

Procedure for drawing up and modifying the Estonian Health Insurance Fund's list of medicinal products; criteria for establishing the list and bodies assessing conformity with these criteria

Regulation no. 129 of October 23, 2002 of the Minister of Social Affairs

The Regulation is adopted under § 43(3) of the Health Insurance Act (RT I 2002, 62, 377).

Part I GENERAL PROVISIONS

§ 1. Scope

This Regulation lays down:

- 1) the procedure for drawing up and modifying the Estonian Health Insurance Fund's list of medicinal products (hereinafter referred to as "the List");
- 2) the exact content of the criteria referred to in § 43(2) of the Health Insurance Act and the bodies assessing conformity with these criteria.

§ 2. Application of the Administrative Procedure Act

The administrative procedures covered by this Regulation shall be subject to the provisions of the Administrative Procedure Act (RT I 2001, 58, 354; 2002, 53, 336; 61, 375), insofar as this Regulation does not apply to such procedures.

§ 3. Medicinal product and manufacturer of medicinal products

(1) For the purposes of this Regulation the preparations for infant use are equivalent to medicinal products.

(2) A person who has been granted the marketing authorisation of a medicinal product is equivalent to the manufacturer of a medicinal product.

(3) The manufacturer of medicinal products shall be represented by a person having the right of representation or by any other person by virtue of a notarised authorisation document issued by the manufacturer.

§ 4. Application of the procedure for modifying the List

(1) Part II of this Regulation shall apply, if either the inclusion of a medicinal product in the List at a discount rate of 100 % or 75 %, the changing of the discount rate of a medicinal product included in the List at a discount rate of 50 % to 75 % or 100 %, or, for a medicinal product included in the List at a discount rate of 75 % or 100 %, the inclusion of a new diagnosis referred to in the list of diseases established by the Government is being applied for.

(2) Part III of this Regulation shall apply, if the inclusion of a medicinal product in the List at a discount rate of 50 % is being applied for. Part III shall also apply in cases provided for in subparagraph 1, if a medicinal product, which contains the same active ingredient in the same pharmaceutical form as the medicinal product for which the procedure of modifying the List has been initiated, is already on the List.

Part II
GENERAL PROCEDURE FOR MODIFYING THE LIST

Chapter 1
Application for including a medicinal product in the List

§ 5. Submission of the application

- (1) The procedure for including a medicinal product in the List shall commence with the submission of an application to the Minister of Social Affairs.
- (2) The manufacturer of the medicinal product shall submit the application for including the medicinal product in the List.
- (3) An application cannot be submitted, if at least six months have not elapsed since the termination of the procedure initiated for an application regarding the same medicinal product.
- (4) In the application the manufacturer of the medicinal product must indicate all circumstances known to it, which are relevant to the processing of the application.

§ 6. Submission of and formal requirements to the application

- (1) The application shall be submitted in writing in three identical copies on paper and electronically in a format viewable by *Acrobat Reader* or *Microsoft Office* software.
- (2) If the application or its annexes contain mathematical models, which support the data in the application and which do not function with *Microsoft Office* software, the application must contain appropriate software together with needed intellectual property rights and other rights for use by the parties to the procedure for the purpose of using this software for the purpose of processing the application.
- (3) If a web site enabling the submission of applications is set up, the submission of the application via the said web site may be requested and to this an announcement shall be published on the web site of the Ministry of Social Affairs.
- (4) The form of the application is set out in the Annex to this Regulation.
- (5) The application and its annexes must be in Estonian, excluding copies of articles and scientific studies.
- (6) The application and its annexes constitute public information.

