



# User Guide to DKMAnet

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## Introduction

The user guide to DKMANet has a dual purpose: It is an introductory guide to the system and a mini reference book for the use of DKMANet.

The Danish Medicines Agency's support team is available to answer any questions or queries at [medicinpriser@dkma.dk](mailto:medicinpriser@dkma.dk).

It is only the representative of the products who can gain access on DKMANet. If you do not have a representative then the MAH is automatically the representative.

## Reading guide

The guide is structured so that the general concepts, icons and structure are explained first, after which the various functions are explained in details.

Functions that are only relevant for security administrators are described in a separate section at the end of the guide.

When there are areas on the pages that are explained in the following text, the areas will be marked on the images of the pages first in the section.

All terms and functions in the manual are marked with quotation marks (""), for example "Overview".

When actions are described, such as selection of a main function and subsequent selection of a sub-function and maybe a tab, these will be separated by the > character. Example: "Overview" > "Prices and assortment" > "Notifications". This means that you must select "Overview", click "Prices and assortment" and finally select the "Notifications" tab to view the section described.

## Before using DKMANet

In order to start using DKMANet, the following conditions must be met:

1. A security administrator, company administrator or a company user must be appointed and created before getting access to DKMANet.

Your company must appoint a security administrator who will then be created by the Danish Medicines Agency. If this has not happened then please contact the Medicines Agency for further information at [medicinpriser@dkma.dk](mailto:medicinpriser@dkma.dk).

2. A digital signature must be installed.

The employee signature must be registered in the name of the company in order for the administrator to be able to log on to DKMANet. If a digital signature is not already installed, the employee signature must be ordered from Nets DanID.

Information on digital signatures may be found (in Danish) on Nets DanID website on [Nets DanID A/S webpage](#). Please note that the signature is personal, and that an employee signature must be issued for each user in the company. When installing an employee signature for the first time, it is important to remember to allow popups.

Security administrators, company administrators and users working for companies that do not have a Danish company registration number must be issued an CUG certificate from the Danish Medicines Agency. You need to fill in the CUG form, [CUG form](#), and send it to [Medicinpriser@dkma.dk](mailto:Medicinpriser@dkma.dk)

3. The browser must be set up to allow popups from DKMANet.

In order to be able to view all data, the browser must be set up to allow popups. This will be necessary when extracts for PDF files are to be made, e.g. for assortment or notifications, because PDF files are opened in a new browser window.

## 1. Terms, shortcut keys and icons









Below you will find an explanation of a number of terms and icons used in the user interface of DKMANet.

### 1.1 Terms














Substitution code A (only applicable to substitutable medicinal products)	The cheapest medicinal product in a substitution group. The pharmacy is obliged to dispense this product to the customer, unless special circumstances apply or it is out of stock.
Substitution code B (only applicable to substitutable medicinal products)	Package with a price below the triviality limit relative to substitution code A packages. May be dispensed by the pharmacy as an alternative to substitution code A packages, if the pharmacy is out of A packages.
Substitution code C (only applicable to substitutable medicinal products)	The most expensive package. Only to be dispensed if the patient specifically asks for it, or if the doctor has indicated that, the product must not be substituted.
Product number	Six-digit unique code identifying a package, which are assigned from The Danish Medicine Agency (DLI) / VNR in Finland.
Name	The trade name of the medicinal product.
Drug form	The form of the medicinal product, e.g. tablet, cream or ointment.
Strength	The volume of active ingredient in the product.
Package size	Number of units in the package.
PPP	Pharmacy purchase price.
Supply estimate	Number of packages that can be delivered to pharmacies at the start of the price period.
Status codes for notifications in  S, R, A, N	S (submitted) – the notification has been submitted to the Danish Medicines Agency  R (registered) – the notification has been received but not accepted by the Danish Medicines Agency  A (accepted) – the notification has been accepted by the Danish Medicines Agency  N (not accepted) – the notification has not been accepted
Market situation	<b>New:</b> A new package has been created  <b>Activated:</b> The package has been entered in the Price List ("Medicinpriser") in the selected period  <b>Deactivated:</b> The package has been temporarily withdrawn from the market in the selected period.

	<b>Removed:</b> The package has been withdrawn from the market and cannot be marketed again later. Consequently, at the end of the selected price period, the package will not be included in the company's assortment.
Price period "Current"	When selecting "Current", the assortment and prices applicable in the pharmacies in the current two-week price period (e.g. weeks 1+2) are shown.
Price period "Upcoming"	When selecting "Upcoming", the assortment and prices entering into force in the next price period, and thus replacing the current assortment and prices, are shown. (If the current price period is weeks 1+2, the upcoming price period is weeks 3+4). The upcoming price period is closed to notifications.
Price period "Open"	When selecting "Open", the assortment open to notifications of packages, prices and, if relevant, supply estimate is shown. If the current price period is weeks 1+2, weeks 5+6 will be open to notifications.

## 1.2 Icons

Column or page	Icon	Meaning
PPP		Substitution code A
PPP		Substitution code B
PPP		Substitution code C
Status		Action: Price change
Status		Action: Package created
Status		Action: Package activated (introduce package and reintroduce package)
Status		Action: Package deactivated
Status		Action: Package removed



Status		Status: Notification accepted
Status		Status: Notification not accepted
Status		Status: Notification received
Status		Status: Notification submitted
		Indicates that a notification has previously been submitted for this package in the price period open to notification (shown in the Market situation column)  Also a shortcut to withdrawing the notification.
Package leaflets		Edit package leaflets
Package leaflets		Indicates that a package leaflet must be updated
General		Indicates that a PDF document is attached to the line. A yellow frame around the PDF icon indicates that the document has not been opened.
General		Changes the font size used on the page.  Please note that changing the font size may affect how the pages are displayed.
General		Info button. Contains a brief description of the content of a column or another functionality, e.g. by the search field.
General		Sorting button. Changes the order of packages in the given column.
General		Warning. When you click this icon, an explanation of the warning will be shown (e.g. that changes have already been submitted or that the user needs to perform an action).
Notifications and New packages		Delete button. Removes a notification added to either the Notifications or the New packages tab.



## 2.Functions in DKMANet

DKMANet is the Danish Medicines Agency's secure Internet portal for companies. On the front page, all of the functions that are available for the main topics are displayed.

The main topics are the following:

1. Prices & Reimbursement
2. Medicines
3. Side effects and trials
4. Company Authorisations
5. Medical Devices
6. Administration
7. Submitted



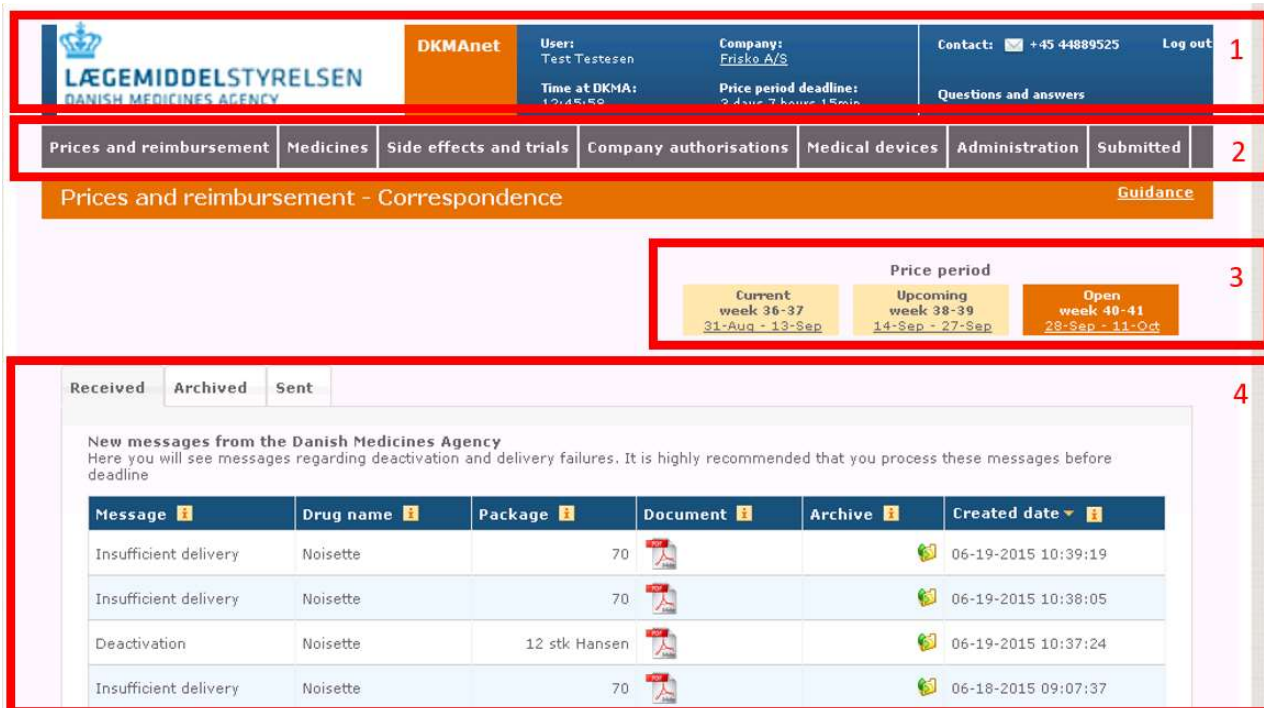
The screenshot shows the DKMANet frontpage. At the top, there is a header bar with the Lægemiddelstyrelsen logo on the left, the DKMANet logo in the center, and user information on the right. The user information includes the user name 'Test Testesen', the company 'Frisko A/S', the time at DKMA '11:37:20', and the price period deadline '4 days 8 hours 23min'. There is also a contact number '+45 44889525' and a 'Log out' button. Below the header bar is a navigation menu with the following items: 'Prices and reimbursement', 'Medicines', 'Side effects and trials', 'Company authorisations', 'Medical devices', 'Administration', and 'Submitted'. The main content area is titled 'Frontpage' and contains several sections. The 'Prices and reimbursement' section lists 'Prices and packages - status', 'Prices and packages - notifications', 'File transfer', 'Correspondence (30 new messages)', and 'General reimbursement'. The 'Medicines' section lists 'Package leaflets' and 'Application for parallel import'. The 'Side effects and trials' section lists 'Clinical trials' and 'Follow-up on adverse reaction reports'. The 'Company authorisations' section lists 'Manufacturing and importation', 'Wholesale distribution', 'Retail sale', 'Handling of euphoriant substances', and 'Conduct of non-clinical tests'. The 'Medical devices' section lists 'Registration' and 'Free Sales Certificate'. The 'Administration' section lists 'User administration', 'Activity log', and 'Company profile'. There is also a 'News' section with a welcome message and a note about the redesigned DKMANet. A small DNA helix logo is visible in the bottom right corner.

