the application to the Ministry of Social Affairs,
excluding the days during which the period of the administrative procedure had been suspended under the
legislation.

(2) The Minister of Social Affairs may apply the following ancillary conditions:
1) a right to amend the directive if the State Agency of Medicines or the Estonian Health Insurance Fund has
provided information about newly discovered properties or misuse of the medicinal product;
2) a right to amend the directive if the manufacturer of medicinal products has violated a price agreement,
has not concluded a price agreement by the term provided in the directive, or has not fulfilled an additional
obligation associated with the directive;
3) restriction of prescribing the medicinal product only by doctors of the relevant profession;
4) age limitation to patients for whom the medicinal product is prescribed;
5) restrictions based on medical criteria;
6) limitations to the duration of prescribing the medicine.

§ 20. Entry of the directive of the Ministry of Social Affairs into force

The directive by which an application of a manufacturer of medicinal products is solved, shall enter into force
from the moment of reception by the parties of the procedure, unless a later date of entry into force is provided
in the directive.

§ 21. Supplementing the list of medicinal products

(1) If the directive by which an application of the manufacturer of medicinal products was satisfied has not
been disputed according to the procedures provided by the legislation, the Minister of Social Affairs shall enter
the medicinal product into the list of medicinal products latest within 6 months from the expiry of the term of
disputing.
(2) If the Minister of Social Affairs and the manufacturer of medicinal products have not concluded a price agreement within the term provided in section 1, the medicinal product shall not be entered into the list of medicinal products.

Part 3
SIMPLIFIED PROCEDURE FOR AMENDMENT
OF THE LIST OF MEDICINAL PRODUCTS

Chapter 5
Application for entry of medicinal products into the list of medicinal products

§ 22. Submission of an application

(1) The simplified procedure for entering a medicinal product into the list of medicinal products begins with the submission of an application to the Minister of Social Affairs.

(2) Provisions of § 5 are applied to the submission of the application.

§ 23. Formal requirements to the application

The application is submitted electronically, relying on the provisions of § 6 of the present Regulation.

[RT I, 15.05.2014, 1 - entered into force 18.05.2014]

§ 24. Application of provisions

(1) The provisions of § 8, 9 and 10 are applied to the acceptance and checking of an application, leaving it unprocessed and withdrawal of an application.

(2) The provisions in section 3 of § 8 shall not be applied to an application without shortcomings.

(3) Provisions in section 4 of § 10 of the present Regulation shall not be applied to the amendment and withdrawal of an application.

[RTL 2007, 14, 210 – entered into force 12.02.2007]

Chapter 6
Solving of an application

§ 25. Solving of an application

(1) The Minister of Social Affairs solves the application and issues the relevant directive by delivering it to the parties of the procedure according to the procedure provided in section 7 of chapter 1 of the Administrative Procedures Act within 90 days from the submission of the application, excluding the days during which the period of the administrative procedure had been suspended under the legislation.

(2) Upon solving of an application, the Minister of Social Affairs considers the criteria provided in section 1 of § 18 of the present Regulation.

[RT I, 17.11.2010, 3 – entered into force 20.11.2010]

(21) Upon the solution of an application in regard to the criterion of compliance with the financial means of health insurance, the Minister of Social Affairs shall also consider the following:

1) in the event of a generic medicinal product the fact that the generic medicinal product is at least 30% cheaper than the original medicinal product with the same active ingredient entered into the list of medicinal products;

2) in the event of a biologically similar medicinal product the fact that the said medicinal product is at least 15% cheaper than the original medicinal product entered into the list of medicinal products;

3) in the event of a secondary medicinal product the fact that the medicinal product with secondary marketing authorisation is at least 10% cheaper than the original medicinal product entered into the list of medicinal products;

4) after the establishment of a reference price in a group of medicinal products with the same active ingredient and method of administration the fact that the price of the medicinal product upon solving of the first three
applications is at least 10% cheaper and upon solving of the following applications not higher than the price of the cheapest medicinal product entered into the list of medicinal products.

[RT I, 17.11.2010, 3 – entered into force 20.11.2010]

(3) Upon satisfaction of an application, the Minister of Social Affairs may establish ancillary conditions provided in section 2 of § 19.

(4) Before the solving of an application the Ministry of Social Affairs may ask an opinion from the Estonian Health Insurance Fund, the State Agency of Medicines and the committee.

(5) The Ministry of Social Affairs submits the application to the committee for an opinion, if:

1) the satisfaction of the application may cause an increase in the expenses of the Estonian Health Insurance Fund above the expenses prescribed for compensation of medicinal products in the budget of the Estonian Health Insurance Fund;

2) the decision is of principle importance for the Estonian policy of medicinal products.