§ 7. Annexes to the application

- (1) The annexes of an application are as follows:
 - 1) a description of the area of application of the medicinal product in Estonia, which forms the basis of the discount (including the number of patients, the applicable treatment methods, an analysis of the product's possible retail volume, and a forecast of the product's retail volume over a period of three years);
 - 2) expected results of the use of the medicinal product (e.g. life-saving, symptomatic, improving the quality of life etc.) together with references to scientific publications and studies as well as copies of the scientific publications and studies referred to;
 - 3) a description of the dosage and the optimal duration of use of the medicinal product;

4) a description of the side effects of the medicinal product and a medico-financial evaluation of such effects, in particular the impact of side effects on the quality of life and any complementary studies necessary for the optimal use of the product or for the prevention of side effects;

5) the wholesale prices of the medicinal product for all pharmaceutical forms, strengths and packaging forms in kroons and a forecast of price development over a period of three years. If in Estonia a marketing authorisation has been granted for the medicinal products of different manufacturers containing the same active ingredient, also the wholesale prices of the medicinal products, which contain the same active ingredient and which have received a marketing authorisation in Estonia, shall be provided in kroons for all pharmaceutical forms, strengths and packaging forms;

6) a pharmaco-economical analysis of the use of the medicinal product in accordance with the guidelines for pharmaco-economical evaluation of medicinal products in the Baltic States published on the web site of the Ministry of Social Affairs;

7) an overview of all scientific publications concerning the medicinal product or medicinal products containing an active ingredient with the same or similar medical effect;

8) a confirmation that no further information is available;

9) a copy of the document certifying the right of representation;

10) other documents provided for by the law.

(2) The annexes to the application must reflect the actual situation as at the date of submission of the application. The confirmation that no further information is available may date back up to 60 days from the submission of the application.

(3) The Ministry of Social Affairs, the Estonian Health Insurance Fund and the State Agency of Medicines may request additional information and documents insofar as these are necessary for the correct and expeditious adjudication of the application.

(4) The running of the terms of procedures shall be suspended for up to a period of 30 days until the requested additional information and documents referred in subparagraph 3 are delivered to the party making such a request. The party requesting additional information or documents shall notify the other parties to the procedure of the suspension and continuance of terms.

§ 8. Receipt and examination of the application

(1) The Ministry of Social Affairs shall examine the applications for conformity with the requirements set out in the Regulation. In case of deficiencies a period of time for the elimination of deficiencies will be determined in 5 days. This period may not be shorter than 10 days or longer than 60 days.

(2) The running of the term of the procedure shall be suspended from the moment the period of time for the elimination of deficiencies is determined and it shall continue from the date by which the manufacturer of the medicinal product has eliminated the deficiencies.

(3) An application free of deficiencies shall be forwarded to the Estonian Health Insurance Fund and the State Agency of Medicines after 5 days.

§ 9. Refusal to review the application

(1) If the deficiencies have not been eliminated during the established period, the

Minister of Social Affairs shall refuse to review the application.

(2) The directive concerning refusal to review the application shall be delivered to the manufacturer of the medicinal product in accordance with the procedure laid down in Section 7 of Chapter 1 of the Administrative Procedure Act.

§ 10. Modification and withdrawal of the application

(1) The manufacturer of the medicinal product has the right to modify the application on its own initiative within a period of 5 days from the submission of the application.

(2) In case of modifications to the application the terms of procedures shall start to run from the submission of modifications.

(3) The manufacturer of the medicinal product has the right to withdraw the application on its own initiative at any time before the end of the procedure.

(4) The Ministry of Social Affairs shall notify the Estonian Health Insurance Fund and the State Agency of Medicines of the modification 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 shall prepare a written opinion on the application within 30 days from the date it received the application.

(2) The State Agency of Medicines may use external experts for forming the opinion. The names of experts shall not be disclosed.

(3) The State Agency of Medicines shall deliver its opinion to the Estonian Health Insurance Fund and the Ministry of Social Affairs without delay.

