

LiiV Handbook

Supplier information in the VARA register

Version 2.11

This handbook describes pharmaceutical companies' work in LiiV



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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 therefore replaced NPL (National Repository for Medicinal Products) since November 2016. LiiV is a system for gathering medicinal product information from various sources (see Section 1.1)

Basic information about medicinal products (authorised medicinal products, medicinal products with special permissions and extemporaneous preparations) in LiiV comes from the 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 www.ehalsomyndigheten.se/lakemedelsflodet-oversikt.

Please note that verification steps that were formerly in NPL have been removed. The information is now 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 Marketed = Yes in LiiV.

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 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 www.ehalsomyndigheten.se/liiv) 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 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 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 Medical Products Agency

When the 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 www.ehalsomyndigheten.se/liiv.

4.1 Forgotten password

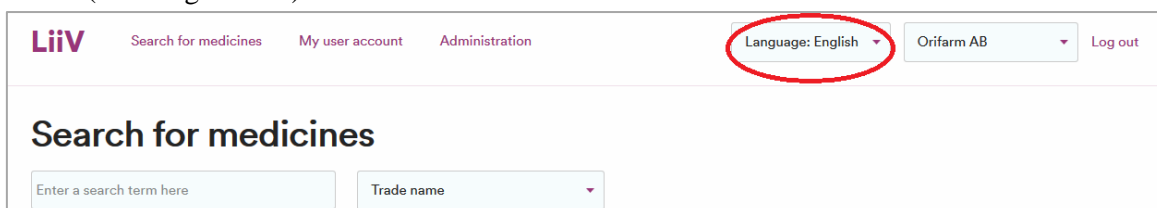
If you forget your password, go to the login page (<https://liiv.ehalsomyndigheten.se/liiv-web>) and click on If you have forgotten your password, click here.

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

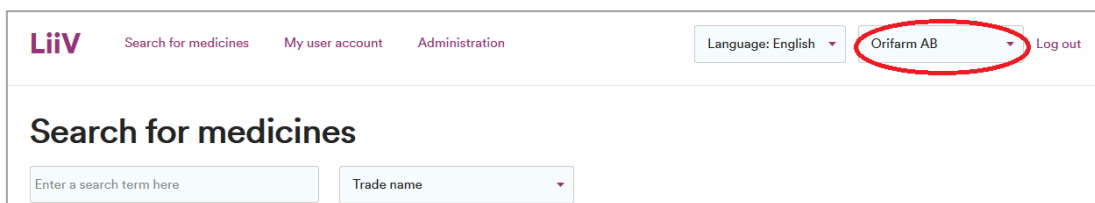
If you would like to change language temporarily, you can do this in the upper-right corner (see image below).



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

4.3 Change authorisation

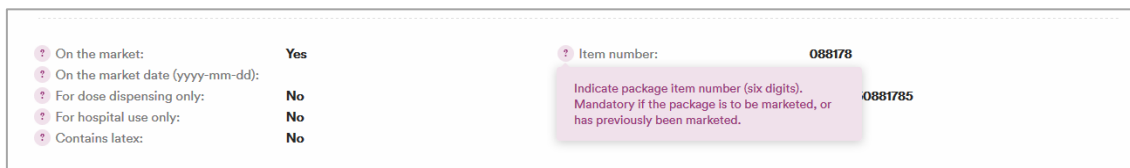
If you are authorised for more than one company, you can switch between these in the top-right corner of LiiV (see image). Products of the selected company then become searchable.



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).

