



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.

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 reimbursement" > "Prices and packages - notifications". This means that you must select "Overview", click "Prices and reimbursement" 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 Danish Medicines Agency for further information at medicinpriser@dkma.dk.

2. A digital ID must be created.

All users must identify themselves with a digital ID to log on to DKMANet.

Users employed in Danish companies must use MitID Erhverv, which the company can order directly at MitID Erhverv. For more information about MitID Erhverv, please see MitID Erhverv's website: www.mitid-erhverv.dk.

The digital ID is personal and each user on DKMANet must be created with their own digital ID.

Users who do not have the opportunity to create MitID Erhverv must have a Closed User Group Certificate (CUG) issued by the Danish Medicines Agency.

Closed User Group Certificate (CUG) must be ordered from the Danish Medicines Agency. The form for ordering the Closed User Group Certificate can be found on the Danish Medicines Agency's website under "Reimbursement and prices", "Prices of medicines" and "Notification of prices and range via DKMANet". The completed form must be submitted via email to: 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	New: A new package has been created Activated: The package has been entered in the Price List ("Medicinpriser") in the selected period Deactivated: The package has been temporarily withdrawn from the market in the selected period. Removed: 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 displays the DKMANet frontpage. At the top left is the logo for Lægemiddelstyrelsen (Danish Medicines Agency). To its right is the 'DKMANet' header. Further right, user information is shown: 'User: Test Testesen', 'Company: Frisko A/S', 'Time at DKMA: 11:37:20', and 'Price period deadline: 4 days 8 hours 23min'. On the far right, contact information is provided: 'Contact: +45 44889525' and a 'Log out' link. Below this is a horizontal navigation menu with tabs for 'Prices and reimbursement', 'Medicines', 'Side effects and trials', 'Company authorisations', 'Medical devices', 'Administration', and 'Submitted'. The main content area is titled 'Frontpage' and features several categorized service lists:

- Prices and reimbursement:** Prices and packages - status, Prices and packages - notifications, File transfer, Correspondence (30 new messages), General reimbursement.
- Medicines:** Package leaflets, Application for parallel import.
- Side effects and trials:** Clinical trials, Follow-up on adverse reaction reports.
- Company authorisations:** Manufacturing and importation, Wholesale distribution, Retail sale, Handling of euphoriant substances, Conduct of non-clinical tests.
- Medical devices:** Registration, Free Sales Certificate.
- Administration:** User administration, Activity log, Company profile.

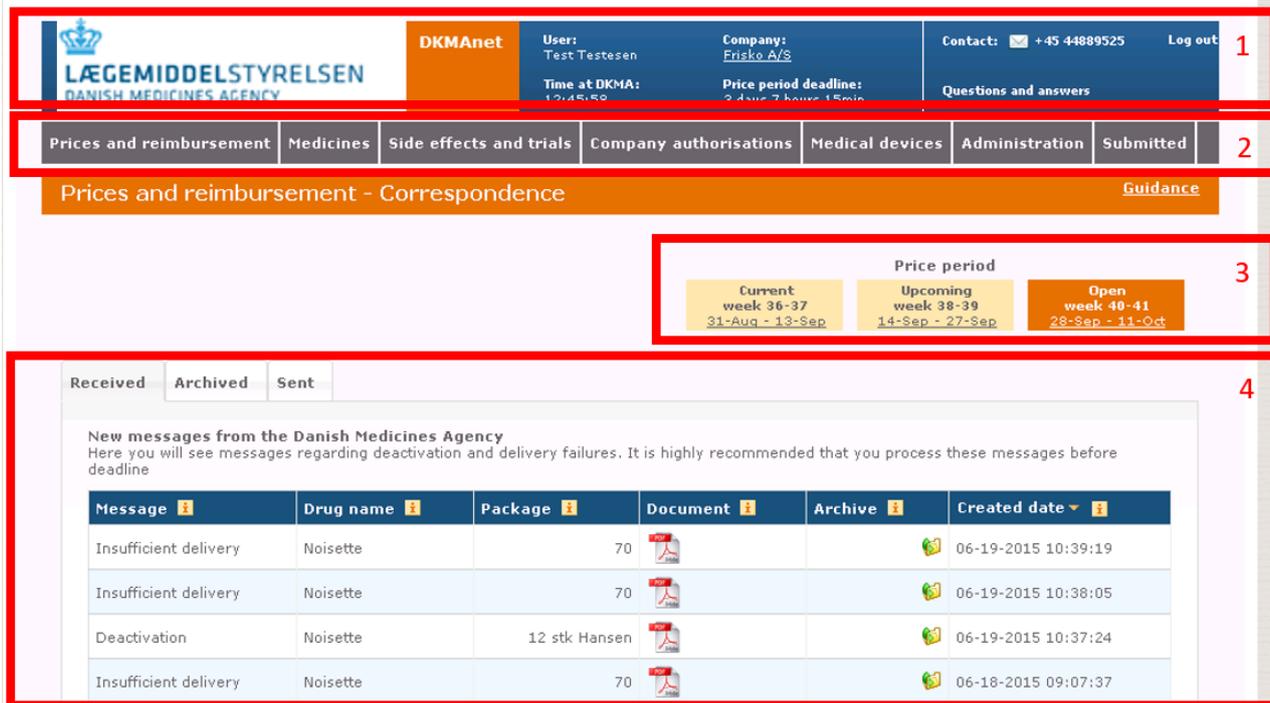
A 'News' section on the right contains a message: 'Welcome to a redesigned DKMANet. New colours and a simpler service structure enhance coherence with the Danish Medicines Agency's official website and provide a better overview. The grey menu above gives you easy access to the front page and the available services.'