(6) Provisions of paragraphs 20 and 21 shall be applied to the entry of the directive of the Minister of Social Affairs into force and supplementing of the list of medicinal products.

§ 26. Processing of an application by the committee

Provisions of chapter 3 of part II are applied to the processing of an application by the committee.

Part 4

EXCLUSION OF A MEDICINAL PRODUCT FROM THE LIST, AMENDMENT OF THE PERCENTAGE OF COMPENSATION APPLIED TO A MEDICINAL PRODUCT OR ESTABLISHMENT OR AMENDMENT OF RESTRICTIONS ON THE USE OF A MEDICINAL PRODUCT

§ 27. Submission of and requirements to an application

(1) The procedure of exclusion of a medicinal product from the list, amendment of the percentage of compensation applied to a medicinal product or establishment or amendment of restrictions on the use of a medicinal product starts by submitting a relevant application to the Minister of Social Affairs. An application may be submitted by every manufacturer of medicinal products, the State Agency for Medicines, the Estonian Health Insurance Fund or another interested person. The procedure may be initiated by the Ministry of Social Affairs. An application is submitted electronically.

[RT I, 15.05.2014, 1 - entered into force 18.05.2014]

(4) The need for exclusion of a medicinal product from the list, amendment of the percentage of compensation applied to a medicinal product or the establishment or amendment of ancillary conditions for using a medicinal product shall be justified according to the criteria established in section 2 of § 43 of the Health Insurance Act.

§ 28. Operations upon receiving an application

(1) Immediately after the initiation of a procedure for exclusion of a medicinal product from the list, amendment of the percentage of compensation applicable to a medicinal product or establishment or amendment of restrictions on the use of a medicinal product the Ministry of Social Affairs asks an opinion from the manufacturer of medicinal products for whose product the application was submitted, the State Agency for Medicines, the Estonian Health Insurance Fund with written evidence of the justification for the exclusion of the relevant medicinal product from the list, amendment of the percentage of compensation applicable to a medicinal product or establishment or amendment of restrictions on the use of a medicinal product.

(2) The State Agency of Medicines and the Estonian Health Insurance Fund are not included in the procedure, if the procedure for exclusion of the medicinal product from the list or decreasing of the percentage of compensation was initiated for the following reasons:

1) the medicinal product is not marketed or the marketing authorisation or price agreement has expired;

2) the price of the medicinal product unproportionally exceeds the reference price established thereto, considering the selection and price of other medicinal products with the same active ingredient and method of administration;

3) the medicinal product has been classified among OTC medicinal products;

4) establishment or amendment of restrictions on prescribing the medicinal product is based on a need to unify the restrictions on prescribing medicinal products with the same or equal active ingredient.

[RT I, 17.11.2010, 3 – entered into force 20.11.2010]

(3) Circumstances for which an opinion is desired and a term for providing an opinion shall be specified in the request provided in section 1, considering the scope and complexity of the fulfilment of the request.
§ 29. Opinion of the Estonian Health Insurance Fund, the State Agency of Medicines and the manufacturer of medicinal products

(1) The Estonian Health Insurance Fund and the State Agency of Medicines may provide a common opinion. The Ministry of Social Affairs shall be informed of the author of the opinion.

(2) The Estonian Health Insurance Fund and the State Agency of Medicines may include experts. The names of the experts are not published.

(3) If a manufacturer of medicinal products has not submitted an opinion in timely manner, it shall be considered that he supports the exclusion of the medicinal product from the list of medicinal products, amendment of the percentage of compensation applied to the medicinal product or establishment or amendment of restrictions on the use of the medicinal product.

§ 30. Application of provisions

(1) the provision of chapter 3 of part II shall be applied to exclusion of a medicinal product from the list of medicinal products, amendment of the percentage of compensation applied to the medicinal product or establishment or amendment of restrictions on the use of the medicinal product, except in the events provided in section 2 of § 28.

(2) The provisions of chapter 4 of part II shall be applied to the solution of an application and amendment of the list of medicinal products.

(3) The minimum time to the exclusion of a medicinal product from the list of medicinal products due to the expiry of marketing authorisation is 3 months from the relevant time.

Part 5
ADMINISTRATIVE PROVISIONS

§ 31. [Excluded from the present text]

Annex Application for entry of a medicinal product into the list of medicinal products

[RTL 2005, 54, 776 – entered into force 27.05.2005]

(4) [Invalid- RT I, 15.05.2014, 1 - entered into force 18.05.2014]