

# Instructions for using the e-service for reporting shortages

The e-service for reporting shortages is intended for marketing authorisation holders or registration holders and their representatives as well as parallel importers and distributors, i.e., companies submitting shortage notifications. At the start, using the service requires a Finnish business ID.

## Logging in to the service

Representatives will use Suomi.fi e-Identification to identify themselves in the e-service. Using the e-service for reporting shortages will be possible once a person is authorised to act on behalf of a company in the Suomi.fi e-Authorizations service. Mandates are granted in the [Suomi.fi e-Authorizations service](#).

[Instructions: Granting Suomi.fi e-Authorization for reporting shortages](#)

You can log in to the service on [Fimea's shortage notifications page](#) or [Fimea's e-services page](#).

## Service home page

After logging in, you end up on the front page of the e-service (Figure 1). Figure 1 shows the view after logging into the service for the first time and the company has no reported shortages. The top bar of the front page shows who has logged into the service and which company has authorised it. You can also change the language from the top bar and log out of the service.

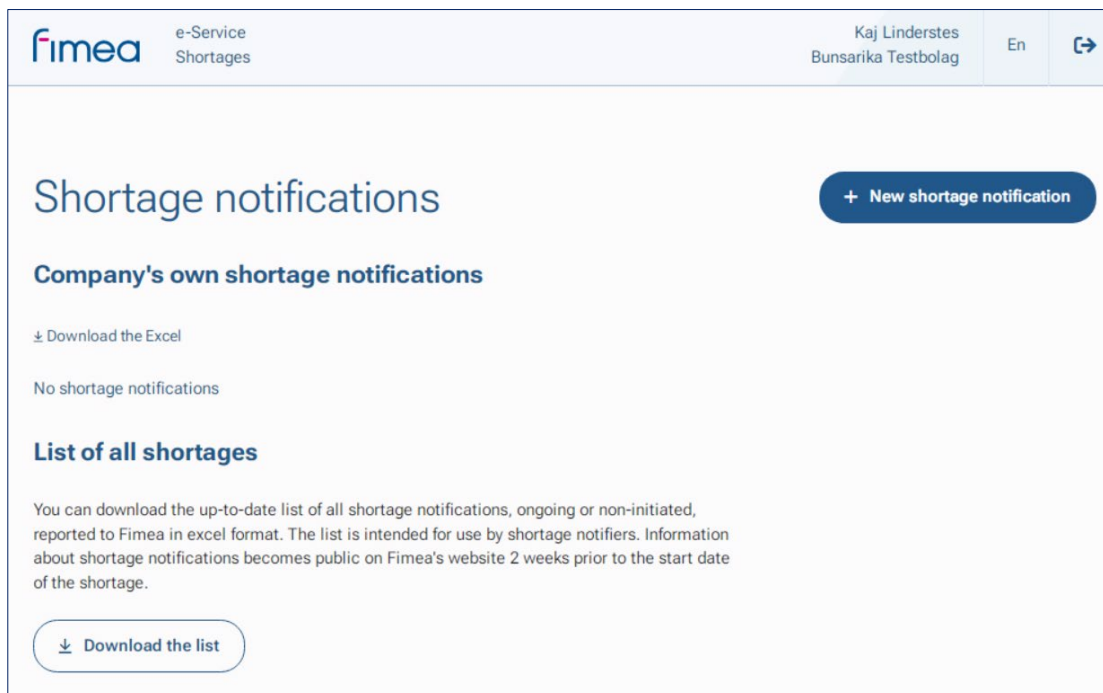


Figure 1. E-service home page when there are no recorded shortages in the service.

You can submit a new shortage notification through the "New shortage notification" button.

## Filling in the shortage notification

To start filling in the notification, select the package for which you want to notify the shortage (Figure 2). You can search for a package with a vnr number or trade name. The searched packages are based on Fimea's Register for Medicinal Products, and shortages can only be reported on products on the market. If the product does not have a vnr number, the search must be done using the product name. **Always check that you report a shortage on the correct package.**

After selecting the package, enter the start date and end date of the shortage. If the exact dates are not known, the current estimate must be entered and, if necessary, the dates can be updated later. The start date and end date can be updated before the indicated dates. **Select the dates on the calendar menu. Depending on your browser settings, the date selection may be in US format and therefore, when manually entering the date, the notification date may be incorrect.**

The contact details for further information for consumers and health care professionals related to a shortage must be entered in the fields of the public additional information provider. Once entered, contact details are stored in the browser cache if the cache is not cleared. Contact information can also be edited when submitting a new shortage notification and when updating a previously reported shortage.

