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Method of the calculation, terms for the establishment and conditions and terms for the amendment of reference prices of medicinal products

Minister of Social Affairs Regulation No. 114, 13 October 2004

This regulation is established on the basis of § 42 (2) of the Health Insurance Act (RT I 2002, 62, 377; 2003, 20, 116; 88, 591; 2004, 37, 253; 49, 342; 56, 400).

Chapter 1

GENERAL PROVISIONS

§ 1. Scope

This regulation sets out the method of calculating reference prices, the terms for the establishment of reference prices, and the conditions and terms for the amendment of reference prices.

§ 2. Definitions

For the purposes of this regulation, the following definitions are used:
(1) manufacturer of medicinal products means a manufacturer of a medicinal product or a person who has been issued with a marketing authorisation of a medicinal product;
(2) wholesaler means a holder of an activity licence for the wholesale trade of medicinal products or an activity licence for the manufacture of medicinal products who is obliged under § 42 (13) of the Health Insurance Act to communicate the wholesale purchase prices of medicinal products to the Ministry of Social Affairs;
(3) preparation means a package containing a specific pharmaceutical form, active substance content and number of units;
(4) Defined Daily Dose (DDD) means the average daily dose of active substance in accordance with the main indication for use;
(5) preparation with a price lower than the reference price means a preparation whose price was taken into account in the calculation of the reference price and whose price is equal to or lower than the reference price;
(6) reference price group means a group of medicinal products with the same active substance in which the same DDD reference prices are established.

Chapter 2

ESTABLISHMENT AND AMENDMENT OF REFERENCE PRICES

§ 3. Establishment of reference prices

(1) Reference prices shall be established for medicinal products which have been entered in the list of medicinal products of the Estonian Health Insurance Fund with 100% and 75% reduced rates.

(2) Reference prices shall be established in a group of medicinal products containing the same active substance and having the same route of administration, of which sub-groups shall be formed where necessary.

(3) No reference price shall be established for a medicinal product if the medicinal products of several manufacturers holding a marketing authorisation belong to the same reference price group, but in reality only the medicinal products of one manufacturer are marketed in Estonia.

§ 4. Amendment of reference prices

(1) Reference prices shall be established and amended four times a year with effective dates of 1 January, 1 April, 1 July and 1 October.

(2) Reference prices shall be amended on the following conditions:
1) a preparation with a price lower than the reference price is added to the reference price group;
2) the price agreement for the preparation with a price lower than the reference price is coming to an end or is being amended;
3) a manufacturer of a preparation with a price higher than the reference price has proposed a price agreement by which the manufacturer agrees to ensure the availability of the preparation at a price lower than the reference price;
4) the marketing authorisation for a preparation with a price lower than the reference price is expiring or the preparation is no longer being marketed.

Chapter 3

CALCULATION OF REFERENCE PRICE

§ 5. Price used as the basis for the calculation of the reference price

(1) Reference prices shall be calculated on the basis of the wholesale purchase prices of medicinal products as indicated in the application for entry of a substance in the list of medicines or in the price agreement proposal and communicated by the wholesalers to the Ministry of Social Affairs.
If the above data is not available, the wholesale purchase prices communicated by the manufacturer of medicinal products shall be taken as the basis.

(2) A reference price shall be calculated on the arithmetic mean wholesale purchase price of the specific preparation as communicated by the wholesalers to the Ministry of Social Affairs.

§ 6. Defined Daily Dose

(1) The calculation of a reference price shall be based on the size, number and price in the preparation of the DDD.

(2) The size of the DDD shall be determined by taking into account the optimum dosing scheme indicated in the summary of the product characteristics of the preparations registered in Estonia and the Defined Daily Doses published by the World Health Organisation.

(3) To find the number of DDDs in a preparation, the quantity of its active substance is divided by the DDD value of the active substance.

(4) To calculate the price of one DDD in a preparation, the maximum retail price of the preparation shall be divided by the number of DDDs in the preparation.

§ 7. Formation of reference price groups

(1) Depending on the pharmaceutical form, the reference price of medicinal products with the same active substance and route of administration can be different.

(2) Medicinal products are grouped as follows according to the pharmaceutical form:
1) oral solid pharmaceutical forms;
2) oral liquid pharmaceutical forms;
3) sublingual pharmaceutical forms and pharmaceutical forms absorbable through oral mucosa;
4) parenteral pharmaceutical forms;
5) inhaled pharmaceutical forms;
6) transnasal pharmaceutical forms;
7) transdermal pharmaceutical forms;
8) transrectal pharmaceutical forms;
9) transvaginal pharmaceutical forms;
10) local pharmaceutical forms.

(3) The sub-groups of inhaled pharmaceutical forms are aerosols, powders and solutions.

(4) Sub-groups may also be formed in the following cases:
1) pharmaceuticals with extended duration of effects;
2) pharmaceuticals whose means of administration allow for varied dosing;
3) local pharmaceutical products whose pharmaceutical form or place of administration is different;
4) combined medicinal products.

(5) Preparations whose content of active substance differs from the relevant DDD size by more than 100% are regarded as falling into different reference price groups.

§ 8. Calculation of reference prices

(1) Where two preparations fall into the same reference price group, the DDD reference price shall be calculated on the basis of the cheaper preparation.

(2) Where more than two preparations fall into the same reference price group, the preparation with the lowest maximum retail price shall be disregarded and the price of the second cheapest preparation shall be taken as the basis. The DDD price of this preparation shall be the DDD reference price.

(3) Preparations containing a larger quantity of medicinal product than needed for a real treatment period shall not be taken into account in the calculation of reference prices.

(4) The reference price of a preparation shall be calculated by multiplying the DDD reference price by the number of DDDs in the preparation.

Chapter 4

APPLICATION OF THE REGULATION

§ 9. Entry into force

This regulation shall enter into force on 1 January 2005.

Minister Marko POMERANTS

Secretary General Maarja MÄNDMAA