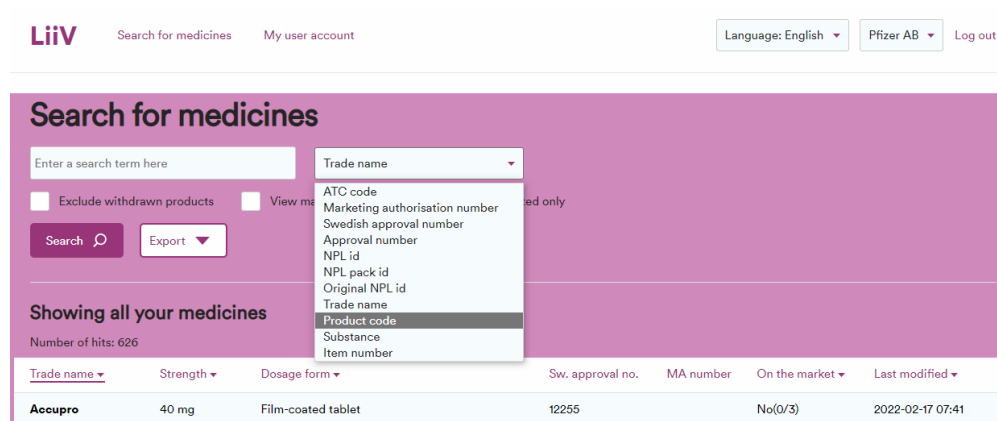
4.4 Help texts

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.



5. Search for medicines

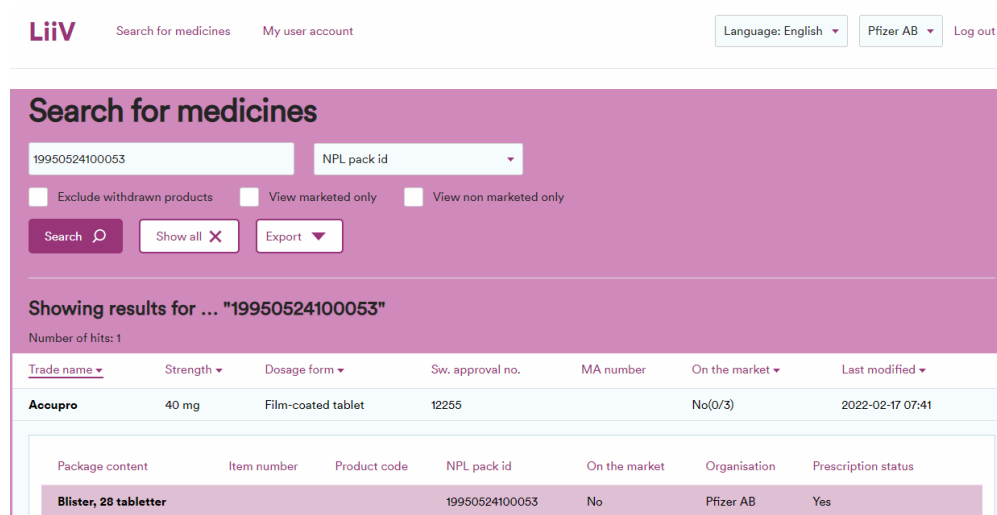
When you log in to LiiV, the page Search for medicines is displayed with the products that the user account is linked to.



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 (e.g. 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 (e.g. trade name). If the search is made with an attribute on the package (e.g. 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 (e.g. trade name). If the search is made with an attribute on the package (e.g. 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

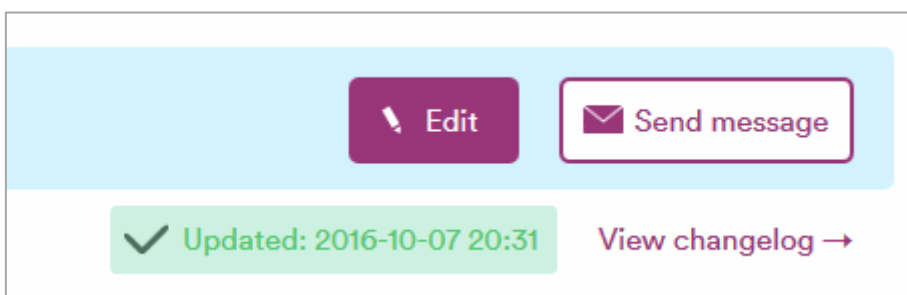
The only variables that can be edited on the product page are Strength numeric and Unit. Strength numeric is to be listed if the product has a strength in the SPC and this strength can be expressed numerically. Combination drugs are an example of products where numerical strength cannot be specified.