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. The top navigation bar (1) includes the logo, 'DKMANet' title, user information (Test Testesen), company (Frisko A/S), contact (+45 44889525), and a 'Log out' button. Below this is a horizontal menu (2) with tabs for 'Prices and reimbursement', 'Medicines', 'Side effects and trials', 'Company authorisations', 'Medical devices', 'Administration', and 'Submitted'. The main content area (3) shows 'Prices and reimbursement - Correspondence' with a 'Price period' section containing 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)'. The bottom section (4) displays a table of messages with columns for Message, Drug name, Package, Document, Archive, and Created date. A notification above the table states: 'New messages from the Danish Medicines Agency. Here you will see messages regarding deactivation and delivery failures. It is highly recommended that you process these messages before deadline.'

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 function.

2.

Contains: Drop-down menu with access to all functions.

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

3.

Contains:

- Price periods

4.

Contains: The details of the selected functions, typically:

- 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 "Prices and packages - Notifications" and "Prices and packages - 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:
medicinpriser@dkma.dk

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 fifteen 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.

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	Carte d'or	Paralleltest 4	Test Testesen	Sent	07-23-2015

4.12 Status

Product no.	Name	Drug form	Strength	Package size	PPP	Supply estimate	Status	Received
							A	04-04-2024 15:13:58
							N	04-04-2024 16:26:11

Under "Status", your company's range of medicinal packages, as well as the status of individual packages if notifications have been made (when either "Upcoming" or "Open" is selected under the price period).

By default, the assortment and any notifications for the period open for notification are displayed. In the menu on the right-hand side of the page, you can also choose to view the assortment for the current or the upcoming pricing period. *Please note that the assortment may vary depending on the selected price period.*

In the "Received" column on the right side of the overview, you can see when a notification was received by the Danish Medicines Agency. If you hover over the timestamp, the name of the user who submitted the notification will be displayed. In the "Status" column, you can see the type of notification, such as a price change, as well as the status of the individual notification, for example, A (Accepted).

To edit or submit new notifications, please select "**Notifications**" in the main menu at the top of the page.

*Note! Only created and marketed packages are displayed on the status page. The company's full range of medicinal products can be found under "**Prices and reimbursement > Prices and Packages - Notifications**" by selecting the "**New Package**" tab.*

*A new package must be created under the tab "**New Package**" before it will appear on the page "Status".*

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 and prices that will take effect in the coming price period. This 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))

Please note that the Danish Medicines Agency may make changes to the information for the upcoming price period. Additionally, be aware that the status page for the upcoming pricing period is empty from 00:00 to 20:00 on the first Monday of each pricing period.

4.12.3 Price period: Open

In the "Open" price period, you can see your company's assortment and the prices that will take effect after the upcoming period, for which it is possible to submit changes to prices and assortment. 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

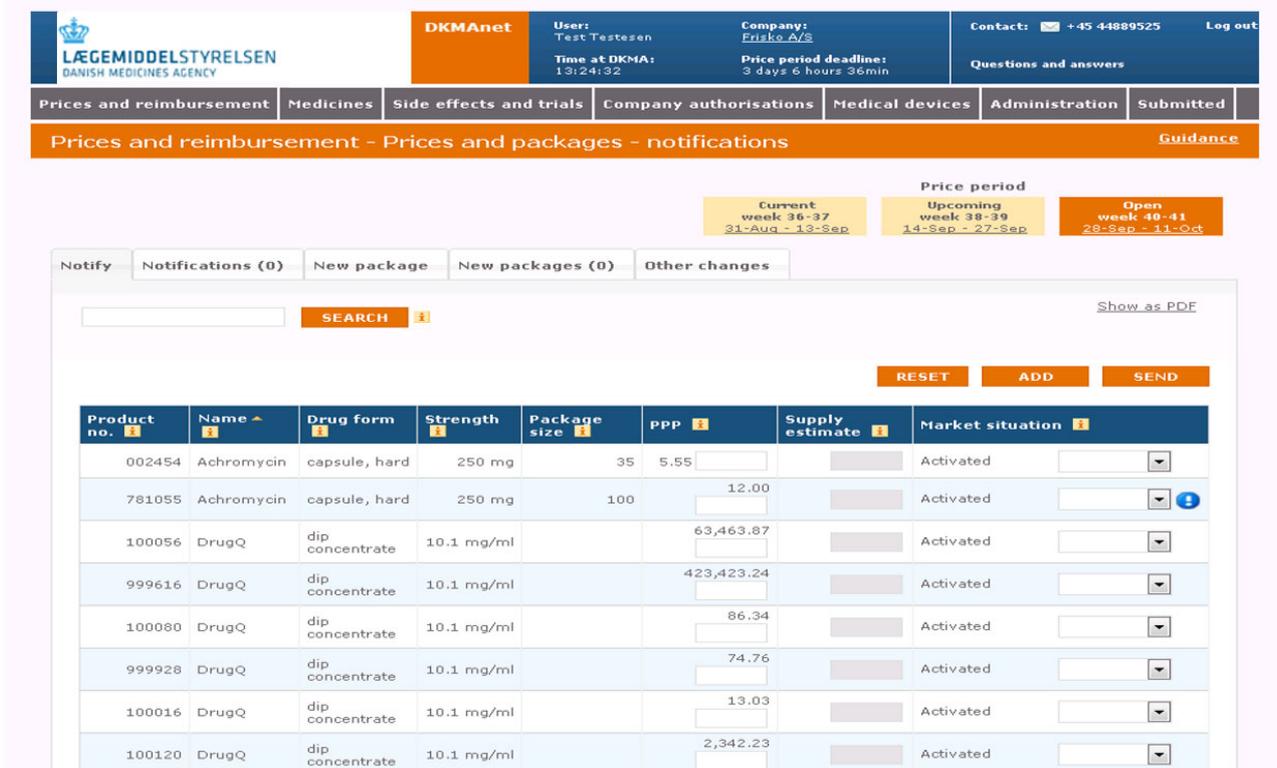
Under "Administration", the security administrator and the company administrator can create and manage the company's company users. This function is not shown if you are logged on as a normal company user. Please refer to Chapter 6 for details about the use of "Administration".

