Ministry of Social Affairs and Health, Finland
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No. 1387/2016

Decree of the Ministry of Social Affairs and Health on the priced services of the Pharmaceuticals Pricing Board

Issued in Helsinki on 29 December 2016

In accordance with the Decision of the Ministry of Social Affairs and Health, the following is enacted in virtue of section 8 of the Act on Criteria for Charges Payable to the State (150/1992), as it reads in Act 348/1994:

Section 1

Reimbursement status and reasonable wholesale price for medicinal products subject to marketing authorization

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State (150/1992) include the processing of applications for confirmation of basic reimbursement status and reasonable wholesale price for a medicinal product referred to in Chapter 6, section 4, of the Health Insurance Act (1224/2004), the processing of applications for special reimbursement status and reasonable wholesale price for a medicinal product referred to in section 8, and the processing of applications for increase of the reasonable wholesale price referred to in section 10, for which the applicants are charged fees as follows:

1) Application for basic reimbursement status and wholesale price or special reimbursement status and wholesale price in case of a new active medicinal substance or other new medicinal product **EUR 8,000**;

2) Application for basic reimbursement status, special reimbursement status and wholesale price for a medicinal product in case of

(a) a new combination of medicinal substances;

(b) renewed application for the original product; or

(c) a new biosimilar product or a renewed application for it **EUR 5,000**;

3) Application for basic reimbursement status and wholesale price or special reimbursement status and wholesale price for a medicinal product in case of

(a) a new combination of medicinal substances;

(b) renewed application for the original product; or

(c) a new biosimilar product or a renewed application for it **EUR 2,500**;

4) Application for basic reimbursement status, special reimbursement status and wholesale price for a medicinal product in case of

(a) a new generic product or a renewed application for it;

(b) a new parallel imported medicinal product or a renewed application for it; or

(c) renewed application for the original product after the generic product has been approved for reimbursement **EUR 3,000**;

5) Application for basic reimbursement status and wholesale price or special reimbursement status and wholesale price in case of

(a) a new generic product or a renewed application for it;

(b) a new parallel imported medicinal product or a renewed application for it; or

(c) renewed application for the original product after the generic product has been approved for reimbursement **EUR 1,500**;

6) Application for basic and special reimbursement status and wholesale price or basic or special reimbursement status and wholesale price for a medicinal product in case of a new product, some of the packages of which are processed under the price confirmation and others under the reference price system **EUR 1,500**;

7) Application for basic and special reimbursement status and wholesale price or basic or special reimbursement status and wholesale price for a medicinal product in case of

(a) a new strength under the same or a new trade name;

(b) a new dosage form under the same or a new trade name; or

(c) renewed application for a product, some of the packages of which fall under the price confirmation and others under the reference price system **EUR 1,000**;

8) Application for increase of the confirmed wholesale price **EUR 2,500**;

9) Application for basic and special reimbursement status and wholesale price or basic or special reimbursement status and wholesale price for a medicinal product in case of a new package size or package form per dosage form for a medicinal product with the same strength approved for reimbursement **EUR 300**.

The subsequent strengths or dosage forms contained in an application for the first strength or dosage form of the medicinal product are included in the fee according to subparagraphs 1–8.

Section 2

Extended reimbursement status and reasonable wholesale price for medicinal products subject to marketing authorisation

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of applications for extension of the confirmed basic reimbursement status for a medicinal product referred to in chapter 6, section 4, of the Health Insurance Act and the processing of applications for extension of the special reimbursement status for a medicinal product referred to in section 8, for which the applicants are charged fees as follows:

1) Application for basic reimbursement status and wholesale price or special reimbursement status and wholesale price for a medicinal product in case of

(a) extension of reimbursement status in extended processing **EUR 8,000**;

(b) extension of reimbursement status in restricted processing **EUR 2,500**;

2) Application for basic reimbursement status and special reimbursement status and wholesale price for a medicinal product or basic reimbursement status or special reimbursement status and wholesale price in case of extension of the reimbursement status of the medicinal product to the extent approved for a medicinal product containing the same medicinal substance **EUR 1,500**.

If extension of both the basic reimbursement status and special reimbursement status is applied for at the same time, the fee under subparagraph 1) (a) or (b) will be charged separately in regard to the application for both basic reimbursement status and that for special reimbursement status.