LÆGEMIDDELSTYRELSEN DANISH MEDICINES AGENCY		DKMANet	Users: Test Testesen	Company: Frisko A/S	Contact: +45 44889525	Log out
			Time at DKMA: 11:37:20	Price period deadline: 4 days 8 hours 23min	Questions and answers	
Prices and reimbursement	Medicines	Side effects and trials	Company authorisations	Medical devices	Administration	Submitted
Frontpage						
<b>Prices and reimbursement</b> Prices and packages - status Prices and packages - notifications File transfer Correspondence (30 new messages) General reimbursement		<b>Company authorisations</b> Manufacturing and importation Wholesale distribution Retail sale Handling of euphoriant substances Conduct of non-clinical tests		<b>News</b> Welcome to a redesigned DKMANet. New colours and a simpler service structure enhance coherence with the Danish Medicines Agency's official website and provide a better overview.  The grey menu above gives you easy access to the front page and the available services.		
<b>Medicines</b> Package leaflets Application for parallel import		<b>Medical devices</b> Registration Free Sales Certificate				
<b>Side effects and trials</b> Clinical trials Follow-up on adverse reaction reports		<b>Administration</b> User administration Activity log Company profile				

### 3.Configuration of DKMANet

The pages in DKMANet are divided into fields of which some are shown on all pages, while others change depending on the function selected. Functions and tabs will vary depending on whether you have logged on as a security administrator, company administrator or a company user. This will be explained further in the following chapters.

On the screenshot below, the fields are marked by a number. The contents of the fields are explained on the next page. The functions on the pages are described in detail on the following pages.



The screenshot shows the DKMANet interface. Callout 1 points to the top header area containing the agency logo, user information (User: Test Testesen, Company: Frisko A/S, Time at DKMA: 12:45:50, Price period deadline: 2 days 7 hours 15 min), contact information (+45 44889525), and a Log out button. Callout 2 points to the navigation tabs: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, Submitted, and Guidance. Callout 3 points to the 'Price period' section, which shows three periods: Current week 36-37 (31-Aug - 13-Sep), Upcoming week 38-39 (14-Sep - 27-Sep), and Open week 40-41 (28-Sep - 11-Oct). Callout 4 points to the 'Received' tab, which displays a table of new messages from the Danish Medicines Agency regarding deactivation and delivery failures.

Message	Drug name	Package	Document	Archive	Created date
Insufficient delivery	Noisette	70			06-19-2015 10:39:19
Insufficient delivery	Noisette	70			06-19-2015 10:38:05
Deactivation	Noisette	12 stk Hansen			06-19-2015 10:37:24
Insufficient delivery	Noisette	70			06-18-2015 09:07:37

#### 1.

Contains:

- The logo of the Danish Medicines Agency.
- User and company information.
- The time on the Danish Medicines Agency's server.
- Deadline for notification.
- Contact information.
- Question and answers (link).
- Log out of function.

#### 2.

Contains:

- Prices & Reimbursement.
- Medicines.
- Side effects and trials.
- Company Authorisations.
- Medical Devices.
- Administration.
- Submitted.

#### 3.

Contains:

- Price periods
- A link to the guidance document

#### 4.

Contains:

- Link to Show as PDF.
- Info buttons in columns.
- Sorting buttons in columns.

## 4. General functions

Below are described a number of functions that appear on all pages.

### 4.1 Searching

Searches are made from one field and it is possible to search on:

- Product number
- Product name
- Drug form
- MA number (MA no.)

It is also possible to search by parts of the product name or drug form, e.g. [eltro] or [ava].

You may also choose to combine your search on the basis of the above criteria with the use of comma separation, e.g. [ava, tablet]. The result of this search will be all medicinal products in tablet form containing "ava" in the product name.

The result of your search will depend on your navigation on functions and/or tabs under "Notifications" and "Status", respectively.

This means that if you e.g. have searched for a product name under "Status" > "Open", the result of your search will follow if you choose the "Upcoming" price period, while it will not follow if you choose "Notifications". Similarly, your search results under "Notifications" will not follow if you proceed to the "Status" page.

If you wish to view the full assortment, you must delete the text in the search field and select "Search" or press [Enter].

If a match cannot be found in a search, the list will be empty and the numbers to the right of the search field will be 0 – 0 | 0.

*Please note! that if you perform a very broad search, e.g. "tablet", the search may return a considerable number of hits. For that reason, it is recommended that you limit your search by using product number or name*

### 4.2 Refresh

To refresh the page you are on, click "Search" with an empty search field.

### 4.3 Guideline

Each page contains a guideline. For example, if you go to "Notifications" > "Prises and assortment" and click the link "Guideline", you will receive instructions about the functions on that page. When clicking "Back", you will return to the page you came from before you clicked "Guideline".

### 4.4 Show as PDF – printouts and receipts

On the primary screens, it is possible to view printouts and receipts as PDF files. This function requires that popups are enabled (check for toolbars from Google, Yahoo, MSN etc. and if any virus program is set up to block popups). The PDF view shows the date, time, user ID and page number. The PDF file will list the contents of the page you are on when clicking the link. Consequently, the file is generated from, for example, a search result of specific medicinal products sorted as shown on the page.

## 4.5 Print/Save function

You can print, among other things, your assortment or notifications by means of "Show as PDF". When the PDF file has been generated, you may choose to save the file on your PC or to print the PDF file.

## 4.6 Contact

Click "Contact" to generate an email to the Danish Medicines Agency's support mailbox.

## 4.7 Log out

This will ensure that you log correctly out of DKMANet when you do not need to use the system anymore. If there are any unsent notifications, you will be prompted whether you are sure that you wish to log out.

Note! If DKMANet is not used for more than twenty minutes, you will automatically be logged out. If there are any unsent notifications when you are automatically logged out, they will be lost.

## 4.8 To company profile

Brief information about the user's company.

## 4.9 Deadline for notification

This indicates the time remaining before the deadline for notification.

We recommend that you submit notifications one hour before deadline, as a minimum, if you want to be sure that you receive a validation of all price notifications and have the opportunity to make any corrections (upon receipt, new price notifications are validated every ten minutes to ensure that they respect the minimum price deviation). Please note that the deadline does not apply to the updating of package leaflets.

## 4.10 The time at the Danish Medicines Agency

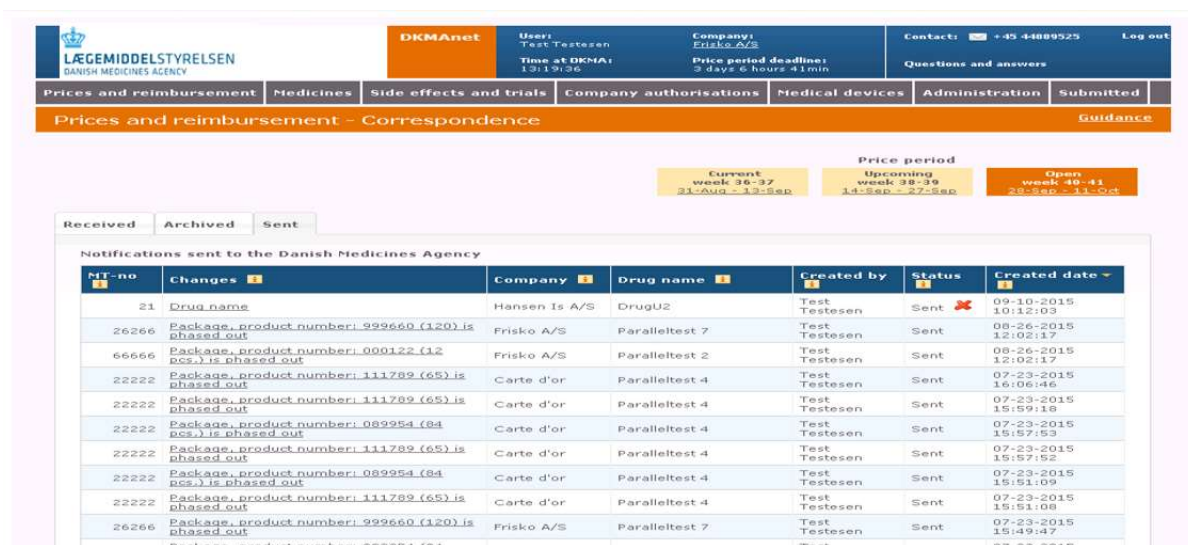
The time on the Danish Medicines Agency's server is the same as the official Danish time and governs the notification deadline.

## 4.11 Correspondence

Under "Correspondence", you can see messages from the Danish Medicines Agency to your company (the "Received" tab). Any messages concern consultation in connection with delivery failure and deactivation.

The "Archived" tab contains the messages you (or other users from your company) have chosen to archive.

The "Sent" tab shows the status of the notifications your company has submitted through "Notifications" > "Other changes" (messages regarding commencement of approved variations) and packages notified as being phased out.