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"



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

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 reimbursement

Medicines

Side effects and trials

Company authorisations

Medical devices

Administration

Submitted

Prices and reimbursement - Correspondence
[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

Received
Archived
Sent

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

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 is a navigation bar with the Lægemedelstyrelsen logo and name. Below it, a blue header contains user information: 'User: Test Testesen', 'Company: Frisko A/S', 'Time at DKMA: 13:50:30', and 'Price period deadline: 3 days 6 hours 10min'. A 'Contact' section shows '+45 44889525' and a 'Log out' link. A secondary navigation bar includes 'Prices and reimbursement', 'Medicines', 'Side effects and trials', 'Company authorisations', 'Medical devices', 'Administration', and 'Submitted'. The main content area has a breadcrumb trail: 'Prices and reimbursement - Prices and packages - notifications' and a 'Guidance' link. A 'Price period' section shows 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)'. Below this are tabs for 'Notify', 'Notifications (1)', 'New package', 'New packages (0)', and 'Other changes'. A 'Show as PDF' link is present. There are 'RESET' and 'SEND' buttons. A table displays the following data:

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

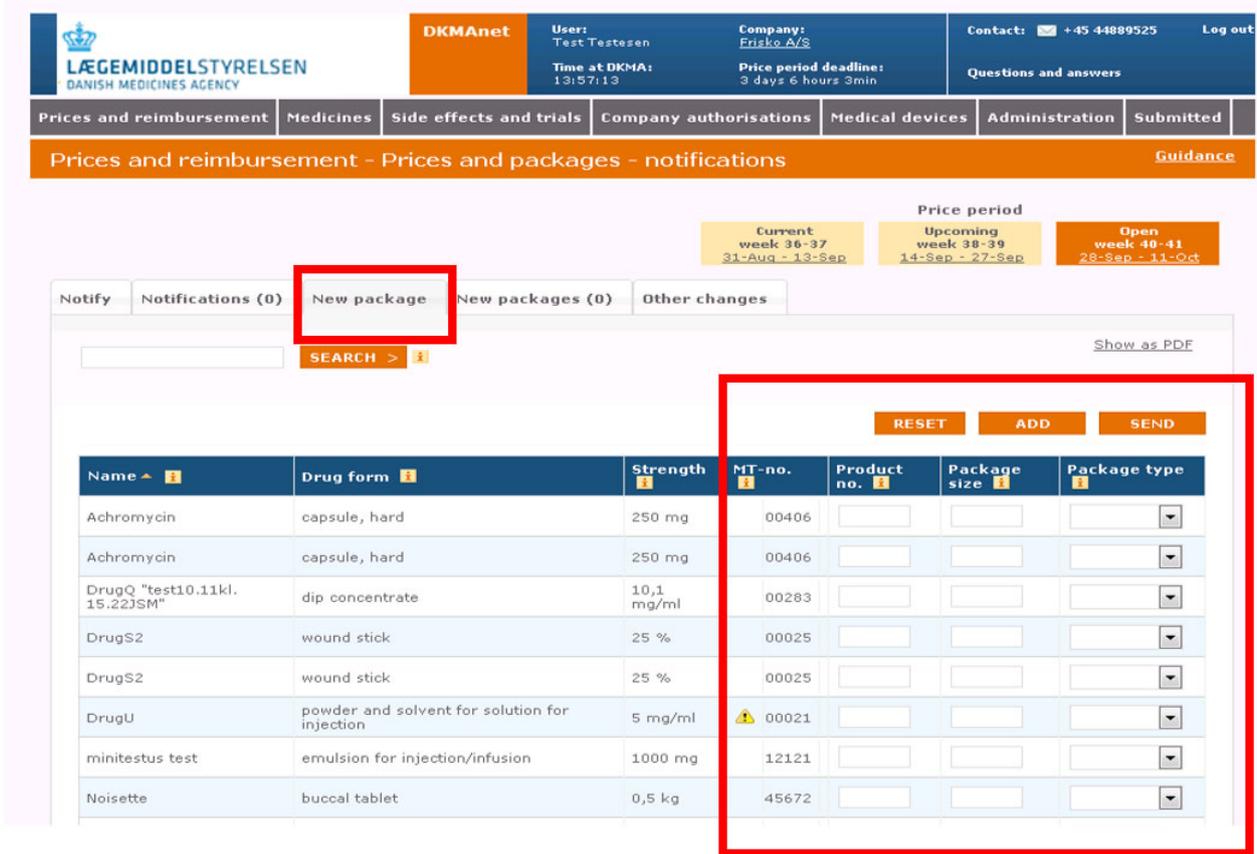
When you are ready to send your notifications to the Danish Medicines Agency, select the "Notifications" tab. In the parenthesis on the tab, you can see how many changes are pending. Before you click "Send", you have the opportunity to verify the notifications and correct them if you have made incorrect 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

You must have applied for and received a package number from VNR Finland via [this page](#). The scheme is administered in Denmark by Signum Life Science ApS. For further information and contact details for Signum Life Science ApS, please see [VNR Wiki](#).

Once you have received a package number, you must use DKMANet to create and market the package.

