eHälsomyndigheten

LiiV Handbook

Supplier information in the VARA register

Version 4.0

This handbook describes pharmaceutical companies' work in LiiV

Contents

1. Introduction

The Swedish eHealth Agency was commissioned by the Swedish Government with taking over the responsibility for the compilation and administration of pharmaceutical suppliers' medicinal product information from the Swedish Medical Products Agency. LiiV (Supplier information in the VARA register) has existed since November 2016. LiiV, which is owned and provided by the Swedish eHealth Agency, is a system for gathering medicinal product information from various sources (see section 1.1).

LiiV together with VARA (the national product- and article register) constitutes the product LiiV and VARA. LiiV and VARA is classified as a national medical information system, NMI, according to the Swedish Medical Products Agency's regulations HSLF-FS 2022:42. The national medical information system consists of the subsystem LiiV and the subsystem VARA.

The product LiiV and VARA is intended to supply healthcare providers, pharmacies and veterinarians with updated and quality-assured information about medicinal products and the medical devices included in the high-cost threshold. The product LiiV and VARA is also intended to supply authorities and other stakeholders with basic information about medicinal products and for the production of statistics.

Basic information about medicinal products (authorised medicinal products, medicinal products with special permissions and extemporaneous preparations) in LiiV comes from the Swedish Medical Products Agency. Pharmaceutical companies then supplement this with their information. The information entered into LiiV is transferred over to VARA and then out to healthcare providers and pharmacies. Both automatic and manual validation of the information in LiiV and VARA are conducted, so that the Swedish eHealth Agency can provide quality assured and coordinated product information concerning medicinal products for human use and medicinal products for veterinary use that are required when prescribing and dispensing, for example. For more details about how the information entered in LiiV is transported through the different systems see Informationsflödet • E-hälsomyndigheten (ehalsomyndigheten.se) (only available in Swedish).

The information is transferred from LiiV to VARA and Fass directly. However, the information about a product is not sent out to pharmacies and healthcare providers prior to the company setting the first package to "On the market = Yes" in LiiV.

As of the end of November 2024, the Swedish eHealth Agency will collect information about the marketing status of products for the Swedish Medical Products Agency via LiiV through what is known as the Marketing Service. The data included in the service is shown in Appendix 3. The Swedish Medical Products Agency also uses data from VARA.

Companies cannot access their medicinal products with special permissions in LiiV. These products are handled by the Swedish eHealth Agency since the packages are a kind of virtual packages that are used regardless of which package size the physician prescribes.

This handbook describes how pharmaceutical companies are to use LiiV.

1.1 Information owner

The various organisations that enter information into LiiV are described below. Every organisation that enters, updates and maintains information in LiiV is responsible for its own information.

- Pharmaceutical companies
- The Swedish Medical Products Agency
- The Dental and Pharmaceutical Benefits Agency (TLV)
- The Swedish eHealth Agency

Please refer to Appendix 1 with information about who owns which field in LiiV.

2. How does LiiV work?

2.1 Publication of information

Changes made by pharmaceutical companies in LiiV are immediately transferred to VARA. The information undergoes quality assurance in VARA. If the information complies with the regulations in VARA, the VARA administrators publish the information and it is included in the VARA file that is created and sent out after midnight. If something needs to be corrected, an email is sent to the company, which is then able to change the information in LiiV. **All changes must be entered into LiiV by 15:00 (Swedish time) so that the information can be published at midnight.** This applies on working days. No publication of information from VARA take place on weekends and public holidays; this takes place on the following working day.

2.2 User account

A personal user account is required in order to log into LiiV.

LiiV has several different types of user accounts:

- Read-only (only able to read the company's information)
- Write access (able to edit the company's information)
- User administrator (able to edit the company's information, set up user accounts for colleagues and issue authorisation to consultants)

- Consultant administrator (able to set up user accounts for colleagues at the consultancy)
- Consultant (becomes searchable by other companies so that they can grant authorisation to this person)

A user account is set up for every person who is to have access to LiiV. Authorisations for one or more companies can be linked to the user account. Normally, the user is only authorised for one company, but consultants, for example, are often authorised for more than one. The authorisations are linked to the company's VAT number.

In accordance with the General Data Protection Regulation (the GDPR), no authorisation will be granted to company users in countries outside the EU/EEA (third countries), that have not been determined by the European Commission to have an adequate level of data protection.

2.3 Who grants authorisation to LiiV?

2.3.1 The first LiiV user in a company – user administrator

Every company that is to have access to LiiV must appoint **one** user administrator. This person fills in an application form (can be obtained from LiiV (Leverantörernas information i VARA) • E-hälsomyndigheten (ehalsomyndigheten.se)) and sends it to the Swedish eHealth Agency via servicedesk@ehalsomyndigheten.se.

The same applies to consultancies. One person is appointed as an user administrator for the consultancy (=consultant administrator), who can then set up accounts for their colleagues.

If a user is to have access to more than one VAT number, these must be specified on the same application form. If the companies are part of the same group, no power of attorney is required. If the user is to be authorised for a company that is not part of the same group, a power of attorney or equivalent is required to demonstrate that the user is permitted to manage the company's products in LiiV. The power of attorney is appended when the application form is submitted.

2.3.2 Other users – authorisation for one company

Once the company's user administrator (see section 2.3.1) has received their account in LiiV, this person can set up user accounts for their colleagues and grant authorisation to any consultants they wish to engage (see sections 10.1 and 10.4 for a description of this).

2.3.3 Other users - authorisation for several companies

If a user needs access to several companies in LiiV the Swedish eHealth Agency needs to be contacted. The process is the following:

1. The user administrator at the company sets up an account with authorisation for one company (see section 10.1).
2. Send an e-mail to servicedesk@ehalsomyndigheten.se. Specify the name of the user, type of account (read-only, write access or user administrator) and which companies the user should have access to.
3. The Swedish eHealth Agency completes the account.

2.3.4 Consultants

All those who receive user accounts with the role of consultant become searchable by all user administrators in LiiV. This allows the user administrators to grant a consultant authorisation for their company without creating a new user account. For the consultant user, this means that they always log in using their consultant account and then choose which company's products they are to work with. Section 10.4 contains a description of how to assign authorisation to a consultant.

3. Email when updates are made by the Swedish Medical Products Agency

When the Swedish Medical Products Agency updates information in LiiV, an email is sent to individuals who have their user account linked to the company that owns the products (or packages) that have been updated. Users can indicate whether or not they wish to receive these emails (listed under "My User Account", see section 9). The email does not usually require any action on the part of the company, but is primarily intended for information about the update. If the update is not correct, the company will contact the Swedish Medical Products Agency. Please refer to Appendix 2 for an example of what this email may look like.

4. Log in

When the user has been given an account in LiiV, an email containing instructions is sent to the listed email address. NOTE! Look in the spam folder if no reply email / activation link appears. When logging in for the first time, the account must be activated; this is done in several steps:

1. Click on the link in the email in order to get to the website where account activation take place.
2. The user name (from the email) is listed on the page "Activate User Account" in LiiV. Read and accept the terms and conditions of use and click "Save".
3. A new email is sent. *Please note that this email is only valid for 15 minutes. If more than 15 minutes have elapsed, you will have to request a new*

activation link (go back to point 1 above). Click on the link in the email. Enter your user name and a password. Enter the password again. Click "Save".

4. Log in

Logging in to LiiV is done via the Swedish eHealth Agency's website LiiV (Leverantörernas information i VARA) • E-hälsomyndigheten (ehalsomyndigheten.se).

4.1 Forgotten password

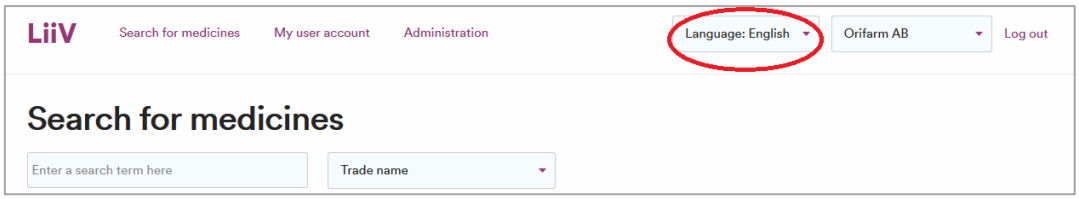
If you forget your password, go to the login page (LiiV-web (ehalsomyndigheten.se)) and click on "If you have forgotten your password, click here".

Enter your user name and click "Save". An email containing information about resetting your password is then sent to the email address listed in your user account.

If you have any questions about your login, please first contact your own company's user administrator. If you still have questions, contact servicedesk@ehalsomyndigheten.se.

4.2 Change language

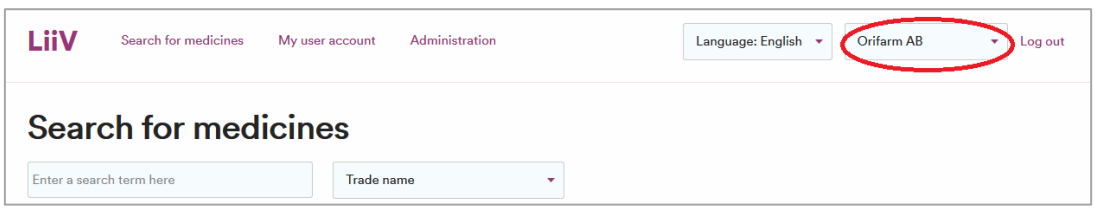
If you would like to change language temporarily, you can do this in the upper-right corner (see image below).



Under "My User Account", you can save your personal language settings (see section 9).

4.3 Change authorisation

If you are authorised for more than one company, you can switch between these in the top-right corner of LiiV (see image). Products of the selected company then become searchable.



Under “My User Account”, those who are authorised for more than one company can select which is to be the default when logging in to LiiV (see section 9).

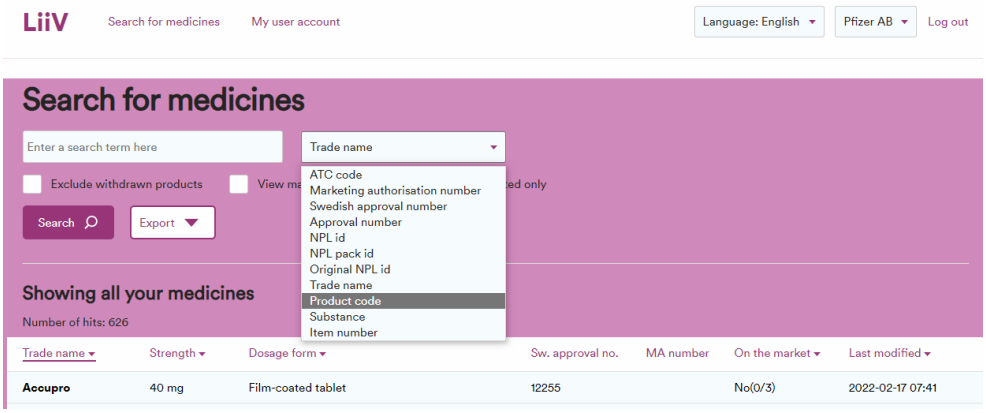
4.4 Help texts

There is a question mark next to the fields where companies can change information. A help text that briefly explains what information is to be filled in is displayed when the mouse pointer is held over this.

