

## Training Material for LiiV (Supplier information in VARA)

# Background

- The register VARA was launched in October 2010, in connection with the re-regulation of the pharmacy market.
- The Swedish Government commissioned the Swedish eHealth Agency to take over the task of compiling supplier information, therefore LiiV was built.
- LiiV was launched in November 2016 and replaced the Swedish Medical Products Agency's system NPL (national repository of medicinal products)

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### **Information flow**



### Flow VARA - LiiV

- When the information is saved in LiiV, it passes on directly to VARA
- In VARA, the information is quality assured by pharmacists before it is published at midnight
- If any deviation is detected during the quality assurance, the company is contacted and is then able to change the information in LiiV

All changes must be entered into LiiV by 15:00 (3 pm) so that the information can be published at midnight

# Handbook LiiV

• The handbook describes pharmaceutical companies' work in LiiV

LiiV (Leverantörernas information i VARA) • E-hälsomyndigheten (ehalsomyndigheten.se) **Relaterad information** 

Ansökan

**Behörighetsadministratör** 

English: Application user administrator form



Riktlinjer för förpackningstyp



# Log in

• Log in via the information page for LiiV: <u>www.ehalsomyndigheten.se/liiv</u>

- A personal user account is required
- Logging in requires a user name and password

LiiV	Read more about LiiV >
Log in	
User name	
Password	
Log in	
If you have forgo	otten your password, click here.

## User accounts in LiiV

Roles:

- 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 and set up new user accounts linked to the company
- 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

# **Application user administrator**

User information (required fields are marked First name* Company name*	ed with *) Surname* VAT number*	an application to <u>servicedesk@ehalsomyndigheten.se</u> . This person is then able to create accounts for colleagues and consultants
E-mail address for information on user account*		
E-mail address for notification on updates of the company's products		
Telephone number*	Contact person for the eHealth	Agency for questions on your company's products*
Comments		

### Log in for the first time

Correct Content of the second	1. An ema create	ail is sent when the d. Click on the link ii	account is n the email.	
<ol> <li>Request activation link</li> <li>Enter password</li> <li>Activate account - Step 1 &gt;</li> <li>LiiV, administered by the Swedish eHealth heeded for purposes such as prescriptions is retrieved from the Medical Products Ager supplementary information on their medical</li> <li>Read more about LiiV &gt;</li> </ol>	unt in LiiV	2. Enter the user Read and agree t	name (from the en the terms of use	nail).
If you have questions about this mail or abo to <u>servicedesk@ehalsomyndigheten.se</u> or c Sincerely, LiiV Administration, Swedish eHealth Agenc I agree to the terms of use for the set	Contraction of use	gheten er account/password reset in '	Enter password	
Send	please disregard this e-mail. Click on the button below to enter a Enter password >	a password. The link is valid for 15 minutes.	User name	4. Enter the desired
3. A new email is sent. Click on the link (only valid for 15 minutes)	If you have questions about this may to <u>servicedesk@ehalsomyndighete</u> Sincerely, LiiV Administration, Swedish eHeat	ail or about LiiV (Leverantörernas information i VARA), please en.se or contact our service desk at +46 771-76 62 00. th Agency	Confirm new Password Save	password

### **Forgotten password**





### **Start page – search for medicines**





### **Search results**

### **Search for medicines**



Number of hits: 56

Trade name ▼	Strength 🕶	Dosage form ▼	Sw. approval no.	MA number	On the market 🕶	Last modified -
ABASAGLAR KwikPen	100 enheter/ml	Solution for injection in pre-filled pen		EU/1/14/944	Yes(7/16)	2023-02-13 21:12
Actos	15 mg	Tablet		EU/1/00/150	No(0/15)	2023-02-13 21:12
Actos	30 mg	Tablet		EU/1/00/150	No(0/15)	2023-02-13 21:12

### **Export search results**

### Search for medicines

A10	ATC code 🔹
Exclude withdrawn products	marketed only View non marketed only
Search Ø Show all X Expo	rt 🔻