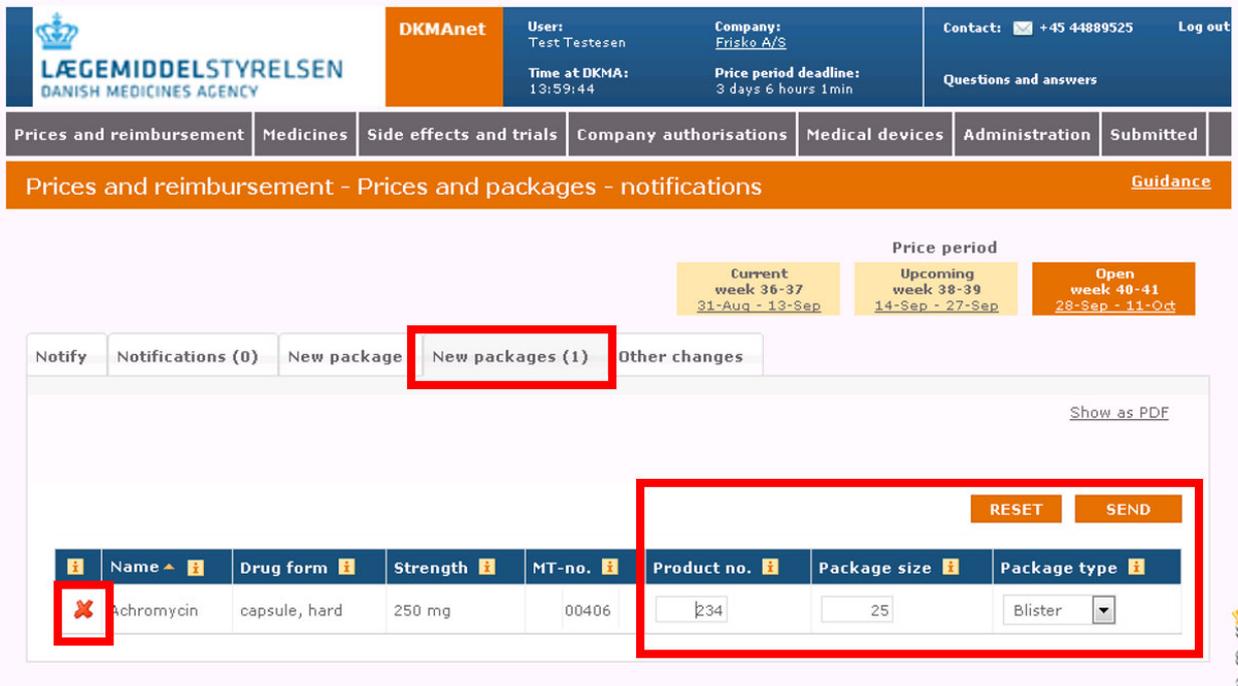


The screenshot shows the DKMANet interface. At the top, there is a navigation bar with the Lægemiddelstyrelsen logo and user information (User: Test Testesen, Company: Frisko A/S, Contact: +45 44889525, Log out). Below this is a menu with options like 'Prices and reimbursement', 'Medicines', 'Side effects and trials', etc. The main content area is titled 'Prices and reimbursement - Prices and packages - notifications'. It features a 'Price period' section with three tabs: 'Current week 36-37', 'Upcoming week 38-39', and 'Open week 40-41'. Below this is a 'Notify' section with tabs for 'Notifications (0)', 'New package', 'New packages (0)', and 'Other changes'. The 'New package' tab is active and contains a search bar with a 'SEARCH >' button. Below the search bar is a table with columns: Name, Drug form, Strength, MT-no., Product no., Package size, and Package type. The table lists several drugs, including Achromycin, DrugQ, DrugS2, DrugU, minitestus test, and Noisette. To the right of the table are three buttons: 'RESET', 'ADD', and 'SEND'. The 'ADD' and 'SEND' buttons are highlighted with a red box.

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

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



DKMAnet

User: Test Testesen
Time at DKMA: 13:59:44

Company: Frisko A/S
Price period deadline: 3 days 6 hours 1 min

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 (1)** | Other changes

[Show as PDF](#)

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

RESET SEND

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.

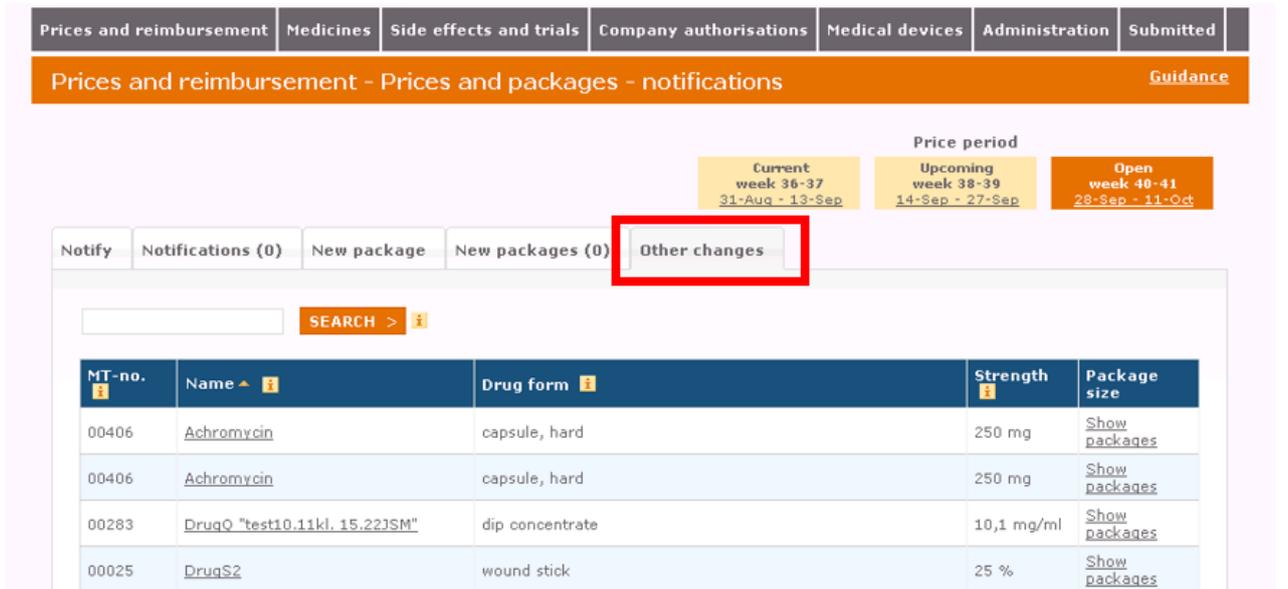
Before you click "Send", you have the option of verifying the changes and correct them if you have made incorrect entries. You can also use the red cross on the left to delete one package from the list.