§ 12. Criteria applicable to the opinion of the State Agency of Medicines

(1) The State Agency of Medicines shall form its opinion taking account of the following criteria:

- 1) the insured persons' need for the medicinal product;
- 2) the availability of other medicinal products and treatment methods as regards the disease giving rise to distribution at a discount rate;
- 3) scientifically proven effectiveness of the medicinal product, including in comparison with other treatment methods, the need for other medicinal products and treatment and diagnostic procedures during treatment, and the availability of information on the optimal user group of the product;
- 4) scientifically proven safety of the medicinal product, including in comparison with other treatment methods;
- 5) the availability of information on the effective use of the medicinal product and other medicinal products and treatment methods in Estonia and other countries for the treatment of the disease giving rise to distribution at a discount rate;
- 6) the possibility and consequences of misusing and overdosing the medicinal product;
- 7) the need to restrict the prescribing of the medicinal product at a discount rate to ensure rational and safe use of the product;

8) the possibility of ensuring the rational use of the medicinal product.

(2) The State Agency of Medicines shall consider scientific, including epidemiological, statistical and clinical information, contained in the application and originating from other sources.

§ 13. Opinion of the Estonian Health Insurance Fund

(1) The Estonian Health Insurance Fund shall prepare an opinion on the application within 30 days from the date it received the opinion of the State Agency of Medicines.

(2) The Estonian Health Insurance Fund may use external experts for forming the opinion. The names of experts shall not be disclosed.

(3) The Estonian Health Insurance Fund shall deliver its opinion to the Ministry of Social Affairs without delay.

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

The Estonian Health Insurance Fund shall form its opinion taking account of the following criteria:

- 1) financial justification of the use of the medicinal product in comparison with other available medicinal products and treatment methods as regards the disease giving rise to distribution at a discount rate;
- 2) the availability of information on the effective use of the medicinal product and other medicinal products and treatment methods in Estonia and other countries for the treatment of the disease giving rise to distribution at a discount rate;
- 3) the possibility and financial consequences of misusing and overdosing the medicinal product;
- 4) the possibility of forecasting the retail volume of the medicinal product in a reliable manner;
- 5) the possibility of ensuring the rational use of the medicinal product;
- 6) compatibility of the financial consequences of including the medicinal product in the List with the funds earmarked in the budget of the Estonian Health Insurance Fund as a benefit for medicinal products for the insured.

Chapter 3

Processing of the application in the Committee

§ 15. Committee for Medicinal Products

(1) The Committee for Medicinal Products (hereinafter referred to as “the Committee”) is an advisory committee set up under a Directive of the Minister of Social Affairs.

(2) The Committee shall be composed of no more than seven members. The Minister of Social Affairs shall appoint the members of the Committee by means of a Directive. The following institutions shall propose the appointment of members as follows:

- 1) the Ministry of Social Affairs – one member and his/her alternate;
- 2) the Management Board of the Estonian Health Insurance Fund – one member and his/her alternate;
- 3) the Director General of the State Agency of Medicines – one member and his/her alternate;
- 4) Estonian Patient Advocacy Association – one member, and his/her alternate;

- 5) Estonian Patient Advisory Board – one member and his/her alternate;
- 6) Estonian Medical Association – one member and his/her alternate;
- 7) Estonian Society of Family Physicians – one member and his/her alternate.

(3) The person preparing the opinion of the Estonian Health Insurance Fund or that of the State Agency of Medicines may be a member of the Committee.

(4) The Minister of Social Affairs shall establish the rules of procedure of the Committee by means of a Directive.

(5) Where appropriate, the Committee may invite specialist committees of doctors and dentists as well as specialist advisers to participate in the work of the Committee.

§ 16. Presentation of positions and objections

(1) The Ministry of Social Affairs shall deliver the opinions of the State Agency of Medicines and the Estonian Health Insurance Fund to the Committee and the manufacturer of the medicinal product.

(2) The manufacturer of the medicinal product may present its position concerning the opinions of the State Agency of Medicines and the Estonian Health Insurance Fund in writing to the Committee within a period of 15 days from delivery of the opinions of the State Agency of Medicines and the Estonian Health Insurance Fund.

