# Instructions for giving a shortage notification

Give notification of a medicinal product shortage using the readymade Excel form or PDF forms. When using the Excel form, fill in one Excel sheet that includes both details of the shortage notification and the appendix information. With one Excel form, it is possible to report several shortages as separate rows. When using PDF forms, fill in a separate shortage notification and appendix for every medicinal product.

**PDF forms have to be filled in using Adobe Reader or Adobe Acrobat, not in a web browser.**

Send the notification by email to registry@fimea.fi
Send the appendix by secure email using Fimea's secure email
If you send the notification and the appendix at the same time, you can send both by secure email.

Questions concerning filling in and sending the notification and appendix:
Registrar’s office, tel. +358 29 522 3602

Questions concerning the information to be provided in the notification and appendix:
Supervision and Licenses, Fimea’s operator, tel. +358 29 522 3341

## Shortage notifications

* Shortage notifications are processed by machine, so the notification information must be in a machine-readable format.
* The information in the notification is published on the Fimea website.
* The date of the notification must always be entered as the date when the notification is submitted to Fimea. This applies to both new and updated shortage notifications.
* No information other than that requested may be entered in the form's date and VNR fields. In the date fields, the date is selected from the calendar menu, while the VNR number is written out using the keypad.
* Please note that the notification fields must not contain blank spaces before the actual text or number/date. Notifications are processed by machine and such spaces are interpreted as an empty field.
* The contact information of the marketing authorization holder should be such that country specific (Finland) information is available for any person wishing to make contact. It is compulsory to provide contact information.
* Notifications arriving at Fimea before 16.00 on a business day will be registered as having arrived on the same day. Notifications arriving after 16.00 will be registered for the following business day.

## Appendix

* The information in the appendix will not be published.
* If an Excel form is being used when notifying the shortage, all the information in the appendix must be sent when sending the actual notification.
* If the shortage notification is made using the PDF form, the information in the appendix must be sent to Fimea as soon as possible before the estimated end date of the shortage.
* The information from the appendix 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.

### Appendix information of the medicinal product

* A list of interchangeable medicinal products can be found on Fimea’s website (only in Finnish)
* Fill in the average sales for the last 12 months.
* Fill in the average package size-specific market share for the last 12 months.
* Ilmoita pakkauskokokohtainen markkinaosuuden keskiarvo viimeisen 12 kuukauden ajalta. The market share is calculated by comparing the sales of the product with those of other interchangeable products.
* Market share should be reported as a number, without the % sign (for example, 30% = 30).

### Bases of the fee and invoicing information

* It is mandatory to provide invoicing information, and e-invoicing information must be provided if needed
* All new 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
* The notification is invoiced on the basis of the date when the notification is registered as received by Fimea.
* No fee will be charged for update notifications if the update is made before the shortage end date indicated in the previous notification.
* If the ‘basis for payment’ field is not filled in, the fee is determined by the date of registration of the notification.

## Updating the notification

* If the shortage has been notified and it does not in the end take place, send an updated notification. In the updated notification, change the end date to the date of the cancellation. Do not update other information in the notification.
* If the information in the notification needs to be updated, it must be submitted to Fimea before the end date specified in the previous notification
* If the shortage ends earlier than estimated, send an updated notification. In the updated notification, change the end date to the new estimated end date or to the actual end date.
* You do not need to send an updated appendix when you update the shortage notification.

## When the shortage ends

* The shortage notification will be removed from Fimea’s website after the estimated end date of the shortage.

## Filling-in instructions for Excel sheet and PDF form

### Please consider the following information when filling in the Excel form

* With one Excel form, it is possible to notify several shortages as separate rows.
* Fill in all columns for every product (notification and appendix).
* Fill in dates using the form dd.mm.yyyy
* The Excel form has drop-down lists. In these cells, choose an answer from the list.
* Do not edit the structure of the Excel form.
* The Excel form is intended to enable bulk data delivery for shortages. This is why all the requested information needs to be given at once (both notification and appendix). If the information needed for the appendix is not available when sending the notification of the shortage, please use the PDF form and send the appendix as a PDF form as well.

### Please consider the following information when filling in the PDF forms

* With one form (notification and appendix), it is possible to notify only one medicinal product shortage (one strength, one package size).
* Fill in all the sections in every PDF form (notification and appendix).
* In a date field, choose the date from the calendar. Select the date by clicking the field.

**NB! PDF forms must be filled in using Adobe Reader or Adobe Acrobat, not in a web browser.**

Download the form to your computer and open it with an Adobe PDF program. The form must be saved using its own ‘Save’ button. This way the form stays in machine-readable form. Lataa lomake työasemalle ja avaa se Adoben pdf-ohjelmalla. Täytetty lomake tulee tallentaa lomakkeen omalla ”Tallenna”-painikkeella. Suoraan verkkoselaimessa täytettynä lomakkeen rakenne ei säily koneluettavassa muodossa. The form can be downloaded by clicking the Download button indicated by the arrow below.