#### Showing results for ... "A10"

chowing results it			A	В	С	D	E	F	G	н	1	J	К	L	М	N	0
Number of hits: 56			Trade nar	n Strength	te Dosage	foi Package	c(On the m	a On the m	a NPL Id	NPL pack i	Approval i	n Swedish a	ar Marketing	tem numb	Previous I	t Product cc	Previous
			ABASAGL	A 100 enhe	et Solution	fc Förfylld	nj No		20130705	20160617:	497040		EU/1/14/	9 409928		05714221(	07046264
Trada nama <del>n</del>	Strongth -	Decesso form =	ABASAGL	A 100 enhe	et Solution	fc Förfylld	nj No		20130705	20130918:	497040		EU/1/14/	9			
Trade name 🔻	Strength •	Dosage form •	ABASAGL	A 100 enhe	et Solution	fc Förfylld	nj Yes		20130705	20151209:	497040		EU/1/14/	9 448060		003000202	07046264
			ABASAGL	A 100 enhe	et Solution	fc Förfylld	nj No		20130705	20160919:	497040		EU/1/14/	9 443065		070462644	
ABASAGLAR	100 enheter/ml	Solution for injection	ABASAGL	A 100 enhe	et Solution	fc Förfylld	nj Yes		20130705	20220128:	497040		EU/1/14/	9 545810		173310090	
			Actos	15 mg	Tablet	Blister, 2	8 No		20001013	20041104:	155950		EU/1/00/	1017858		070462601	
	45	<b>T</b> 11.	Actos	15 mg	Tablet	Blister, 1	96 No		20001013	20100604:	155950		EU/1/00/	1			
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Actos	30 mg	Tablet	Actos	15 mg	Tablet	Blister, 1	12 No		20001013	20100604:	155950		EU/1/00/	1			
	_		Actos	15 mg	Tablet	Blister, 2	8 No		20001013	20001013:	155950		EU/1/00/	1 003423		070462600	
			Actos	15 mg	Tablet	Blister, 9	8 No		20001013	20041104:	155950		EU/1/00/	1017752		070462601	
			Actos	15 mg	Tablet	Blister, 9	8 No		20001013	20111215:	155950		EU/1/00/	1 107229		07046261(	
			Actos	15 mg	Tablet	Blister, 5	6 No		20001013	20001013:	155950		EU/1/00/	1			
			Actos	15 mg	Tablet	Rlister 3	0 No		20001013	200509081	155950		FU/1/00/	1			

# **Display product**

LiiV Search for medicines	s My user account	Administration	Language: English 🔻	Orifarm AB 🔹	Log out
Abilify 10 mg Tablet		Click here to edit information about the product	Updated	Edit Send	angelog →
Previous trade name: On the market: ? Strength numeric with unit: ATC code:	Yes 10 mg N05AX12	Dose dispensing: Dose disp. shelf life: Contains lactose: Contains latex:	Yes 6 months Yes No	Click he the chai	ere to display ngelog
Product type: NPL id: Swedish approval number: Approval number:	Medicinal product 20040607011409 182700	Biological medicinal pro Controlled medicinal pro Narcotic class: Prescription drug:	duct: oduct: No Not classifie Prescription	d as a narcotic only	
Marketing authorisation number: Approval date: Authorisation procedure: Substance description:	EU/1/04/276 2004-06-04 Centralised procedure Aripiprazol	Repeat prescription: Additional monitoring: Dispensing restriction: Dosage unit: Routes of administration	No tablett : Oral use		

Interchangeability

A : :	
Substance group Pharmaceutical form group	Strength group

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### **Display product continued**

Pharmaceutical pro Amounts given per bas	duct 1: ic pharmaceutical unit				
Ingredient role	Substance	Quantity	Unit	Additional	CAS no.
Active ingredient	alfakalcidol	0,5	microgram	The amount given is the target amount	41294-56-8
Excipient	allurarött AC aluminiumlack				68583-95-9
Excipient	butylhydroxianisol				25013-16-5
Excipient	butylhydroxitoluen				128-37-0
Excipient	glycerol				56-81-5
Excipient	sorbitol				50-70-4

### Packaging

Package content 🔻	ltem number	Product code	NPL pack id	Prescription status 🔻	On the market 🔻	Organisation 🗸		
Blister, 100 kapslar	104259	07046261042598	20101013100856	Yes	Yes	Orifarm Generics AB	Edit	Click here
Blister, 100 × 1 kapslar (endos)			20101013100870	Yes	No	Orifarm Generics AB	Edit	to edit the
Blister, 98 kapslar			20101013100849	Yes	No	Orifarm Generics AB	Edit	package
Blister, 98 × 1 kapslar (endos)			20101013100863	Voc	No	Orifarm Generics AB	Edit	directly
	Clic	k on the	desired	row in				
Organisations: Marketing Authorisation Holder:	orde	er to disp	lay the	package				
Orifarm Generics A/S, Energivej 15	5, POB 69, DK-52	260 Odense S <mark>,</mark> Denma	ark (DK25674030)					

#### Local representative:

Orifarm Generics AB, Box 56048, Ingmar Bergmans Gata 2, 102 17, Stockholm, Sweden (SE556622893701)