(3) If the manufacturer of the medicinal product has substantive objections to the opinion of the State Agency of Medicines or of the Estonian Health Insurance Fund that have not been made known earlier, the Ministry of Social Affairs may request the State Agency of Medicines and the Estonian Health Insurance Fund to take a position on the objections within a period of 15 days. The Ministry of Social Affairs shall notify the parties to the procedure thereof, and the running of the term for processing the application shall be suspended until the State Agency of Medicines and the Estonian Health Insurance Fund have presented their position.

§ 17. Summoning to and attendance at the meeting of the Committee

(1) The manufacturer of the medicinal product may be summoned to a meeting of the Committee.

(2) The summons to a meeting of the Committee in accordance with in § 17(2) of the Administrative Procedure Act shall be delivered to the parties to the procedure pursuant to Section 7 of Chapter 1 of the Administrative Procedure Act at least 15 days before the meeting takes place.

(3) The legal entity summoned to the meeting is required to authorise a person able to attend in accordance with the summons.

(4) If the person cannot attend the meeting of the Committee in accordance with the summons for a good reason, he/she must promptly notify the Committee thereof.

(5) If the manufacturer of the medicinal product or a party to the procedure or another summoned party does not attend the meeting of the Committee for a good reason, the meeting may take place without their presence.

§ 18. Opinion of the Committee

- (1) The Committee shall give its opinion in the light of the criteria laid down by the law.
- (2) The opinion of the Committee must be reasoned and in written form. The opinion of may be conditional.
- (3) The reasons must indicate the considerations as to why the opinions and objections of the manufacturer of the medicinal product and any third parties were disregarded.
- (4) Where compliance with the opinion of the Committee would cause an increase in the expenditure of the Estonian Health Insurance Fund or the redistribution of funds, the opinion must provide financial calculations showing how the additional expenditure will be financed or how the funds will be redistributed within the limits of expenditure on the benefits for medicinal products in the budget of the Estonian Health Insurance Fund.
- (5) The Committee shall deliver its opinion to the parties to the procedure and the Minister of Social Affairs without delay.

Chapter 4

Adjudication of the application and modification of the List

§ 19. Adjudication of the application

- (1) The Minister of Social Affairs shall adjudicate the application and deliver the relevant Directive to the parties to the procedure in accordance with Section 7 of Chapter 1 of the Administrative Procedure Act within 180 days from the submission of the application to the Ministry of Social Affairs, without counting the days when the running of the term of the administrative procedure was suspended pursuant to the law.
- (2) In conjunction with acceding to an application the Minister of Social Affairs may lay down the following additional conditions:
 - 1) the right to amend the Directive, if the State Agency of Medicines has provided information on newly discovered properties or forms of misuse of the medicinal product;
 - 2) the right to amend the Directive, if the manufacturer of the medicinal product has violated the price agreement or has not signed a price agreement for the medicinal product with the Minister of Social Affairs within the time limit set out in the Directive;
 - 3) a restriction limiting the right of prescription of the medicinal product to relevant medical specialists only;
 - 4) an age limit on patients whom the medicinal product is prescribed to;
 - 5) restrictions stemming from medical criteria;
 - 6) restrictions on the length of the prescription period of the medicinal product.

§ 20. Entry into force of a Directive of the Minister of Social Affairs

The Directive of the Minister of Social Affairs adjudicating the application of the manufacturer of the medicinal product shall enter into force from delivery of the Directive to the parties to the procedure, unless the Directive provides for a later date of entry into force.

§ 21. Modification of the List

- (1) If the Directive of the Minister of Social Affairs providing for accession to the application of the manufacturer of the medicinal product has not been challenged in accordance with the law, the Minister of Social Affairs must, no later than 6 months from

the final date for the submission of challenges, adopt a Regulation modifying the List.

(2) The Regulation referred to in subparagraph 1 shall not be adopted and the procedure shall terminate, if the Minister of Social Affairs and the manufacturer of the medicinal product have not signed a price agreement conforming to the conditions laid down in the Directive adjudicating the application and other legislative provisions within the period indicated in subparagraph 1.

