Shortage notifications Q&A

Below are a few general questions and answers concerning the shortage notification and its appendix. Be sure to also read the instructions on how to fill out the shortage notification and its appendix.

1. What is a shortage?

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

Read more:

2. 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 the accessibility requirements.

3. 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. As regards special permit products, we would like to receive a notification of shortage so that we can publish it on the Fimea website. The details of the appendix need not be filled out with regard to special permit products if the information is not available. After the turn of the year, special permit products can no longer be notified, because the details of special permit products are not shown in the medicines search.

4. Why must shortages be notified at a daily level, is weekly level not enough?

Information about an interruption in availability will be shown in the details of Fimea’s medicines search at the date level.
 Estimates about the date when the interruption in availability 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.

5. 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.

6. 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.

7. Section 5 of the appendix asks whether other authorities have been informed of the shortage. What does ‘other authorities’ mean here?

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

8. Section 7 of the appendix asks whether there are other medicinal products with the same indication available on the Finnish market. 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 the additional question is to determine whether there are interchangeable products available for the product indicated in the shortage notification so as to make clear the impact of the shortage on the users of the medicinal product concerned. The impact on healthcare services is significantly larger if a pharmacy will not be able to make an interchangeable product available and the medicine concerned is widely used.