

INFORMATION on DKMAnet

Electronic notification to Medicinal product prices

In the autumn of 2006 we introduced electronic notification via the Danish Medicines Agency's extranet **DKMAnet**, and over half of the companies that market medicinal products in Denmark now make electronic notification. On the website www.DKMAnet.dk all companies that have registered and gained access will be given access to the module **Prices & Packages**. **1 January 2009**, Prices & Packages on DKMAnet replaces the fax communication which has been the basis for changes of Medicinal product prices every two weeks.

The transition to electronic notification provides obvious advantages, e.g. better data security, improved overview of own product range, a much more efficient routine for all parties and unambiguous responsibility for the changes of medicinal product prices and product range.

A number of aspects of Prices & Packages are described in the following. To ensure a distinct and direct presentation we have structured the information as questions and answers. All information on this page is available on www.dkma.dk under Companies > The Price List of Proprietary Medicinal Products > DKMAnet - Prices & Packages > Material and guidelines on Prices & Packages. We update the website on an ongoing basis with news about Prices & Packages.

If you subscribe to the Danish Medicines Agency's electronic newsletter NetNyt, you will be informed of ongoing updates of DKMAnet - Prices & Packages by email. To subscribe to NetNyt via the website: Home> News > Subscribe to NetNews.

If you have questions that are not answered in this information, please do not hesitate to contact us via email to dkmanet.pp@dkma.dk or on telephone +45 4488 9525.

RESPONSIBILITY AND NOTIFICATION.....	2
SECURITY.....	3
REGISTRATION TO DKMANET.....	4
THE ROLE OF COMPANY ADMINISTRATOR.....	5
ACQUISITION OF DIGITAL EMPLOYEE SIGNATURE.....	7
QUESTIONS OR CHANGES TO THE INFORMATION RECORDED BY THE DANISH MEDICINES AGENCY	8
MODULE PRICES & PACKAGES - OPTIONS AND USE.....	12
INFORMATION AND COURSES	14

Responsibility and notification

Who is responsible for notifications made to module Prices & Packages?

Once the notification system goes electronic it will no longer be possible to enter data manually at the Danish Medicines Agency. The employees of the Danish Medicines Agency will not be able to make notifications to module Prices & Packages on behalf of the company. In this way it is ensured that only the company can affect the notification data.

Please be aware that once you are registered to make electronic notifications via module Prices & Packages you will not be able to make notifications by fax. This appears from the Executive Order on prices of medicinal products and delivery conditions that took effect on 7 November 2006. If you are registered to make electronic notification, fax notifications are therefore only acceptable if the problems encountered in making electronic notifications are due to errors in the Danish Medicines Agency's systems

It is also important to note that all notifications that the company administrator or the company users make on behalf of the company in module Prices & Packages are binding on the company at the transition to a new price period. If the company administrator creates company users outside the company, the company is solely responsible for the necessary agreements. The Danish Medicines Agency does not check the company administrator's creation of company users.

I have problems making notifications via module Prices & Packages – what do I do?

If you have problems making electronic notifications of price and product range changes via module Prices & Packages, please contact **DKMANet Support** IMMEDIATELY by sending an e-mail to dkmanet.pp@dkma.dk or telephone +45 4488 9525 from 10:00 to 15:00 and from 10:00 - 18:00 on days of deadlines. If a deadline falls on a holiday, support will be open from 12:00 to 16:00, cf. our website.

If you have problems making notifications on a notification Monday after 6 pm, please make your notifications on the indicated forms by fax on +45 4494 3828 before 8 pm. You should also state why you are not submitting your notification electronically.

Security

How high is the level of security in connection with notification to module Prices & Packages?

In connection with the transition to electronic notification to Medicinal product prices it is extremely important to ensure that the individual company only has access to information on its own product range, and that the submitted changes can only be viewed by the company in question. SSL encryption according to internationally recognised security standards is used for submitting data.

In order to ensure the highest level of security the users must use an employee signature (OCES standard) when logging on as identification to the system. As a user you will automatically be disconnected from the system if you have not made entries or been active on module Prices & Packages for 15 minutes. All log-on attempts and actions in module Prices & Packages are logged.

Will the Danish Medicines Agency have access to module Prices & Packages?