(3) The Minister of Social Affairs may amend the Directive to the detriment of the manufacturer of the medicinal product and refuse to adopt the Regulation referred to in subparagraph 1, if the manufacturer has not complied with additional obligations stemming from the Directive.

Part III SIMPLIFIED PROCEDURE FOR MODIFYING THE LIST

Chapter 5 Preliminary procedure

§ 22. Submission of the application

(1) The simplified procedure for modifying the List shall commence with the submission of the application to the Minister of Social Affairs.

(2) Submission of the application shall be subject to the provisions of § 5.

§ 23. Formal requirements and annexes to the application

The application together with its annexes shall be submitted in writing in a single copy pursuant to the provisions of § 6 of this Regulation.

§ 24. Application of provisions

(1) The provisions of § 8, § 9 and § 10 shall apply to the submission, examination, refusal to review, modification and withdrawal of the application.

(2) The provisions of § 8(3) shall not apply to an application free of deficiencies.

Chapter 6 Adjudication of the application

§ 25. Adjudication of the application

(1) The Minister of Social Affairs shall adjudicate the application and deliver the relevant Directive to the parties to the procedure in accordance with Section 7 of Chapter 1 of the Administrative Procedure Act within 180 days from the submission of the application, without counting the days when the running of the term of the administrative procedure was suspended pursuant to the law.

(2) The Minister of Social Affairs shall adjudicate the application in the light of the following criteria:

- 1) the insured persons' need for the medicinal product in conjunction with the health services provided;
- 2) the proven medical effectiveness of the medicinal product and the insured persons'

need for other medicinal products during treatment;
 3) the financial justification of the use of the medicinal product;
 4) the availability of alternative medicinal products or treatment methods;
 5) compatibility with the funds for health insurance, including the bulk purchase prices of the same medicinal product in the Republic of Latvia, the Republic of Lithuania, the French Republic, the Republic of Portugal and the Republic of Hungary, and, in the case of a generic medicinal product, the fact that the generic medicinal product is at least 30 % cheaper than the original medicinal product included in the List and containing the same active ingredient.

(3) In conjunction with acceding to an application the Minister of Social Affairs may lay down additional conditions as set out in § 19(2).

(4) The Ministry of Social Affairs may ask the opinion of the Estonian Health Insurance Fund, the State Agency of Medicines and the Committee before adjudicating the application.

(5) The Ministry of Social Affairs shall refer the application to the Committee for an opinion, if:

- 1) acceding to the application may cause the expenditure of the Estonian Health Insurance Fund to exceed the expenditure on the benefits for medicinal products earmarked as such in the budget of the Estonian Health Insurance Fund;
- 2) the decision has substantial importance for the pharmaceutical policy in Estonia;

(6) Entry into force of the Directive of the Minister of Social Affairs and modification of the List shall be subject to the provisions of § 20 and § 21.

§ 26. Processing of the application in the Committee

The provisions of Chapter 3 of Part II shall apply to the processing of the application in the Committee.

Part IV

EXCLUSION OF A MEDICINAL PRODUCT FROM THE LIST, DECREASE IN THE DISCOUNT PERCENTAGE APPLICABLE TO THE PRODUCT AND IMPOSITION OF RESTRICTIONS THE USE OF THE PRODUCT

§ 27. Submission of and formal requirements to the application

(1) The procedure for excluding the medicinal product from the List, decreasing the discount percentage applicable to the product or imposing restrictions on the use of the product shall commence with the submission of an application to the Minister of Social Affairs.

(2) Any manufacturer of medicinal products, the State Agency of Medicines, the Estonian Health Insurance Fund or any other interested party may submit the application. The Ministry of Social Affairs may initiate the procedure for the exclusion of medicinal products from the List on its own initiative.

(3) The application shall be submitted in written form in a single copy.

(4) The exclusion of a medicinal product from the List, decrease in the discount percentage applicable to the product or the imposition of additional conditions to the use

of the product must be justified in the light of the criteria laid down in § 43(2) of the Health Insurance Act, except where the price agreement has been violated.

