

Send notification to Fimea's registry by 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.

Shortage information Information is published on Fimea's webpage
Notification date (select date from the calendar)
Type of the notification First notification Update to previously sent notification Cancellation of previously notified shortage
Date when the shortage was notified for the first time (select date from the calendar)
Estimated starting date of the shortage (select date from the calendar)
Estimated ending date of the shortage (select date from the calendar)
Nordic Article Number (Vnr) (fill only number without spaces)
Medicinal product name
Strength
Pharmaceutical form
Active ingredients
Package size
ATC-code
Contact details Company Contact person (name, phone number, e-mail)

Additional information for shortage Confidential, information will not be published
Marketing authorization number
Reason for the shortage
Estimated arrival date of the next delivery and batch size
Are other EU/ETA countries impacted by this shortage? Which countries?
Are there pending applications in Fimea related to the shortage?
Are there other medicinal products on the Finnish market with the same indication?
How does the company estimate that the shortage will affect medical treatments in Finland, and how the possible effects are planned to be reduced?

Notification fee
<p>The fee of shortage notification is based on the Decree of the Ministry of Social Affairs and Health on fees chargeable by the Finnish Medicine Agency.</p> <p>An exemption from the fee can be applied, if the company can prove that the shortage is due to one of the reasons mentioned in the following section.</p> <p>Do you apply for a release from the fee?</p>

<p>Reason for exemption of the fee:</p> <ul style="list-style-type: none"> 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
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<p>Invoice information</p> <p>If the information has been sent to Fimea earlier, please fill only the name of the organization</p>
<p>The official name of the organization</p>
<p>Billing address (post address, postal code, city, country)</p>
<p>Language</p>
<p>Phone number (with country code)</p>
<p>E-mail</p>
<p>VAT-number</p>
<p>PO-number</p>
<p>E-invoice address, OVT-number</p>
<p>Operator ID / Opus Capita</p>

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

GENERAL

- You can use the PDF form or the Excel template to report a shortage.
- You can report the shortage of several products at once on one Excel file.
- **The PDF form can be used to only provide information on one product in one package size.**
- Complete the PDF 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 notifying an update to a shortage, only fill in the section 'Shortage information'. It is not possible to fill in the other sections (Additional information on the shortage, Notification fee and Invoicing information).
- 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 (Additional information on the shortage, Notification fee and Invoicing information).

- 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

- Select the reason for the shortage from the menu and, if necessary, fill in the additional information in the free text field.
- Fill in the details of the next shipment, if known.
- Fill in the information on the shortage in other EU/EEA countries, if known.
- Applications related to shortages include applications related to the obligatory storage, an exemption from the requirements set in the marketing authorisation or an importer's special licence.
- 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.
- 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 16:00.
- 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 filling in and submitting the notification and the appendix:
Fimea registry office, tel. +358 29 522 3602

Questions related to the information in the notification:
Section of Availability, Fimea switchboard tel. +358 29 522 3341