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:

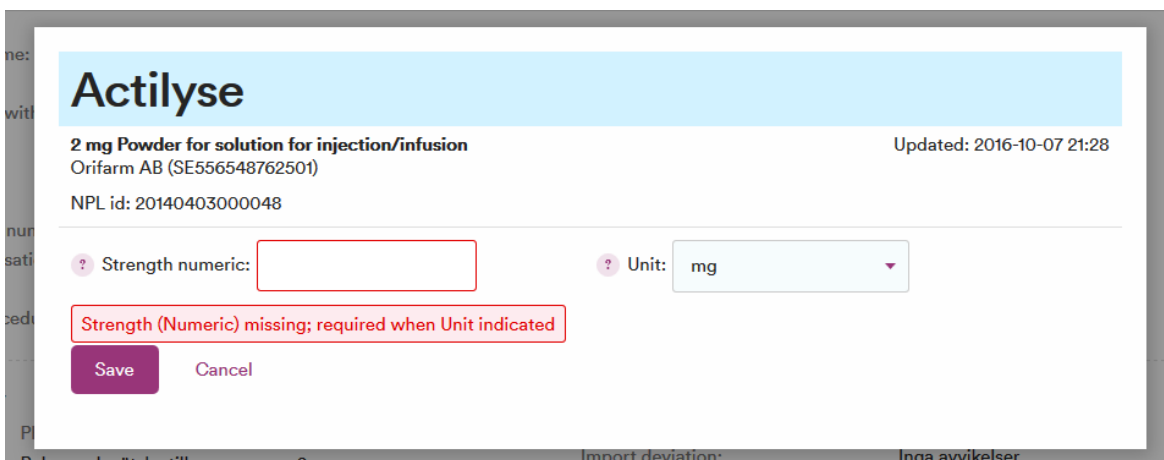
1. Enter the desired value in Strength numeric and Unit.
2. Click on Save. A green box indicating that the update is complete is displayed.



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.



Actilyse

2 mg Powder for solution for injection/infusion
Orifarm AB (SE556548762501)
NPL id: 20140403000048

Updated: 2016-10-07 21:28

Strength numeric: Unit: mg

Strength (Numeric) missing; required when Unit indicated

Save Cancel

Import deviation: Inga avvikelser.

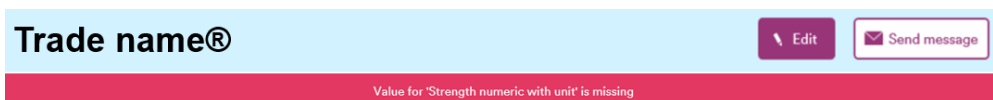
6.3 Reminder to fill in strength numeric with unit

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 7.1.4 and 7.1.5.

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 strength numeric with unit blank (see 6.1) even if the reminder (the red warning) remains on the product.

A reminder on the product level:

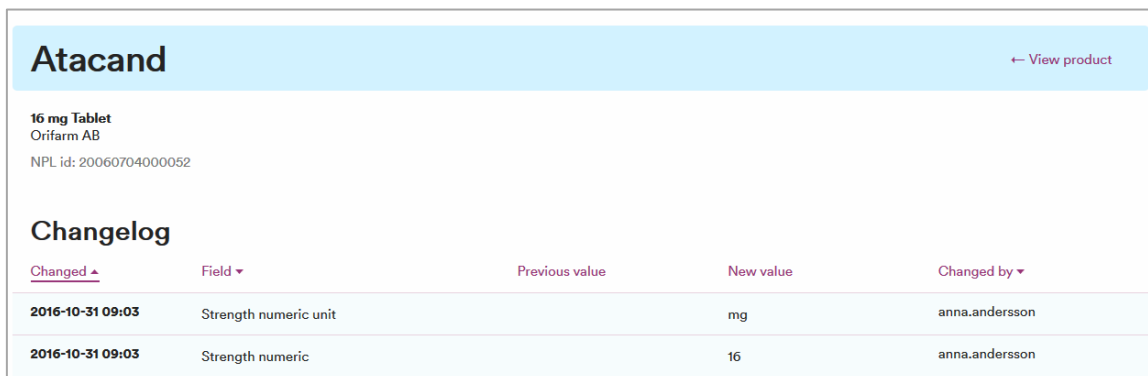


Trade name® Edit Send message

Value for 'Strength numeric with unit' is missing

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 Medical Products Agency.