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



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

Prices and reimbursement - Prices and packages - notifications Guidance

Price period

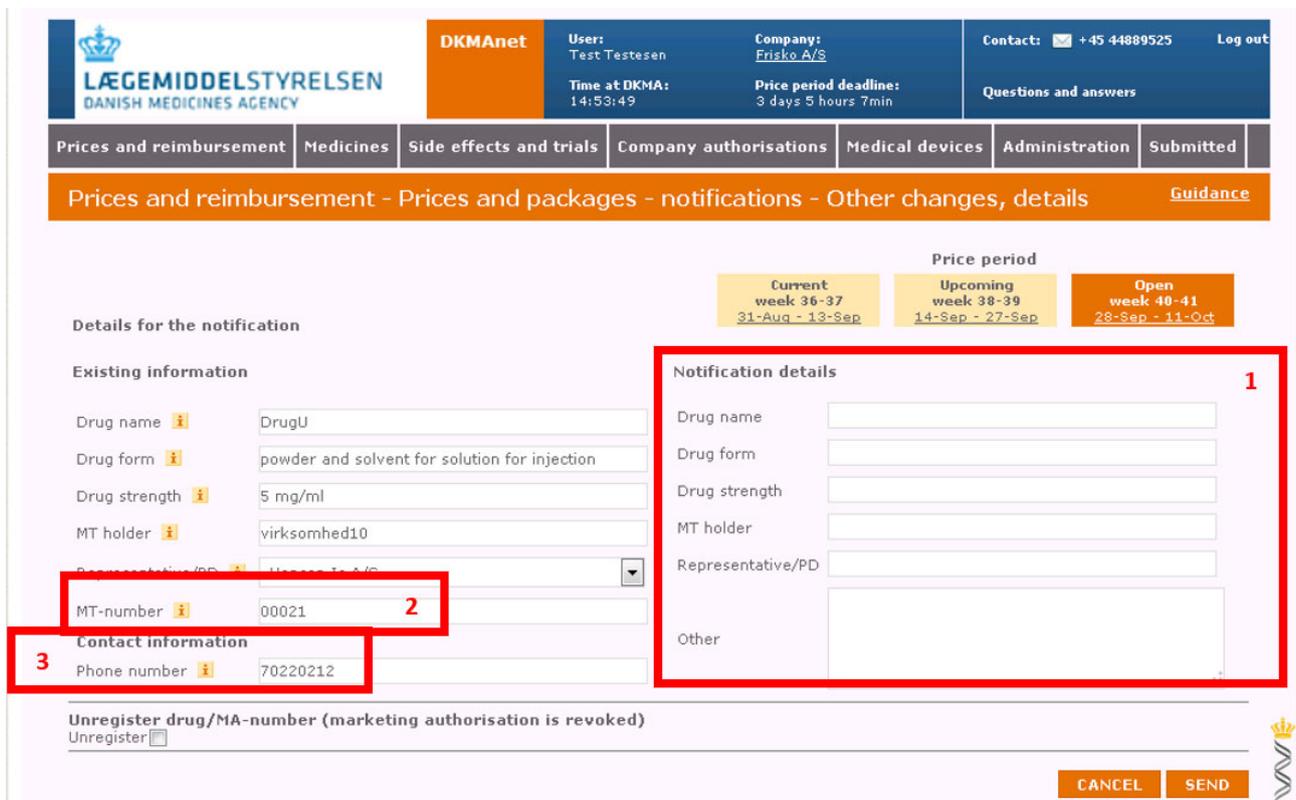
Current week 36-37
31-Aug - 13-Sep
Upcoming week 38-39
14-Sep - 27-Sep
Open week 40-41
28-Sep - 11-Oct

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

SEARCH > ⓘ

MT-no. ⓘ	Name ⓘ	Drug form ⓘ	Strength ⓘ	Package size
00406	Achromycin	capsule, hard	250 mg	Show packages
00406	Achromycin	capsule, hard	250 mg	Show packages
00283	DrugQ "test10.11kl. 15.22JSM"	dip concentrate	10,1 mg/ml	Show packages
00025	DrugS2	wound stick	25 %	Show packages

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:



 **LÆGEMIDDELSTYRELSEN**
DANISH MEDICINES AGENCY

DKMAnet User: Test Testesen Company: Frisko A/S Contact: +45 44889525 Log out

Time at DKMA: 14:53:49 Price period deadline: 3 days 5 hours 7min Questions and answers

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

Prices and reimbursement - Prices and packages - notifications - Other changes, details 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