The screenshot shows the DKMANet interface. At the top, there is a header bar with the Lægemiddelstyrelsen logo and navigation tabs: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, Submitted, and Guidance. Below this, there is a section for 'Prices and reimbursement - Correspondence'. A 'Price period' section shows three tabs: Current week 36-37 (21-Aug - 12-Sep), Upcoming week 38-39 (14-Sep - 27-Sep), and Open week 40-41 (29-Sep - 11-Oct). The 'Received' tab is selected, showing a table of notifications sent to the Danish Medicines Agency.

MT-no	Changes	Company	Drug name	Created by	Status	Created date
21	Drug name	Hansen Is A/S	DrugU2	Test Testesen	Sent	09-10-2015 10:12:03
26266	Package, product number: 999660 (120) is phased out	Frisko A/S	Paralleltest 7	Test Testesen	Sent	08-26-2015 12:02:17
66666	Package, product number: 000122 (12 pcs.) is phased out	Frisko A/S	Paralleltest 2	Test Testesen	Sent	08-26-2015 12:02:17
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 16:06:46
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:59:18
22222	Package, product number: 089954 (84 pcs.) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:57:53
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:57:52
22222	Package, product number: 089954 (84 pcs.) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:53:09
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:51:08
26266	Package, product number: 999660 (120) is phased out	Frisko A/S	Paralleltest 7	Test Testesen	Sent	07-23-2015 15:49:47
-----	Package, product number: 089954 (84	-	-	Test	-	07-23-2015

## 4.12 Status

Under Status, your company's full assortment is shown as well as the status of the individual packages if notifications have been submitted (when either "Upcoming" or "Open" has been chosen under price-period).

The overview shows 25 packages at a time. Use the arrows to view the next or previous 25 packages. If you wish to view all packages, click "View all".

You can use the search field to find a specific package within the selected price period.

*Note! Please note that the assortment may vary depending on the selected price period.*

### 4.12.1 Price period: Current

In the "Current" price period, you can see your company's assortment in the pharmacies in the current price period.

The period is locked and cannot be edited. If the medicinal product is substitutable, the "PPP" column will show which substitution code your package has been allocated in this period.

### 4.12.2 Price period: Upcoming

In the "Upcoming" price period, you can see the assortment in the coming price period. The period is locked and cannot be edited. In this price period, you can see:

1. For which packages your company has made notifications
2. Which changes have been notified
3. When the notifications were made
4. Status of the individual notifications (accepted (A), not accepted (N))

### 4.12.3 Price period: Open

In the "Open" price period, you can see your company's assortment in the period which is still open for notifications. In this price period, you can see:

1. For which packages your company has made notifications
2. Which changes have been notified
3. When the notifications were made
4. Status of the individual notification (Submitted, Received, Not accepted)

## 4.13 Administration

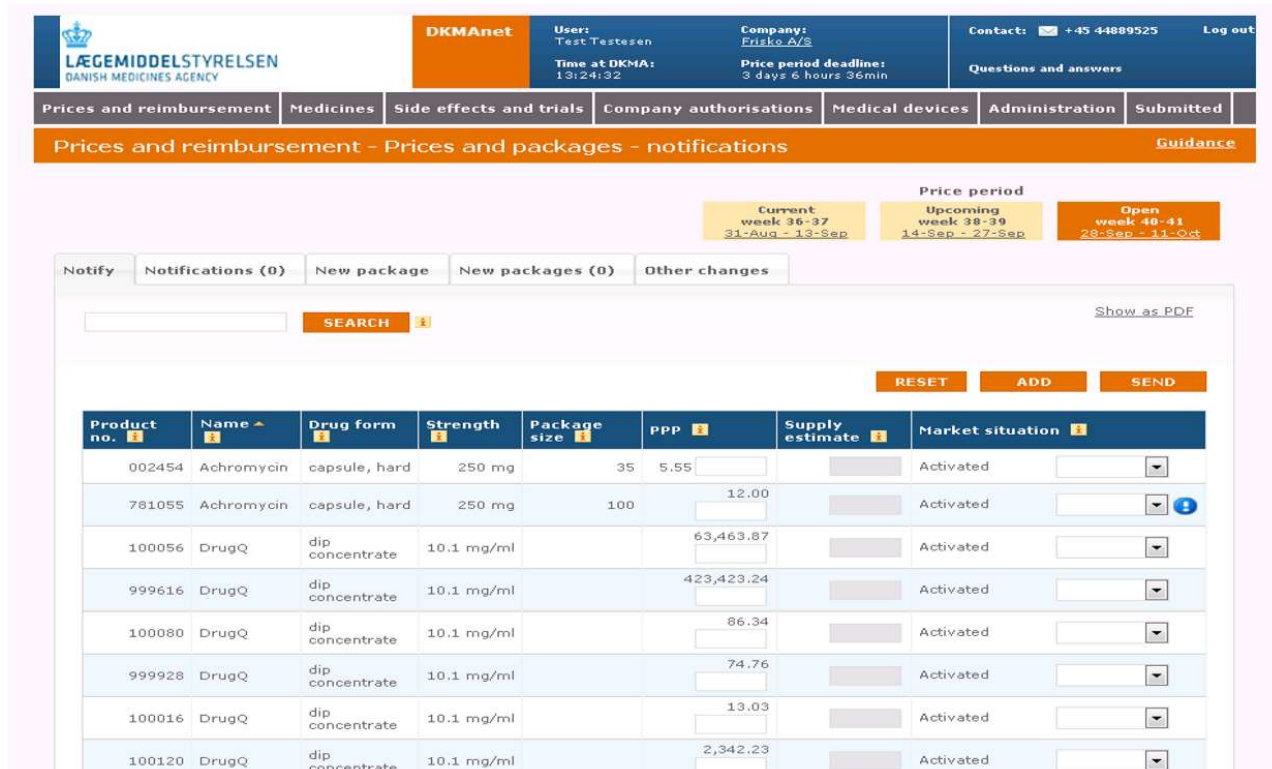
Under "Administration", the security administrator and the company administrator can create and manage the company's company users. This function is not shown if you are logged on as a normal company user. Please refer to Chapter 6 for details about the use of "Administration".

## 4.14 Company profile

Company profile shows the master data for the company/companies to which the current user has access. It also features an overview of the other company users associated with the company as well as a link to administration of these users (only available to security administrators and company administrators).

## 5. Notifications

Under "Prices and reimbursement" you find the sub-functions "Prices and packages – notification" and "File transfer". "Prices and packages" are used for manual entry of notifications and "File transfer" is used for transfer of XML files.



Product no.	Name	Drug form	Strength	Package size	PPP	Supply estimate	Market situation
002454	Achromycin	capsule, hard	250 mg	35	5.55		Activated
781055	Achromycin	capsule, hard	250 mg	100	12.00		Activated
100056	DrugQ	dip concentrate	10.1 mg/ml		63,463.87		Activated
999616	DrugQ	dip concentrate	10.1 mg/ml		423,423.24		Activated
100080	DrugQ	dip concentrate	10.1 mg/ml		86.34		Activated
999928	DrugQ	dip concentrate	10.1 mg/ml		74.76		Activated
100016	DrugQ	dip concentrate	10.1 mg/ml		13.03		Activated
100120	DrugQ	dip concentrate	10.1 mg/ml		2,342.23		Activated

"Reset" cancels all entries made under the "Notify" and "New package" tabs. If you select this function, you will be prompted to confirm that you wish to reset.

Please note that you will only cancel notifications that have not been submitted.

"Add" is a temporary save function where you can collect all notifications before they are submitted to the Danish Medicines Agency. Changes made on the "Notify" tab are collected on the "Notifications" tab, while changes made on the "New package" tab are collected on the "New packages" tab.


"Send" will submit all changes to the Danish Medicines Agency immediately.

Notifications may be overwritten up to the deadline. This means that only the last notification is valid.

*Note! If you wish to have time to discover and correct any errors in your notifications after the Danish Medicines Agency's validation, it is recommended that you submit all notifications by 7:00 pm on the day of the deadline.*

*Note! Please note that notifications not submitted to the Danish Medicines Agency will be lost if you close your browser window without submitting them.*

## 5.1 Prices and assortment

When notifications have been made for a medicinal product, the  icon will appear to the right of the line containing the product. By hovering the mouse over the icon, you will see which notification you have made. If you wish to withdraw a notification, you must hover the mouse over the icon and right-click. Then, you will be prompted to confirm or cancel the withdrawal.

To view all changes submitted to the Danish Medicines Agency in the "Open" price period, you must select "Overview" > "Status" and ensure that "Open" is the active price period.

### 5.1.1 Notify

To notify the Danish Medicines Agency of a new price, market situation and/or supply estimate, you can go to "Notifications" > "Prices and assortment" and click "Notify".

Find the package to be changed, either by scrolling down the list or by searching for the package(s).

If a notification has already been made for a package, a blue icon – an exclamation mark – will appear to the right of the package. By hovering the mouse over the icon, you will be shown a box containing information on the notification.

Please note that the supply estimate field is only active for the packages where notification of the supply estimate is mandatory. If the field is not active, it is not possible to enter a supply estimate.

Make the required notification and click "Add" or "Send".