Picture taken from a test environment

5. Search for medicines

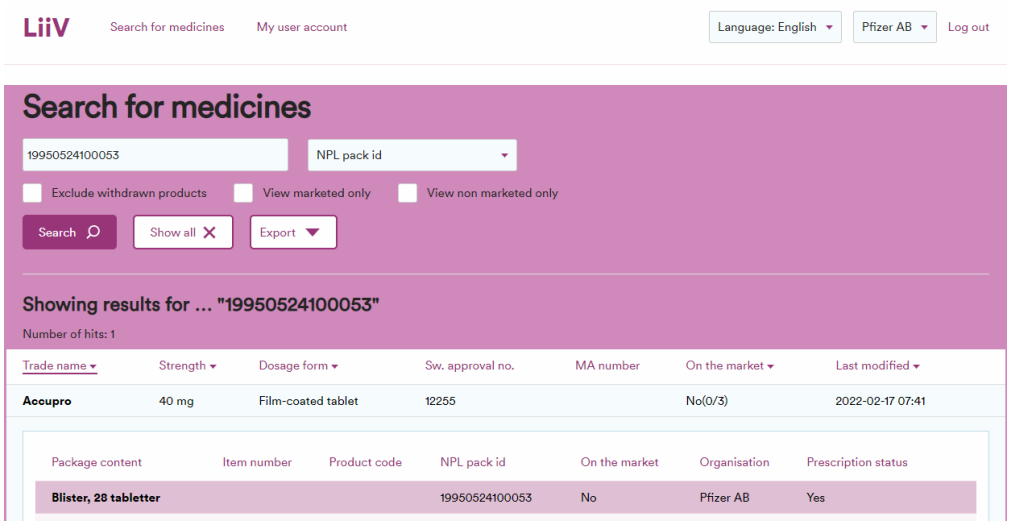
When you log in to LiiV, the page “Search for medicines” is displayed with the products that the user account is linked to.



Picture taken from a test environment

Search by “Trade name” is the default option. If you wish to search by other criteria, these can be selected from the list. Enter the desired search string in the search box and click “Search”.

When searching for an attribute on the package (for example NPL pack id), the list of search results is shown with the product in question and the package searched for is marked (see image below).



Picture taken from a test environment

5.1 Display product

Click on the product name in the list of search results in order to display the product page.

5.2 Display package

Click on anywhere other than the trade name in the list of search results to expand the list and display all packages registered on the product. When the packages are displayed, you can click on the desired row in order to get to the package page.

5.3 Filter search results

There are three ways to filter the search results in LiiV:

- Exclude withdrawn products – no withdrawn products are displayed in the list of search results.
- View marketed only – only products that are marketed are displayed when searching for attributes on the product (for example trade name). If the search is made with an attribute on the package (for example product code), only those products whose packages are marketed are displayed in the list of search results.
- Display only non-marketed – only products that are not marketed are displayed when searching for attributes on the product (for example trade name). If the search is made with an attribute on the package (for example product code), only those products whose packages are not marketed are displayed in the list of search results.

Check the desired box and press “Search”.

5.4 Export search results

When you have performed a search, you can choose to export the search results to a CSV file that can be processed using Excel, for example.

Click on the “Export” button and a CSV file containing all the packages that are included in the search results is created.

6. Edit product

When you have searched for a product and want to edit it and have clicked through to the product page (see section 5.1), click on “Edit” in order to display the product in edit mode.

6.1 Strength numeric with unit

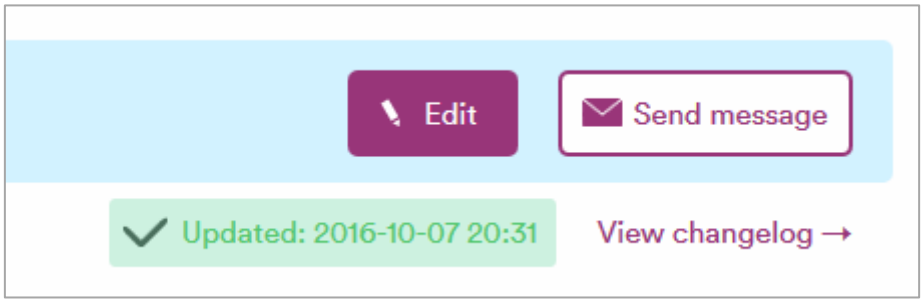
The only variables that can be edited on the product page are “Strength numeric” and “Unit”. “Strength numeric” with “Unit” is to be listed if the product has a strength in the SPC and this strength can be expressed numerically. Combination drugs are an example of products where numerical strength cannot be specified.

Some examples:

	Example 1	Example 2	Example 3
Strength in the SPC	10 mg	1 mg/0.5 mg	Missing
Strength numeric	10	Cannot be specified	Not to be specified
Unit	mg	Cannot be specified	Not to be specified

When numeric strength is to be specified:

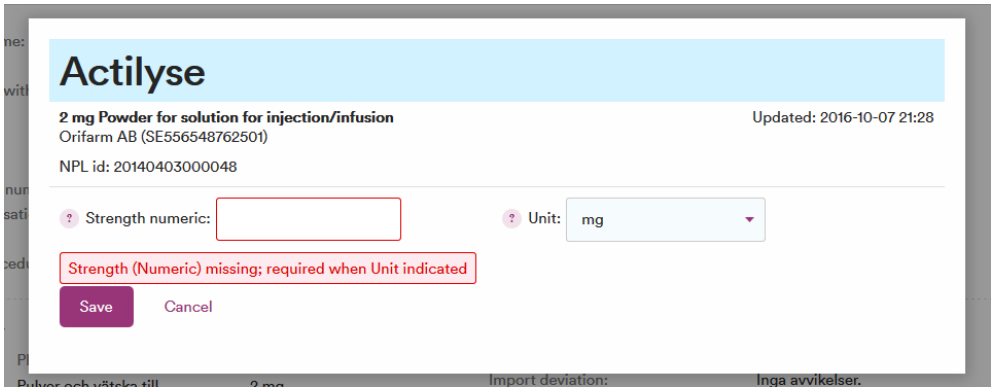
1. Enter the desired value in “Strength numeric” and “Unit”.
2. Click on “Save”. A green box indicating that the update is complete is displayed.



Comments: The list of units contains the same values, regardless of whether you have chosen Swedish or English.

6.2 Validation

An error message is displayed if the information that is fed in is in breach of any of the validation rules. Change the information to make it correct and then click on "Save".

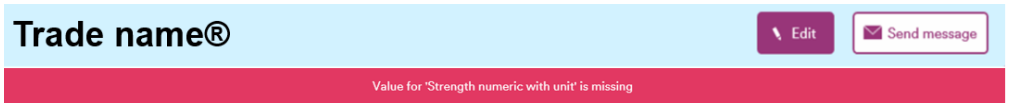


6.3 Reminder to fill in strength numeric with unit

A reminder to fill in "Strength numeric" with "Unit" is displayed in several different places if this is not filled in when a package is placed on the market or when a package gets a future marketing date, according to section 7.1.4.

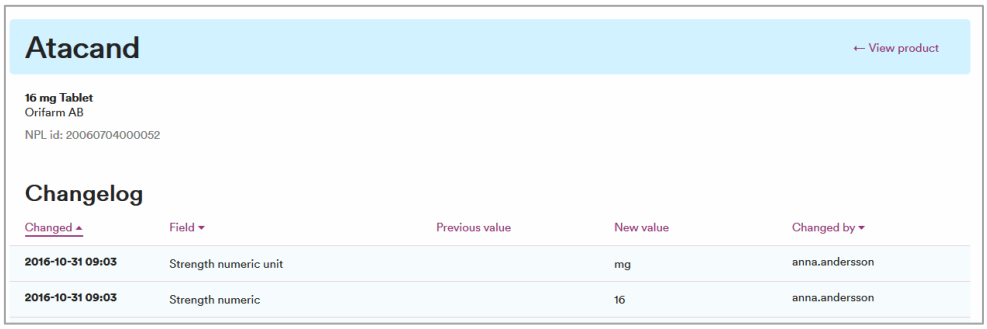
If "Strength numeric" with "Unit" is not stated, the product does not pass the validation check and is therefore not transferred to VARA until the fields are filled in.

Note that in some cases it is correct to leave the fields blank (see section 6.1) even if the reminder (the red warning) remains on the product. A reminder on the product level:



6.4 Change log product

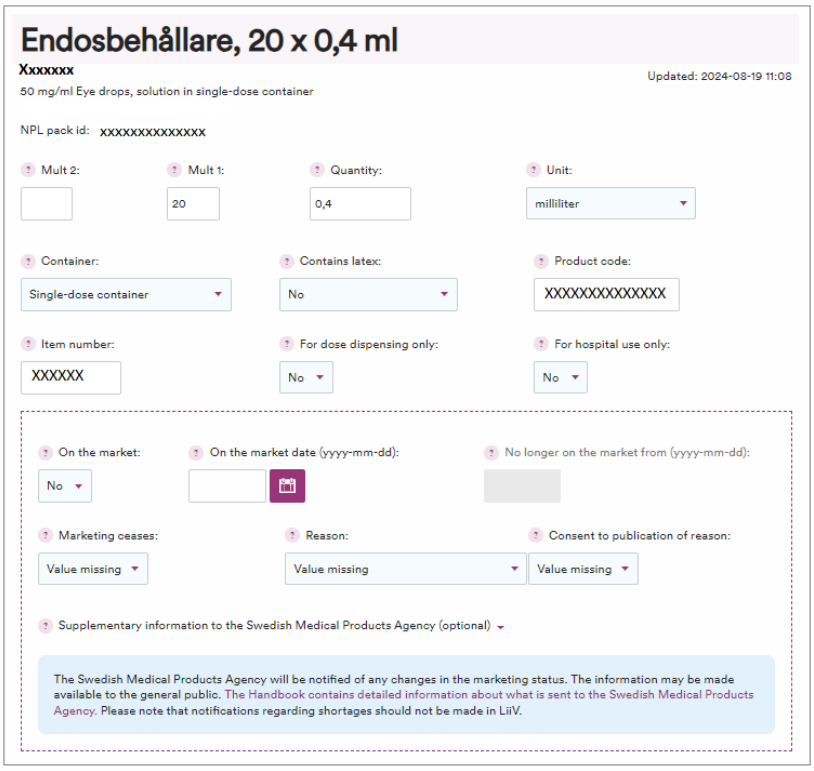
There is a link on the product page to the change log for the product (“View changelog"). The change log shows the changes that have been made by individual users, the Swedish eHealth Agency and the Swedish Medical Products Agency.