The subsequent strengths or dosage forms contained in an application for the first strength or dosage form of the medicinal product are included in the fee according to subparagraphs 1– 2.

Section 3

Reimbursement status and price notification under the reference price system

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of wholesale price notifications referred to in Chapter 6, section 20, of the Health Insurance Act and the processing of applications for reimbursement status under the reference price system referred to in section 23, for which fees are charged as follows:

1) Application for basic reimbursement status and special reimbursement status or basic reimbursement status or special reimbursement status for a medicinal product **EUR 1,000**;

2) Application for special reimbursement status for a medicinal product in case of a new active medicinal substance **EUR 5,000**;

3) Application for basic reimbursement status and special reimbursement status or basic reimbursement status or special reimbursement status for a medicinal product in case of

(a) extension of reimbursement status in extended processing **EUR 5,000**;

(b) extension of reimbursement status in restricted processing **EUR 2,000**;

(c) extension of the reimbursement status for a medicinal product to the extent approved for a medicinal product containing the same medicinal substance **EUR 1,000**;

4) Application for basic reimbursement status and special reimbursement status and wholesale price or basic reimbursement status or special reimbursement status and wholesale price for a medicinal product during the period of transition within the reference price system **EUR 1,000**;

5) Application for basic reimbursement status and special reimbursement status or basic reimbursement status or special reimbursement status for a medicinal product in case of a new package size or package form per dosage form for a medicinal product with the same strength approved for the reference price system **EUR 300**;

6) Package-specific reference price notification **EUR 30**.

If it is question of an application for extension of the reimbursement status where extended basic reimbursement status and special reimbursement status or extended basic reimbursement status or special reimbursement status is applied for at the same time under both the price confirmation and reference price system, the fee is collected according to section 2.

The subsequent strengths or dosage forms contained in an application for the first strength or dosage form of the medicinal product are included in the fee according to subparagraphs 1– 4.

Section 4

Fee related to conditional reimbursement status

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of applications for reimbursement status or reimbursement status and wholesale price for medicinal products referred to in Chapter 6 of the Health Insurance Act, for which the applicants are charged, in addition to the fees determined in accordance with sections 1 – 2 of this Decree, a fee for the processing of conditional reimbursement status EUR 8,000. The fee for the processing of conditional reimbursement status is, however, EUR 4,000 if the preparation related to conditional reimbursement status does not result in a conditional reimbursement status.

Section 5

Fees related to a health economic evaluation in special situations

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of applications for reimbursement status or reimbursement status and wholesale price for medicinal products referred to in Chapter 6 of the Health Insurance Act, for which the applicants are charged, in addition to the fees determined in accordance with sections 1 – 3 and 7 of this Decree, the following fees:

1) Application including a health economic evaluation except for applications referred to in section 1, subparagraph 1, section 2, subparagraph 1(a) or section 3, subparagraph 2 and 3(a); or

2) Application supplemented while it is being processed by a new health economic evaluation or a health economic evaluation including major changes **EUR 3,000**.

Section 6

Clinical nutritional preparations

Priced services of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of applications for confirmation of reimbursement status and reasonable wholesale price for a clinical nutritional preparation referred to in Chapter 6, section 13, of the Health Insurance Act, for which the applicants are charged fees as follows:

1) Application for reimbursement status and wholesale price for a new clinical nutritional preparation **EUR 2,000**;

2) Application for extended reimbursement status and wholesale price for a clinical nutritional preparation approved for reimbursement **EUR 1,500**;

3) Application for increase of the confirmed wholesale price for a clinical nutritional preparation approved for reimbursement **EUR 1,500**;

4) Renewed application for a clinical nutritional preparation approved for reimbursement **EUR 1,000**;

5) A new dosage form for a clinical nutritional preparation approved for reimbursement **EUR 1,000**;

6) A new package size or a new package form for a clinical nutritional preparation approved for reimbursement **EUR 300**.

The subsequent dosage forms contained in an application for the first dosage form of a clinical nutritional preparation are included in the fee in accordance with subparagraphs 1–5.

