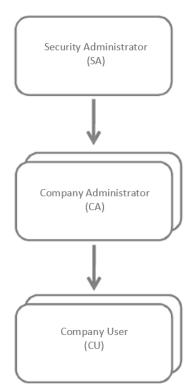


Guidelines for DKMAnet user administration

User roles in DKMAnet

There are 3 possible user roles in DKMAnet: Security Administrator (SA), Company Administrator (CA), and 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.
- 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 CA. An unlimited number of CUs can be set up.



One person can have several roles

It is possible for one person to have one or several roles. The only requirement raised by the Danish Medicines 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 and 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 ID (MitID Erhverv or Closed Usergroup Certificate).

Employees of companies with an address and CVR number in Denmark can obtain a digital ID themselves via MitID Erhverv. Employees of companies without a Danish CVR number must be issued a Closed User Group Certificate (LBC)



by the Danish Medicines Agency. Please note that a digital ID is personal. For more information, visit the Danish Medicines Agency's website at www.lmst.dk.

DKMAnet services

DKMAnet offers companies a secure digital management of various business processes. These different business processes on DKMAnet are referred to as services. The option to apply for general reimbursement for medicinal products is an example of a service on DKMAnet. DKMAnet user administration allows companies to manage their users' access to the individual services themselves.

Services and company numbers

The company's product range is linked to its company number(s) in the Danish Medicines Agency's systems. This means that access to various medicinal product data can be differentiated depending on which company number a Company Administrator (CA) or Company User (CU) has access to in DKMAnet.

Companies can allocate access for the use of services in a combination of company number and services. To use a service, a CU must have access to both the service and the company number(s) relevant to the service.

A CU is granted access by a CA, who in turn receives their access delegated by the Security Administrator (SA). It is important to understand this hierarchy when managing a company's use of DKMAnet.

The company number is the Danish Medicines Agency's identification of the company. The company number is indicated in the correspondence you receive from the Danish Medicines Agency and is the exact key to access information from the Danish Medicines Agency's IT systems.

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

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 Medicines Agency.

The SA role can:

- manage CAs' access to services within the company number(s) the SA is authorized for. The SA decides
 whether they or other individuals should have CA access and can choose to allow CAs to have overlapping
 rights.
- view all the rights that have been assigned to CAs for the company number(s) the SA manages.
- search the business log, providing an overview of when users within the same company have logged into DKMAnet and what actions they have performed.

The SA role CANNOT:

- view the information entered or submitted through the CU's use of the individual services, e.g. drafts and submitted application forms.
- use DKMAnet services (if desired, the person must first set up himself as a CA and then as a CU).



The CA role can:

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

The CA role CANNOT:

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

THE CU role can:

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

Support

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

- Email: medicinpriser@dkma.dk
- Telefonnummer: +45 4488 9694

DKMAnet support is open Monday to Friday from 9:00 to 15:00. In addition to the national holidays, the Danish Medicines Agency is closed on the day after Ascension Day, the Danish Constitution Day (5 June) and between Christmas and New Year.