## New shortage notification

### Shortage information – public

**Package \***

  ⓘ You can search for the package using the VNR number or the trade name of the product.

**Estimated duration of the shortage \***

  –   ⓘ Please select the estimated start and end date from the calendar.

### Additional info provider – public

**Company \***

ⓘ Fill in additional information provider for consumers and healthcare professionals. The default contact information is saved per browser and can be edited when the notification is being completed.

**Contact person name \***

**Email address \***

**Phone number \***

Please enter the phone number in country code format (+050 00000000).

Figure 2. Public information on the shortage notification.

## Additional information on shortages

The information in the "Additional information for shortage" fields is not published on Fimea's website (Figure 3). If there are changes related to the time or size of the next delivery batch during the shortage, we request that the information be updated in the electronic services. The contact information intended for Fimea must be such that Fimea can, if necessary, contact the person for additional information related to the shortage. The contact details entered are stored in your browser, just like public contacts. Fill in the field on shortages in other EU countries if you know other countries affected by the shortage. A report on the impacts on pharmacotherapy must be provided on a shortage-specific basis.

After the notification has been sent, only the information related to the arrival of the next batch and the contact information intended for Fimea can be updated from the additional information.

### Additional information for shortage – not public

Reason for the shortage \*

Please select

Further information on the cause of the shortage

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Estimated arrival date of the next delivery and batch size

mm/dd/yyyy

**i** If there are any changes in the information about the batch during the shortage, we kindly ask you to update the information.

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Are you aware of shortages of this product in other EU/ETA countries? \*

Yes  No

How does the company estimate that the shortage of the product will impact pharmaceutical treatment in Finland, and how does it aim to reduce the potential impact? \*

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### Contact person for Fimea's requests for additional information

Contact person's name \*

**i** Default contacts are saved browser-specific and can be modified when filling in the notification.

Email address \*

Telephone number \*

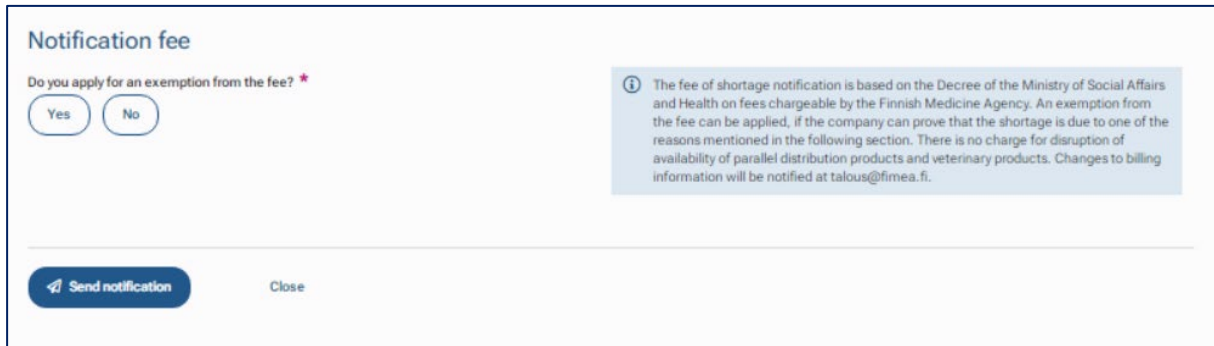
Please enter the phone number in country code format (+358 00 0000000).

Figure 3. Additional information for the shortage.

## Notification fee

The notification fee is determined in accordance with the Decree on fees chargeable by the Finnish Medicines Agency in force at the time of the notification (Figure 4). It is possible to apply for an exemption from the fee for a justified reason if the operator can prove that the shortage is due to a reason subject to the exemption.

No fee is charged for parallel distribution products and veterinary medicinal products. The system automatically recognises that parallel distribution products and veterinary medicinal products are not invoiced, so these products are not subject to a separate exemption for these products, and the item in question should be answered with "No" (Figure 4).



**Notification fee**

Do you apply for an exemption from the fee? \*

Yes  No

**i** 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. 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. There is no charge for disruption of availability of parallel distribution products and veterinary products. Changes to billing information will be notified at talous@fimea.fi.

[Send notification](#) [Close](#)

Figure 4. Notification fee.