*Note! Please note that price changes must be +/- 1 Danish krone. The notifications submitted are automatically validated every ten minutes. If the price is changed by less than 1 krone, the status of the notification will change to "N" – Not accepted.*

*Note! If a supply estimate is required, but not entered, you will see an error message if you attempt to send the notification to the Danish Medicines Agency or add it to "Notifications".*





## 5.2 Phasing out of packages:

In order to phase out a package select "Being phased out". When such message is sent, the package will automatically be phased out over three price periods. The message can be seen under "Status" > "Correspondence" > "Sent"

**DKMANet**

User: Test Testesen  
Time at DKMA: 13:39:03

Company: Frisko A/S  
Price period deadline: 3 days 6 hours 22min

Contact: +45 44889525 Log out  
Questions and answers

Prices and reimbursementMedicinesSide effects and trialsCompany authorisationsMedical devicesAdministrationSubmitted

Prices and reimbursement - CorrespondenceGuidance

Current week 36-37  
31-Aug - 13-Sep

Upcoming week 38-39  
14-Sep - 27-Sep

Open week 40-41  
28-Sep - 11-Oct

ReceivedArchivedSent

Notifications sent to the Danish Medicines Agency

MT-no	Changes	Company	Drug name	Created by	Status	Created date
21	Drug name	Hansen Is A/S	DrugU2	Test Testesen	Sent	09-10-2015 10:12:03
26266	Package, product number: 999660 (120) is phased out	Frisko A/S	Paralleltest 7	Test Testesen	Sent	08-26-2015 12:02:17
66666	Package, product number: 000122 (12 pcs.) is phased out	Frisko A/S	Paralleltest 2	Test Testesen	Sent	08-26-2015 12:02:17
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 16:06:46
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:59:18
22222	Package, product number: 089954 (84 pcs.) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:57:53
22222	Package, product number: 111789 (65) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:57:52
22222	Package, product number: 089954 (84 pcs.) is phased out	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015 15:57:52

Phasing out does not mean that it is not possible to notify the Agency of prices and market situation regarding the package.

If you have chosen to use "Add", the "Send" button will disappear and you will then have to enter "Notifications" to send the entire package of changes.





## 5.3 Sending the notifications

The screenshot shows the DKMANet interface. At the top, there's a header with the Lægemiddelstyrelsen logo and name. To the right, a blue box contains user information: User: Test Testesen, Company: Frisko A/S, Time at DKMA: 13:50:30, Price period deadline: 3 days 6 hours 10min, Contact: +45 44889525, and a Log out link. Below this is a navigation bar with tabs: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, Submitted, and a Guidance link. The main content area has a sub-header "Prices and reimbursement - Prices and packages - notifications". Below this, there's a "Price period" section with three buttons: "Current week 36-37 31-Aug - 13-Sep", "Upcoming week 38-39 14-Sep - 27-Sep", and "Open week 40-41 28-Sep - 11-Oct". A row of tabs includes "Notify", "Notifications (1)", "New package", "New packages (0)", and "Other changes". The "Notifications (1)" tab is active, showing a table with one notification. The table has columns: Product no., Name, Drug form, Strength, Package size, ppp, Supply estimate, and Market situation. The notification for product 999723, Noisette, is shown with a red cross icon in the first column. At the bottom right of the table, there are "RESET" and "SEND" buttons. A "Show as PDF" link is also visible.

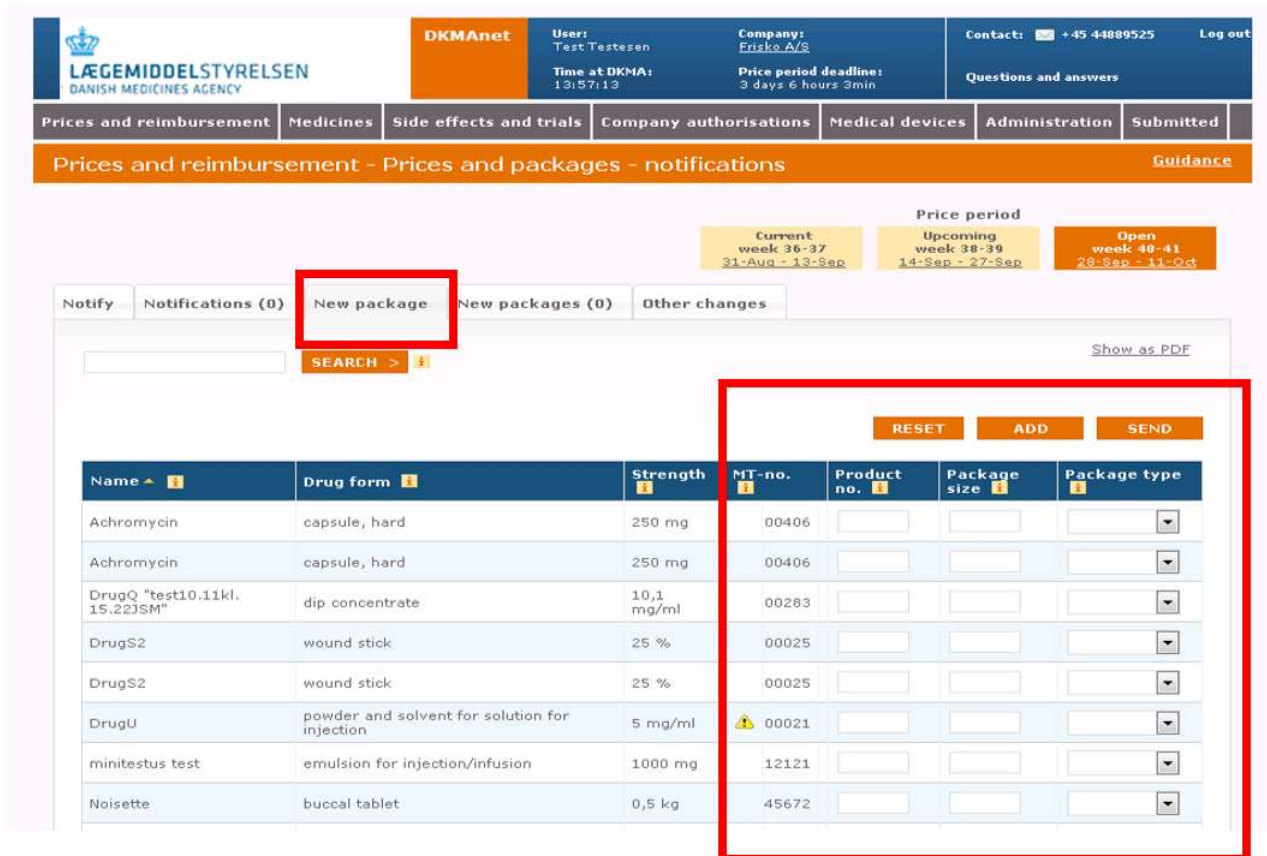
	Product no.	Name	Drug form	Strength	Package size	ppp	Supply estimate	Market situation
	999723	Noisette	buccal tablet	1.2 kg		0.00 42.43	876	New Activated

When you are ready to send your notifications to the Danish Medicines Agency, select the "Notifications" tab. In the parenthesis on the tab, you can see how many changes are pending. Before you click "Send", you have the opportunity to verify the notifications and correct them if you have made incorrect entries. You can also use the red cross in the left part of the overview to delete one notification from the list.

Click "Send" when all notifications are correct. When all notifications and any new packages have been sent to the Danish Medicines Agency, the status page will automatically be shown. Here, you can see your notifications in the assortment overview.

## 5.4 New package

In order to use DKMANet, you must have applied for and received a product number from Danish Medicinal Product Information (DLI). Then, you can start using DKMANet to create and market the package.



DKMANet

User: Test Testesen  
Time at DKMA: 13:57:13

Company: Frisko A/S  
Price period deadline: 3 days 6 hours 3min

Contact: +45 44889525 Log out

Questions and answers

Prices and reimbursement Medicines Side effects and trials Company authorisations Medical devices Administration Submitted

Prices and reimbursement - Prices and packages - notifications Guidance

Price period

Current week 36-37  
31-Aug - 13-Sep

Upcoming week 38-39  
14-Sep - 27-Sep

Open week 40-41  
28-Sep - 11-Oct

Notify Notifications (0) **New package** New packages (0) Other changes

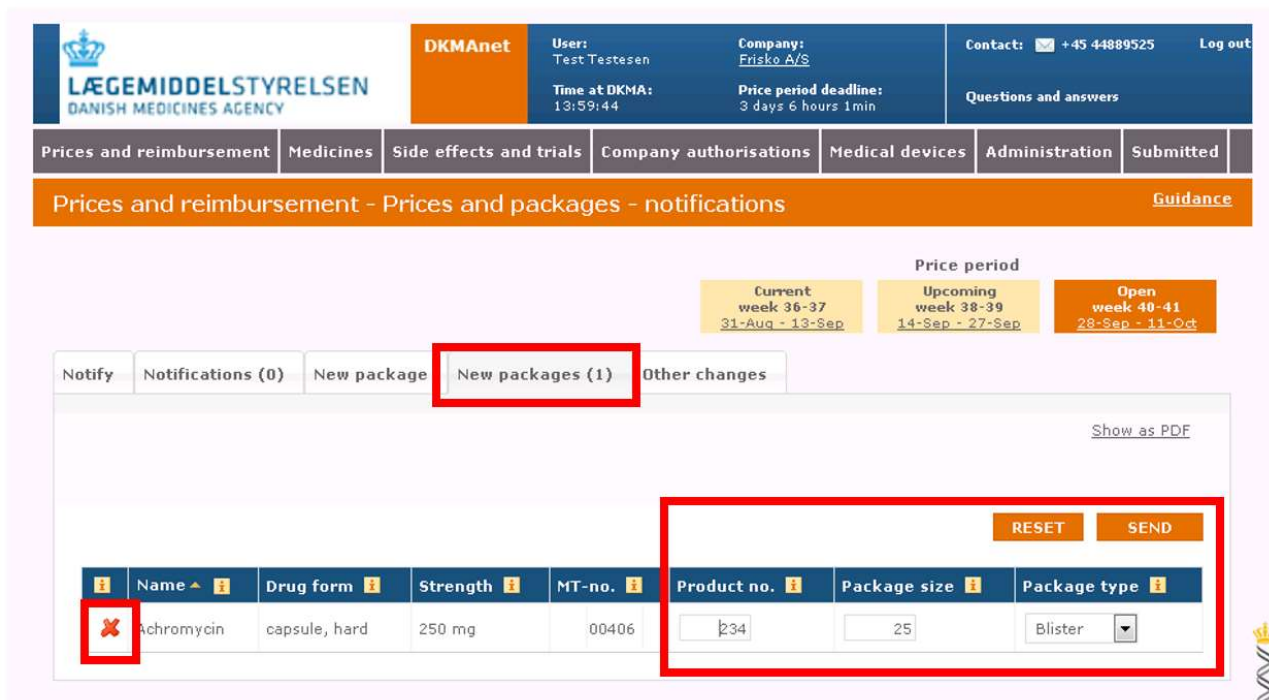
SEARCH > Show as PDF

Name	Drug form	Strength	MT-no.	Product no.	Package size	Package type
Achromycin	capsule, hard	250 mg	00406			
Achromycin	capsule, hard	250 mg	00406			
DrugQ "test10.11kl. 15.22JSM"	dip concentrate	10,1 mg/ml	00283			
DrugS2	wound stick	25 %	00025			
DrugS2	wound stick	25 %	00025			
DrugU	powder and solvent for solution for injection	5 mg/ml	00021			
minitestus test	emulsion for injection/infusion	1000 mg	12121			
Noisette	buccal tablet	0,5 kg	45672			

