



## Shortage notification, foreign company

Send the notification to shortagesSPOC@fimea.fi via secure mail: <https://secmail.fimea.fi/>

All requested information needs to be given at once.

Filling instructions can be found at the end of the form.

### 1. Shortage information

Information is published on Fimea's webpage

Notification date	
Type of the notification	
<input type="checkbox"/> First notification <input type="checkbox"/> Update to previously sent notification <input type="checkbox"/> Cancellation of previously notified shortage (See instructions)	
Date when the shortage was notified for the first time	
Estimated starting date of the shortage	
Estimated ending date of the shortage	
Nordic Article Number (Vnr) (fill only number without spaces)	
Medicinal product name	
Strength	
Pharmaceutical form	
Active ingredients	
Package size	
ATC-code	
Additional info provider -public Company	Information provider
Phone number (in county code format)	E-mail





Reason for exemption of the fee:
Unexpected increase in demand in Finland based on the pandemic or other special situation
Natural catastrophe which has led to a blockage of the distribution chain of the product
Shortage of a competing product, which market share is more than 20 percent units higher based on average sales in the previous 5 months
Extensive recall based on an authority decision, which marketing authorization holder has not been able to anticipate

#### 4. Invoice information

If the information has been sent to Fimea earlier, please fill only the name of the organization

The official name of the organization
Billing address (post address, postal code, city, country)
Language
Phone number (with country code)
E-mail
VAT-number
PO-number
E-invoice address, OVT-number
Operator ID / Opus Capita

Please note that Fimea is not able to send invoices by e-mail.

## GENERAL

- You can use the PDF form to report a shortage.
- **One form can be used to only provide information on one product in one package size.**
- Complete the notification in Adobe Reader or Adobe Acrobat, not directly in the browser.
- Notifications are processed by machine, so it is important that the information is entered in the correct format.
- First notification: When a shortage of a product is reported for the first time, **complete all sections of the notification form** (Shortage information, Additional information on the shortage, Notification fee and Billing information). **All information must be provided at once.**
- Updated notification: When updating the notification, you can update the duration of the shortage, contact information and information regarding the next delivery.
- Cancellation of previously notified shortage: When notifying the cancellation of a shortage, only fill in the section 'Shortage information'. It is not possible to fill in the other sections.

Cancellation of previously notified shortage means that the shortage didn't happen. Cancellation needs to be done before previously mentioned starting date of the shortage. All the changes in the duration of the shortage, needs to be notified as an update.

- The information on the shortage is published on Fimea's website. Shortage information regarding special permit products will not be published.

## SHORTAGE INFORMATION – Information published on Fimea's website

- Always select dates from the calendar menu and check carefully that the dates are correct.
  - The notification date is always entered as the date when the notification is made and submitted to Fimea.
  - The first notification date of the shortage refers to the date when the product shortage is reported to Fimea for the first time.
  - The start date of the shortage is marked with an estimate of the date on when the shortage begins.
  - The end date of the shortage is marked with an estimate of the end date of the shortage.
  - When notifying the cancellation of a shortage, the start and end date of the shortage do not need to be filled.

- The "Nordic Article Number" field must only contain numbers (e.g. "112233") and must not contain letters or spaces. Incorrect data in this field prevents the shortage information from being submitted to Fimea's website.
- Contact details needs to such, that the authority and consumers may request further information on the shortage in question.

#### **ADDITIONAL INFORMATION ON SHORTAGES – Information not published without permission**

- Select the reason for the shortage from the menu and, if necessary, fill in the additional information in the free text field.
- Select "Yes" or "No" depending on whether the reason for the shortage can be published.
- Fill in the details of the next shipment, if known.
- Fill in the information on the shortage in other EU/EEA countries, if known.
- The additional information may be used in Fimea's public summary reports in such a way that the individual marketing authorisation holder or medicinal product cannot be identified.

#### **NOTIFICATION FEE AND INVOICING INFORMATION**

- First shortage notifications are subject to a fee. The fee is determined in accordance with the applicable decree of the Ministry of Social Affairs and Health. There is no charge for disruption of availability of parallel distribution products and veterinary products.
- Select "Yes" or "No" depending on whether you are applying for an exemption from the fee and fill in the justification if an exemption is applied for. **An exemption cannot be granted if the criterion has not been filled.**
- The invoicing information must include at least the name, invoicing address, language, telephone number and VAT-number of the company to be invoiced. If the information has been submitted to Fimea earlier, filling in the company name is sufficient.

#### **SUBMITTING THE INFORMATION AND PUBLICATION ON FIMEA'S WEBSITE**

- Submit shortage notifications by secure email to kirjaamo@fimea.fi
- The information in the notification is updated on Fimea's website the following day if the notification arrives at Fimea's registry on the previous business day before 14:45.
- The information on the shortage will be automatically removed from Fimea's website after the notified end date or after the cancellation notification.

#### **ADDITIONAL INFORMATION**

Questions related to the information in and to the filling in and submitting the notification:

Section of Availability, Fimea switchboard tel. +358 29 522 3341 or [shortagesSPOC@fimea.fi](mailto:shortagesSPOC@fimea.fi)