**When all notification information is complete, make sure to send the notification.**

## View shortage notifications

Initially, the list of your own shortages is empty if no notifications have been entered through the service, as shown in Figure 1. When notifications have been entered through the service, they are displayed on the front page of the service on the "Company's own shortage notifications" list (Figure 5). **Please note that shortages that were previously reported to Fimea using a PDF or Excel form will not be automatically transferred to the service.**

The list shows all current shortages entered by the company's employees and the shortages that have not yet started. You can sort the list in the order you want by selecting the appropriate column in the title bar. If there are more than 20 notifications, the system will arrange the notifications on different pages, and the "Next" button at the bottom of the list will take you to the next page. At the top right of the list, you can download an Excel list of your company's notified shortages. The Excel list shows all shortages reported by the company (not yet started, valid, ended and cancelled).

In addition, it is possible to download a list of all shortages reported to Fimea that are valid or have not started. The list of all shortages reported to Fimea can be downloaded at the bottom left of the front page. The lists of the company's own notifications and all shortages reported to Fimea are real-time.

## Shortage notifications

[+ New shortage notification](#)

### Company's own shortage notifications

[Download the Excel](#)

VNR	Product trade name	Strength	Package size	Pharmaceutical form	Marketing Authorisation Holder	Start date	End date	Status	Actions
077887	Tamsulosinihydrokloridi Orion	0.4 mg	90	prolonged-release capsule, hard	Orion Corporation	23.06.2023	07.07.2023	Not started	<a href="#">Edit</a>
508886	Bufomix Easyhaler	160 mikrog / 4.5 mikrog / inhalaatio	60 annosta	inhalation powder	Orion Corporation	10.06.2023	08.07.2023	Not started	<a href="#">Edit</a>
445888	Gabapentin Accord	300 mg	100	capsule, hard	Accord Healthcare B.V.	04.06.2023	04.07.2023	Started	<a href="#">Edit</a>
540418	Abacavir Accord	300 mg	60	film-coated tablet	Accord Healthcare B.V.	04.06.2023	08.07.2023	Started	<a href="#">Edit</a>

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### List of all shortages

You can download the up-to-date list of all shortage notifications, ongoing or non-initiated, reported to Fimea in excel format. The list is intended for use by shortage notifiers. Information about shortage notifications becomes public on Fimea's website 2 weeks prior to the start date of the shortage.

[Download the list](#)

Figure 5. List of notified shortages.

## Editing and cancelling a shortage notification

Editing and cancelling the shortage notification is done by clicking the "Edit" button in the last column of the shortage row in question (Figure 5).

After the necessary modifications have been made, click the "Submit your changes" button at the end of the notification (Figure 6). If you intend to cancel the shortage notification, the notification information does not need to be changed. In this case, click the "Cancel notification" button at the bottom of the page.

**The notification can only be cancelled if the shortage has not started.**

If the notification has been made accidentally on the wrong package and the shortage has already started, the end date of the notification must be marked as ended and a new notification must be submitted on the correct package.

### Notification fee

Do you apply for an exemption from the fee? No

↩ Submit your changes

Close

✕ Cancel notification

The Finnish Medicines Agency Fimea

The Finnish Medicines Agency Fimea is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health it promotes the health and safety of the population by regulating medicines, medical devices, blood and tissue products and biobanks, and by developing the pharmaceutical sector.

Need help?  
shortagenotifications@fimea.fi  
+358 (0)29 522 3341

Figure 6. Editing and cancelling a notification.

## Publication of shortage notifications

Shortage notifications are published on Fimea's website 2 weeks before the start of the shortage. All public information is published on FimeaWeb Search and the Shortage search. In addition, the information on the pharmaceutical product and the dates of the shortage are published as open data.

## Invoicing

An invoice for the processing of a shortage notification is automatically sent to the company that granted the authorisation in whose name the service is used. Notifications on shortages of veterinary products and parallel distribution products are not invoiced. If invoicing information changes, it must be notified to Fimea's Financial Unit at [talous@fimea.fi](mailto:talous@fimea.fi).

## User register

Fimea administers the users of the service and adds any companies with a business ID that have reported shortages to Fimea during the past year (2022) as users.

If logging in to the system is not possible, submit a request to Fimea to add the company as a user of the service to [shortagenotifications@fimea.fi](mailto:shortagenotifications@fimea.fi). The company's name, business ID and invoicing information must be provided in connection with the request.

## Contact information for issues

If you have any problems when using the e-service, contact Fimea at: [shortagenotifications@fimea.fi](mailto:shortagenotifications@fimea.fi).

If you have any problems managing Suomi.fi e-Authorizations, contact the Digital and Population Data Services Agency's [customer service for organisations](#).