7. Edit package

When you have searched for a product and want to edit it and have clicked through to the package page (see section 5.2), click on “Edit” in order to display the package in edit mode.

1. Enter the desired value and click on “Save”.
2. When the change has been saved, a green box is displayed, indicating that the update is complete (see section 6.1).



7.1 Information to be filled in on packages

In this section the information to be filled in on packages is specified. Some fields are mandatory when the package is marketed, has a date in “On the market date” or has been marketed earlier. This applies to the following fields:

- Quantity and Unit
- Container
- Contains latex
- Item number

The reason for why the information is mandatory even if the package is no longer on the market is that the information can still be used. The pharmacies can have packages left and valid prescriptions can still exist. The information is also used for statistical purposes.

7.1.1 Mult 1 and 2, quantity and unit

These fields are used to describe the quantity in the package. See examples:

	Example 1	Example 2
Package content	Endosbehållare, 3 x 60 x 0.5 ml	Blister, 100 tablets
Mult 2	3	left empty
Mult 1	60	left empty
Quantity	0.5	100
Unit	milliliter	tablet(s)

7.1.2 Container

Select the container that best describes the package. The example in the image above is the container” Single-dose container” (in Swedish *Endosbehållare*). For guidance about which container should be selected, please refer to the reference guide “Riktlinjer för förpackningstyp” on LiiV (Leverantörernas information i VARA) • E-hälsomyndigheten (ehalsomyndigheten.se).

Comment: The reference guide (“Riktlinjer för förpackningstyp”) is only available in Swedish.

7.1.3 Contains latex

State if there is latex in the package.

7.1.4 On the market

Is set to "Yes" if the package is available for sale. Please note that this needs to be done one workday prior to marketing of the package commencing, in order for the information to be quality assured in VARA before it is sent out to pharmacies and healthcare providers. Longer notice is needed at public holidays and weekends. For more details about how the information entered in LiiV is transported through the different systems and how long this takes, see Informationsflödet • E-hälsomyndigheten (ehalsomyndigheten.se) (only available in Swedish)

The date when a medicinal product is first placed on the Swedish market and when sales resume after a cessation is collected by the Swedish Medical Product Agency via the Marketing Service, and **no separate notification of placing the product on the market needs to be made** to the Swedish Medical Product Agency. See Appendix 3 for more details.

Reference guide for defining "on the market"

- A "Yes" in the field "On the market" states a company's intention to sell the package in Sweden and shall be set when the package is available for order. In cases when the package is not available in Sweden, but still exists in LiiV/VARA, it shall not be set as "On the market". This is the case, for example, when there is a reference approval in Sweden without the package being available for order.
- The field shall not be set to "Yes" prior to the package being available (for example in relation to public procurement).
- The field shall not be set to "No" to reflect back-orders/shortages. Information regarding back-orders/shortages is communicated through the Swedish Medical Products Agency Medicinal shortages | Swedish Medical Products Agency (lakemedelsverket.se)
- Packages that have been marketed previously and then set to "No" are still able to be sold by pharmacies in case there is residual stock at individual pharmacies.

7.1.4.1 On the market date

This field is used if you in advance want to state the date from which "On the market" is to be set to "Yes". Please note that this date needs to be one working day prior to marketing of the package commencing, in order for the information to be quality assured in VARA before it is sent out to pharmacies and healthcare providers. Longer notice is needed at public holidays and weekends.

As an example a package will start being marketed on Monday 2021-02-01. Then the company needs to enter (Friday) 2021-01-29 as the marketing date. The update will then be transferred to VARA 2021-01-29. When the update has undergone the quality assurance, it is published in the VARA export file the next day. If the user

enters in advance that the packaging will start being marketed on Monday 2021-02-01, the update will be transferred to VARA 2021-02-01 and published in VARA export file 2021-02-02.

NOTE! The healthcare providers receive information from VARA via the Swedish Information Services for Medicines (Sil). Sil is updated every workday. The information must be registered in LiiV no later than Friday 15.00 (Swedish time) to be included in Monday's delivery of the Sil database.

When a future date is entered in the field “On the market date”, after a temporary marketing cessation, the notification to the Swedish Medical Products Agency is automatically updated for the medicinal products subject to mandatory notification and for products for which the company has opted for voluntary notification. See Appendix 3 for more details.

7.1.4.2 On the market No / No longer on the market from

“On the market” should be set to “No” when the package is not available for sale, but this should not be used for reporting shortages. Please note that this date must be one working day prior to the intended date. Longer notice is needed at public holidays and weekends. The field “No longer on the market from” is used when you want to specify in advance the date that “On the market” is to be set to “No”. **For medicinal products for human use that are subject to so called mandatory notification, these notifications must be made at least two months in advance of the date of marketing cessation.** See Appendix 3 for more information regarding which products are subject to mandatory notifications.

The Swedish Medical Products Agency collects information about the marketing status and the information **corresponding to a notification of temporary or permanent marketing cessation** via the Marketing Service**.** The same applies to the email notification of the reason and actions related to the marketing cessation of veterinary medicinal products. This reporting is also replaced by the Marketing Service. **No separate notification of marketing cessation needs to be made** to the Swedish Medical Products Agency.

Mandatory notification of marketing cessation

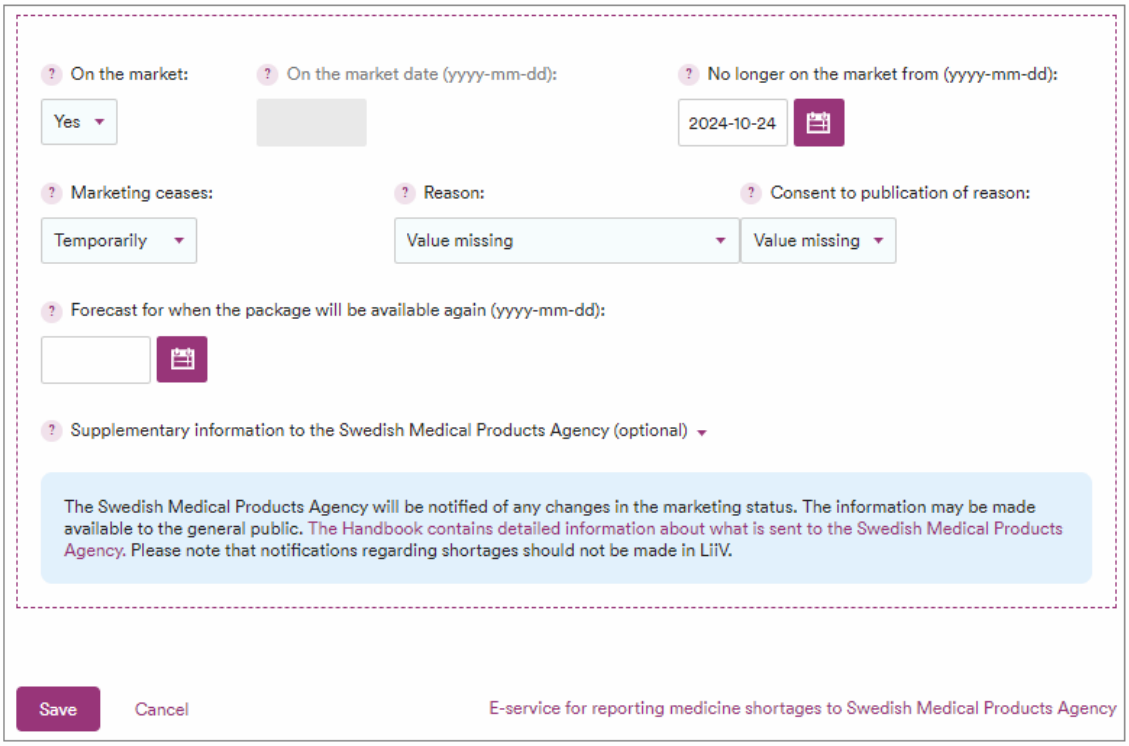
When the field “On the market = No” or “No longer on the market from” is filled in, additional fields are displayed.

- Marketing ceases (Temporarily/Permanently)
- Reason: (Market-related/Quality-related/Safety-related/Effect-related/Incorrectly indicated as on the market)
- Consent to publication of reason: (Yes/No)
- Forecast for when the package will be available again (only shown when Temporarily has been selected)

- Supplementary information to the Swedish Medical Products Agency (free text field)

More detailed information on how to fill in the fields is found in Appendix 3.

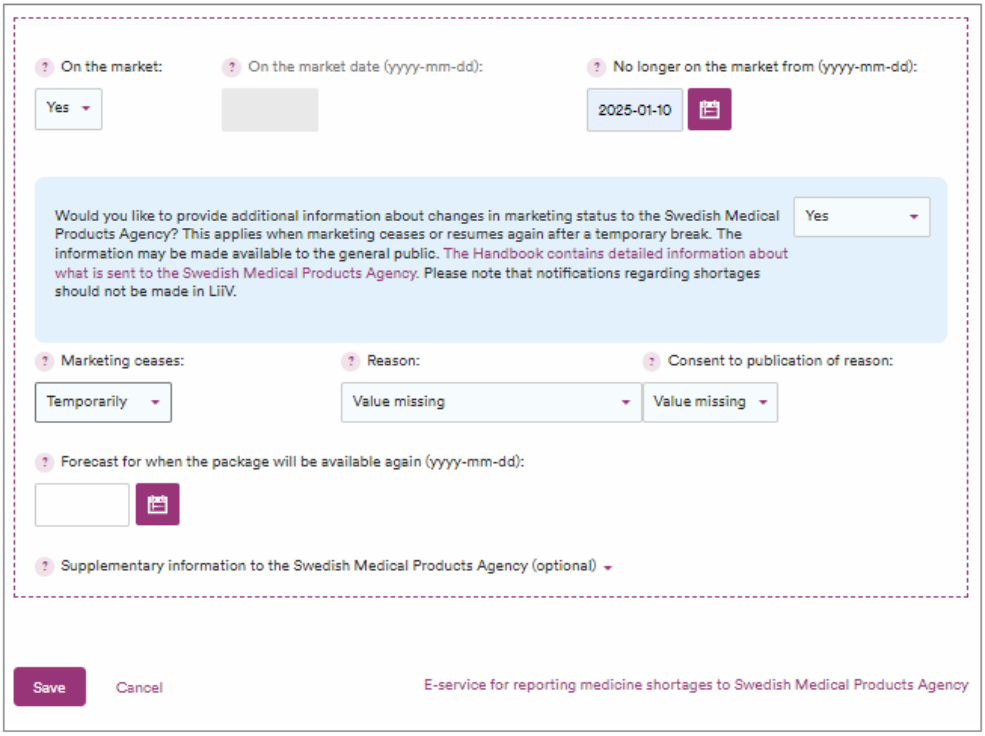
Note that for veterinary medicinal products, intended actions in the event of marketing cessation must be specified in the free text field “Supplementary information to the Swedish Medical Products Agency”.



