Decision of the Pharmaceuticals Pricing Board authorizing the Director of the Board to decide on matters concerning the reference price system and the reimbursement status and price of a medicinal product

In virtue of Chapter 6, section 3(2 and 3), as section 3(2) reads in Act 1074/2018 and section 3(3) in Act 252/2015, of the Health Insurance Act (1224/2004) the Pharmaceuticals Pricing Board has decided as follows:

1 §

Confirmation of the reimbursement status of a new medicinal product

The Director of the Pharmaceuticals Pricing Board may confirm the basic reimbursement status of a medicinal product if it is question of a new package size, strength or pharmaceutical form of a product approved for reimbursement or in a case of a new combination product containing the same active substances as the products approved for reimbursement. The basic reimbursement status can be confirmed at most to the extent it has been confirmed for other packages, strengths or pharmaceutical forms of the product or products containing the same active substances as a combination product.

On application the Director may confirm the special reimbursement status of a medicinal product if a product containing the same active substance or substances has been approved for special reimbursement. The special reimbursement status can be confirmed at most to the extent it has been confirmed for medicinal products containing the same active substance or substances.

Approval of the reimbursement status referred to above in subsections 1 and 2 presupposes, in addition, that the Director has the right to confirm a reasonable wholesale price for the medicinal product.

2 §

Confirmation of the wholesale price for a new medicinal product

The Director may confirm a reasonable wholesale price for a medicinal product if it is question of a medicinal product approved for reimbursement and the application is for:

1) a new package size and the highest unit price ratio of the proposed wholesale price conforms to the following pricing policy:

unit(s) 100 units=1.00	unit price ratio
1 unit	1,11
5 units	1,11
10 units	1,11
15 units	1,11
20 units	1,11
30 units	1,11
40 units	1,07
50 units	1,05
60 units	1,03
70 units	1,02
80 units	1,01
90 units	1,01
100 units	1,00
200 units	0,98

2) a new strength provided that the wholesale price proposed for the higher strength is at least 10 per cent below that of the lower strength as calculated per active substance or substances;

3) a new pharmaceutical form provided that the wholesale price proposed for a pharmaceutical form requiring a more exacting manufacturing technology is not significantly higher than that of a conventional medicinal product and that acceptable grounds have been provided for the higher wholesale price.

The Director may confirm a reasonable wholesale price for a new combination product provided that the wholesale price proposed for the product does not exceed the combined costs of products containing the same active substances.

3 §

Confirmation of reimbursement and wholesale price for a generic medicinal product, biosimilar product and parallel-imported product

The Director may confirm the reimbursement status of a generic medicinal product, biosimilar product or parallel-imported product corresponding to a medicinal product approved for reimbursement at most to the extent it was confirmed for corresponding medicinal products containing the same active substance.

If it is question of the first generic product for which reimbursement status is applied, the Director may confirm the wholesale price for a generic medicinal product provided that the price does not exceed 40 per cent of the wholesale price approved for a corresponding product. If this generic product includes a new dosing device, the Director may nevertheless confirm a wholesale price that the price does not exceed 50 per cent of the wholesale price approved for the corresponding product. The wholesale price for the next generic medicinal products for which reimbursement status is applied may be confirmed by decision of the Director, provided that the proposed wholesale price is not higher than that approved for a corresponding generic product.

If it is question of the first biosimilar product for which reimbursement status is applied, the Director may confirm the wholesale price for a biosimilar product provided that the price does not exceed 70 per cent of the wholesale price approved for a corresponding product. The wholesale price for the next biosimilar products for which reimbursement status is applied may be confirmed by decision of the Director, provided that the proposed wholesale price is not higher than that approved for a corresponding biosimilar product.

The Director may confirm the wholesale price for a parallel-imported product, provided that the proposed wholesale price is not higher than the wholesale price approved for a corresponding product used for the treatment of the same illness.

In confirming the reimbursement status and reasonable wholesale price for generic medicinal products, biosimilar products and parallel-imported products the Director must also comply with the provisions in sections 1 and 2 on confirmation of the reimbursement status and reasonable wholesale price.

Provisions on the renewal of the reimbursement status and reasonable wholesale price for generic medicinal products, biosimilar products and parallel-imported products are laid down in section 5.

4 §

A new package size for a clinical nutritional preparation and basic ointment

The Director may confirm the reimbursement status of a new package size for a clinical nutritional preparation and basic ointment that has been approved for reimbursement at most to the extent it has been confirmed for other packages of the product.

The Director may confirm the wholesale price for a new package size of a clinical nutritional preparation and basic ointment, provided that the wholesale price proposed for the bigger package size is not higher than the wholesale price approved for the smaller package calculated per dose unit.

5 §

Renewal of the reimbursement status and confirmed wholesale price

The Director may confirm the reimbursement status and reasonable wholesale price for a medicinal product, clinical nutritional preparation and basic ointment, if it is question of renewal of the reimbursement status and wholesale price that is valid for a fixed period of time.