Atacand ← View product

16 mg Tablet
Orifarm AB
NPL id: 20060704000052

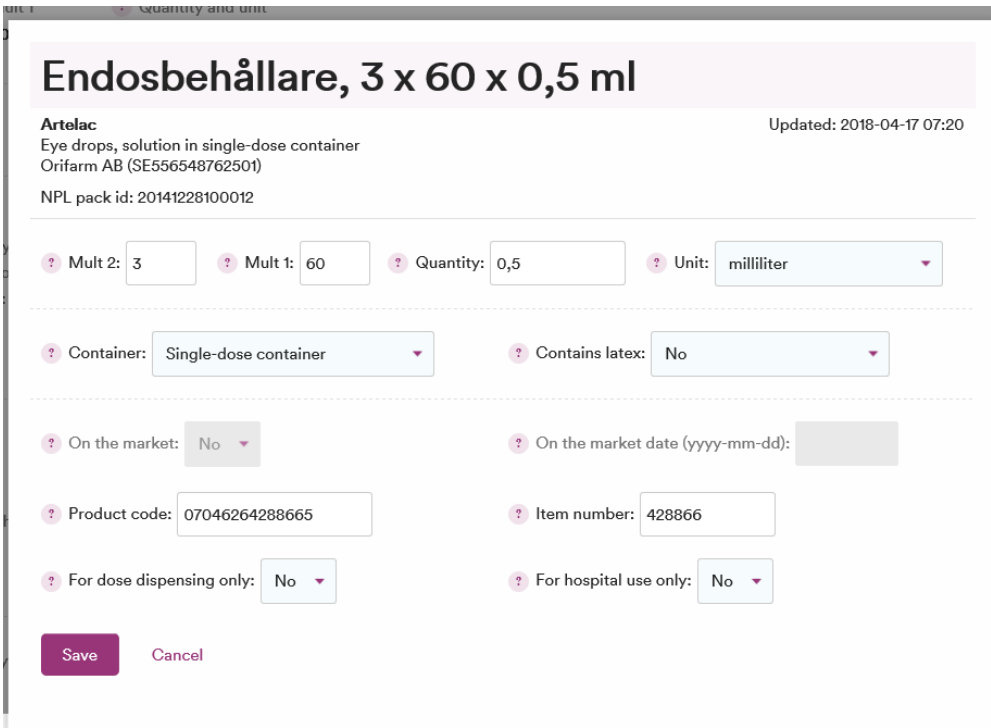
Changelog

Changed	Field	Previous value	New value	Changed by
2016-10-31 09:03	Strength numeric unit		mg	anna.andersson
2016-10-31 09:03	Strength numeric		16	anna.andersson

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).



The screenshot shows a web form for editing a package. The title is 'Endosbehållare, 3 x 60 x 0,5 ml'. Below the title, it says 'Artelac' and 'Eye drops, solution in single-dose container'. There is also a date 'Updated: 2018-04-17 07:20'. The form contains several input fields and dropdown menus, each with a question mark icon indicating a mandatory field. The fields are: Mult 2 (3), Mult 1 (60), Quantity (0,5), Unit (milliliter), Container (Single-dose container), Contains latex (No), On the market (No), On the market date (empty), Product code (07046264288665), Item number (428866), For dose dispensing only (No), and For hospital use only (No). At the bottom, there are 'Save' and 'Cancel' buttons.

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 www.ehalsomyndigheten.se/liiv.

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 working day prior to (longer in the event of weekends and holidays) 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. For more details about how the information entered in LiiV is transported through the different systems and how long this takes, see www.ehalsomyndigheten.se/lakemedelsflodet-oversikt.

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. Information regarding back-orders is communicated through the Medical Products Agency <https://lakemedelsverket.se/OVRIGA-SIDOR/Restnoteringar/>
- 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.

7.1.5 On the market date

This field is used if you 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 (longer in the event of weekends and holidays) 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.

As an example of whether 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 receives information from VARA via the Swedish Information Services for Medicines (Sil). Sil is only updated once a week, and the information is based on Monday's export file from VARA. Sil in turn publishes the information every Wednesday. It then becomes available to the healthcare providers. The information must therefore be registered in LiiV no later than Friday 15.00 (Swedish time) in order for it to be available in Sil the following week.

7.1.6 Reminder to fill in strength numeric with unit

A reminder to fill in the field 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 7.1.4 and 7.1.5.

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 strength numeric with unit blank (see 6.1) despite the reminder.