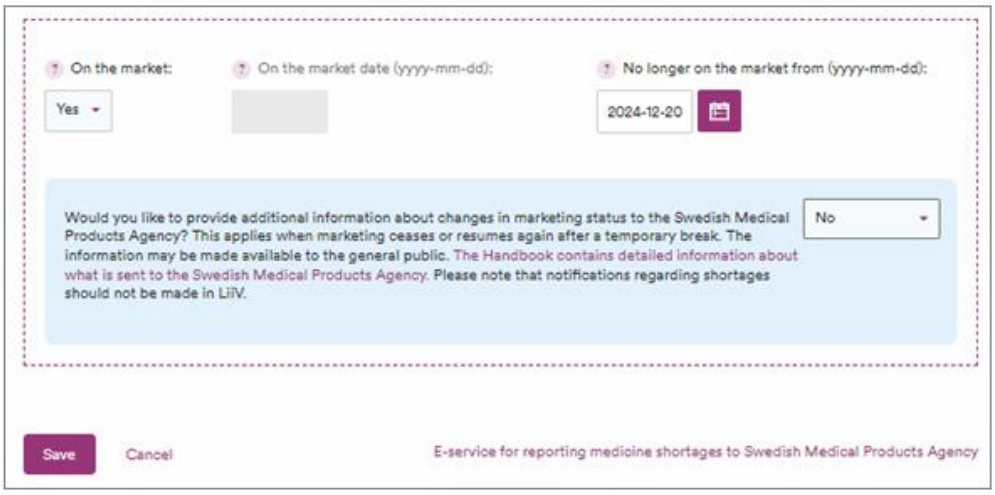
Voluntary notification of marketing cessation

A voluntary notification includes the same data sets as a mandatory notification. More detailed information on how to fill in the fields is found in Appendix 3.

If “Yes” is selected from the drop-down list for voluntary submission of additional information to the Swedish Medical Products Agency, additional fields are shown which are then mandatory. See the example below:



If "No" is selected from the drop-down list for voluntary submission of additional information to the Swedish Medical Products Agency, no additional fields are shown. See the example below:



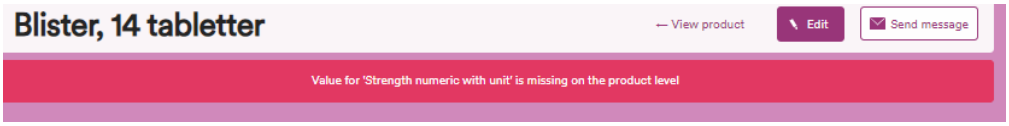
7.1.5 Reminder to fill in strength numeric with unit

A reminder to fill in the fields "Strength numeric" with "Unit" is displayed in several different places if this is not filled in when a package is placed on the market, or when a package gets a future marketing date, according to section 7.1.4.

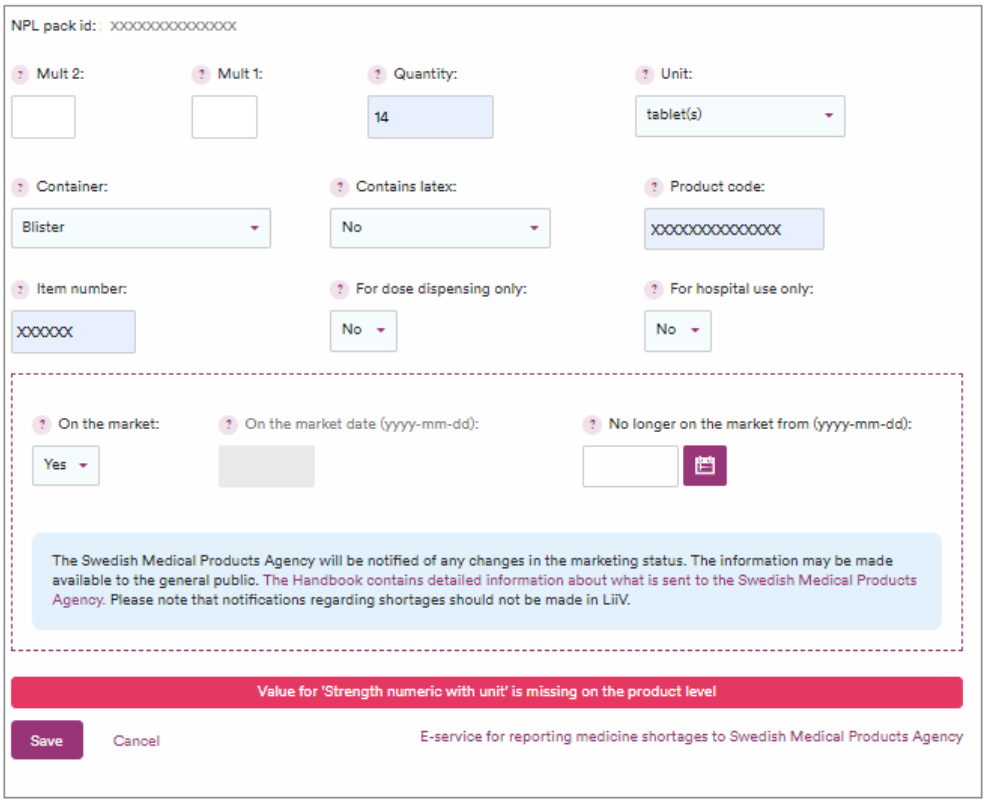
If “Strength numeric” with “Unit” is not stated, the product does not pass the validation check and is therefore not transferred to VARA until the fields are filled in.

Note that in some cases it is correct to leave the fields blank (see section 6.1) despite the reminder.

A reminder on the package level:



A reminder when editing a package:



7.1.6 Product code

In the “Product code” field in LiiV, enter the package's GTIN or NTIN. The system automatically adds zeros at the beginning in order to make the number of digits 14. When a new product code is entered, the system automatically fills in the “Previous product code” field with the old product code.

Comments: The word product code is also used to designate the actual carrier of the code on the package, which may for example be EAN-13 or a 2D data matrix code. For more information about NTIN and GTIN see [VnrWiki.]

7.1.6.1 Handling of multiple product codes per NPL pack id

In LiiV, all product codes are saved, including those that are no longer valid. This means that pharmacies can handle several packaging variants on the market at the same time, for example, when a package is changed and results in a new product code.

There are two exceptions where the product code history is not saved. These may need to be considered in cases where there is a need to add multiple product codes on the same NPL pack id from the start:

- On a package that has never been placed on the market, no product code history is saved. “Previous product code” will be empty even if there was a product code registered previously. This means that it is only possible to add **one** product code *before* the article is initially placed on the market.
- If multiple product codes are added on the same day, only the most recently entered product code will be saved. “Previous product code” will then show the product code that the package had the day before. At present, LiiV can only handle one switch per day. To save multiple product codes on the same package requires them to be registered on different days.

7.1.7 Item number

In the “Item number” field in LiiV, enter the package’s current item number (ordered from Nordic Number Centre (NNC) located at the Pharmaca Health Intelligence Ltd https://pharmaca.fi/en/ (formerly Pharmaceutical Information Centre (PIC)). When a new item number is entered, the system automatically fills in the “Previous item number” field with the old item number.

The item number may not appear on any other package in LiiV (with the exception of parallel import packages). An error message will be displayed if the item number is already found on any package in LiiV.

7.1.7.1 Handling of multiple item numbers per NPL pack id

In LiiV, all item numbers are saved, including those that are no longer valid. This means that pharmacies can handle several packaging variants on the market at the same time, for example, when a package is changed and results in a new item number.

There are two exceptions where the item number history is not saved.

- On a package that has never been placed on the market, no item number history is saved. “Previous item number” will be empty even if there was an item number registered previously.

- If you change item number several times on the same day, only the most recently entered item number will be saved. “Previous item number” will then show the item number that the package had the day before.

When changing item number, it is important that the item number is changed at the right moment in LiiV. The pharmacies orders are based on the current item number for a particular package. The change of item number may need to be coordinated with the distributor. Otherwise there is a great risk that the order will be rejected by the distributor. If the item number changes on a weekday before 15:00 (Swedish time) in LiiV, the new item number is available for pharmacies after midnight in the VARA export file. Provided that the VARA specialist does not find anything that needs to be adjusted when the quality assurance is performed. Please contact the Swedish eHealth Agency (servicedesk@ehalsomyndigheten.se) if you have questions about item number changes as they can be a little complicated.

7.1.7.2 Reminder to contact NNC/Pharmaca in case of changes

Every manufacturer with products on the Nordic pharmaceutical market is responsible for informing the NNC/Pharmaca (formerly PIC) of any changes regarding Nordic item numbers.

Please note that changes to a product and its packaging must be notified and confirmed with NNC/Pharmaca, see VnrWiki

7.1.8 For dose dispensing only

Is set to “Yes” for those packages of human medicines that are only used for dose dispensing and therefore may not be sold to private customers (because the package lacks complete labelling/package leaflet). The aim of this information is to make it possible to easily differentiate between these packages so that, for example, they are not ordered by an out-patient care pharmacy.