Section 7

Basic ointments

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Charges Payable to the State include the processing of applications for confirmation of reimbursement status and reasonable wholesale price for a basic ointment referred to in Chapter 6, section 13, of the Health Insurance Act, for which the applicants are charged fees as follows:

1) Application for reimbursement status and wholesale price for a new basic ointment **EUR 1,500**;

2) Application for increase of the wholesale price confirmed for a basic ointment approved for reimbursement **EUR 1,500**;

3) Renewed application for a basic ointment approved for reimbursement **EUR 850**;

4) A new dosage form for a basic ointment approved for reimbursement **EUR 850**;

5) A new package size or a new package form for a basic ointment approved for reimbursement **EUR 300**.

The subsequent dosage forms contained in an application for the first dosage form of a basic ointment are included in the fee in accordance with subparagraphs 1–4.

Section 8

Products subject to special marketing authorization

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of applications for confirmation of reimbursement status and reasonable wholesale price for medicinal products referred to in section 21 f of the Medicines Act (395/1987) dispensed subject to special marketing authorization, for which the applicants are charged fees as follows:

1) New application of the manufacturer, importer or wholesaler of medicinal products for basic reimbursement status, special reimbursement status and wholesale price **EUR 1,000**;

2) New application of the manufacturer, importer or wholesaler of medicinal products for basic reimbursement status and wholesale price or special reimbursement status and wholesale price **EUR 500**;

3) Renewed application of the manufacturer, importer or wholesaler of medicinal products for basic reimbursement status, special reimbursement status and wholesale price **EUR 400**;

4) Renewed application of the manufacturer, importer or wholesaler of medicinal products for basic reimbursement status and wholesale price or special reimbursement status and wholesale price **EUR 200**;

5) Patient-specific application **EUR 30**.

The subsequent strengths and dosage forms contained in an application for the first strength or dosage form of a medicinal product are included in the fee in accordance with subparagraphs 1–5.

Section 9

Notifications regarding medicinal products, basic ointments and clinical nutritional preparations

Priced services under public law of the Pharmaceuticals Pricing Board referred to in section 6 of the Act on Criteria for Charges Payable to the State include the processing of certain notifications to be submitted to the Pharmaceuticals Pricing Board, for which fees are charged as follows:

1) Notification of transfer of the reimbursement status and wholesale price confirmed for a medicinal product to

a) a new trade name;

b) a new marketing authorization number, or

c) a new Nordic product number for the product (Vnr), **EUR 100**;

2) Notification of change in the summary of product characteristics for a medicinal product in a situation when the marketing authorisation authority has changed the confirmed indication of the medicinal product to be more limited than the indication on which the confirmed reimbursement status is based **EUR 200**;

3) Notification of transfer of the reimbursement status and wholesale price confirmed for a basic ointment or clinical nutritional preparation to a new trade name **EUR 100**;

4) Notification of withdrawal of a medicinal product, basic ointment or clinical nutritional preparation approved for reimbursement from the reimbursement system **EUR 100**.

The fee is product-specific and includes all the packages notified at the same time.

Section 10

Fee for a negative decision

Fees in accordance with this Decree are also charged in case of a negative decision on the application.

Section 11

Other priced services

Services referred to in section 7 of the Act on Criteria for Charges Payable to the State, which the Pharmaceuticals Pricing Board prices on commercial grounds, include opinions and services that are not directly associated with the processing of price confirmation applications or hearing procedures.

The Pharmaceuticals Pricing Board decides on the fees to be charged for retrieval of information referred to in section 34 (2) of the Act on the Openness of Government Activities (621/1999) and for providing copies and printouts referred to in paragraph 3 taking into account what is provided in the said section.

Section 12

Exemption from payment

The processing fee may be waived upon application if the processing fee for a medicinal product subject to marketing authorisation, a clinical nutritional preparation or basic ointment is higher than one third of the estimated regular annual sale of the product. What is provided in this paragraph shall not apply to applications for a new active medicinal substance or another new medicinal product or to applications that concern extension of the reimbursement status in extended processing.

The processing fee for a renewed application is waived if the previous affirmative decision has been in force less than six months.

Section 13

Entry into force

This Decree enters into force on 1 January 2017 and will remain in force until 31 December 2018.

Helsinki, 29 December 2016

Pirkko Mattila, Minister of Social Affairs and Health

Kirsi Päivänsalo, Ministerial Adviser