The employees of the Danish Medicines Agency will NOT have access to enter notifications on behalf of the companies in module Prices & Packages. The notifications are transferred to the internal system of the Danish Medicines Agency only after deadline for notification (notification Mondays after 8 pm). However, the employees of the Danish Medicines Agency have access to a log of all activities on module Prices & Packages and in case of doubt they will be able to document an action with identification of user ID, date, time and action.

How does the Danish Medicines Agency ensure that the information shown is the correct information?

The connection between company and medicinal product range is established by means of the company number(s) assigned to your company. It is extremely important that this connection is verified by the company, and consequently we have submitted an overview of the medicinal products registered under each company number. This way we ensure that you are given access to the correct information when you log on to module Prices & Packages for the first time. The overview must be verified by a person authorised to sign for the company.

If the information on the overview is incorrect, please contact **DKMANet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk. It is a prerequisite for gaining access to DKMANet that the information is correct and that the company has verified the information to the Danish Medicines Agency.

The company numbers – our key to the companies' medicinal product ranges – must also be stated on the form to be used for access to module Prices & Packages (Form for appointment of company administrator for DKMANet). The form for the appointment of company administrator is submitted together with the form for confirmation of medicinal product information, and is available from this website.

Registration to DKMANet

Who can be created as a user on DKMANet?

If your company is either:

- A marketing authorisation holder (and has not appointed a representative for the medicinal product)
- A representative for a marketing authorisation holder, or
- A parallel distributor

of one or several medicinal products and has to make notification of changes of prices and product range to the Danish Medicines Agency (cf. Executive Order no. 875 of 17 August 2006 on prices of medicinal products and delivery conditions) then your company can be created as a user on DKMANet. It gives you access to make notification of changes of prices and product range of the medicinal products in question.

If you are not sure if you can become a user of DKMANet, please contact **DKMANet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk.

How does the company gain access to DKMANet?

To gain access to DKMANet the user must have a digital employee signature or a CUG signature installed, and then the user is to have access created to DKMANet.

The company gains access to DKMANet by submitting the following two forms to the Danish Medicines Agency:

- Confirmation of medicinal product information form
- Appointment of company administrator form

We kindly ask you to return the forms duly completed no later than **1 October 2008**. Otherwise, we cannot guarantee that you have electronic access from **1 January 2009**.

Access is given as we receive registrations. Once you have been given access to submit notifications electronically, you will no longer be able to make notifications by fax.

Please note that we cannot connect your company unless all information recorded under your company is correct and you have completed the forms.

Guideline on the completion of the Confirmation of medicinal information form:

The connection between company and medicinal product range is established by means of the company number(s) assigned to your company. It is extremely important that this connection is verified by the company, and consequently, we have submitted an overview of the medicinal products registered under each individual company number connected to each individual company. This way we ensure that you are given access to the correct information when you log on to module Prices & Packages for the first time.

Guideline on the completion of the form for Appointment of company administrator:

In order to complete the form correctly the company should:

1. Appoint one company administrator to function as the main responsible person in the company for notifications – please note that only one company administrator can be appointed per company.
2. Acquire an employee signature from TDC for the company administrator (if the employee in question already has an employee signature of OCES standard installed on his/her work computer this may be used) or for CUG signatures from the Danish Medicines Agency.
3. Install the digital signature.
4. State the RID number from the employee signature of the company administrator (13 digits)
5. State the company number(s) – please note that statement of these company numbers will determine the product ranges to which the company will have access in module Prices & Packages.
6. State the company name and CVR number. Only Danish companies must state the CVR number.

Please note that the form for appointment of company administrator must be signed by the Managing Director or another person authorised to sign for the company. The Danish Medicines Agency processes the forms for appointment of company administrator as quickly as possible and in the order they are received.

What is a CVR number?

A CVR number is a unique number for identification of companies in Denmark. CVR numbers are registered in the Central Business Register of the Danish Commerce and Companies Agency, see www.cvr.dk. You do not need to state the CVR number in the forms if your company is a foreign company, as the CVR numbers are reserved for Danish companies.

The role of company administrator

What are the role and tasks of the company administrator?

Appointed by the company

The company administrator is appointed by the company, either by the Managing Director or another authorised employee. We recommend that the company administrator for module Prices & Packages should be the company employee responsible for notification of medicinal product prices.

There can only be one company administrator per company. However, the same person can be company administrator for several companies.

The Danish Medicines Agency's contact

The company administrator is the Danish Medicines Agency's contact regarding DKMANet. Thus, enquiries and questions regarding access and notification should be via the company administrator. In this way we can offer a good and uniform service.