Details for the notification

Existing information

Drug name ⓘ DrugU

Drug form ⓘ powder and solvent for solution for injection

Drug strength ⓘ 5 mg/ml

MT holder ⓘ virksomhed10

Representative/PD ⓘ

MT-number ⓘ 00021 **2**

3 Contact information

Phone number ⓘ 70220212

1 Notification details

Drug name

Drug form

Drug strength

MT holder

Representative/PD

Other

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

CANCEL SEND 

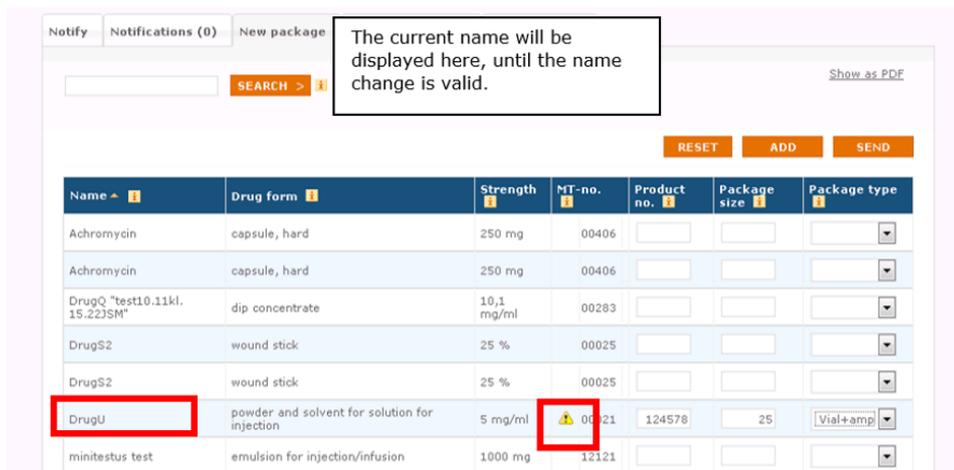
1. Enter the relevant text from the approval letter on the right side of the formula.
 - a. The name, form and strength of the medicinal product must be written exactly as indicated in the approval letter.
 - b. For changes regarding the MA-holder and Representative, the company number should be written 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.

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"



Name	Drug form	Strength	NT-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	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 (withdrawal). 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

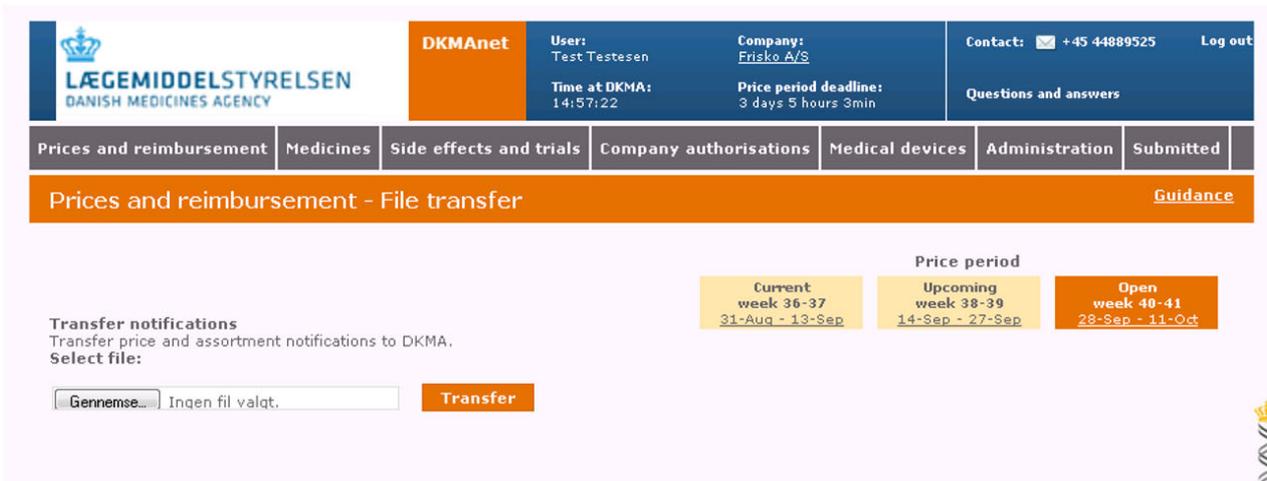
5.6.3 Veterinary subpacks

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 VNR Finland 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 user interface for file transfer. At the top, there is a header with the Lægemedelstyrelsen logo and name. Below this is a navigation bar with tabs for 'Prices and reimbursement', 'Medicines', 'Side effects and trials', 'Company authorisations', 'Medical devices', 'Administration', and 'Submitted'. The 'Prices and reimbursement' tab is selected, and the sub-tab 'File transfer' is active. A 'Guidance' link is visible in the top right of the sub-tab.

Below the navigation bar, there is a 'Transfer notifications' section. It includes a 'Select file:' label and a file selection area with a 'Gennemse...' button and a text input field containing 'Ingen fil valgt.'. A 'Transfer' button is located to the right of the file selection area.

To the right of the 'Transfer notifications' section, there is a 'Price period' section with three columns: '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).

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 "Gennemse/Browse". You will now be able to select your XML file on your PC or network. Click "Transfer" when the file has been selected.

When the transfer is complete, you will receive a notification of receipt. If the transfer is accepted, you will be taken to the status page. Please note that all data must be completely correct in all data entries for the file to be accepted. A single data error (syntax error and/or incorrect value) means that the entire transfer will be rejected.

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, consumers have access to package leaflets for medicinal products. These package leaflets can be maintained in the "Package leaflets" function:

Prices and reimbursement	Medicines	Side effects and trials	Company authorisations	Medical devices	Administration	Submitted	
Medicines - Package leaflets						Guidance	
<input type="text"/> 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	Parallelest 4	tablet	4 g	✓		
Smith and Nephew	406	Achromycin	capsule, hard	250 mg	✓		

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:

Prices and reimbursement	Medicines	Side effects and trials	Company authorisations	Medical devices	Administration	Submitted								
Medicines - Package leaflets - Edit						<< Back Guidance								
<div style="text-align: right;"> <input type="button" value="CANCEL"/> <input type="button" value="SAVE"/> </div>														
Upload a package leaflet or change the marketing status, and then select the strengths to be updated														
Basis information Company <input type="text" value="virksomhed10"/> Product name <input type="text" value="DrugU"/> Pharmaceutical form <input type="text" value="powder and solvent for injection"/> Marketing status <input type="text" value="Marketed"/> 1 Package leaflet <input type="text" value="DrugU_powder_and_solvent_..."/> 2 <input type="button" value="Gennemse..."/> Ingen fil valgt			Strengths <table border="1"> <thead> <tr> <th>MA no.</th> <th>Strength</th> <th>Status</th> <th>Selected</th> </tr> </thead> <tbody> <tr> <td>21</td> <td>5 mg/ml</td> <td>⚠️ ✓</td> <td><input checked="" type="checkbox"/> 3</td> </tr> </tbody> </table>				MA no.	Strength	Status	Selected	21	5 mg/ml	⚠️ ✓	<input checked="" type="checkbox"/> 3
MA no.	Strength	Status	Selected											
21	5 mg/ml	⚠️ ✓	<input checked="" type="checkbox"/> 3											

