

Procedure for Entry into a Price Agreement

Regulation no. 142 of December 11, 2002 of the Minister of Social Affairs

The Regulation is adopted under § 45(6) of the Health Insurance Act (RT I 2002, 62, 377).

Chapter 1 GENERAL PROVISIONS

§ 1. Scope

This Regulation establishes the procedure for entry into agreements governing the price of medicinal products (hereinafter referred to as “price agreements”) between the Minister of Social Affairs and the manufacturer of a medicinal product or the person holding the marketing authorisation for a medicinal product (hereinafter referred to as “the manufacturer”).

§ 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), having due regard to the specific requirements of this Regulation.

§ 3. Parties to the procedure

The parties to the procedure for entry into a price agreement are the manufacturer and any person whose rights or obligations may be affected by the price agreement (hereinafter referred to as “a third party”).

§ 4. Definitions

For the purposes of this Regulation:

- 1) “bulk purchase price of the medicinal product” means the price of the medicinal product, which consist of the purchase price of the product, the cost of loading in the warehouse of the seller/consignor, the cost of transport in the country of shipment, the export duties, the cost of loading in the terminal of the country of dispatch, the cost of international carriage, the cost of unloading in the terminal of the country of destination and the cost of transport in the country of destination [CIP (in the wholesaler’s warehouse in the territory of the Republic of Estonia) according to INCOTERMS 2000];
- 2) “maximum wholesale price of the medicinal product” means the bulk purchase price of the medicinal product increased by the maximum wholesale margin;
- 3) “maximum retail price of the medicinal product” means the maximum retail price increased by the maximum retail margin.

Chapter 2

INITIATION OF THE PROCEDURE FOR ENTRY INTO A PRICE AGREEMENT

§ 5. Making of the proposal

The procedure for entry into a price agreement commences with the making of a proposal for a price agreement by the manufacturer.

§ 6. Formal requirements to and submission of the proposal

- (1) The proposal and its annexes shall be submitted in written form electronically.
- (2) The proposal shall be submitted in accordance with the form set out in the Annex to this Regulation.
- (3) If the Ministry of Social Affairs sets up a web site enabling the submission of proposals, it may require the submission of the proposals via the said web site, publishing an announcement to this end on its web site.

§ 7. Annexes to the proposal

- (1) A proposal shall include the following annexes:
 - 1) justification of the bulk purchasing price of the medicinal product indicated in the proposal;
 - 2) a forecast of the retail volume of the medicinal product indicated in the proposal together with the reasoning;
 - 3) an overview of the system of benefits related to the medicinal product indicated in the proposal and of the retail volume of the product with regard to those countries listed in the Annex to this Regulation where the price of the product is lower than that given in the proposal.
- (2) The Ministry of Social Affairs may, by publishing the relevant announcement on its web site and by notifying the manufacturer in writing, require the submission of further information needed to accelerate the procedure for entry into a price agreement or to assess pharmaco-economical criteria, and do so in each like procedure for entry into a price agreement.

Chapter 3

PROCESSING OF THE MANUFACTURER'S APPLICATION IN THE MINISTRY OF SOCIAL AFFAIRS

§ 8. Examination and modification of the manufacturer's proposal

- (1) The Ministry of Social Affairs examines the proposal as to its conformity with the requirements laid down by the law. In case of deficiencies a period of time for their removal shall be set in 5 days. This period may not be shorter than 10 days or longer than 60 days.
- (2) The running of the term for processing the proposal shall be suspended from setting the period for the elimination of deficiencies until such elimination.
- (3) The manufacturer may modify the proposal within 5 days from its submission.
- (4) If the manufacturer modifies the proposal, the running of procedural terms shall commence with the submission of modifications.
- (5) The Ministry of Social Affairs shall transmit the proposal to the Estonian Health Insurance Fund for an opinion to be given in writing, if a substantial financial effect on the health insurance budget of the Fund is foreseen. The Fund shall, within 10 days from the receipt of the proposal, prepare a written opinion on the proposal and send it to the Ministry.

§ 9. Draft price agreement

(1) The Ministry of Social Affairs shall prepare the draft price agreement within 30 days from the receipt by the Ministry of the proposal meeting the requirements laid down by the law.

(2) The draft price agreement must be in accordance with the conditions set out in § 45(2) of the Health Insurance Act.

(3) The pricing of the medicinal product indicated in the draft price agreement shall take account of the bulk purchase price of the product in countries listed in the Annex to this Regulation and the prices of medicinal products falling within the group denominated by the first five symbols of the product's ATC code.

(4) The draft price agreement shall set out the requirements to the availability of the medicinal product and the guarantees for complying with these requirements and with the agreed price.