Creation of other company users

In addition to making notifications on behalf of the company the company administrator has access to create additional company users on DKMANet. Local company users are created on a special page of DKMANet, to which only the company administrator has access. This means that the company administrator has to ensure the acquisition and

installation of employee signatures for any other employees of the company that are to have access to module Prices & Packages. Other company users cannot use the company administrator's digital signature, as a digital signature is personal and is installed on the computer of the person in question.

Furthermore, the company administrator is responsible for the administration of the company users if, for instance, a user should have access to less or more information or if a user should have the access closed. Due to the log information it is not possible to completely delete a user, but only to close the person's access to DKMANet. Company administrators who have not had access for two years are then deleted by the Danish Medicines Agency.

Responsible for notifications

It is important to note that the notifications made by the company administrator in module Prices & Packages are binding on the company. The same applies to notifications made by company users created by the company administrator, also if the company administrator has created company users outside the company. In this connection, the company is responsible for the necessary agreements being in place for creating persons outside the company as company users. The Danish Medicines Agency does not check the company administrator's creation of company users.

Can company users have different profiles on module Prices & Packages?

The company administrator can create company users with different profiles:

- Company users with write access – with access to transfer and enter data in module Prices & Packages
- Company users with read-only access – with access only to read and search in module Prices & Packages
- Company users with a Danish user interface
- Company users with an English user interface

The company administrator may also differentiate the access of the individual company users at company level, if, for instance, a company user is to have access only to make notification of part of the company product range, see the question below on differentiated access.

How many users of module Prices & Packages can each company create?

It is up to the individual company how many company users are to be given access to module Prices & Packages apart from the company administrator. Consequently, it is the responsibility of the company how many company users may make notifications or view information on module Prices & Packages. Please note that the contact to the Danish Medicines Agency regarding module Prices & Packages must be via the company administrator.

Each company user must have his/her own employee signature and it is the responsibility of the company administrator to ensure the creation and installation of the signatures. Furthermore, the company administrator is responsible for the administration of company users if, for instance, a company user should have access to less or more information or if a company user should have the access closed. The Danish Medicines

Agency does not register who or how many company users are created locally in the companies. Via the log we can identify who has been logged on when, but the log is only used in case of doubt.

Can one company administrator be the company administrator for several companies?

Yes, a company administrator can be the company administrator for several companies at the same time. Thus, the company administrator is given access to the product ranges of the companies in question via the companies' company numbers. This means that the respective companies' medicinal products and medicinal product packages are collected in one overview on module Prices & Packages. Each company must appoint one company administrator even if this person has already been appointed company administrator for another company.

What actions should be taken if a company administrator leaves the company?

If a company administrator should choose to leave the company/companies he or she is linked to in DKMANet, it is crucial that he or she contacts DKMANet support IMMEDIATELY by email dkmanet.pp@dkma.dk or telephone +45 4488 9525 BEFORE leaving the company.

The company administrator must inform the Danish Medicines Agency of the name of the new company administrator to be appointed. If the new company administrator is a user of DKMANet, the administrator must deactivate the user before the person can be set up as the new company administrator. The new company administrator must fill out the form "Appointment of company administrator for DKMANet" and submit the form to the Danish Medicines Agency. The Danish Medicines Agency will then make sure that the current company administrator no longer has access to DKMANet and setup the new user as company administrator.

Acquisition of digital employee signature**What is a digital employee signature?**

TDS's Employee Signature is normally referred to as a digital signature or a digital certificate. The difference between an employee signature and the signatures used for private purposes, for instance for self-service at the Danish tax authorities, is that the former type can only be ordered by stating a valid CVR number and it thus requires an authorisation for the employee who is to use the employee signature.

A digital signature is personal and is installed at the PC of the person involved.

Which users of DKMANet must have a digital employee signature?

All users of DKMANet must have a digital employee signature. When your company is connected and thus gains access to DKMANet, you need to state the appointed company administrator's employee signature ID number (RID number) on the form. To find the RID number you must first install the digital signature.

How do you acquire an employee signature?

Acquisition of employee signature for Danish company administrators and users:
The employee signatures are ordered from TDC. This can be done online on

www.digitalisignatur.dk. So far, in Denmark the signatures are free of charge, and thus, there are no expenses in connection with the acquisition. If the appointed company administrator or future company users already have an employee signature for work-related use, this can be used for access to DKMAnet.