§ 28. Action to be taken following the receipt of the application

(1) After the procedure for excluding a medicinal product from the List, decreasing the discount percentage applicable to the product or imposing restrictions on the use of the product has been initiated, the Ministry of Social Affairs shall immediately request the manufacturer whose product is the subject of the application, the State Agency of Medicines and the Estonian Health Insurance Fund to submit their opinions together with written evidence justifying the exclusion of the product from the List, the decrease in the discount percentage applicable to the product or the imposition of additional conditions to the use of the product.

(2) The matters in which an opinion is requested and the time limit for giving the opinion shall be indicated in the request referred to in subparagraph 1, taking account of the amount and complexity of work required to this end.

§ 29. Opinions of the Estonian Health Insurance Fund, the State Agency of Medicines and the manufacturer of the medicinal product

(1) The Estonian Health Insurance Fund and the State Agency of Medicine may give a joint opinion.

(2) The Estonian Health Insurance Fund and the State Agency of Medicines may use external experts. The names of experts shall not be disclosed.

(3) If the manufacturer of the medicinal product has not presented the opinion in time, the manufacturer shall be deemed to support the exclusion of the medicinal product from the List, the decrease in the discount percentage of the product or the imposition of restrictions on the use of the product.

§ 30. Application of provisions

(1) The procedure for excluding a medicinal product from the List, decreasing the discount percentage applicable to the product or imposing restrictions on the use of the product shall be subject to the provisions of Chapter 3 of Part II.

(2) Adjudication of the application and modification of the List shall be subject to the provisions of Chapter 4 of Part II.

Part V IMPLEMENTING PROVISIONS

§ 31. Entry into force of the Regulation

This Regulation shall enter into force on November 1, 2002.

Minister Siiri OVIIR

Secretary General Maarja MÄNDMAA

Annex to Regulation no. 129 “Procedure for drawing up and modifying the Estonian Health Insurance Fund’s list of medicinal products; criteria for establishing the list and bodies assessing conformity with these criteria” of the Minister of Social Affairs of
October 23, 2002

APPLICATION FOR INCLUDING A MEDICINAL PRODUCT IN THE LIST
APPLICATION FOR INCLUDING A MEDICINAL PRODUCT IN THE LIST

Date of reception and registration number

1. Manufacturer of the medicinal product or a person who has been granted authorisation to market the product

Name:

Address:

Country:

Telephone:

E-mail address:

Fax:

2. Designation of the proprietary medicinal product

3. Designation(s) of active ingredient(s) (international non-commercial name in Latin)

4. ATC classification of the product

5. Pharmaceutical form, strength, dimensions of package(s), method and route of administration

6. Discount percentage applied for and the relevant therapeutic indication

7. Number and date of registration of the medicinal product at the State Agency of Medicines (number and date of the marketing authorisation)

8. Bulk purchase price, maximum wholesale price and maximum retail price of the medicinal product (in EEK and inclusive of VAT)

9. Wholesale prices (VAT included) in Estonia of medicinal products containing the same active ingredient

10. A brief statement of grounds

11. Possible alternative treatment methods and/or medicinal products available for the relevant therapeutic indication

12. Necessary cautions and restrictions related to the use of the medicinal product

13. Main side effects and contraindications

14. Information on the sales trends of the proprietary medicinal product in the preceding three years (broken down by calendar years; indicate separately the periods when the product was not available for wholesale for longer than 7 calendar days in succession)

- 1)
- 2)
- 3)

15. Information on the volume and value of sales of the proprietary medicinal product in Estonia in the preceding three years (broken down by calendar years)

- 1)
- 2)
- 3)

16. Forecast of retail volume and value:

- 1) in the current year
- 2) in the next year
- 3) in the next but one year

17. The list and number of pages of additional documents annexed to the application (indicate the location in the documentation or the reason for non-submission)

- 1) copies of documents concerning the right of representation
- 2)
- 3)
- 4)
- 5)

.....

Date

.....
Signature of the applicant

.....
Name of the applicant