

Notice 11.8.2021

## Notice to collaboration partners

This notice contains information on a number of important points about substitutable medicinal products and quarterly price notifications. It is a collaboration of Kela, Fimea and the Pharmaceuticals Pricing Board (Hila).

### Checking Fimea's list of substitutable medicines

Fimea publishes a list of substitutable medicinal products at least 45 days before the first day of each quarter. The list is published in two versions: a [list of drugs \(PDF in Finnish\)](#) and a [list of packaging data \(ASCII\)](#). Marketing authorisation holders should check their products and that the marketing information is up to date every time an updated list is released, and notify Fimea within seven days of any corrections or additions that may be required. Fimea's list is the basis for Hila's [list of medicinal products subject to the price notification procedure under the reference price or generic substitution systems \(in Finnish\)](#).

### Importance of submitting a price notification

A price notification must be submitted to Kela for any medicinal product for which notification is required under the reference price and generic substitution systems. The notification must be made no later than 21 days before the first day of each quarter. Kela forwards the price notifications to Hila. On the basis of the prices notified, Kela determines the price bands and Hila determines the reference prices.

If no notification is made about a product included in the reference price system, the product becomes non-reimbursable at the beginning of the following quarter.

The price notification must be made even if the price of a product does not change. Further, notifications are also required for non-reimbursable products. This ensures that pharmacies' price lists are accurate and up to date about all products included in the generic substitution and reference price systems.

If a product comes out or its wholesale price changes at the beginning of a quarter, a price notification must be made to Kela no later than 21 days before the first day of the quarter. Prices cannot be notified to Kela after this date, nor is it possible to notify them to the Pharmaceutical Database or the pharmacies' price lists after the deadline has passed.

## Accuracy of the information provided in the price notification

The price notification must indicate the wholesale price of the product at the beginning of the quarter and information about its availability on the market. The notified wholesale price and availability details may be changed [until 16:15 on the final scheduled date of notification](#).

When determining the price bands and the reference prices, only products that are generally available are taken into account. If a specific product is not generally available, 'No' must be indicated in the price notification under the availability details. Generally available means that the product is available from the wholesalers at the time of notification and throughout the following quarter.

The accuracy of the availability details is important to ensure that the price bands and reference prices calculated on the basis of the notifications are based on verified availability data.

## More information

- on Kela's website: <https://www.kela.fi/web/en/pharmaceutical-companies>
- on Fimea's website:  
[https://www.fimea.fi/web/en/databases\\_and\\_registeries/substitutable\\_medicinal\\_products](https://www.fimea.fi/web/en/databases_and_registeries/substitutable_medicinal_products)
- on Hila's website: <https://www.hila.fi/en/reference-price-system/>

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