



NOTIFICATION OF EXCEEDING THE SALES ESTIMATE FOR A MEDICINAL PRODUCT FOR WHICH A MARKETING AUTHORISATION HAS BEEN GRANTED

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1. Background

Under Chapter 6, section 15, of the Health Insurance Act the holder of the marketing authorisation for a medicinal product shall without delay notify the Pharmaceuticals Pricing Board if the sales of the medicinal product increase so as to exceed considerably the preliminary estimate on which the decision on its reimbursement status and reasonable wholesale price was based.

2. Limit values for the notification

The holder of the marketing authorisation shall make a notification of exceeding the sales estimate when the total sales in terms of wholesale price of a medicinal product subject to reimbursement considerably exceed the sales estimate given by the applicant for the year concerned. The notification is made when the sales of the calendar year concerned exceed the limit values given in the table below. If the estimated total sales of a product in terms of wholesale price are less than EUR 500,000 a year, a notification is made when the estimated total sales are exceeded by more than EUR 50,000. If the estimated total sales of a product in terms of wholesale price are EUR 500,000 or more than EUR 500,000 a year, a notification is made when the estimated total sales are exceeded by more than 10 per cent.

Table. The total sales estimate in terms of wholesale price for a medicinal product and the limit value determined for the sales exceeding the estimate, after the exceeding of which the holder of the marketing authorisation shall submit a notification to the Pharmaceuticals Pricing Board.

estimated wholesale (€)/calendar year	limit value
less than 500 000	€50 000
500 000 or more than 500 000	10 %

The sales exceeding the sales estimate are examined at the level of a calendar year. If the exceeding of the sales estimate takes place before the end of the calendar year, the notification is made based on the sales up to that date and the sales are estimated in terms of the sales for the whole calendar year. When estimating the sales in question the holder of the marketing authorisation may take into account for instance possible seasonal fluctuations in the sales of the product.

3. Content of the notification

A notification of exceeding the sales estimate shall be made according to medicinal product. An account of the sales shall be given in terms of both the total sales of the medicinal product and the sales per package.

The notification shall include information on

- the giver of the notification
- the medicinal product
- the year that the notification applies to
- the actual sales of the medicinal product in terms of wholesale price and the sales per package
- the estimated sales of the medicinal product in terms of wholesale price and the sales per package
- the exceeding of the sales estimate in EUR
- the exceeding of the sales estimate in percentage
- the reasons that have led to the exceeding.

The notification shall be dated and signed.

4. Sending of the notification

The notification is sent by mail to the following address:

Lääkkeiden hintalautakunta – Pharmaceuticals Pricing Board
PL 33 / POB 33
00230 VALTIONEUVOSTO – GOVERNMENT, FINLAND

Notifications can also be delivered directly to the Pharmaceuticals Pricing Board, which is situated in Helsinki at the visiting address: Snellmaninkatu 13, 5th floor

5. Further measures

If the notification of exceeding the sales estimate of a medicinal product leads to further measures, such as a request for additional reports or introduction of a process of abolishment of the reimbursement status and the confirmed wholesale price, the holder of the marketing authorisation will be informed thereof in writing.