A reminder on the package level:

Rör, 20 brystabletter
← View product
Edit
Send message

Value for 'Strength numeric with unit' is missing on the product level

A reminder when editing a package:

NPL pack id: XXXXXXXXXXXXXXXX

? Mult 2: <input type="text"/>	? Mult 1: <input type="text"/>	? Quantity: <input type="text" value="20"/>	? Unit: <input type="text" value="pieces"/>
? Container: <input type="text" value="Jar"/>		? Contains latex: <input type="text" value="No"/>	
? On the market: <input type="text" value="Yes"/>	? On the market date (yyyy-mm-dd): <input type="text"/>		
? Product code: <input type="text" value="XXXXXXXXXXXXXX"/>	? Item number: <input type="text" value="XXXXXX"/>		
? For dose dispensing only: <input type="text" value="No"/>	? For hospital use only: <input type="text" value="No"/>		

Value for 'Strength numeric with unit' is missing on the product level

Save
Cancel

7.1.7 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 on NTIN and GTIN see [VnrWiki](#).

7.1.7.1 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.

7.1.8 Item number

In the item number field in LiiV, enter the package's current item number (ordered from the Pharmaceutical Information Centre <http://www.laaketietokeskus.fi/en>).

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.

7.1.8.1 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) if you have questions about item number changes as can be a little complicated.

7.1.9 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.

7.1.10 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 Medical Products Agency.

Endosbehållare, 3 × 60 × 0,5 ml ← View package

Artelac
 Eye drops, solution in single-dose container
 Orifarm AB (SE556548762501)
 NPL pack id: 20141228100012

Changelog

Changed	Field	Previous value	New value	Changed by
2016-10-07 21:14	Sales information		May be sold under direct supervision outside pharmacies (LVFS 2009:20)	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.

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.

Search for medicines My user account Administration

Language: English
Orifarm AB
Log out

Artelac

Eye drops, solution in single-dose container

Updated: 2016-10-07 21:14
View changelog →

Edit
Send message

When you click on Send message, a box is displayed in which you can select the email's recipient (the 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.

Send message

For questions regarding the information in LiiV please contact the organisation responsible for the information. See handbook for more information.

Information owner:
 the Medical Products Agency: nplcentral@mpa.se
 the Dental and Pharmaceutical Benefits Agency (TLV): registrator@tlv.se
 the Swedish eHealth Agency: servicedesk@ehalsomyndigheten.se

Cancel

Skicka	Från ▾	Outlook
	Till...	servicedesk@ehalsomyndigheten.se
	Kopia...	
Ämne:		Accupro® Comp 19930629000083 - Question regarding information in LiiV

9. My user account

Under My User Account, you can change your account settings in LiiV.

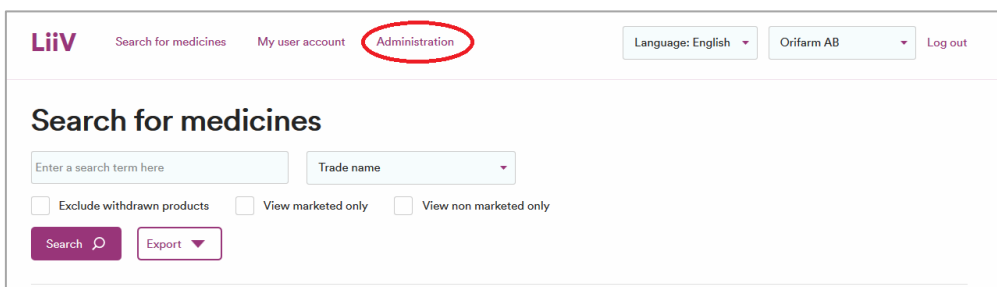
- First name
- Last name
- Language – choose the language that LiiV is to be set to when you log in.
- E-mail – the email address to which information about your user account is sent (e.g. if you forget your password)
- Telephone (number)
- Selected login – if the user account is linked to more than 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 (e.g. 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.