Acquisition of employee signature for foreign company administrators and users:

Employee signatures for both company administrators and company users employed by a foreign company must be ordered from the Danish Medicines Agency. This is done by completing the Order for Closed User Group Certificate form and submitting it to the Danish Medicines Agency, which administers the allocation of CUG – Closed User Group Certificate. The company administrator will subsequently receive an email confirming the allocation together with a link to an online installation guide in English. The same procedure applies when companies abroad need employee signatures for other company users.

The issue of CUG signatures is subject to an administrative fee of DKK 110.-, which the Danish Medicines Agency will charge the company.

How do I find my employee signature's RID number?

Once you have installed your employee signature on your computer, you do the following to find the RID number: Open an Internet browser and select Tools > Internet options > Content > Certificates. You then select the certificate required (more than one certificate may be installed) > View > Details > Subject. Please note that an RID number has 13 digits and that it is not the same as a PID number.

Questions or changes to the information recorded by the Danish Medicines Agency

Which medicinal products appear from the received overview of my company's medicinal products?

The overview states the medicinal products that your company is authorised to market on the date of submitting the overview. Medicinal products in quarantine or which have not been authorised on the date of submitting the overview will not appear from the list.

Section 1 of Executive Order on prices of medicinal products and delivery conditions states the medicinal products for which notification of price changes must be made to the Danish Medicines Agency.

What is a company number?

A company number is the Danish Medicines Agency's unique ID number for your company. The company number is the number under which the Danish Medicines Agency recognises your company and under which your company's medicinal products are registered.

The connection between your company's access to DKMAnet and the information shown in module Prices & Packages is established using the company number which the Danish Medicines Agency has assigned to your company.

What is an application for variation?

An application for variation is an application concerning amendment of the summary of product characteristics and the documents forming the basis of the marketing authorisation.

You can find out more about applications for variation on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

My company has two company numbers? Can I have that changed?

If your company has two company numbers, you can ask the Danish Medicines Agency to change the medicinal products' links to the company numbers to combine them under the same company number. This is done by submitting an application for variation.

You can find out more about variation applications on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

Your company does not have to submit an application for variation if you have documentation that the information you wish to transfer from one company number to another has been registered incorrectly. You might think that our information is incorrect in relation to your previous application, or maybe you have an application for variation being processed by the Danish Medicines Agency. Please contact **DKMAnet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk to be informed about how to proceed.

My company has changed its address, however, the old address appears from the forms I have received. Can I have the address changed?

You can have the address of your company changed so that the medicinal products are linked to the new address. This is done by submitting an application for variation.

You can find out more about applications for variation on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

You do not have to submit an application for variation if you think that our information is incorrect compared with your previous application or if you have an application for variation being processed by the Danish Medicines Agency. Please contact **DKMAnet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk to be informed about how to proceed.

My company has been authorised by the Danish Medicines Agency. So why are my company's medicinal products not registered under the address?

Even if your company has been authorised by the Danish Medicines Agency in connection with an inspection of the company's facilities, this does not mean that we register your company's medicinal products under that address. Your company must submit an application for variation to have your company's medicinal products registered under the new address. You can find out more about applications for variation

on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

If you take over medicinal products from another company, please contact the company from which you are to take over medicinal products and ask them to submit an application for variation. The Danish Medicines Agency then updates the address information of each individual medicinal product. You can find out more about applications for variation on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

My company has medicinal products for both human use and veterinary use distributed on different company numbers in the Danish Medicines Agency's database. Can I have the medicinal products registered so that medicinal products for human use and for veterinary use are connected to each their company number?

Yes, you can have your company's medicinal products registered so that medicinal products for human use and veterinary use are registered under each their company number. The motivation for such split must be that two different companies act as Marketing Authorisation Holder, representative or parallel distributor, respectively, of the medicinal products in questions, for instance NewMedicin A/S and NewMedicin Animal Health. You can have your product range split by submitting an application for variation.

You can find out more about applications for variation on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

You do not have to submit an application for variation if you have documentation that the medicinal products you wish to transfer from one company number to another have been registered incorrectly. You might think that our information is incorrect in relation to your previous application, or maybe you have a variation being processed by the Danish Medicines Agency. Please contact **DKMANet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk to be informed about how to proceed.

My company is no longer the marketing authorisation holder (MA holder) or representative for one or more of the medicinal products listed in the overview we have received from the Danish Medicines Agency. How can we have that changed?