The Director may confirm reimbursement status to the valid extent and a new fixed-term wholesale price for a medicinal product, on condition that during the validity of the reimbursement and price of the medicinal product no changes have occurred in the conditions affecting price formation. Such factors are, for instance, the market situation, international price level, extension of therapeutic indications or a significant increase in sales. The Director may also confirm such a wholesale price that does not comply with the unit price ratios laid down in section 2, on condition that the Pharmaceuticals Pricing Board has approved the valid price ratios in connection with a previous consideration of the issue.

Should such changes as referred to in subsection 2 have occurred in circumstances affecting the reimbursement status and price formation, the Director may confirm the reimbursements status and wholesale price to the extent and in accordance with the price level the Pharmaceuticals Pricing Board has separately determined.

In case of a medicinal product corresponding to a product included in the reference price system, the Director may confirm the reimbursement status at most to the valid extent and the wholesale price at most to the valid amount.

6 §

Establishment of reference price groups, confirmation of reference prices and inclusion of medicinal products in reference price groups

The Director may decide on the reference price groups for medicines and the reference price for each reference price group. The Director may also decide on the inclusion of a medicinal product in a reference price group.

7 §

Reimbursement status of a medicinal product to be included in a reference price group

The Director may confirm the reimbursement status for a product covered by the reimbursement system and be included in a reference price group to the valid extend. If reimbursement status is applied for a new product, which is suggested to be included in a reference price group, the Director may confirm the reimbursement status at most to the extent it has been confirmed for products covered by the reference price system and containing the same active substance.

8 §

Confirmation of a maximum wholesale price for a product included or to be included in a reference price group

The Director may confirm a maximum wholesale price for a product to be included in a reference price group.

The maximum wholesale price for a medicinal product which is to be included in a reference price group and which is covered by the reimbursement system is at most the same as the reasonable wholesale price confirmed for the product. Otherwise the maximum wholesale price for a product may not be higher than the maximum wholesale price approved for a corresponding product.

In cases referred to in Chapter 6 section 22 a of the Health Insurance Act, the Director may decide to reduce the maximum wholesale price of a medicinal product included in the reference price group.

9 §

Confirmation of the reimbursement status and wholesale price for a medicinal product subject to special licence

The Director may confirm the reimbursement status and wholesale price for a medicinal product delivered under special licence referred to in section 21 f of the Medicines Act that has or has had reimbursement status and confirmed wholesale price, on condition that the proposed wholesale price is not markedly higher than the wholesale price that was last valid. The reimbursement status can be confirmed to the extent that is or has been valid. In confirming the reimbursement status and wholesale price the Director shall also comply with the provisions of sections 1 and 2.

On conditions laid down in subsection 1 above the Director may also confirm the reimbursement status and reasonable wholesale price for a product subject to special licence corresponding to a medicinal product delivered under special licence and approved for reimbursement, notwithstanding what is provided in paragraph 4.

Furthermore, the Director may confirm the reimbursement status and wholesale price for such a medicinal product delivered under special licence that has been previously reimbursed as a product subject to marketing authorization, provided that the proposed wholesale price is not higher than the confirmed wholesale price of the product subject to marketing authorization that was last valid. The Director may confirm the reimbursement status of the product at most to the extent it was confirmed for a corresponding product subject to marketing authorization.

The Director may also confirm the basic reimbursement status and wholesale price for a medicinal product referred to in section 21 f of the Medicines Act that has not had a basic reimbursement status and a confirmed wholesale price, provided that the Social Insurance Institution is in favour of confirmation of the basic reimbursement status and the wholesale price.

10 §

Termination of confirmed reimbursement status

The Director may decide on termination of the reimbursement status of a medicinal product in cases referred to in Chapter 6 section 3(2)(5) if the marketing authorization authority has reduced

the therapeutic indications approved for the product, and the indications used as basis for the reimbursement status do not anymore correspond to the approved indications.

11 §

Certificate of approved wholesale price

On request, the Director of the Pharmaceuticals Pricing Board shall issue a certificate of the reasonable wholesale price approved by the Pharmaceuticals Pricing Board to the holder of the marketing authorization of the medicinal product for the export of medicinal products.

12 §

Exemption from payment of application processing fee

The Director of the Pharmaceuticals Pricing Board may decide on exemption from payment of an application processing fee with regard to a product subject to market authorization in accordance with the Decree of the Ministry of Social Affairs and Health on the priced services of the Pharmaceuticals Pricing Board (1023/2024).

13 §

Entry into force

This decision enters into force on 6 March 2025 and applies to decisions made after its entry into force.

This Decision repeals the Pharmaceuticals Pricing Board decision from 10 January 2019 authorizing the Director of the Board to decide on matters concerning the reference price system and the reimbursement status and price of a medicinal product. However, applications submitted to the Pharmaceuticals Pricing Board before 1 January 2025 shall be subject to section 3(2) of the decision to be repealed.

Issued in Helsinki on 6th March 2025.

Chairman Susanna Grimm-Vikman

Lawyer Suvi Neuvonen