7.1.9 For hospital use only

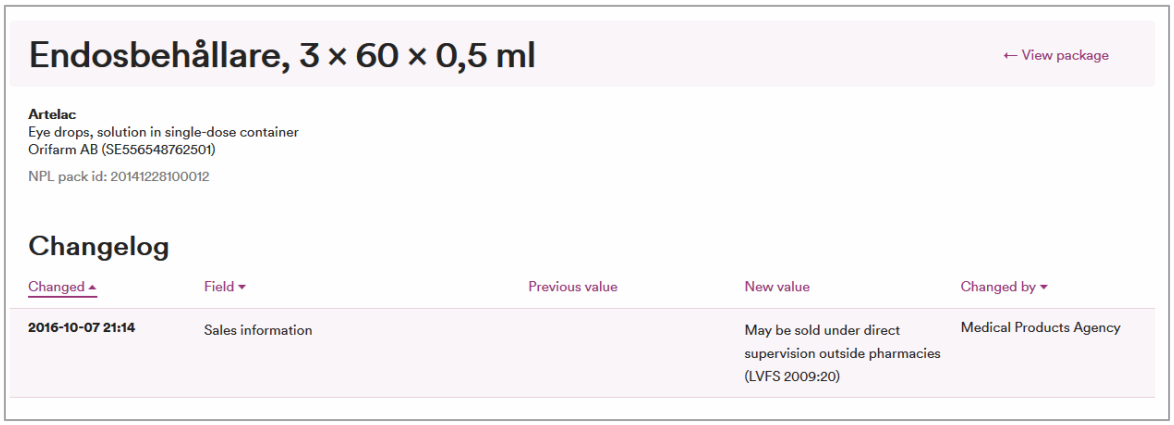
Is set to “Yes” for those packages that are approved with the restriction *Only for hospital use* and may therefore not be sold to private customers (because the package lacks complete labelling). When the packaging is approved as *Only for hospital* use by the Swedish Medical Products Agency, the information is in the field “Packaging contents”.The aim of this information is to make it possible to easily differentiate between these packages so that, for example, they are not ordered by an out-patient care pharmacy.

7.2 Validation

An error message is displayed if the information that is fed in is in breach of any of the validation rules. Change the information to make it correct and then click on “Save”.

7.3 Change log package

There is a link on the package page to the change log for the package (“View change log”). The change log shows the changes that have been made by individual users, the Swedish eHealth Agency and the Swedish Medical Products Agency.



Comments: TLV’s updates to price and product of the month are not displayed in the change log as these updates may be rather frequent and there is a thus a risk of creating a very extensive log.

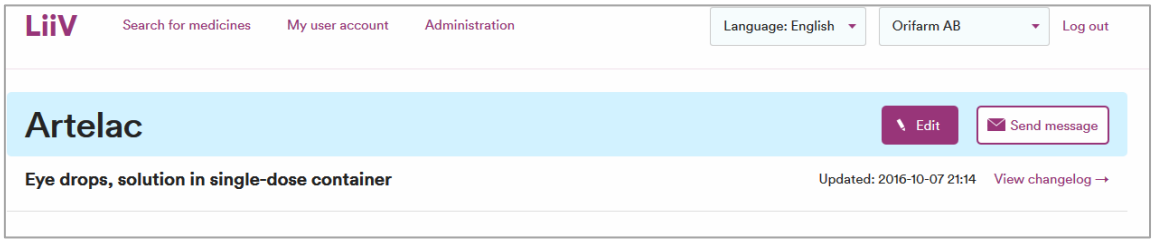
7.4 In the event of a granted exemption to sell other package

In the event of a medicinal shortage, the Swedish Medical Products Agency can in certain cases grant a company an exemption to sell an approved medicinal product in a package that does not meet the requirements of the Swedish Medical Products Agency's regulations regarding labelling and package leaflets for medicines. When a company has applied for and been granted an exemption to sell such a package that corresponds to the same package size as the package found in LiiV, it is generally fine to change the product code in LiiV to the product code found on the exemption package. When the ordinary package is available again, the product code should be changed back in LiiV.

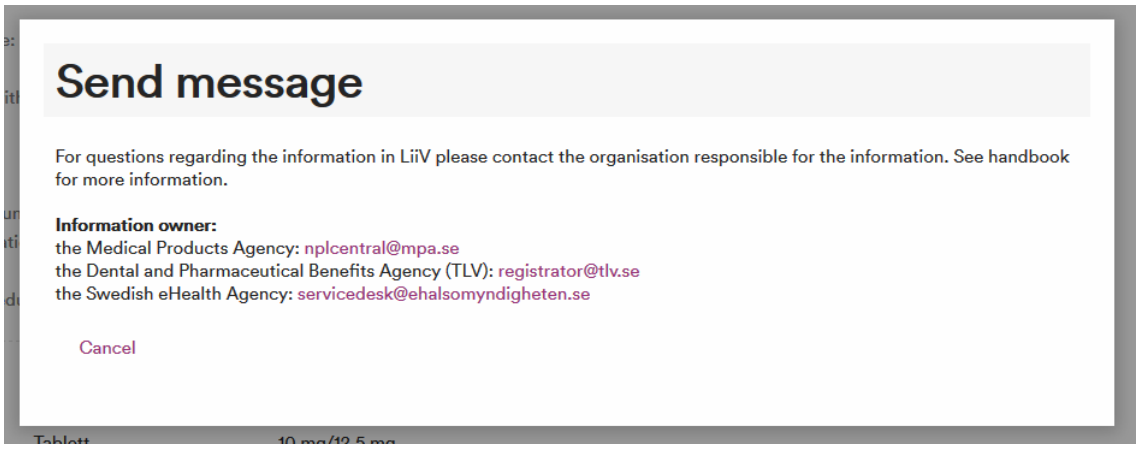
In the case of a granted exemption to sell a package where the package size differs from the package size that already exists in LiiV, the Swedish Medical Products Agency register a new NPL pack id for the exemption package. In order for a pharmacy to be able to find such a package in VARA, the pharmaceutical company needs to enter the item number and product code, and put the article as “On the market = Yes” in LiiV.

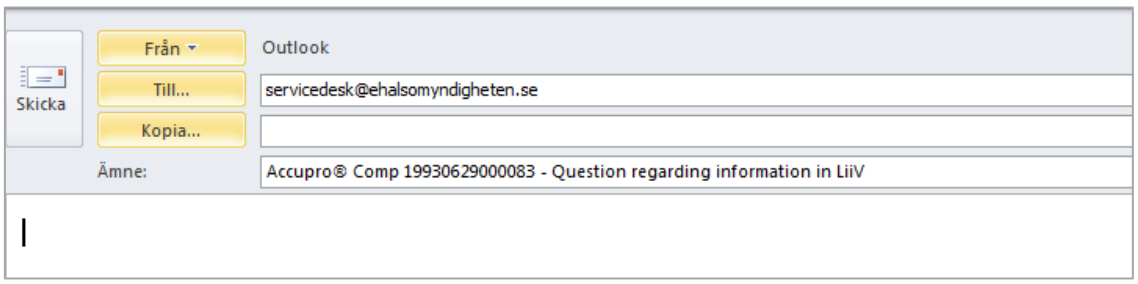
8. Send message

The function “Send message” is available on the product and package page and this is used if you have questions about the information in LiiV.



When you click on “Send message”, a box is displayed in which you can select the email’s recipient (the Swedish Medical Products Agency, the Swedish eHealth Agency or TLV). Click on the desired recipient and a new email will open with the recipient’s email address and the subject field already filled in. For further information on who is the information owner of each field and who should be contacted, see section 11.1 and Appendix 1.





9. My user account

Under “My user account”, you can change your account settings in LiiV.

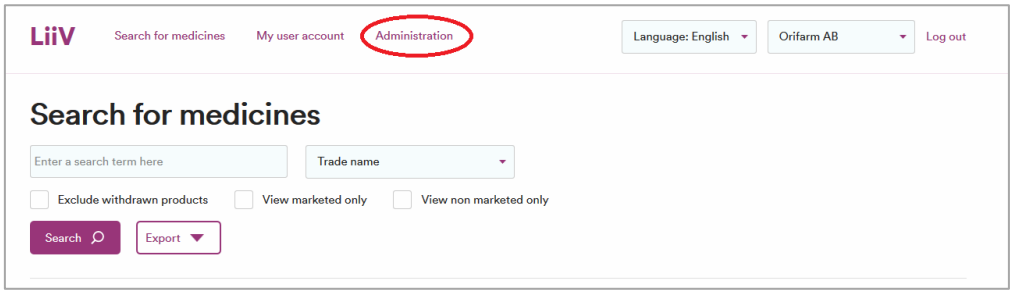
- First name
- Last name
- Language – choose the language that LiiV is to be set to when you log in.
- E-mail – the email address to which information about your user account is sent (for example if you forget your password)
- Telephone (number)
- Selected login – if the user account is linked to more than one supplier, this is used to set which of these is the default when you log in to LiiV (displays only the products that belong to this supplier).
- E-mail for notifications – email address for emails about updates in LiiV (see section 3). If you do not wish to receive these emails, this field can be left empty.

  If you are authorised for more than one company, you can use a different email address for each of these.

  Comments: If more than one person enters the same email address (for example for a shared inbox), only one email will be sent to this address.

10. Administration

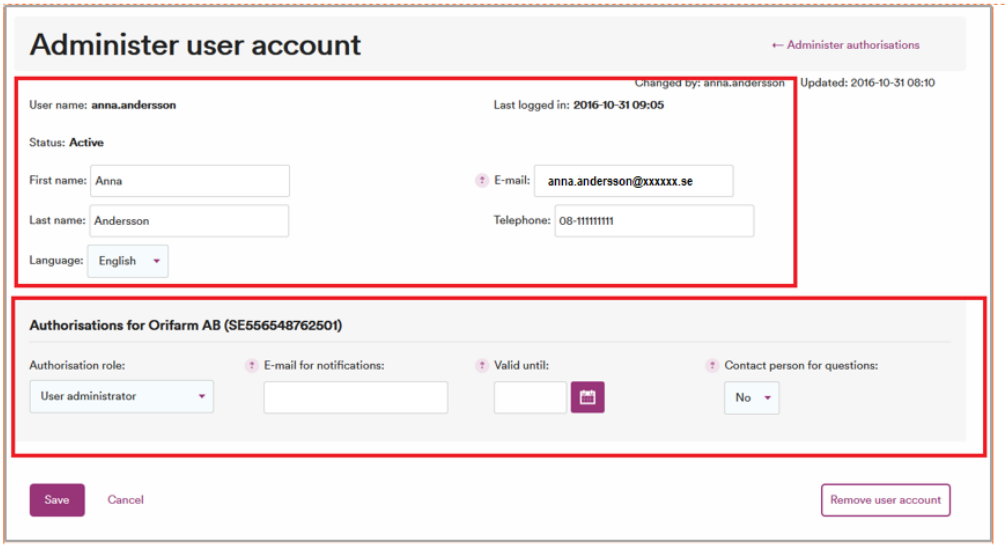
This function is only available for users with the roles “User administrator” or “Consultant administrator” (see description in section 2.2). The link “Administration” is visible to users with either of these roles.



A user account has two parts:

1. User information
2. Authorisation

Every person has one user account in LiiV. It is then possible to link one or more authorisations to this account. An authorisation corresponds to a VAT number.



10.1 Creating user accounts

User accounts can only be created for the company or companies for which you are authorised. If the authorisation is linked to Company A, only accounts for this company can be created.

Please note that a person who is registered in LiiV must be informed of this as they are registered in a register held by the Swedish eHealth Agency (in accordance with the General Data Protection Regulation). No account may be created for users in countries outside the EU/EEA (third countries), that have not been determined by the European Commission to have an adequate level of data protection.