RESET ADD SEND

1. Find the package to be created in the list, either by scrolling down the list or by means of the search function. Please note that tab "New package" may be used to search for a package using the relevant name, drug ID or drug form. To search for a package using the MA no., the tab "show all" should be clicked before you use the browser's search function.
2. Enter the product number received from DLI as well as the package size and type.
3. Click "Add" or "Send".
4. If you click "Send", the newly created package will be shown on the "Notify" tab, and you can now activate the package (in the "Market situation" column in section 5.1.2) and then enter price and supply estimate. Please note that you must always enter a supply estimate when activating new packages. Finally, click "Send" on the "Notify" tab.

## 5.5 New packages



The screenshot shows the Lægemiddelstyrelsen web portal. The top navigation bar includes the agency logo, user information (User: Test Testesen, Company: Frisko A/S, Time at DKMA: 13:59:44, Price period deadline: 3 days 6 hours 1 min), and contact information (Contact: +45 44889525, Log out). The main menu includes links for Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, and Submitted. The 'New packages (1)' tab is selected, showing a table with one package entry for 'Achromycin'. A red box highlights the 'New packages (1)' tab, and another red box highlights the 'RESET' and 'SEND' buttons. A third red box highlights the red 'X' icon next to the package name.

Name	Drug form	Strength	MT-no.	Product no.	Package size	Package type
Achromycin	capsule, hard	250 mg	00406	234	25	Blister

When you are ready to send the packages created to the Danish Medicines Agency, select the "New packages" tab. In the parenthesis on the tab, you can see how many packages are pending.

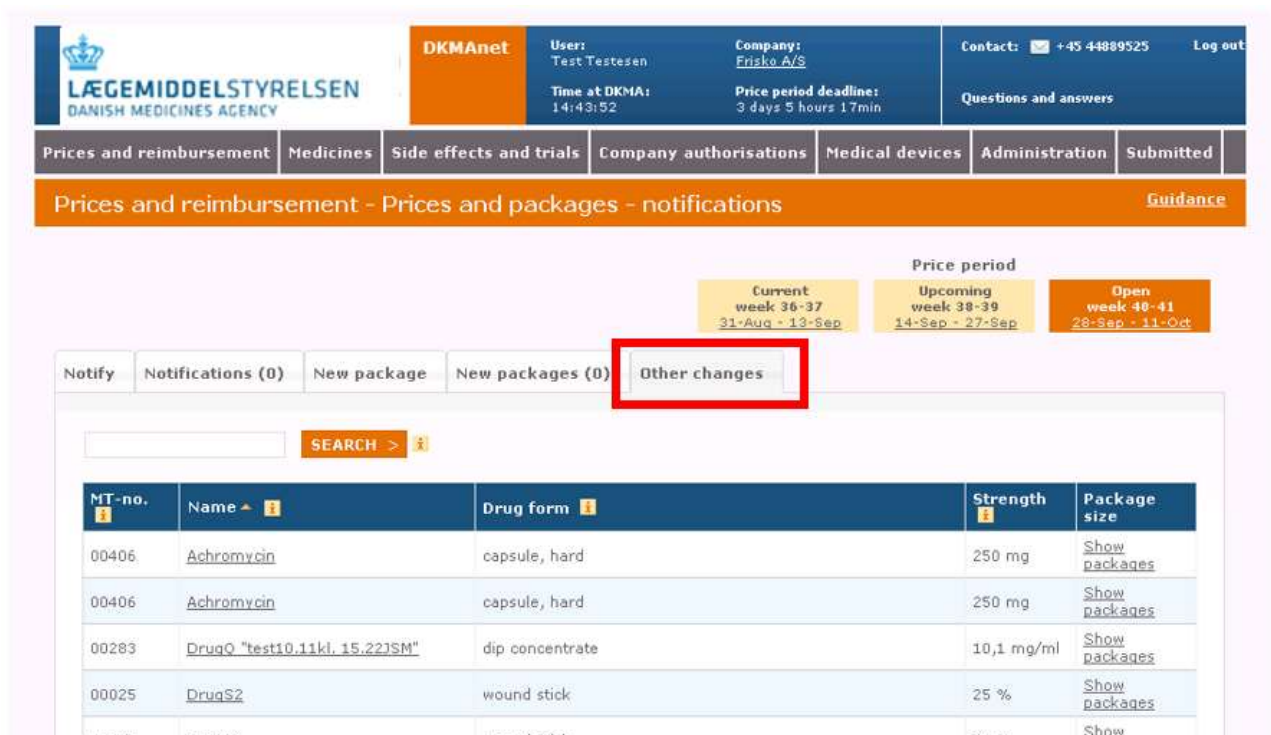
Before you click "Send", you have the option of verifying the changes and correct them if you have made incorrect entries. You can also use the red cross on the left to delete one package from the list.

Click "Send" when all changes are correct.

If you click "Send", the newly created package will be shown on the "Notify" tab, and you can now activate the package (in the "Market situation" column) and then enter price and supply estimate. Please note that you must always enter a supply estimate when activating new packages. Finally, click "Send" on the "Notify" tab.

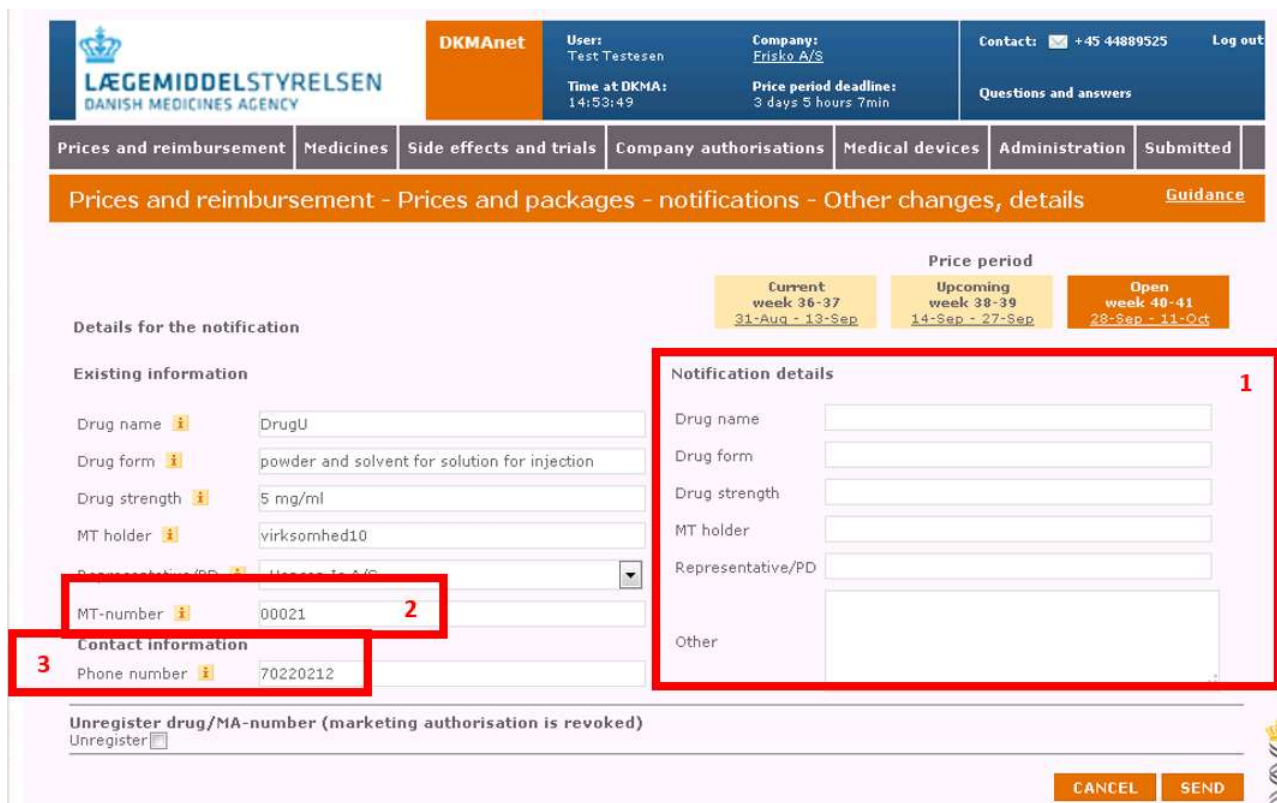
When you have created and activated (marketed) a new package, it will immediately appear as "created" in your assortment. By hovering the mouse over the blue exclamation mark to the right of the overview on the "Notifications" tab, you will see that in addition to being created, the price of the package has also been notified to the next open price period.