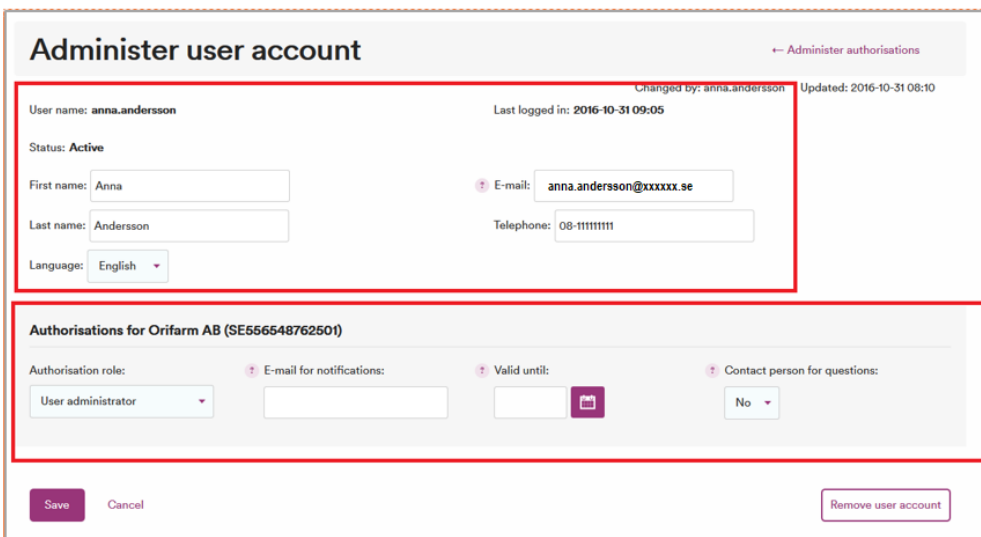


The screenshot shows the LiiV user interface. At the top, there is a navigation bar with the LiiV logo, a search bar, and several menu items: 'Search for medicines', 'My user account', and 'Administration' (which is circled in red). To the right of the navigation bar are dropdown menus for 'Language: English' and 'Orifarm AB', and a 'Log out' button. Below the navigation bar is a section titled 'Search for medicines' with a search input field, a 'Trade name' dropdown, and three checkboxes: 'Exclude withdrawn products', 'View marketed only', and 'View non marketed only'. There are also 'Search' and 'Export' buttons.

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.



The screenshot shows the 'Administer user account' form. At the top right, there is a link to 'Administer authorisations'. The form displays user information for 'anna.andersson', including 'Last logged in: 2016-10-31 09:05', 'Changed by: anna.andersson', and 'Updated: 2016-10-31 08:10'. The user's status is 'Active'. The form includes input fields for 'First name: Anna', 'Last name: Andersson', 'E-mail: anna.andersson@xxxxx.se', and 'Telephone: 08-11111111'. There is also a 'Language' dropdown set to 'English'. Below this is a section for 'Authorisations for Orifarm AB (SE556548762501)' with fields for 'Authorisation role' (set to 'User administrator'), 'E-mail for notifications', 'Valid until', and 'Contact person for questions' (set to 'No'). At the bottom, there are 'Save', 'Cancel', and 'Remove user account' buttons.

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 (e.g. 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 (e.g. 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 (e.g. 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. Who do I contact for queries regarding LiiV?

11.1 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.

11.2 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.

11.3 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

12. Document history

Version	Date	Update
1.0	2016-10-31	First version
1.1	2017-01-05	<p>More information about medicinal products with special permission (section 1).</p> <p>Users which needs access to several companies (section 2.3.3).</p> <p>Information about mandatory fields (section 7.1).</p> <p>More information about On the market (section 7.1.4).</p> <p>Incorrect links are now updated.</p>
2.0	2017-10-31	<p>Added information about automatic removal of user accounts (section 10.3).</p> <p>More information about barcodes and item numbers (section 7.1.6 and 7.1.7)</p>
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

Appendix 1 – Information owners in Liiv

MPA = 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


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 (e.g. 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, e.g. medicinal product with a special permission.	MPA


Repeat prescription	Indicates whether repeat prescriptions of this product may be prescribed (=is iterated).	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
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
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 (e.g. tablet).	TLV
AUP	Pharmacies' sales price.	TLV
AUP per unit	Pharmacies' sales price per unit (e.g. tablet).	TLV
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
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

Mult 1	In cases where the package consists of more than one unit, these can be specified using multiples. E.g. 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
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
Restriction of reimbursement	Any limitation of the pharmaceutical benefit.	TLV

Sales information	Lists information about sales of the package, e.g. 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
Temperature	Information about the temperature at which the package is to be stored.	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 Medical Products Agency

Från: noreply@ehalsomyndigheten.se Skickat: må 2016-10-3
 Till:  Annika Forsén
 Kopla:
 Ämne: Update available in Liiv

 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