Comments: If you are a user administrator for more than one company, the company for which you can create accounts is determined by the company you have selected in the multiple-choice list (see section 4.3).

1. Click on “Administration”.
2. Select “Create new user account”.
3. Fill in the user information for the person who is to receive an account in LiiV:

- First name
- Last name
- Language – select the default language in LiiV for this person.
- E-mail – the email address to which information about the user account is to be sent (for example when a new account is created or the password is forgotten).
- Telephone (number)

- Authorisation role – read only, write access or user administrator (the options consultant administrator and consultant are available to consultant administrators).
- E-mail for notifications – email address for emails about updates in LiiV (see section 3). If you do not want these emails this field can be left empty.

  Comments: If more than one person enters the same email address (for example for a shared inbox), only one email will be sent to this address.
- Valid until – only entered if the authorisation is temporary.
- Contact person for questions – state whether this person is to be a contact for the Swedish eHealth Agency in the event of questions about the company's products.

4. Click on "Save". A user name for the new account is generated automatically and a green box is shown to confirm that an email has been sent to the new user. The user account can now be activated by the person for whom it has been created (see section 4).

10.2 Editing user accounts

1. Click on Administration and then on the user account that is to be edited.
2. Change the desired value and click on Save.

10.3 Removing user accounts

Each company is responsible for ensuring the information in LiiV is up-to-date. It is therefore important that user accounts that are no longer valid are removed.

1. Click on "Administration" and then on the user account that is to be removed.
2. Click on "Remove user account".
3. Answer "Yes" to the question *"Are you sure you want to delete this user account?"*

If the user account is authorised for more than one company, it cannot be removed and the following error message will be displayed: *Current user account cannot be deleted, as there are several authorisations linked to the account. Contact the Swedish eHealth Agency for more information.*

User accounts are automatically deleted if they have been inactive for two years, due to the General Data Protection Regulation.

10.4 Assigning authorisation to consultants

When a company wants to engage a consultant to manage the company's products in LiiV, this person is assigned authorisation in LiiV.

Please note that you cannot create a new user account for a consultant. The user account must already have been created by the user administrator at the consultancy.

1. Click on “Administration” and then on “Assign authorisation to consultant”.
2. Select the consultancy that is to be engaged from the list.
3. Select the consultant that is to be engaged.
4. Select the consultant’s authorisation:
    - Authorisation role – read only, write access or user administrator.

      E-mail for notifications – email address for emails about updates in LiiV (see section 3). If you do not wish to receive these emails, this field can be left empty.

      Comments: If more than one person enters the same email address (for example for a shared inbox), only one email will be sent to this address.
    - Valid until – only entered if the consultant’s authorisation is to be temporary.
    - Contact person for questions – state whether this consultant is to be a contact for the Swedish eHealth Agency in the event of questions about the company’s products.
5. Save. Please note that no email is sent when authorisation is assigned to an existing user.

10.5 Removing consultants’ authorisation

Each company is responsible for ensuring the information in LiiV is up-to-date. It is therefore important that authorisations that are no longer valid are removed.

1. Click on “Administration” and then on the user account that is to be removed.
2. Click on “Remove authorisation role”.
3. Answer “Yes” to the question *“Are you sure you want to remove the authorisation role for this user?”*

11. Incident reporting

Upon discovery of incorrect or unauthorized use of LiiV that poses a risk to patient safety, the user must immediately notify the Swedish eHealth Agency`s Service Desk and also report to the Swedish Medical Products Agency. This is in order to comply with applicable regulations regarding incident reporting (cf. Chapter 6 of the Swedish Medical Products Agency's regulations, HSLF-FS 2022:42, about national medical information systems (NMI)).

12. Intended IT environment for LiiV

LiiV is intended for use on a desktop or laptop computer with the following operating systems:

- Windows
- Ubuntu

LiiV supports the following browsers:

- Google Chrome
- Microsoft Edge
- Mozilla Firefox

13. Operating status

Operating status for LiiV is communicated at Driftstatus • E-hälsomyndigheten (ehalsomyndigheten.se). It may also be relevant to notify users via email in the event of a planned service interruption or in the event of an incident. An assessment of which communication is considered necessary is always made based on each situation.

14. Format

In addition to PDF format via LiiV (Leverantörernas information i VARA) • E-hälsomyndigheten (ehalsomyndigheten.se), Handbook LiiV can be provided in paper format upon request.

15. Who do I contact for queries regarding LiiV?

15.1 Questions about content

Appendix 1 indicates who is responsible for which field in LiiV. Contact the relevant organisation responsible, based on what the question pertains to. Please use the "Send message" function (see section 8).

General questions about LiiV are sent to servicedesk@ehalsomyndigheten.se. Alternatively, please contact our customer service team by phone on +46 771–76 62 00.

15.2 Questions about user accounts

Questions about user accounts are initially to be dealt with by the supplier's user administrator. If the question cannot be answered, contact the Swedish eHealth

Agency at servicedesk@ehalsomyndigheten.se. Alternatively, please contact our customer service team by phone on 46 771–76 62 00.

15.3 Technical questions

In the event of faults with the system or technical questions, contact the Swedish eHealth Agency by sending an email to servicedesk@ehalsomyndigheten.se. Alternatively, please contact our customer service team by phone on +46 771–76 62 00.

Appendix 1 - Information owners in LiiV

Appendix 2 - Examples of emails concerning updates

Appendix 3 - Marketing Service – information about changes of marketing status to the Swedish Medical Products Agency

16. Document history

Version	Date	Update
1.0	2016-10-31	First version
1.1	2017-01-05	More information about medicinal products with special permission (section 1). Users which needs access to several companies (section 2.3.3). Information about mandatory fields (section 7.1). More information about On the market (section 7.1.4). Incorrect links are now updated.
2.0	2017-10-31	Added information about automatic removal of user accounts (section 10.3). More information about barcodes and item numbers (section 7.1.6 and 7.1.7)
2.1	2017-11-17	Added information about safety features (Appendix 1)
2.2	2018-05-24	Updated from PUL to the General Data Protection Regulation
2.3	2018-12-14	Added temporary warnings about editing (section 6,7 and 10)

2.4	2019-04-08	Removed temporary warnings since the error is corrected
2.5	2019-10-08	Added reference guide for defining “on the market”. Updated barcode to product code.
2.6	2020-04-02	Added information about Biological medicinal product (Appendix 1)
2.7	2020-10-05	Added Reminder to fill in strength numeric (section 6.3 and 7.1.6)
2.8	2020-10-20	Updated a yes to a no in 7.1.4
2.9	2022-04-21	Updated section 3, 4, 6.1, 6.3, 7.1.5, 7.1.8, 7.1.9, 7.1.10. Updated Appendix 1. Updated pictures in section 5.
2.10	2022-06-03	Updated pictures in section 5.
2.11	2022-10-17	Added information regarding third countries in section 2.2 and 10.1
2.12	2023-08-30	Updated information in section 7.1.5 about Sil.
3.0	2024-02-26	Added information regarding NMI classification in section 1. Updated information about Pharmaca Health Intelligence Ltd in section 7.1.8 New sections 7.1.8.2 Reminder to contact NNC/Pharmaca in case of changes, 7.4 In the event of a granted exemption to sell other package, 11. Incident reporting, 12. Intended IT environment for LiiV, 13. Operating information and 14. Format
3.1	2024-09-18	Updated information in section 1. Updated Appendix 1. with Dosage unit, Routes of administration, Substance description, UPD-id L1, UPD-id L2 and UPD-id L3.
3.2	2024-09-26	Updated information in section 7.1.5 about Sil.
4.0	2024-11-28	Added information regarding the Marketing Service to the Swedish MPA:

		Section 7.1.4 updated with information about new fields. Previous section 7.1.5 is now a part of section 7.1.4, affecting the numbering under section 7.1. New appendix - Appendix 3. Appendix 1 has been updated with new fields. Updated pictures in section 7. Format.

Appendix 1 – Information owners in LiiV

MPA = Swedish Medical Products Agency

TLV = Dental and Pharmaceutical Benefits Agency

Attribute (on product)	Description	Information owner
Additional monitoring	Indicates whether the medicinal product is subject to additional monitoring.	MPA
Approval date	Date the product first received marketing authorisation.	MPA
Approval number	(Swedish) authorisation number that is entered by the MPA in conjunction with authorisation. Will be replaced by a new Swedish approval number with correct format.	MPA
ATC code	International classification system for medicinal products. Medicinal products are divided up based on anatomical, therapeutic and chemical affiliation.	MPA
Authorisation procedure	The authorisation procedure through which the product was most recently authorised.	MPA
Biological medicinal product	Indicates whether the medicinal product is biological.	MPA
Contains lactose	Calculated on the basis of the product's composition. Is set to yes if the product contains lactose monohydrate or anhydrous lactose.	The Swedish eHealth Agency
Contains latex	Calculated by the system on the basis of the marketed and previously marketed packages' latex content.	The Swedish eHealth Agency
Controlled medicinal product	Indicates whether a medicinal product is classified as a controlled medicinal product.	MPA
Dispensing restriction	Indicates if the product may only be dispensed from pharmacies if it has been prescribed by a doctor with a certain specialist qualification.	MPA
Dosage form	Form in which the medicinal product appears.	MPA

Dosage unit	Presents the dosage units associated with the product. If a default value is recommended, the value will be highlighted in bold.	MPA
Dose disp. shelf life	Indicates the product's shelf life after the packaging has been opened in months.	MPA
Dose dispensing	A permit that allows the package to be opened for dose dispensing.	MPA
Import deviation	Indicates the way in which a parallel imported medicinal product differs from the reference product.	MPA
Interchangeability	Only entered if the product is interchangeable. Contains information about strength, substance and pharmaceutical form of the interchange group.	MPA
Marketing authorisation number	Authorisation number for products authorised through the centralised procedure.	MPA
Narcotic class	Indicates the class of narcotics to which the product belongs.	MPA
National licence	Indicates whether the extemporaneous preparation has been granted a national license.	MPA
NPL id	Unique medicinal product identifier.	MPA
On the market	Is set by the system automatically. Is set to yes if at least one package is marketed.	The Swedish eHealth Agency
Organisations	The company or companies what are registered to the product (for example as MAH and Local Agent).	MPA
Original NPL id	All parallel imported products have an original NPL id that is the NPL id of the Swedish reference product.	MPA
Parallel import country	Indicates the country from which the product is parallel imported.	MPA
Pharmaceutical product	A medicinal product may consist of one or more pharmaceutical product, i.e. parts. Describes the composition.	MPA