## 5.6 Other changes



The screenshot shows the Lægemiddelstyrelsen website interface. At the top, there is a header with the agency logo and name, a DKManet login section, and user information. Below the header is a navigation bar with tabs: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, and Submitted. A sub-navigation bar shows 'Prices and reimbursement - Prices and packages - notifications' with a 'Guidance' link. The main content area displays 'Price period' information for Current week 36-37, Upcoming week 38-39, and Open week 40-41. Below this, a menu shows 'Notify', 'Notifications (0)', 'New package', 'New packages (0)', and 'Other changes' (which is highlighted with a red box). A search bar is present, followed by a table of notifications. The table has columns for MT-no., Name, Drug form, Strength, and Package size. The first two rows show 'Achromycin' capsules, and the next two show 'DrugQ' and 'DrugS2' products.

For medicinal products for which the company wishes to let an approved variation application enter into force from the "Open" period, the relevant product must be selected by the underlined link containing the name of the product. Then, the following page will be shown:



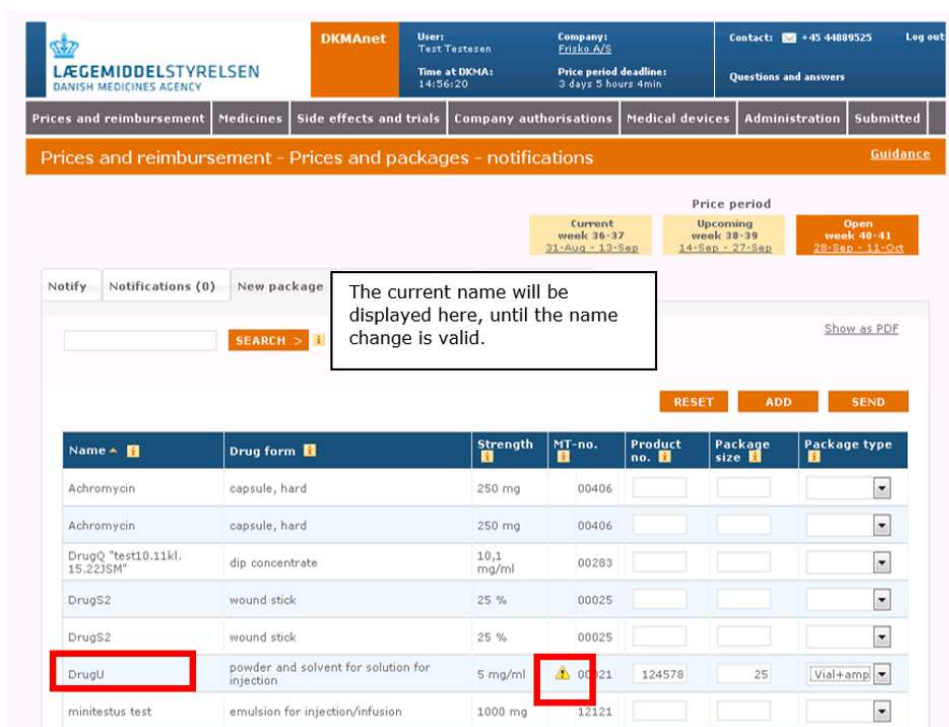
The screenshot shows the 'Other changes, details' page. The header and navigation bar are identical to the previous screenshot. The sub-navigation bar shows 'Prices and reimbursement - Prices and packages - notifications - Other changes, details' with a 'Guidance' link. The main content area displays 'Price period' information. Below this, the 'Details for the notification' section is shown. It includes 'Existing information' and 'Notification details' (highlighted with a red box and labeled '1'). The 'Existing information' section has fields for Drug name, Drug form, Drug strength, MT holder, Representative/PO, MT-number (highlighted with a red box and labeled '2'), and Contact information (highlighted with a red box and labeled '3'). The 'Notification details' section has fields for Drug name, Drug form, Drug strength, MT holder, Representative/PO, and Other. At the bottom, there is a section for 'Unregister drug/MA-number (marketing authorisation is revoked)' with an 'Unregister' checkbox. The page ends with 'CANCEL' and 'SEND' buttons.

1. Enter the relevant text from the approval letter on the right side of the formula.
  - a. The name, form and strength of the medicinal product must be written exactly as indicated in the approval letter.
  - b. For changes regarding the MA-holder and Representative, the company number should be written in the "other" section of the formula.
  - c. Remember to add the case number found in the approval letter to the "other" section of the formula.
  
2. Please enter a telephone number where the Danish Medicines Agency may reach you (or a colleague in case of sickness or holidays)

*Note! It is only the company transferring a medicinal product to a new company that is responsible for notification. For this reason, the acquiring company cannot see the medicinal product in DKMANet before a notification has been submitted.*

*Note! The non-filled in the fields on the right side will automatic be filled in with the existing text from the left side.*

*Note! If your notification concerns a change of names (or the like), you will be able to create new packages. You should, however, note that the name of the product will only be changed after the change of periods. In connection with changes of names, you must look for ⚠ (outstanding notification) in front of the MA no. on "Notifications" > "Prices and assortment" > "New package"*



The current name will be displayed here, until the name change is valid.

Name	Drug form	Strength	MT-no.	Product no.	Package size	Package type
Achromycin	capsule, hard	250 mg	00406			
Achromycin	capsule, hard	250 mg	00406			
DrugQ "test10.11kl. 15.22JSM"	dip concentrate	10,1 mg/ml	00203			
DrugS2	wound stick	25 %	00025			
DrugS2	wound stick	25 %	00025			
DrugU	powder and solvent for solution for injection	5 mg/ml	⚠ 00021	124578	25	Vial+amp
minitestus test	emulsion for injection/infusion	1000 mg	12121			

### 5.6.1 Change of address for MA-holder or the local representative

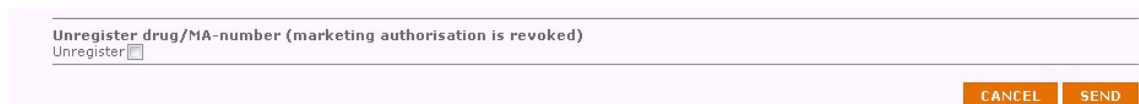
When you notify a change of address of either MAH or the local representative, you need to do this under the tab "other Changes" → and in the "Other" field. Here you for example write "New address for MAH or representative and the address".

You must have received a letter of approval for the change of address before you can notify it on DKMANet. In the field "other", you add the case number noted on the approval letter and the company number to which it is to be moved to.

If it is a Central approved product, you will not receive an approval letter. Here, the change must be approved by EMA before a notification can be made. In the field "other", you write that it is approved by the EMA.

### 5.6.2 Unregister a medical product

If you select "Unregister drug", you must enter a reason code for the deregistration. This will prompt a warning to ensure that you do not inadvertently deregister a product.



Unregister drug/MA-number (marketing authorisation is revoked)

Unregister

CANCEL SEND

### 5.6.3 Veterinary subpacks

When you need to notify an inner package/partial package in a large package/multipack, you must do so under the "Other Changes" tab in the "Other" field.

Here, for example, you can write: inner package item number/partial package item number YYYYYY must be applied to large package/multipack XXXXXX.

*Note! The package must be listed as a partial package at DLI with a format so that it appears that it is an inner package. For example, YYYY/24xYYYY ml.*





## 5.7 File transfer

The screenshot shows the Lægemiddelstyrelsen DKMAnet interface. At the top, there is a header with the agency logo and name. Below this is a navigation bar with tabs: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, Submitted, and a Guidance link. The 'Prices and reimbursement' tab is selected, and the 'File transfer' sub-tab is active. The main content area displays 'Transfer notifications' with instructions to transfer price and assortment notifications to DKMA. It includes a 'Select file:' label, a file selection button labeled 'Gennemse...', and a 'Transfer' button. To the right, there is a 'Price period' section with three boxes: 'Current week 36-37' (31-Aug - 13-Sep), 'Upcoming week 38-39' (14-Sep - 27-Sep), and 'Open week 40-41' (28-Sep - 11-Oct). A small DNA helix icon is visible in the bottom right corner of the interface.

Very often, it is more practical to transfer notifications by means of a file transfer. If you have many notifications, a file transfer will be a quicker solution. Another advantage is that the risk of error is greatly reduced because you will not have to enter data manually.

Select "File transfer" under "Prices & reimbursement" and click "Browse". You will now be able to select your XML file on your PC or network.

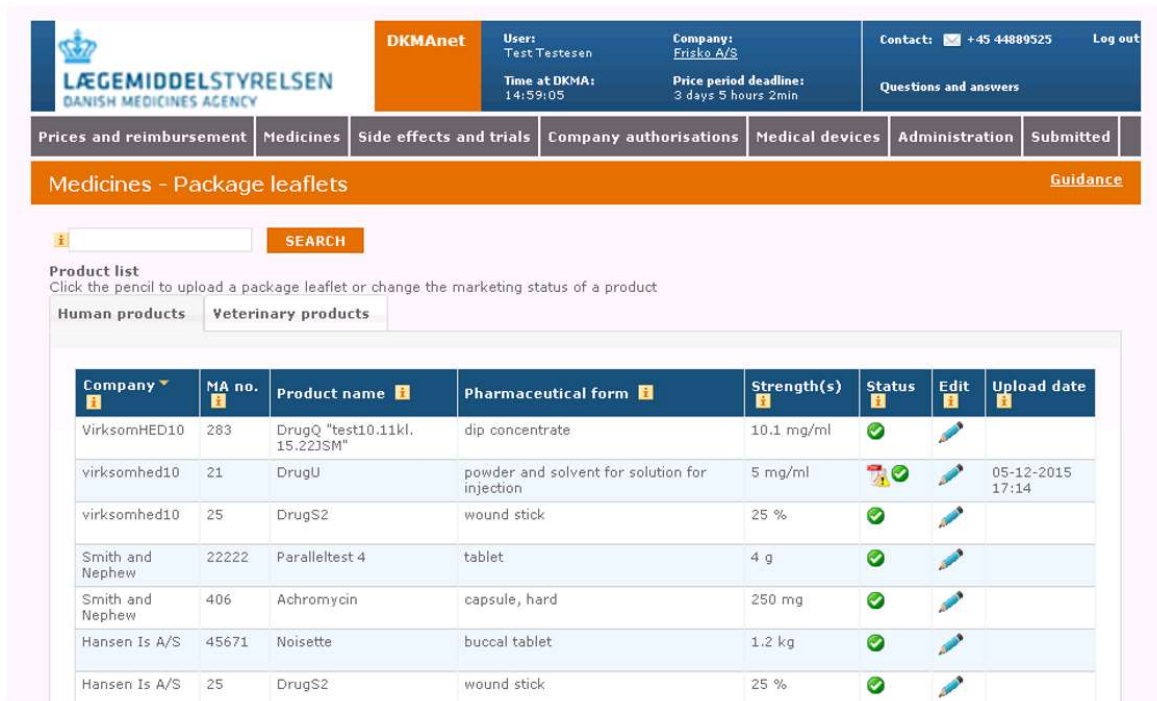
Click "Transfer" when the file has been selected. If the notification data in the file are correct, they will be uploaded to the system and automatically shown on the "Status" page.