If your company is no longer the MA holder for one or more of the medicinal products listed in the submitted overview, we ask you to submit an application for variation and state the new MA holder. If there is no new MA holder, we ask you to deregister the medicinal product by submit scheme C – Notification of withdrawal of medicinal product or package to The Danish Medicines Agency, Medicinal product prices. If you are in doubts please contact **DKMANet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk. We will then look into the matter.

If your company is no longer the representative for one or more of the medicinal products listed in the submitted overview, please contact the MA holder. The MA holder

must submit an application for variation to the Danish Medicines Agency stating the new representative.

If the MA holder has already submitted an application, for variation the information about the medicinal product should appear from your company's access to DKMANet in module Prices & Packages once the application has been processed.

You can find out more about applications for variation on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms

The submitted overview of my company's medicinal products comprises incorrect information about one or more nationally authorised medicinal products. What should I do?

If the overview of your company's medicinal products comprises incorrect information about nationally authorised medicinal products, for instance an incorrect address, you probably have not submitted an application for variation. If you are in doubt, please contact **DKMANet Support** on +45 4488 9525 or dkmanet.pp@dkma.dk, we will then look into the matter.

You can find out more about applications for variation on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms

You need not contact the Danish Medicines Agency if you have already submitted an application for variation regarding the information missing in the overview. In this case there is no need for you to receive new material with the updated information. The data in the form is a "snapshot" on the date of submission. Once the application for variation has been processed the new information will automatically appear from DKMANet.

If the missing information does not concern failure to submit an application for variation, please contact **DKMANet Support** on dkmanet.pp@dkma.dk and let us know which information it concerns. Please also forward a copy of the submitted application for variation. The Danish Medicines Agency will then process the case and revert to you.

The received overview of medicinal products comprises incorrect information or information is missing about one or more centrally authorised medicinal products. What should I do?

If the submitted overview of your company's medicinal products comprises incorrect information or lacks information about centrally authorised medicinal products, please contact **DKMANet Support** on dkmanet.pp@dkma.dk and let us know which information it concerns. If your company has already submitted an application for variation to EMEA about the missing or incorrect information, please forward a copy of the application together with EMEA's reply to DKMANet Support on dkmanet.pp@dkma.dk. You may also forward a copy of the documents by letter.

You can find more information about centrally authorised medicinal products on the Danish Medicines Agency's website under Companies > Authorisation of medicinal products > Guidelines and forms.

Module Prices & Packages - Options and use

As a user, what can I do on module Prices & Packages?

As a user of module Prices & Packages you have the following options:

- File transfer of changes of prices and product range, including creation and marketing of new packages.
- Manual entry of changes of prices and product range, including creation and marketing of new packages.
- Overview of the company's product range in Medicinal product prices for both current and next medicinal product price periods.
- Overview of current changes of prices and product range until next open medicinal product price period.

File transfer must take place in XML format. Detailed specifications of XML files for Prices & Packages are available on the Danish Medicines Agency's website. Please go to Companies > The Price List of Proprietary Medicinal Products > DKMANet - Prices & Packages > Material and guidelines on Prices & Packages.

The current changes of prices can be overtyped until deadline, which will still be Monday at 8 pm in odd-numbered weeks. For instance, if you have changed the price notification of a specific package several times, it will always be the latest notification that applies. If you create a new package and before deadline you find out that you have made a mistake, then the company administrator or an authorised person in the company can inform the Danish Medicines Agency of this in writing. And only the latest notification of the individual package will be invoiced by the Danish Medicines Agency.

Which medicinal product information will I be able to view in module Prices & Packages?

In module Prices & Packages you will have access to information on the registrable medicinal products and packages which you market or have authorisation to market in Denmark..

The overviews on module Prices & Packages will state the following information about each package created:

- Product number
- Name of medicinal product
- Form
- Strength
- Package size
- AIP (apotekets indkøbspris – pharmacy cost price) for the selected price period
- Market situation (i.e. is the package being marketed or has it been temporarily withdrawn from the market)

The overview on module Prices & Packages will show the following information for each authorised medicinal product (not in quarantine):

- Name of medicinal product
- Form
- Strength
- MA number/record number

Can I deregister a medicinal product on DKMANet?