### **Edit product**

<b>0,5 mikrogram Capsu</b> Orifarm Generics AB ( NPL id: 201006120001	l <b>le, soft</b> SE556622893701) 47		Upda	Enter the desire	d information
Save Cancel	0,5	<sup>2</sup> Unit: mikrog	•	and click Save	
el	0,5 mikrog			_	
₀ de name	0,5 mikrog			Edit	In the even

@ eHälsomyndigheten

### Withdrawn product

Search for medicines          A10       ATC code         Exclude withdrawn products       View marketed only         Search P       Show all X         Export        Export          Showing results for "A10"         Number of hits: 7						Withdra package grey in l with a re product	wn produc es are mark lists and ar ed stripe or /package p	ts and ked in e shown n the bage
Number of hits: 7								
Trade name ▼	Strength 🔻	Dosage form ▼	Swe appr no On the n	narket • Last modified •				
Glimepirid Copyfarm	1 mg	Tablet	Climonirid S	ondo-				
Glimepirid Copyfarm	2 mg	Tablet	Gilmepind 3	anuoz				Send message
Glimepirid Copyfarm	3 mg	Tablet			Withdrawal date: 2018	3-11-19		
Glimepirid Copyfarm	4 mg	Tablet						
Metformin Orifarm	1000 mg	Film-coated tablet	3 mg Tablet				Updated: 2024-05-30 14:25	View changelog →
Metformin Orifarm	500 mg	Film-coated tablet	Davis da da namer		Danadia		Y	
			Previous trade name:	No	Dose dis	pensing:	res 6 montho	
			<ol> <li>Strength numeric with unit:</li> </ol>	3 mg	Contains	lactose:	Yes	
			ATC code:	A10BB12	Contains	latex:	No	
			Product type:	Medicinal product	Biologica	I medicinal product:		
			NPL id:	20050701000032	Controlle	d medicinal product:	No	
			Swedish approval number:	22657	Narcotic	class:	Not classified as a narcotic	
			Approval number:	226570	Prescript	ion drug:	Prescription only	
			Marketing authorisation number	r:	Repeat p	rescription:		
			Approval date:	2005-12-09	Addition	al monitoring:	No	
			Authorisation procedure:	Mutual recognition procedure	Dispensi	ng restriction:		
			Substance description:		? Dosage u	nit:		
					Routes o	administration:		

### Changelog

Atacand				← View product
<b>16 mg Tablet</b> Orifarm AB NPL id: 2006070400005	2			
Changelog				
Changed 🔺	Field <b>v</b>	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

The changelog shows changes that have been made by the Swedish eHealth Agency, medicinal companies and the MPA. There is also a changelog on the package page. @ eHälsomyndigheten

### **Display package**

LiiV Search for medicines My user account	Administration	Language: English 🔻	Orifarm Generics AB 🔻	Log out	
Blister, 100 kapslar		← View product	🔪 Edit 🕅 Send	message	
<b>Alfacalcidol Orifarm</b> 0,5 mikrogram Capsule, soft Orifarm Generics AB (SE556622893701) NPL pack id: 20101013100856		Updated:	2023-02-13 21:12 View cha	ngelog →	
Mult 2     Mult 1     Quantity and unit       X     X     100 pieces	Click here to information the package	o change about	hange out the changelog		
Container: Blister	Prescription status:	Yes			
<ul> <li>? On the market: Yes</li> <li>? On the market date (yyyy-mm-dd):</li> <li>? For dose dispensing only: No</li> <li>? For hospital use only: No</li> <li>? Contains latex: No Safety features: Yes</li> </ul>	<ul> <li>? Item number: Previous item number:</li> <li>? Product code: Previous product code</li> </ul>	104259 070462610	42598		



Blister, 100 kapslar		c
<b>Alfacalcidol Orifarm</b> 0,5 mikrogram Capsule, soft Orifarm Generics AB (SE556622893701)	Updated: 2023-02-13 21:12	
NPL pack id: 20101013100856		
? Mult 2: ? Mult 1: ? Quantity	: 100 ? Unit: pieces -	2
? Container: Blister	? Contains latex: No	
? On the market: Yes 🔻	? On the market date (yyyy-mm-dd):	
Product code: 07046261042598	? Item number: 104259	
Por dose dispensing only: No	• For hospital use only: No • Only the are disp information	e fields that can be changed layed. Enter the desired tion and click "Save".
Save Cancel		

### Important to know

- All information that the Swedish Medical Products Agency sends to LiiV passes directly on to VARA and FASS.
- A reference guide for defining "on the market" is found in the LiiV handbook, section 7.
- Information about a product is passed on to pharmacy operators and healthcare stakeholders when the company sets the first package of the product to "on the market" = yes in LiiV.