If you have any changes to one or more of the notifications from the transferred file, you may either transfer a new file with corrections or correct them manually on the "Notify" page (see the description of "Notify").

*Note! It is only possible to use file transfer for price changes and notifying of new packs, each in its own XML file. It is not possible to use file transfer when notifying under "Other Changes".*

## 6. Package leaflets

On [www.indlaegsseddel.dk](http://www.indlaegsseddel.dk), consumers have access to package leaflets for medicinal products. These package leaflets can be maintained in the "Package leaflets" function:



**Medicines - Package leaflets** [Guidance](#)


**SEARCH**

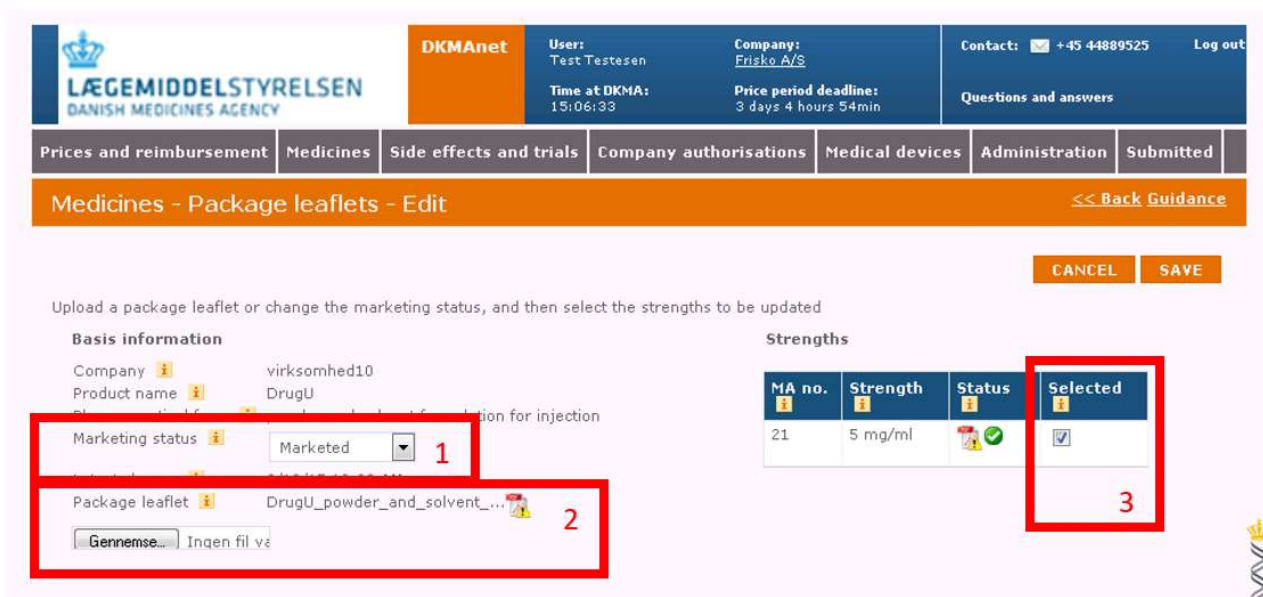
**Product list**  
 Click the pencil to upload a package leaflet or change the marketing status of a product

**Human products** **Veterinary products**

Company	MA no.	Product name	Pharmaceutical form	Strength(s)	Status	Edit	Upload date
VirksomHED10	283	DrugQ "test10.11kl. 15.22JSM"	dip concentrate	10.1 mg/ml			
virksomhed10	21	DrugU	powder and solvent for solution for injection	5 mg/ml			05-12-2015 17:14
virksomhed10	25	DrugS2	wound stick	25 %			
Smith and Nephew	22222	Paralleltest 4	tablet	4 g			
Smith and Nephew	406	Achromycin	capsule, hard	250 mg			
Hansen Is A/S	45671	Noisette	buccal tablet	1.2 kg			
Hansen Is A/S	25	DrugS2	wound stick	25 %			

Package leaflets are attached to medicinal products with the same form with the possibility of attaching one or more package leaflets to the individual strengths within the same name and form.

Click  to attach a package leaflet. Then, the following page will be shown:



**Medicines - Package leaflets - Edit** [<< Back](#) [Guidance](#)

**CANCEL** **SAVE**

Upload a package leaflet or change the marketing status, and then select the strengths to be updated

**Basis information**

Company  virksomhed10

Product name  DrugU

Marketing status  Marketed **1**

Package leaflet  DrugU\_powder\_and\_solvent\_... **2**

Ingen fil valgt

**Strengths**

MA no.	Strength	Status	Selected
21	5 mg/ml		<input checked="" type="checkbox"/> <b>3</b>



1. "Marketed"/"Not marketed". Here, you can indicate the market situation of medicinal products not included in Price List (e.g. herbal medicinal products).

*Note! The function only serves an informative purpose for the consumers and does not concern the product's approval status.*

2. View the existing package leaflet or upload a new one by clicking "Browse".

*Note! Package leaflets must be in Danish and in PDF format. The layout and content is the exclusive responsibility of the company.*

3. If there are more strengths for the product name and form in question, you can check "Selected" to indicate whether the package leaflet applies to one or more strengths.

Press "save" if the package leaflet should be available on [www.indlaegsseddel.dk](http://www.indlaegsseddel.dk) or click "cancel" to undo the action.



Prices and reimbursement | Medicines | Side effects and trials | Company authorisations | Medical devices | Administration | Submitted

Medicines - Package leaflets - Edit << Back Guidance

Upload a package leaflet or change the marketing status, and then select the strengths to be updated

**Basis information**

Company: virksomhed10  
 Product name: DrugU  
 Pharmaceutical form: powder and solvent for solution for injection  
 Marketing status: Marketed  
 Latest change: 9/10/15 10:30 AM  
 Package leaflet: DrugU\_powder\_and\_solvent\_... 

**Strengths**

MA no.	Strength	Status	Selected
21	5 mg/ml		<input checked="" type="checkbox"/>

The attached package leaflet is outdated and you need to upload an updated version. Click 'Guidance' above for further guidance. Click here to display the package leaflet.

*Note! A yellow warning triangle on the package leaflet means that you have changed the attachment between strengths and package leaflets. For example, you may have chosen to upload a package leaflet for one strength without uploading a new one for another strength.*


*Note! Once a medicinal product has a package leaflet attached, you will not be able to remove it. You will only be able to upload a new and better version.*

## 7. Administration

This chapter is only directed at security and company administrators. Other company users do not have access to the Administration function.

Administration comprises the following functions

- Create CA (company administrators)
- Create CU (other company users)

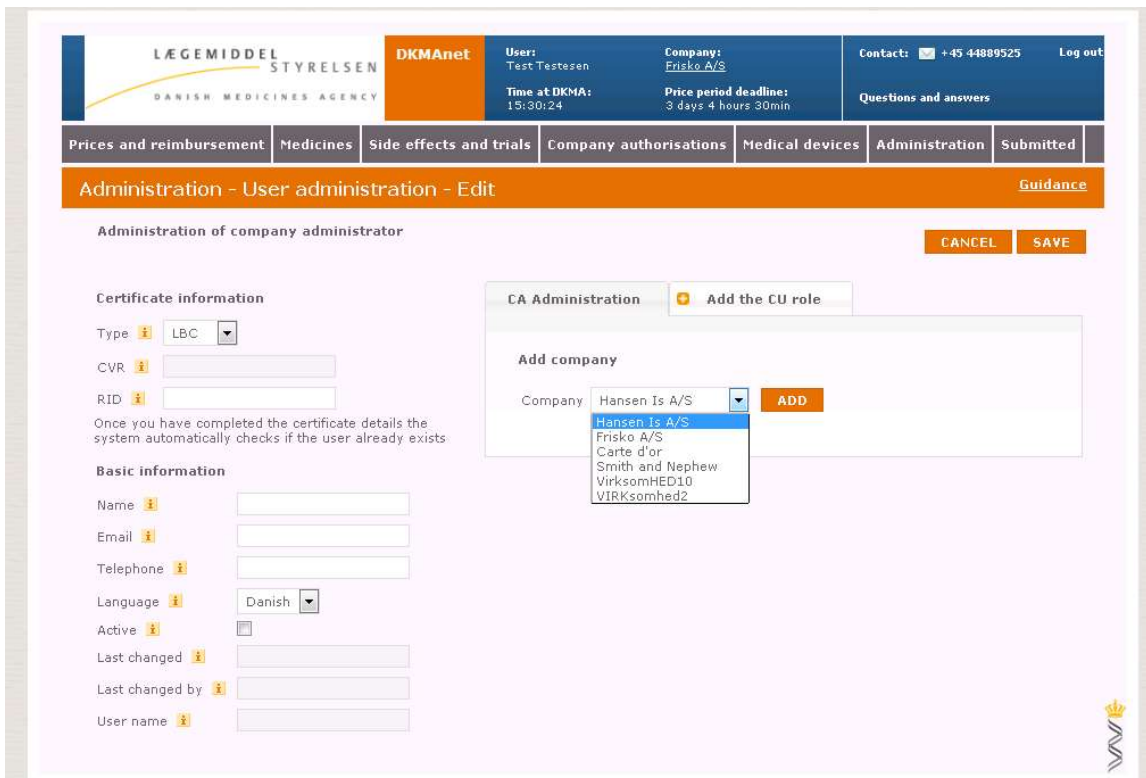


The screenshot shows the 'Administration - User administration' page. At the top, there is a header with the agency logo, 'DKMANet' branding, and user information: User: Test Testesen, Company: Frisko A/S, Contact: +45 44889525, and a price period deadline of 3 days 4 hours 34min. Below the header is a navigation bar with tabs: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration (selected), and Submitted. The main content area has a title 'Administration - User administration' and a 'Guidance' link. It includes a search bar and 'CREATE CA' and 'CREATE CU' buttons. A table lists users:

Company name	Name	Type	Status	Language	Last edited
Frisko A/S	Test Testesen	SA CA CU	Active	English	09-11-2015 10:58
HjemmeIS A/S	Testbruger07	SA CA CU	Active	Danish	09-10-2015 15:56

### 7.1 Create company administrators and other users

After clicking on the tab "Create CA" or "Create CU" the following page will be shown:



The screenshot shows the 'Administration - User administration - Edit' page. It has a title 'Administration of company administrator' and 'CANCEL' and 'SAVE' buttons. The page is divided into two main sections: 'Certificate information' and 'Basic information'. The 'Certificate information' section includes fields for Type (LBC), CVR, and RID. The 'Basic information' section includes fields for Name, Email, Telephone, Language (Danish), Active (checkbox), Last changed, Last changed by, and User name. On the right, there is a 'CA Administration' section with an 'Add the CU role' button and an 'Add company' dropdown menu. The dropdown menu is open, showing a list of companies: Hansen Is A/S (selected), Frisko A/S, Carte d'or, Smith and Nephew, Virksomhed10, and VIRKsomhed2.

When creating new users in your company, you must fill in the following fields under Certificate information's, the Basic information's and the company number.

This is applicable for both the CA's and the CU's:

### 7.1.1 Certificate information

Type	Select the certificate type for the company.  OCES = digital signature for Danish companies and individuals  LBC = Closed user group certificate. To be created as agreed with the Danish Medicines Agency.
CVR no.	Your company's registration number which is shown on the company's certificate and to which the certificate is attached. The CVR number contains eight digits. If it is a LBC-certificate then the field are dark grey and you do not need to type a CVR-no.
RID	The RID number is shown on the employee certificate with the CVR number. The RID number contains between eight and thirteen digits.

### 7.1.2 Basic information

Field name	Information
Name	The user's name
Email	The user's email address
Phone	The user's phone number
Language	Select Danish or English in the drop-down box.  <i>Please note that the selection of language also controls whether DKMANet is shown in Danish or English</i>
Rights	Select whether the user should have read-only or writing rights.
Active	Indicate whether the user is to be activated immediately.
Last edited	Automatically completed by DKMANet.
Last edited by	Automatically completed by DKMANet.

### 7.1.3. Associated Companies

Company	Enter the six-digit company number and select add. If there are several they are added one at a time.
---------	---

If you have access to several company numbers, you can choose which company or companies the user will have access. If different addresses or companies exist, you must choose which main company the user will be associated with.

Click "Apply" when all fields have been filled in. The user has then been created and will be shown on the user list on the "Users" tab.

Once the user has been created and attached to a number of companies a range of functionalities will appear. Assigning a specific functionality to a CA means that, the CA can designate the same functionality to another CU's (and them self).



### 7.1.4 Functionality areas

Choose which rights the user in question should have. A user with read-only access to Prices and Packages (P and p) is not permitted to make notifications. A user with writing access to P and p is permitted to make all types of notifications regarding prices and assortment.

Access to package leaflets may be divided between human and veterinary products.

The screenshot displays the 'Administration - User administration - Edit' page. The left sidebar contains navigation links: 'Prices and reimbursement', 'Medicines', 'Side effects and trials', 'Company authorisations', 'Medical devices', 'Administration', and 'Submitted'. The main content area is titled 'Administration of company administrator' and includes a 'Certificate information' section with fields for Type (LBC), CVR, and RID. Below this is a 'Basic information' section with fields for Name, Email, Telephone, Language (English), Active status, Last changed, Last changed by, and User name. On the right, there are tabs for 'EA Administration' and 'EU Administration'. The 'EU Administration' tab is active, showing a 'Add company' section with a 'Company' dropdown (set to 'Carte d'or') and an 'ADD' button. Below this are several tables: 'Associated companies' (listing Hansen Is A/S and Frisko A/S), 'Main company' (set to Frisko A/S), 'Service areas' (listing Prices and packages), 'Medicines' (listing Leaflets hum and Leaflets vet), 'Side effects and trials' (listing Clinical trials and Pharmacovigilance), 'Company authorisations' (listing GMP, GDP, Retail sale, EUP, GLP), and 'Medical devices' (listing Registration & Export certificate). Each table has columns for Company number, Company name, Address, and Action (delete).

Administration of company administrator

CANCEL SAVE

Certificate information

Type

CVR

RID

Once you have completed the certificate details the system automatically checks if the user already exists

Basic information

Name

Email

Telephone

Language

Active ☐

Last changed

Last changed by

User name

EA Administration EU Administration

Add company

Company  ADD

Associated companies

Company number	Company name	Address	Action
950315	Hansen Is A/S	Sølvgade 7	<a href="#">delete</a>
950314	Frisko A/S	Sølvgade 5	<a href="#">delete</a>

Main company

Service areas

Prices and packages

Company number	P og p - read	P og p - write	General reimbursement
950315	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
950314	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Medicines

Company number	Leaflets hum	Leaflets vet	Parallel import
950315	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
950314	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Side effects and trials

Company number	Clinical trials	Pharmacovigilance
950315	<input type="checkbox"/>	<input type="checkbox"/>
950314	<input type="checkbox"/>	<input type="checkbox"/>

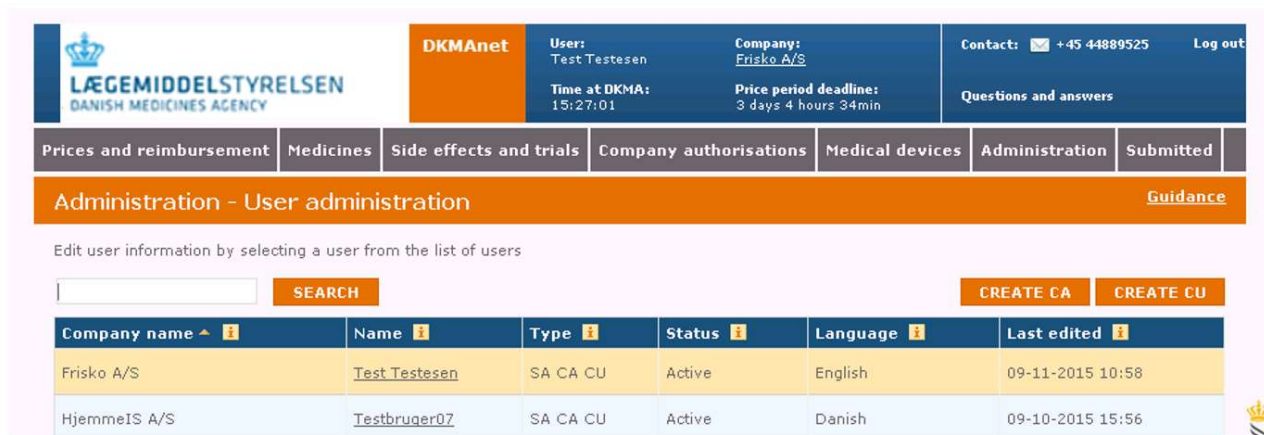
Company authorisations

Company number	GMP	GDP	Retail sale	EUP	GLP
950315	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
950314	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Medical devices

Company number	Registration & Export certificate
950315	<input type="checkbox"/>
950314	<input type="checkbox"/>

## 7.2 Administration of users



Company name	Name	Type	Status	Language	Last edited
Frisko A/S	Test Testesen	SA CA CU	Active	English	09-11-2015 10:58
HjemmeIS A/S	Testbruger07	SA CA CU	Active	Danish	09-10-2015 15:56

The "Users" tab shows a list of the company's users. Please note that your account is displayed first on the list and the line is marked with yellow. The list contains both active and inactive users, as all user information must be saved in accordance with the Danish Act on Processing of Personal data and for the purposes of data security.

When new users are created, the system will automatically generate a user ID based on the users name. The user ID makes it possible to create more than one user with the same name, and the system is still able to differentiate between these, thanks to the user ID. Thus, it is possible for users with similar names to make notifications, because they will be distinguished by the user ID.

Changes to the users name later on, will not influence the user ID and it will remain unchanged.

Users may be retrieved in the "User name" column or by using the search field.

By clicking the user's name, the "Create user" page will be opened (see the next picture).

This page is the same as the page where users are created. The only difference is that all data for the user have been filled in.

You now have the option of:

1. Correcting relevant data (email, phone)
2. Changing the language in the user's interface (Danish/English)
3. Activating the user by selecting the "Active" field
4. Deactivating the user by deselecting the "Active" field
5. Remove access to companies (i.e. company numbers)
6. Add access to companies (i.e. company numbers)

Click "Apply" to save the corrections or "Cancel" to undo the action. When clicking "Apply", you will automatically be taken to the user overview.