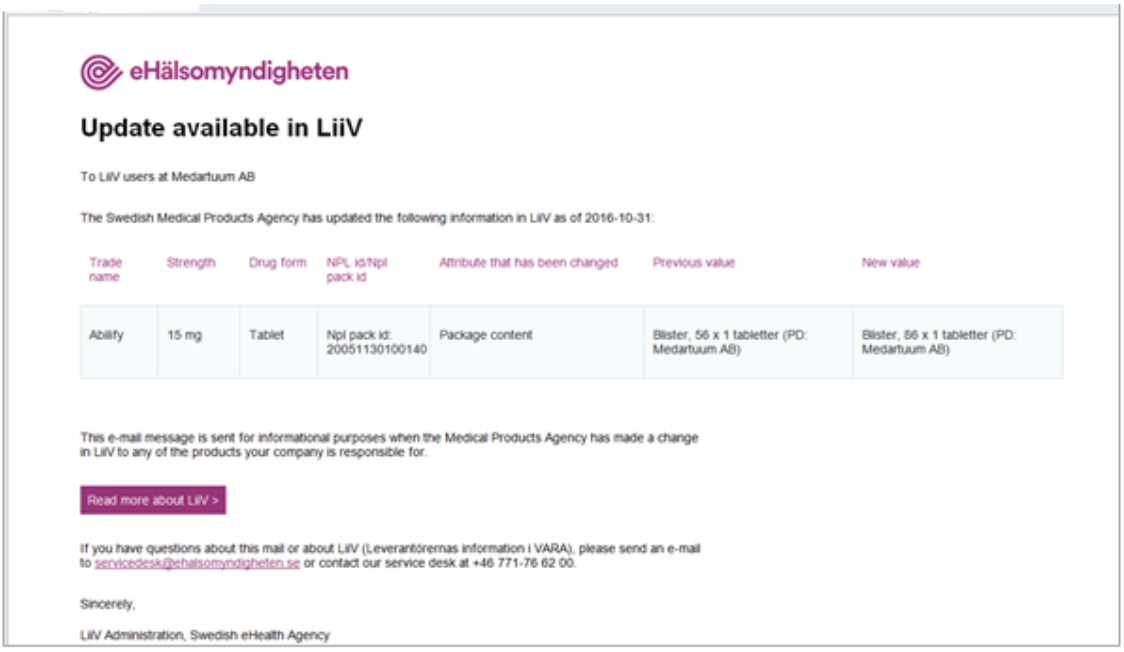
Prescription drug	Indicates whether or not the product is available on prescription only or if some packages can be supplied without a prescription.	MPA
Previous trade name	The product's previous trade name.	MPA
Product type	Type of medicinal product, for example medicinal product with a special permission.	MPA
Repeat prescription	Indicates whether repeat prescriptions of this product may be prescribed (=is iterated).	MPA
Routes of administration	Specifies the route of administration that indicates the part of the body that the medicinal product is to be administered on, through or into.	MPA
Sales stopped	Indicates whether the product's marketing authorisation has been temporarily withdrawn.	MPA
Strength	Free-text field that indicates the product's strength and unit.	MPA
Strength numeric with unit	Numerical field that indicates the product's strength.	Supplier
Substance description	A uniform description of the substances in a medicinal product, which in some cases is simplified to make it easier to understand.	MPA
Swedish approval number	Swedish approval number with correct format that is entered by the MPA in conjunction with authorisation. Will replace the previous Approval number.	MPA
Trade name	The product's current trade name.	MPA
UPD-id L1, UPD-id L2	Identifiers for veterinary medicinal products issued by the EMA and connected to the veterinary legislation. Note! Shown only for veterinary medicinal products.	MPA
Withdrawal date	Indicates the date the product's authorisation will expire/has expired.	MPA
Field (package)	**Description**	**Information owner**
AIP	Pharmacies' purchase price.	TLV

AIP per unit	Pharmacies' purchase price per unit (for example tablet).	TLV
AUP	Pharmacies' sales price.	TLV
AUP per unit	Pharmacies' sales price per unit (for example tablet).	TLV
Consent to publication of reason	A yes or no indicates whether the Swedish Medicines Product Agency is allowed to publish the cause choice or not.	Supplier
Product code	The package's current product code.	Supplier
Container	Describes the container the medicinal product is in.	Supplier
Contains latex	Indicates whether there is latex in the package.	Supplier
For dose dispensing only	Indicates if the package may only be used for dose dispensing.	Supplier
Forecast for when the package will be available again	Specifies the date when the package is expected to be available again.	Supplier
For hospital use only	Indicates if the package may only be used in hospitals (and not sold to private customers).	Supplier
Item number	The package's current item number.	Supplier
Marketing authorisation number	Authorisation number for packages authorised through the centralised procedure.	MPA
Marketing ceases	Indicates whether marketing ceases temporarily or permanently.	Supplier
Mult 1	In cases where the package consists of more than one unit, these can be specified using multiples. For example a product for injection contains 60 ampoules packaged as 6 units, with 10 ampoules in each unit. Each ampoule contains 5 ml. In this case, 'multiple 1' is specified as 10 and 'multiple 2' as 6, 'quantity, numerical' is 5 and 'quantity, numerical unit' is millilitres.	Supplier
Mult 2	See Mult 1.	Supplier
No longer on the market from	Indicates the date when marketed should be set to no.	Supplier

NPL pack id	Unique medicinal product article identifier.	MPA
On the market	Indicates whether the package is marketed in Sweden. Is set to no by the system when the package is deregistered.	Supplier
On the market date	Indicates the date when on the market is to be set to yes.	Supplier
Pack size group	Indicates which package size group the package is included in.	TLV
Package content	Describes the contents of one package.	MPA
Period end	End date for product of the month information.	TLV
Period start	Start date for product of the month information.	TLV
Prescription status	Indicates whether or not the package is prescription only.	MPA
Prescriptive authority	Indicates which professional categories can prescribe the package.	MPA
Previous product code	The package's previous product code. Is set by the system when the product code is changed in LiiV.	The Swedish eHealth Agency
Previous item number	The package's previous item number. Is set by the system when the item number is changed in LiiV.	The Swedish eHealth Agency
(Product of the month) Rank	Indicates whether the article is the product of the month, first reserve or second reserve.	TLV
Quantity and unit	Indicates how many tablets/capsules/ampoules/etc. are in the package.	Supplier
Reason	Indicates the reason for marketing cessation: Market-related Quality-related Safety-related Effect-related Incorrectly indicated as on the market	Supplier
Restriction of reimbursement	Any limitation of the pharmaceutical benefit.	TLV

Sales information	Lists information about sales of the package, for example unrestricted sale in retail trade.	MPA
Sales stopped	Indicates whether the package's marketing authorisation has been temporarily withdrawn. Is set by the system when the product's marketing authorisation is temporarily withdrawn.	The Swedish eHealth Agency
Safety features	Indicates whether or not the package is subject to the regulations for safety features.	MPA
Shelf life	Indicates the package's shelf life.	MPA
Start date (price)	Start date for the price information.	TLV
Supplementary information to the Swedish Medical Products Agency	Free text field for additional information to the Swedish Medical Products Agency regarding the marketing cessation.	Supplier
Temperature	Information about the temperature at which the package is to be stored.	MPA
UPD-id L3	Identifiers for veterinary medicinal products issued by the EMA and connected to the veterinary legislation. Note! Shown only for veterinary medicinal products.	MPA
Withdrawal date	Indicates the date the package's authorisation will expire/has expired.	MPA

Appendix 2 – Examples of emails when updates are made by the Swedish Medical Products Agency



eHälsomyndigheten

Update available in LiiV

To LiiV users at Medartuum AB

The Swedish Medical Products Agency has updated the following information in LiiV as of 2016-10-31:

Trade name	Strength	Drug form	NPL id/Npl pack id	Attribute that has been changed	Previous value	New value
Abilify	15 mg	Tablet	Npl pack id: 20051130100140	Package content	Blister, 56 x 1 tabletter (PD: Medartuum AB)	Blister, 86 x 1 tabletter (PD: Medartuum AB)

This e-mail message is sent for informational purposes when the Medical Products Agency has made a change in LiiV to any of the products your company is responsible for.

Read more about LiiV >

If you have questions about this mail or about LiiV (Leverantörernas information i VARA), please send an e-mail to servicedesk@ehalsomyndigheten.se or contact our service desk at +46 771-76 62 00.

Sincerely,

LiiV Administration, Swedish eHealth Agency

Appendix 3 – Marketing Service – information about changes of marketing status to the Swedish Medical Products Agency

The Swedish Medical Products Agency (MPA) collects information about the marketing status of medicinal products from LiiV to avoid double reporting and to be able to collect the necessary information about marketing status in a structured manner. This gives the Swedish Medical Products Agency a better overview and enables it to publish relevant information about the availability of medicines. It is also important for the Swedish Medical Products Agency to receive additional information about the reason for the marketing cessation and, if possible, a forecast of when a particular package of medicine will be made available again. This information is used to assess the risk of medicinal product shortages.

From the end of November 2024, the Swedish Medical Products Agency will obtain information about changes in marketing status from LiiV via a service called the Marketing Service. Through this service, the Swedish Medical Products Agency will obtain the latest information on a nightly basis from the Swedish eHealth Agency, from LiiV via the Marketing Service, and from the VARA product and article register.

LiiV and VARA use the term “marketed/placed on the market” to reflect that a medicinal product is made available for sale on the Swedish market by the company. The terms used in communication about the availability of medicinal products from different parties may differ in Swedish due to the preference of different Swedish terms (for example on the market/for sale/available).

Further information about how notification of a change in marketing status is handled is available on the Swedish Medical Product Agency's website.

If you have any questions regarding notification to the Swedish Medical Products Agency, please contact registrator@lakemedelsverket.se.

Different types of notification regarding the availability of a medicinal product on the Swedish market

Start marketing / Resumed marketing

The Swedish Medical Products Agency must be notified of market introduction for medicinal products for human use that are nationally authorised under the mutual recognition (MRP), decentralised (DCP) or national (NP) procedure, and the EMA must be notified for medicinal products authorised centrally. The Swedish Medical Products Agency has decided that the notifications of market introduction of veterinary medicinal products that are nationally authorised (within the MRP, DCP, NP and SRP (subsequent recognition) procedures) should be handled in the same

way as medicinal products for human use. This also applies when marketing resumes after a temporary cessation.

The Swedish MPA has made this assessment based on support in the Veterinary Medicinal Products Regulation, where it is permitted for member states to have national rules that govern retail trade, and for a medicinal product to be distributed in Sweden, the status must be updated in LiiV also for veterinary medicinal products.

For more information, see the Swedish Medical Product Agency's website.

