

DKMAnet - User administration - Guidelines

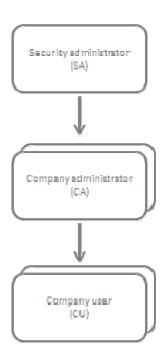
DKMAnet user administration

These guidelines are intended for administrators who control the companies' access to DKMAnet.

3 user roles for company employees

There are three employee user roles: security administrator (SA), company administrator (CA), company user (CU):

- Security administrator (SA). The SA role has overall responsibility for the
 access to a company number. The SA role can also have overall responsibility
 for several company numbers at the same time. There can be only one SA role
 per company number. The SA role can delegate rights for all DKMAnet
 services
 - The SA role's task is to appoint CAs for company numbers and to allocate these CAs access rights to individual DKMAnet services.
 - The SA role cannot itself use DKMAnet services, but can delegate rights to company administrators.
- 2. Company administrator (CA). The CA role can appoint CUs with access to company services. The CA role cannot itself use DKMAnet services, but can delegate rights to company users. There can be several company administrators in a company, and there can be several CAs with access to allocating user rights for the same services. This all depends on how the SA has chosen to allocate rights.
- 3. Company user (CU). The CU role can use DKMAnet services for the companies and service areas allocated to the CU by the company administrator. An unlimited number of CUs can be set up.



DKMAnet services

DKMAnet offers companies secure, digital handling of a number of business processes. These various business processes are termed services on DKMAnet.

One such service is the possibility of applying for general reimbursement for medicines.

The new user management setup allows companies to administer their users' access to the individual services.



One person can have several roles.

It is possible for one person to have one or several roles, which is entirely up to the companies. The only requirement raised by the Agency is to be informed of whom the company has appointed as security administrator. It is up to the SA to decide if he or she wants to act as CA or perhaps even CU. While the security solution offers a clear division of responsibility, it does not prevent companies from choosing a division that fits the individual needs of the company.

Digital signatures identify individuals

DKMAnet verifies user authenticity and authorisation by means of a digital signature (OCES employee certificate or a closed user group certificate). NemID for companies is, according to DanID, expected to be introduced later, which the Danish Health and Medicines Authority will naturally take into account. The digital signature controls which services the user is allowed to access on DKMAnet.

Employees in companies with an address and CVR number in Denmark can themselves obtain a digital employee signature. Digital signatures are issued by DanID, see www.danid.dk.

Employees who do not operate from a Danish address must obtain a digital signature from the Danish Health and Medicines Authority (closed user group certificate). For more information, please see the website of the Danish Health and Medicines Authority at www.dkma.dk.

It is also possible for a person to use the same digital signature for several user roles simultaneously. Hence, an SA can appoint himself as both CA and CU and can access all services using the same digital signature. Note that a digital signature is personal.

In turn, the CA can also set up himself as CU if needed.

Services and company numbers

In the Danish Health and Medicines Authority's systems, the company's product range is linked to the company's company number(s). This means that the access to the various medicinal product data can be differentiated based on the company number which the CA or CU has access to in DKMAnet. Companies can allocate access to use services through a combination of company number and services. In other words, if a CU is to use a service, he or she must have access to the service as well as to the company number(s) which the service is to be used for.



The company number identifies the company to the Danish Health and Medicines Authority.

The company number appears from the correspondence you receive from the Danish Health and Medicines Authority and represents the exact key to gain access to information from the Agency's IT systems.

The company number is NOT the company's CVR number.

The CU receives his access rights from the CA, who in turn has received his rights from the SA. This hierarchical setup is a key element in understanding and being responsible for the company's use of DKMAnet.

Which information can the different roles see?

First, a distinction should be made between the information about allocated rights (at administrative level) and information originating from the use of the individual services, e.g. drafts and application forms submitted to the Danish Health and Medicines Authority.

The SA role can:

- administer CAs' access to services within the company number(s) under the SA's authorisation. The SA decides if he, himself, or others should have CA access and can choose to allow CAs to have overlapping rights.
- see all rights allocated to CAs with respect to the company numbers administered by the SA.

The SA role CANNOT:

- see the information entered or submitted through the CUs' use of the individual services, e.g. drafts and submitted application forms.
- use DKMAnet services (if the SA wants to use these services, he must set up himself first as CA and then as CU)

The CA role can:

- set up and administer CUs with all or some of the rights the CA has himself and can choose for CUs to have overlapping rights.
- only see and administer CUs which have one or several of the CA's own rights.

The CA role CANNOT:

- see the information entered or submitted through a CU's use of the individual services, e.g. drafts and submitted application forms.
- use DKMAnet services (if the CA wants to use these services, he must first set up himself as CU)



The CU role can:

- use the services to which he or she has been given access by a CA.
- see application forms and all information from any other CU in the company who has been given access to the same services. CUs who have overlapping rights within the same services can see the application forms and information that may have been saved as drafts or submitted to the Danish Health and Medicines Authority within the overlapping rights area(s).

Support

Please address questions about DKMAnet and user administration to DKMAnet support:

Email address: <u>dkmanet@dkma.dk</u>
Telephone number: +45 4488 9525

DKMAnet Support is open Monday to Friday from 09:30 to 15:00 and every other Monday in straight weeks until 16:30.