(5) The draft price agreement shall set out the guarantees for complying with the volume agreed for the medicinal product.

(6) The Ministry of Social Affairs shall communicate the draft price agreement to the Estonian Health Insurance Fund and the manufacturer.

(7) The Estonian Health Insurance Fund shall, within 10 days, prepare a written opinion on the draft price agreement and send it to the Ministry of Social Affairs.

§ 10. Publication of the draft price agreement

(1) The Ministry of Social Affairs shall publish the following particulars of the draft price agreement on its web site:

- 1) parties to the price agreement;
- 2) designation of the active ingredient and the medicinal product and ATC classification of the product;
- 3) pharmaceutical form, strength, size of the package;
- 4) number and date of the marketing authorisation for the medicinal product.

(2) Other particulars included in the draft price agreement shall not be subject to publication, unless the manufacturer provides otherwise.

§ 11. Examination of the opinion and the objections of a party to the procedure

(1) The manufacturer and third parties may present in writing their opinion and objections concerning the draft price agreement within 10 days from the publication of the particulars of the draft price agreement on the web site of the Ministry of Social Affairs.

(2) If a third party objects to the draft price agreement, the Ministry of Social Affairs shall inform the manufacturer accordingly.

Chapter 4

ENTRY INTO A PRICE AGREEMENT

§ 12. Entry into a price agreement

(1) A price agreement shall be entered into:

- 1) within 5 days from the expiry of the period of time for the submission of opinions and objections concerning the draft price agreement;
- 2) within 15 days from the modification of the draft in accordance with the manufacturer's modification proposals.

(2) The Minister of Social Affairs may extend the time limits in points 1 and 2 of subparagraph 1 by 30 days in duly substantiated cases, in particular because of the large number of procedures for entry into a price agreement, by notifying the parties to the procedure of such extension within the time limits laid down in points 1 and 2 of subparagraph 1.

(3) The price agreement must indicate the date of entry into force of the agreement and the date of establishment of rights and obligations stemming from the agreement.

Chapter 5 IMPLEMENTING PROVISIONS

§ 13. Entry into force

This Regulation enters into force on January 1, 2003.

Minister Siiri OVIIR
Secretary General Maarja
MÄNDMAA

Annex to Regulation no. 142 "Procedure
for Entry into a Price Agreement" of
December 11, 2002 of the Minister of
Social Affairs

PROPOSAL FOR ENTRY INTO A PRICE AGREEMENT

Ministry of Social Affairs

Gonsiori 29

Tallinn 15027

1. Manufacturer of or person holding the marketing authorisation for the medicinal product		
Name:		
Address:		
Country:		
Telephone:	E-mail:	Fax:
2. The manufacturer(s) of the medicinal product and the location of the manufacturer(s)		
Name:		

Address:		
Country:		
Telephone:	E-mail:	Fax:
3. Designation of the medicinal product and, in case of a medicinal product containing an active ingredient enjoying patent protection in the Republic of Estonia, information on the basis and validity of patent protection:		
4. Designation(s) of active ingredient(s) (international non-commercial name in Latin and English):		
5. ATC classification of the medicinal product:		
6. Pharmaceutical form, strength, size(s) of package(s):		
7. Number and date of registration of the medicinal product at the State Agency of Medicines (number and date of the marketing authorisation):		
8. The currency used for calculating the medicinal product's prices in Estonian kroons:		
9. The bulk purchase price, the maximum wholesale price and the maximum retail price in Estonian kroons, inclusive of VAT:		
10. The bulk purchase prices on the basis of the daily exchange rate of the Bank of Estonia in Estonian kroons in the following countries, if the medicinal product is registered there: 1) the country of location of the manufacturer 2) Latvia 3) Lithuania 4) France 5) Portugal 6) Hungary		
11. Information on the designations of the medicinal product in countries listed in point 10:		
12. The wholesale prices in Estonia, inclusive of VAT, of medicinal products containing the same active ingredient:		
13. Information on the sales trends of the medicinal product in Estonia in the preceding three years (indicate separately for each calendar year the periods when the product was not available for wholesale for longer than 7 calendar days in succession): 1) 2)		

3)

14. Information on the volume of retail sale of the medicinal product in Estonia in the preceding three years (broken down by calendar years):

1)

2)

3)

15. Expected retail volume of the medicinal product:

1) in the current year

2) in the next year

3) in the next but one year

16. 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) justification of the price of the medicinal product indicated in the proposal;

2) the expected retail volume of the medicinal product indicated in the proposal together with the reasoning;

3) justification in case the bulk purchase price in a country listed in point 10 is lower;

4) a copy of the document certifying the right of representation and of the passport of the person submitting the proposal.

Date

Signature of the person
submitting the proposal

Name of the person
submitting the proposal