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

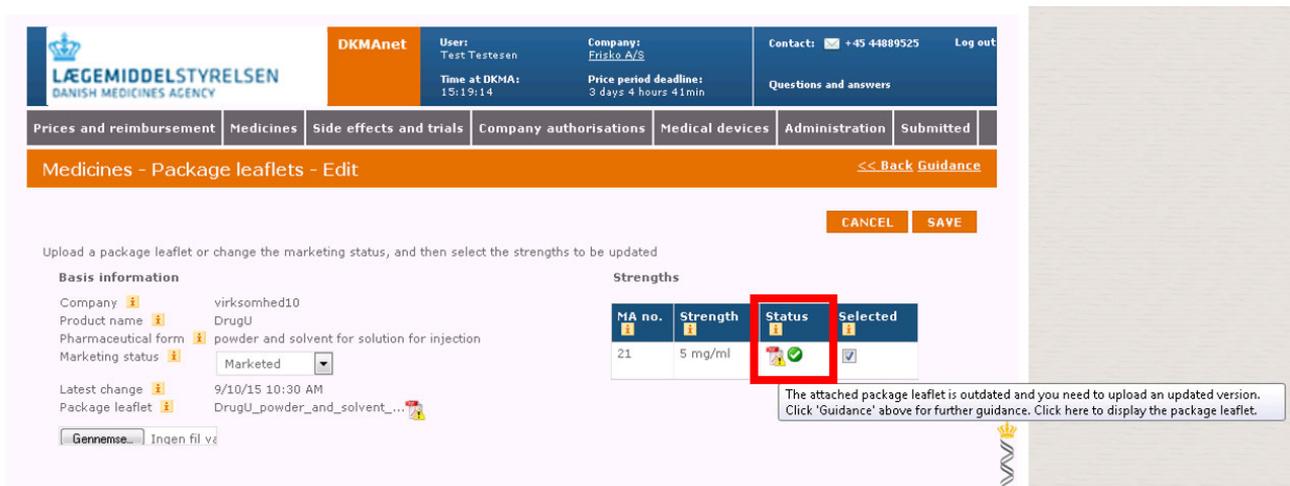
Note! The function only serves an informative purpose for the consumers and does not concern the product's approval status.

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 or click "cancel" to undo the action.



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.

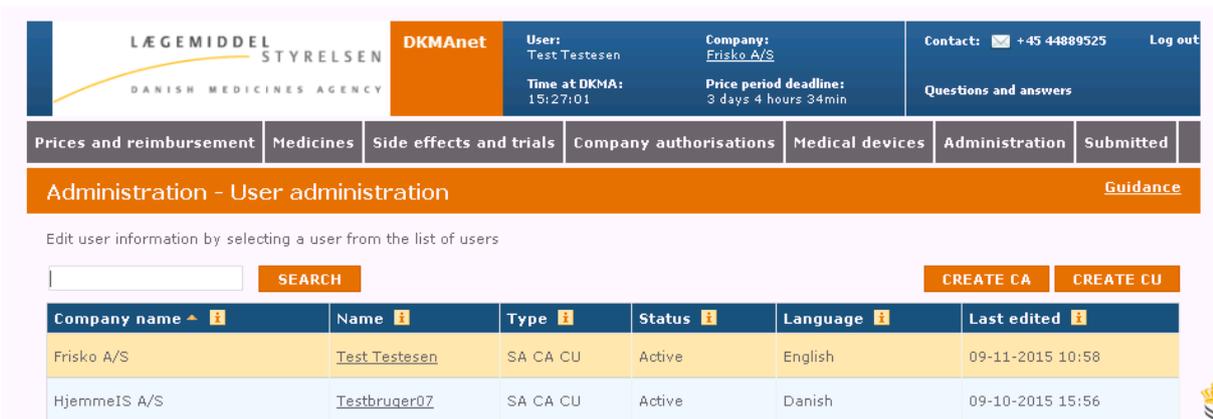
Note! Once a medicinal product has a package leaflet attached, you will not be able to remove it. You will only be able to upload a new and better version.

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)

