# Frequently Asked Questions: Shortage notification

Below are some general questions and answers concerning the shortage notification and its appendix. Please also read the instructions for shortage notifications.

## General

**What is a shortage?**

A shortage is defined on the EMA website in the document linked below: A shortage of a medicinal product for human or veterinary use occurs when supply does not meet
demand at a national level.

<https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-detection-notification-shortages-medicinal-products-marketing-authorisation-holders-mahs_en.pdf>

<https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines#medicine-shortages-section>

Furthermore, Fimea regulation 4/2019 on applying for and maintaining a marketing authorisation for a medicinal product states the following: ‘If there are interruptions in the marketing of a medicinal product or a package...such that the product is not actually available to end users..."

## Fee for a shortage notification

**Which shortage notifications are subject to a fee?**

All new shortage notifications submitted after 1 June 2021 are subject to a fee. The size of the fee is determined in accordance with the applicable decree issued by the Ministry of Social Affairs and Health.

**Is an update to a shortage notification subject to a fee?**

No it isn’t, provided that the update is done before the end date indicated in the previous notification.

**How is the size of the shortage notification fee determined?**

If the notification has been submitted to Fimea at least two months (= 60 days or more) before the start of the shortage, the fee is **EUR 70**. This also applies to notifications after which the shortage does not actually occur.

If the notification is submitted to Fimea less than two months (= less than 60 days) but more than 14 days before the start of the shortage, the fee is **EUR 200**.

If the notification is submitted to Fimea less than two weeks (= less than 14 days) before the start of the shortage, the fee is EUR 1000.

**Is it possible to receive an exemption from the shortage notification fee?**

All new shortage notifications are subject to a fee. In special cases, exemptions may be applied to increased fees, in which case the fee is EUR 70 even though the notification has been submitted to Fimea less than two months before the start of the shortage.

**In what situations can you apply for an exemption to the increased notification fee?**

You can apply for an exemption to the increased fee in the following situations:

* The shortage is due to an unpredictable increase in demand in Finland because of the current pandemic
* Demand has increased due to a competitor's lack of availability of the product and the competitor's market share is above 30%
* The supply chain has been cut by a natural disaster
* Other reasons comparable to those mentioned above (justification must be given)

**What information should be provided for invoicing?**

All invoicing contact information requested in the appendix must be provided. The PO number must be filled in if necessary. If the company wishes to receive an electronic invoice, the electronic invoicing information must also be provided.

## Shortage notifications

**Must a shortage notification and its appendix be submitted for special permit products?**

The shortage notification process pertains to medicinal products with a marketing authorisation. With regard to special permit products, we would wish to receive a shortage notification so that Fimea is informed of the shortage. The information requested in the appendix does not need to be provided for special permit products in cases were this information is not available. Shortages of special permit products are not published on the Fimea website.

**Why has a separate form been prepared for the new shortage notification in Finnish, Swedish and English?**

Shortage notification forms are available in different language version because of accessibility requirements.

**How do I fill out and upload the PDF form? And how about Excel files?**

Download the PDF form to your workstation and open it using Adobe PDF. The completed form must be saved using the ‘Save’ button on the form. When filled in directly in a web browser, the form’s structure does not remain in a machine-readable format, which means that the information cannot be utilised in other systems. Once the form has been saved, send it as an e-mail attachment to Fimea. The updated instructions contain helpful illustrations on this topic.

Download the Excel template to your workstation and fill it out in Excel. Once all data is filled in, save the Excel file in the normal way and send it as a secure email attachment to Fimea.

**I am reporting five shortages at once. Should there be a separate notification for each one?**

You can use the Excel template to simultaneously report a shortage of several products. The information for each product is recorded on a separate line and each box must be filled in for each product even if the information is the same for all the products being reported (e.g. strength or contact information). The Excel template has an alert and attachment on the same Excel, so make sure to fill in both.

If you wish to submit notifications using PDF forms, you must fill in a separate notification form and an appendix for each product. All information in the notification and the annex must be filled in for each product.

**How do I report any additional information related to an shortage?**

If the notification and the appendix have been completed carefully, there is no need for additional information. If changes occur in the shortage, these must be reported with an updated notification. If necessary, Fimea will request additional information.

Information relevant to the shortage should not be recorded in accompanying messages.

**Why must shortages be notified at a daily level; is the weekly level not enough?**

Information about the shortage will be shown in the details of the FimeaWeb medicines search at the daily level. Estimates about the date when the shortage begins and when the product will be available again are precise enough. If the estimate given differs from the actual situation, the shortage notification can always be updated.

**Is it necessary to provide contact details?**

Providing contact details is mandatory. The contact details provided must be such that they can be published on the Fimea website so that citizens can use them to obtain further information about the shortage.

## Shortage notification appendix

**The appendix asks if other authorities have been informed? What does ‘other authorities’ mean here?**

The authorities to whom the matter concerns, such as the EMA.

**The appendix asks if other medicinal products are available for this purpose. What does this mean?**

The first question is meant for stating whether there are other medicinal products available for the same therapeutic indication.

The purpose of this supplementary question is to determine whether there are products that can be substituted for the product indicated in the shortage.

**The appendix asks for the monthly average sales. What does this mean?**

The average sales means the average level of sales for each package size of the product over the last 12 months.

**The appendix asks for the package-specific market share. What does this mean?**

The average market share is reported for the last 12 months.

As the notification is made for each package size, the average market share must also be reported for the specific package. The market share is the market share of the specific package size for the product being declared in relation to the interchangeable products. In the absence of interchangeable products, the market share is 100%. When assessing the criticalness of an shortage, Fimea may, if necessary, investigate other ATC class products, so these should not be taken into account in the market share reported.

## Updating a shortage notification

**What should I do if the estimated duration is longer or the shortage ends earlier than estimated?**

If the estimated duration is extended, an updated notification of the shortage must be made. Similarly, if the shortage ends earlier than estimated, an updated notification must also be submitted.

Notifications of the end of a shortage are not longer submitted, as the notification information is simply removed from the medicines search service on the indicated end date.

**What do I do if a product from a shortage notification receives a special permit?**

A shortage notification should be made as normal when it is known that there is an interruption in the availability of the product. The end date of the shortage should be the date on which the product is expected to be available again.

The appendix to the shortage notifications asks if application-related matters have been submitted for the product in connection with the shortage. In this section, the option for special permit should be selected.

If a special permit has been granted for the product's market presence, an updated notification of the shortage must be made. In this updated notification, the estimated end date should be given as the date on which the special permit product will actually be in distribution (not the date the special permit was issued).

**Must the information given in the appendix be updated if the shortage notification is updated?**

The information in the appendix need not be updated if it has not significantly changed.