You cannot deregister a medicinal product via DKMANet. For deregistration of medicinal products (withdrawal of the medicinal product) Form C should be submitted to the Danish Medicines Agency, for further information please see The Danish medicines website under Companies > The Price List of Proprietary Medicinal Products > Notification of changes of price and product range. If you do not wish to deregister the medicinal product but just withdraw one or more packages from the rate temporarily (deactivation) or delete an individual package from the product range (the package will be marked as deleted and cannot be marketed again at a later date), you can do this in DKMANet - module Prices & Packages.

Please note that even though you have deleted all packages connected to a medicinal product, you still have to deregister the medicinal product.

Will the company still receive a proof list per fax from the Danish Medicines Agency?

The proof list which you receive by fax Thursday around 10 am is discontinued when we start to receive only electronic notification. We expect to start to receive only electronic notification during 2007. Already now nearly half of the companies that market medicinal products in Denmark make electronic notifications.

Instead of the proof list the company can make a print of the data submitted via Prices & Packages immediately after making the notification. This is supported in the user interface as an overview of notifications is automatically shown when the user has entered or file-transferred notifications. This overview can be printed directly in pdf format. Apart from the notification data a printed overview from module Prices & Packages will always include:

- The name of the company
- Date and time of print
- Date of notification
- Name of the person making the notification (at package level)
- Price period (the period for which the notifications apply)

This means that the company after the transition to electronic notification is responsible for reviewing its own notifications until the next open price period.

Will the company still receive a letter from the Danish Medicines Agency stating whether the medicinal product has mark A, B or C?

Letters informing of the medicinal product's mark A, B or C (ABC letters) that are submitted from the Danish Medicines Agency on the Friday of the week in which you have made the notification will stop completely when we start to receive only electronic notifications.

Instead of the so-called ABC letter the company can have the information of mark A, B or C by making a screenshot of the screen in module Prices & Packages. The marks

ABC will be available from Thursday around 10 am of the week where you have made the notification and can be considered final on the Friday around 6 pm of the week before they take effect

Apart from the notification data, a printed overview in pdf format from module Prices & Packages will always include:

- The name of the company
- Date and time of print
- Date of notification
- Name of the person making the notification (at package level)
- Price period (the period for which the notifications apply)

This means that the company itself after the transition to electronic notification is responsible for keeping informed of its own notifications until the next open price period.

Will the company still receive a receipt by mail of product range changes from the Danish Medicines Agency?

When the company is connected to electronic notification via DKMANet, the Danish Medicines Agency only submits receipts by letter on product range changes to the company entitled to make the notification, if the change concerns deregistration or change of name of medicinal products or a change of marketing authorisation holder or representative of the medicinal product.

Receiptletters on product range changes will as usual be submitted in the week before the product range change takes effect.

Information and Courses

Where will I find further information?

All the information submitted on DKMANet - module Prices & Packages is available on this website under Companies > The Price List of PPDproprietary Medicinal Products > DKMANet – prices & Packages. We update the website on an ongoing basis with news about Prices & Packages. The forms for appointment of company administrator and ordering of CUG signature are also available here.

If you subscribe to news about Priser og Medicintilskud in the Danish Medicines Agency's electronic newsletter NetNyt, you will be informed of ongoing updates per email. To subscribe to NetNyt via the website: Home > News > Subscribe to NetNews, see the fact box on the right-hand side.

What is DKMANet Support?

DKMANet Support is the Danish Medicines Agency's hotline regarding contact to Medicinal product prices. We answer questions on connection to and electronic notification via DKMANet – Prices & Packages. The employees work in shifts on our hotline, so you may not talk to the same person every time.

DKMANet Support is open from 10.00 – 15.00 and from 10.00 – 18.00 on days of deadlines. If a deadline falls on a holiday, support will be open from 12:00 to 16:00, cf. our website.

Will I have access to a guide of the use of module Prices & Packages?

On the Danish Medicines Agency's website you will find a guide for using module Prices & Packages. The guide is available in both English and Danish. It contains a stepwise review of the functions on module Prices & Packages as well as an explanation of the terms used.

On the website you will also find a practice booklet which we use at the courses we organise about the system.

Does the Danish Medicines Agency offer courses in module Prices & Packages?

In connection with the transition to electronic notification via DKMANet – module Prices & Packages the Danish Medicines Agency offers a free half-day course in the system, and here you can ask questions and try out the Prices & Packages system. The courses take place at the Danish Medicines Agency on an ongoing basis. The courses are given in both Danish and English. You can enrol in a course by sending an email to dkmanet.pp@dkma.dk. The next time we are holding a course, we will send an email with a date for the course.