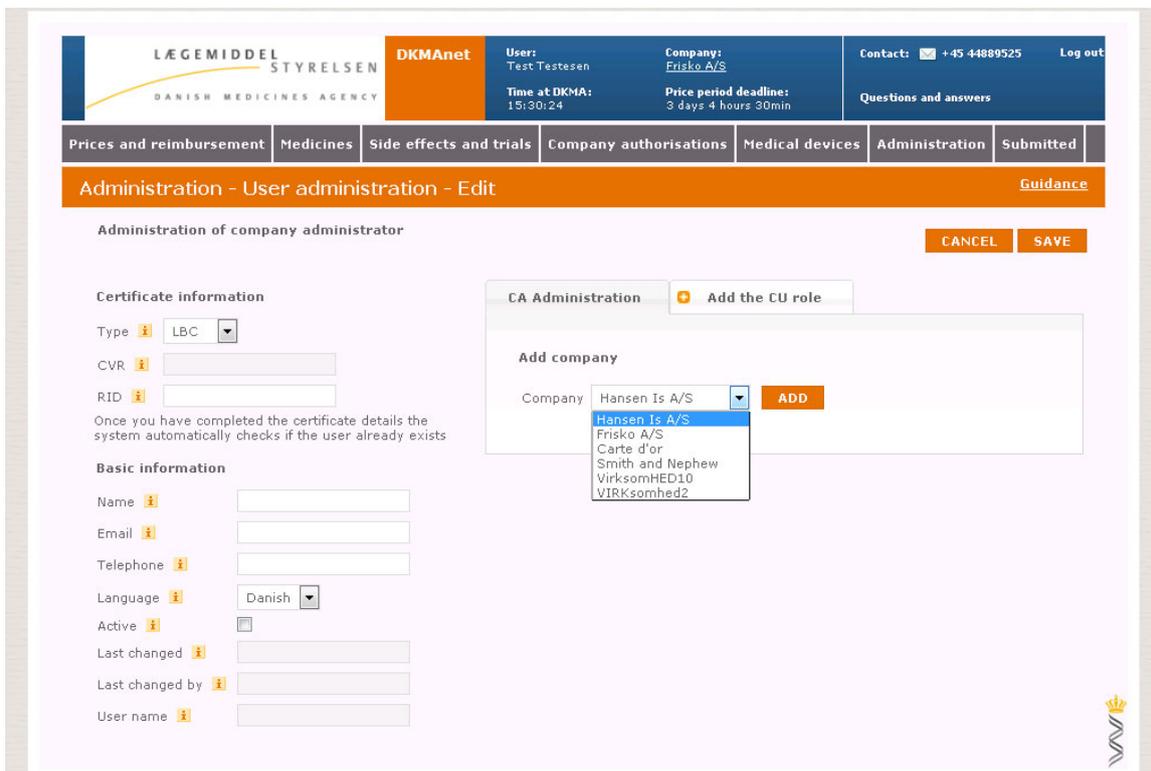


Company name	Name	Type	Status	Language	Last edited
Frisko A/S	Test Testesen	SA CA CU	Active	English	09-11-2015 10:58
HjemmeIS A/S	Testbruger07	SA CA CU	Active	Danish	09-10-2015 15:56

The company must appoint a security administrator (SA). It is only possible to have one security administrator for each company.

7.1 Create company administrators and other users

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





When creating new users in your company, you must fill in the following fields under Certificate information, the Basic information 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 ID for Danish companies and individuals (MitID) 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 associated with the digital ID. The RID number contains between ten and thirteen digits.

7.1.2 Basic 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 "Save" 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 shows the 'Administration - User administration - Edit' page for a company administrator. The interface includes a top navigation bar with various menu items and a main content area with several sections for configuring user permissions.

Navigation Bar: Prices and reimbursement, Medicines, Side effects and trials, Company authorisations, Medical devices, Administration, Submitted, Guidance.

Administration of company administrator: CANCEL SAVE

Certificate information: Type: LBC, CVR, RID. Note: Once you have completed the certificate details the system automatically checks if the user already exists.

Basic information: Name, Email, Telephone, Language: English, Active, Last changed, Last changed by, User name.

CA Administration / CU Administration:

- Add company:** Company: Carte d'or ADD
- Associated companies:**

Company number	Company name	Address	Action
950315	Hansen Is A/S	Sølvgade 7	delete
950314	Frisko A/S	Sølvgade 5	delete
- Main company:** Frisko A/S
- 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:**

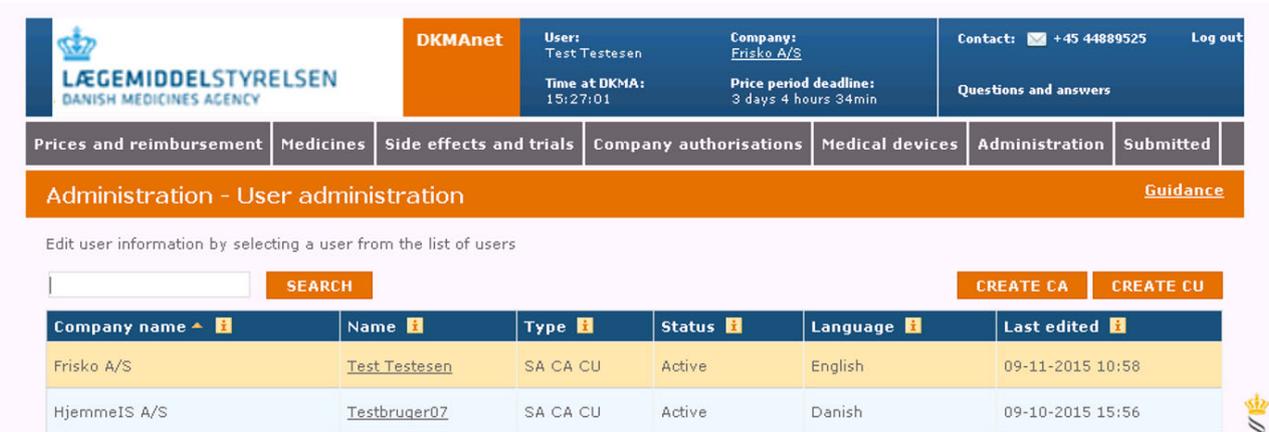
Company number	Leaflets hum	Leaflets vet	Parallel import
950315	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
950314	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
 - Side effects and trials:**

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	EUF	GLP
950315	<input type="checkbox"/>				
950314	<input type="checkbox"/>				
 - Medical devices:**

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

7.2 Administration of users



DKMANet

User: Test Testesen
Time at DKMA: 15:27:01

Company: Frisko A/S
Price period deadline: 3 days 4 hours 34min

Contact: +45 44889525 Log out

Questions and answers

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

Administration - User administration [Guidance](#)

Edit user information by selecting a user from the list of users

[SEARCH](#) [CREATE CA](#) [CREATE CU](#)

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



8. Change Log

Date	Version	Change
03-2025	01	<ul style="list-style-type: none">• Section "Before using DKMANet" – Text updated following the transition to MitID Erhverv.• Section 4.12 "Status" – Content updated.• Section 5.4 "New package" – Text updated; no changes to the process.• Section 5.7 "File transfer" – Text updated; no changes to the process.• Section 7 "Administration" – Text updated; no changes to the process.• General adjustments – Text reviewed and aligned with DKMANet terminology.• Table of contents – Updated.• Front page – Update date added.• Change log – Added.