### **Email when updates are made by the Medical Products Agency**

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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:

When a change has been made to any product/package that the company owns, an email is sent to those who have provided an email address for notifications.

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



Ski

LiiV	Search for medicines My user account Administration	Language: English  Orifarm AB Log out
Artela	с	Ledit Send message
Eye drops, s	olution in single-dose container	Updated: 2016-10-07 21:14 View changelog →
2	. Choose recipient	Send message For questions regarding the information in LiV 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
Från ▼ Till Kopia	Outlook servicedesk@ehalsomyndigheten.se	3. An email is created with



### My user account

change information LiiV Search for medicines My user account Administration Language: English Orifarm Generics AB 🔹 Log out about your user account My user account Updated: 2016-10-31 08:10 User name: anna.andersson Email address for ? E-mail: annika.forsen@ehalsomyndigheten.s First name: Anna information about your Last name: Andersson Telephone: 08-11111111 account, e.g. if you ? Selected login: Orifarm Generics AB Language: English forget the password Authorisation Organisation: Authorisation role: ? E-mail for notifications: Valid until: Contact person for questions: SE556548762501 - Orifarm AB User administrator No SE556622893701 - Orifarm Generics AB User administrator No Email address for information Save about updates in LiiV (can be left empty)

On this page you can

#### @ eHälsomyndigheten **Administration** This page is only available for users with the roles user administrator and consultant administrator LiiV Search for medicines My user account Administration Language: English 💌 Orifarm AB Log out Provide authorisation Create an account Administer authorisations to a consultant here for a colleague here Orifarm AB (SE556548762501) Assign authorisation to consultant E-mail, user account Authorisation E-mail for notifications Consultant Name Contact person annika.forsen@ehalsomyndigheten.se User administrator No No Annika Test A list of the users of the current company is shown here (in this case, Orifarm AB)

# eHälsomyndigheten Creating user accounts



### © eHälsomyndigheten User account created

LiiV Search for medicines My user account Administration	Language: English 🔻 Orifarm AB 🔻 Log out
Administer user account	← Administer authorisations Changed by: annika.test ✓ Updated: 2016-10-31 14:48 Last logged in:
Status: Inactive First name: Per	P-mail: annika.forsen@ehalsomyndigheten.si Telephone: 08.tttttttt
Language: English  An e-mail message with information about activating the account has been sent	to annika.forsen@ehalsomyndigheten.se
Authorisations for Orifarm AB (SE556548762501)	
Authorisation role:     ? E-mail for notifications:       User administrator     •	? Valid until:     ? Contact person for questions:       Yes
Save Cancel	Remove user account

### Assigning authorisation to consultants (1)

Assign auth	norisation to consu	1. Search for the		
Orifarm AB (SE556	548762501)		consultancy that is to be engaged	
Select consultant organisatio	n: Select organisation 🔹			
Cancel	Select organisation Kemdok AB Methra Uppsala AB NDA Regulatory Service AB Pharm Assist Sweden AB Regulate AB Scandinavian Regulatory Services AB	Assign authorisation to consultant		
		Orifarm A	B (SE556548762501)	
Sofus Regulatory Affairs AB TFS AB		Select consultan	t organisation: Sofus Regulatory Affairs AB	
		User with	consultant organisation Sofus Regulatory Affairs AB	
2	Salaat tha	Name	E-mail, user account	Authorisat
۷.	Select the	Sofus Sofus	annika forsen@ehalsomvndigheten se	

consultant that is

to be engaged

 Name
 E-mail, user account
 Authorisations for Orifarm AB

 Sofus Sofus
 annika.forsen@ehalsomyndigheten.se

 Cancel

### Assigning authorisation to consultants (2)

E dia south suite st	<b>.</b>			
User name: sofus.sofus Status: Inactive	ons for consult	Last logged in:	← Administer autho Changed by: liivsadmin Updated: 2016-	<sup>10-30 22:33</sup> The consultant is already set up in Liiv (at their consultancy)
Consultant organisation: <b>Sofus Regulat</b> First name: Sofus Last name: Sofus Language: English •	tory Affairs AB	? E-mail:       annika.forsen@eh         Telephone:	alsomyndigheten.s	The only thing that can be edited is the authorisation to you own company
Authorisations for Orifarm AB (S Authorisation role: Value missing Value missing User administrator Read only Write access	SE556548762501)  Control Contr	Valid until:	<ul> <li>? Contact person for questions</li> <li>No ▼</li> </ul>	prisation role



### **Questions?**

### servicedesk@ehalsomyndigheten.se

### Tel. +46 771-76 62 00