

Granting Suomi.fi e-Authorization for reporting shortages

1 What is the mandate needed for?

Identification for using the Service for reporting shortages in medicinal products requires Suomi.fi e-Identification. Identification is carried out using, for example, online banking codes or a Mobile certificate.

It is possible to use the service when a company has granted the person a Suomi.fi e-Authorization to act on behalf of the company in matters related to shortages.

Suomi.fi e-Authorization is not required if the person acts on behalf of a company or organisation in which they have an official role entered in the Trade Register

- Managing director
- Substitute for the managing director
- Partner
- Holder of procuration authorised to sign alone for the company/organisation
- Self-employed business operator
- Liquidator

At first, the service is only available to companies with a Finnish business ID. The reception of notifications from foreign operators will continue in PDF-format until electronic identification can also be introduced for foreign companies.

2 Description of the mandate

There is one type of Suomi.fi authorisation for reporting shortages of medicinal products in the e-service:

Submission of notifications concerning shortages of medicinal products

This mandate allows the assignee to use all the features of the e-service related to shortages of medicinal products, including:

- submit notifications on shortages of a medicinal products subject to a marketing authorisation and any changes to shortages.
- manage data related to shortages of medicinal products subject to a marketing authorisation.



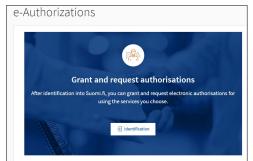
Who can give a mandate and how is it done?

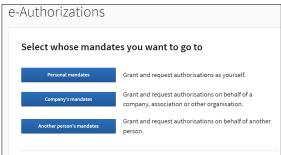
A mandate may be granted by a person who has one of the official roles mentioned in paragraph 1 (e.g., managing director or holder of procuration) entered in the Trade Register for the company or organisation in question. The role information is checked in the Trade Register, the Business Information System, the Finnish Register of Associations and Suomi.fi e-Authorizations.

Instructions for granting mandates can be found on the Suomi.fi e-Authorizations website under Instructions for Suomi.fi e-Authorizations.

Do the following to grant a mandate for acting on behalf of a company:

1. Open the <u>Suomi.fi e-Authorizations home page</u> and identify yourself to log in to Suomi.fi e-Authorizations. Go to the section "Company's mandates".





- 2. Select the company you are acting on behalf of. Add a mandate for the person you are authorising to use the "Submission of notifications concerning shortages of medicinal products". To add a mandate, you need the name and personal identity code of the person to whom the mandate is being granted. You can specify a period of validity for the mandate.
- 3. You will receive an email notification when the mandate has been confirmed.

4 How is the service for reporting shortages restricted?

The Service for reporting shortages in medicinal products 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. Logging in to the service is not possible for other actors, such as retail distributors.

Fimea administers the users of the service, adding 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 fails and the company is a party submitting notifications as specified in the first paragraph, a request should be submitted to Fimea to add the company as a user of the service. The company's name, business ID and invoicing information must be provided in connection with the request.

5 Point of contact if any problems occur

If you have any problems when using the e-service, contact: shortagenotifications@fimea.fi. Requests to use the service (see paragraph 4) are also sent to this address.

If you have any problems managing Suomi.fi e-Authorizations, contact the Digital and Population Data Services Agency's <u>customer service for organisations</u>.