Notifications are to be submitted in LiiV, and the form “Marketing information for medicinal products - Sunset Clause” at the Swedish Medical Products Agency should no longer be used.

For parallel imported, parallel distributed and centrally authorised medicinal products, no notification to the Swedish Medical Products Agency is required. For more information see the table “Specification of data sets sent to the Swedish Medical Products Agency in the Marketing Service”.

Temporary or permanent cessation of marketing

If the company decides to stop selling its medicinal product (temporarily or permanently), notification of this must be sent to the Swedish Medical Products Agency only via LiiV. Notification is done at package level. The notification form for marketing information – Sunset Clause that was previously supposed to be sent to the Swedish Medical Products Agency should no longer be used. The data sets included in the notification are detailed in the section “Notification of marketing cessation”. Notification is mandatory for certain medicinal products; see the section “Medicinal products subject to mandatory notification of marketing cessation”.

The same applies to information about the reasons for and actions in the event of a marketing cessation of veterinary medicinal products, as emails no longer need to be sent to the Swedish Medical Products Agency. Notification of the start and cessation of sales of veterinary medicinal products must also be made in the UPD (Union Product Database). Additional provisions regarding veterinary medicinal products are found in the Veterinary Medicinal Products Regulation.

A temporary or permanent cessation of marketing means that the medicine is still authorised for sale, i.e. pharmacies can continue to sell their remaining stock of the product.

In case of a temporary disruption in supply a notification shall be submitted to the Swedish Medical Products Agency using the e-service for reporting medicine shortages. For more information, see the Swedish Medical Product Agency's website.

Medicinal products subject to mandatory notification of marketing cessation

For medicinal products that are nationally approved (procedures MRP, DCP, NP and SRP) there is a requirement to provide additional information in LiiV when the marketing status is about to be changed to "No". Marketing cessation (temporary or permanent) must be notified to the Swedish Medical products Agency two months in advance for medicinal products for humans. Corresponding information for medicinal products for animals must be notified as soon as the MAH becomes aware of it, or in cases where it concerns intended actions and reasons for them, before the actions are taken. For more information please see the Swedish Medical Products Agency's website.

Medicinal products subject to voluntary notification of marketing cessation

For centrally authorised medicinal products, as well as for parallel imported and parallel distributed medicinal products, providing the Swedish Medical Products Agency with additional information in LiiV when the marketing status is changed to "No" is voluntary. This applies to both human medicinal products and veterinary medicinal products.

It is important for the Swedish Medical Products Agency to be aware of additional information regarding the marketing cessation of medicinal products that may create a shortage due to lack of available alternatives. A voluntary notification includes the same data sets as a mandatory notification.

For parallel imported medicines, where availability often varies, a voluntary notification can complete the picture of which medicinal products are available on the market, or not, thus providing a better overall assessment.

Shortage notification

A medicine shortage notification should be made to the Swedish Medical Products Agency when a pharmaceutical company is unable to supply a medicinal product (package) in quantities that meets the demand at a national level. Reporting, updating, and closing of shortage notifications is made by the market authorisation holder (MAH) or its local representative, using the Swedish Medical Product Agency's e-service. For more information, please see Responsibility of the pharmaceutical company | Swedish Medical Products Agency (lakemedelsverket.se).

The marketing status in LiiV should not be used to reflect a shortage due to disruption in supply, i.e. "On the market" shall not be set to "No" if the company intends to continue selling the medicinal product when the supply issue causing a medicinal shortage is resolved. In cases where a company decides to cease marketing and no longer provide a medicinal product on the market, no shortage notification is required. If a shortage notification has already been made to the Swedish Medical Products Agency, but a decision is later made to stop selling the medicinal product, the shortage notification should be closed and the status changed in LiiV. This is

done by setting the marketing status to “No” in LiiV, or by specifying a future date when the product will no longer be available.

Withdrawal of marketing authorisation

In order to withdraw the marketing authorisation for a medicinal product a specific application of withdrawal of marketing authorisation needs to be made to the Swedish Medical Products Agency. Once the marketing authorisation ceases to be valid the product may no longer be sold in the Swedish market. See Withdrawal of marketing authorisation for medicinal products | Swedish Medical Products Agency (lakemedelsverket.se).

Notification of a permanent cessation in LiiV is not the same as an application of withdrawal of marketing authorisation but should specify the intent of the company of not resuming marketing of that package of medicinal product again.

Notification of changes in marketing status using LiiV

Notification of start of marketing

Notification takes place automatically when the marketing status of a package is changed to “Yes”. This applies to all medicinal products.

Notification of marketing cessation

In order for the notification to be complete, the Swedish Medical Products Agency needs information about the date when the product is no longer available, how long cessation period is expected (if it is temporary and this information is known), and the reason for the cessation.

The following fields are included in the notification to the Swedish Medical Products Agency, se the table below. The fields below can be filled in and fields marked with an asterisk (*) are mandatory for those subject to mandatory notification or for those who submit a voluntary notification to the Swedish Medical Products Agency. All entered values can be changed. The data sets may be published by the Swedish Medical Products Agency, unless otherwise stated.

Field in LiiV	Guidance and information about the field
No longer on the market from*	The date the package ceases to be available from the distributor for further sale. The Swedish Medical Products Agency receives the date entered in LiiV + 1 day since it normally takes one day before the information is updated in VARA.

Marketing ceases*	This field is used to indicate whether marketing cessation will be temporary or permanent. Regardless of which is chosen (temporarily/permanently), “On the market” can be reset to “Yes” when the product is once again available for ordering from the distributor.
Reason*	The reason for marketing cessation should be chosen here. See the examples below to select the correct reason description. Market-related: • Low turnover, poor profitability or product rationalisation. Quality-related: • Qualitative and quantitative composition not in line with the specifications. • Manufacturing and control methods are not as specified. • Requirements that were a prerequisite for the manufacturing authorisation have not been met. Safety-related: • The medicinal product has been shown to be harmful under normal conditions of use, or the risk-benefit balance has changed. • The conditions of the marketing authorisation have not been met. Effect-related: • The medicinal product has been shown to lack therapeutic effect or more modern preparations are available. Incorrectly indicated as on the market: • Used if the medicinal product has been mistakenly marketed. Please note that packages with the reason “Incorrectly indicated as on the market” will be treated as if they have been placed on the market.

Consent to publication of reason*	The Swedish Medical Products Agency may only publish the stated reason with the company's consent. If the consent is later changed to “No”, the Swedish Medical Products Agency will remove public information regarding the reason (if it has been published).
Forecast for when the package will be available again	If the marketing cessation is temporary, a forecast of when the package will be available for ordering from the distributor again should be given, if possible. The date can be updated if the forecast changes. If it is not possible to provide a forecast date, the field can be left blank.
Supplementary information to the Swedish Medical Products Agency	Information should be provided to the Swedish Medical Products Agency if there is a risk of shortage with patient impact, for example if equivalent alternative products are not available on the market. The rationale for the chosen reason for the marketing cessation can also be provided here. Please note that the intended actions to address and the reasons behind the cessation of veterinary medicinal products, which are to be notified to the competent authority before the action is taken, must be specified here. *This information is used only by the Swedish Medical Products Agency and will be kept confidential.* The intention is for this to facilitate the assessment of the impact of shortages. This information should be kept brief (maximum 1,000 characters). If necessary, the Swedish Medical Products Agency will follow up on the information with the reporting company.

Notification of resumed marketing

When a future date is entered in the field “On the market date”, the notification to the Swedish Medical Products Agency is automatically updated for the medicinal products subject to mandatory notification and for products for which the company has opted for voluntary notification.

Contact details

The Swedish Medical Products Agency will obtain the contact details of the LiiV user who provided information about marketing status in order to be able to contact the company if necessary. The information sent to the Swedish Medical Products

Agency is first name, surname, email address and telephone number. This information is only used internally at the Swedish Medical Products Agency and will not be published.

Specification of data sets sent to the Swedish Medical Products Agency in the Marketing Service

When information in the data sets is changed in the Marketing Service, they are made available to, and can be retrieved by, the Swedish Medical Products Agency.

Data set	**Mandatory notification** For nationally authorised human medicinal products and veterinary medicinal products	**Voluntary notification** For centrally authorised human medicinal products and veterinary medicinal products, and parallel imported and parallel distributed medicinal products
NPL pack id (Identifies the package)	Always included.	Always included.
On the market [“Yes”/“No”]	Always sent. Date of change of status in LiiV plus one day to match the information in the VARA file.	Always sent. Date of change of status in LiiV plus one day to match the information in the VARA file.
On the market date [date]	Sent only if marketing is being resumed after a period of marketing cessation. Replaces the forecast date, if such has been reported. Date entered in LiiV plus one day to match the information in the VARA file.	Sent only if marketing is resumed after a period of marketing cessation if “Yes” is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency. Date entered in LiiV plus one day to match the

		information in the VARA file.
No longer on the market from [date]	Date is always sent. Date entered in LiiV plus one day to match the information in the VARA file.	Date is always sent if "Yes" is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency. Date entered in LiiV plus one day to match the information in the VARA file.
"Would you like to provide additional information about changes in marketing status to the Swedish Medical Products Agency?" ["Yes"/"No"]	N/A	If "Yes", additional fields become available in the following cases: • On the market = "No" • A date is entered at "No longer on the market from".
Marketing ceases ["Temporarily"/"Permanently"]	The choice "Temporarily"/"Permanently" is always sent.	The choice "Temporarily"/"Permanently" is always sent. The field is only shown if "Yes" is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency.
Forecast for when the package will be available again [date]	Date (if provided) is always sent. The field is only shown if "Temporarily" is indicated.	Date (if provided) is always sent. The field is only shown if "Temporarily" is indicated and "Yes" is

		indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency.
Reason [“Market-related”/“Quality-related”/ “Safety-related”/“Effect-related”/“Incorrectly indicated as on the market”]	Selected reason is always sent.	Selected reason is always sent. The field is only shown if “Yes” is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency.
Consent to publication of reason [“Yes”/“No”]	“Yes”/“No” is always sent	“Yes”/“No” is always sent The field is only shown if “Yes” is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency.
Supplementary information to the Swedish Medical Products Agency [“Text”]	Text (if provided) is always sent.	Text (if provided) is always sent. The field is only shown if “Yes” is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency.
Today's date [date]	When information is sent to the Swedish Medical Products Agency, the date on which the change	When information is sent to the Swedish Medical Products Agency, the date on which the change

	was made in LiiV is included.	was made in LiiV is included.
Contact details	The first name, surname, email address and telephone number of the user who made the change to the information are always sent.	The first name, surname, email address and telephone number of the user who made the change to the information are always sent if “Yes” is indicated when asked whether there should be voluntary notification to the Swedish Medical Products Agency.