LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Requirements and deadlines for applications for company authorisations

Table of contents

1. General

This document describes the general requirements and deadlines for applications for company authorisations.

The Danish Medicines Agency issues company authorisations for the following activities:

- Manufacture and/or importation of medicinal products and intermediates
- Wholesale distribution of medicinal products within the EEA
- Retail sale of non-pharmacy restricted medicinal products outside pharmacies, including over-the-counter medicinal products (HF, HX, HX18), V-marked medicinal products (HV), medical gases (GH) and medicinal products for production animals (AP, BP, HP, APK, BPK, HPK, premix)
- Distribution of medicine chests for life boats and life rafts
- Handling of radiopharmaceuticals in hospitals
- Conduct of toxicological and pharmacological trials (non-clinical trials)
- Handling of euphoriant substances including authorisation to cultivate and handle cannabis with a view to producing cannabis suitable for medicinal use
- Manufacture of cannabis bulk and cannabis primary products
- Manufacture of cannabis intermediate products

The handling of medicinal products, euphoriant substances, cannabis bulk, cannabis primary products and cannabis intermediate products as well as the conduct of toxicological and pharmacological tests (non-clinical trials) must only take place with authorisation from the Danish Medicines Agency. You can find further information on each of the different company authorisations under their respective areas under Company authorisations and registrations at dkma.dk.

Our unit Authorisations & Security of supply reviews applications for and issues company authorisations. If you have questions about an application, an existing company authorisation or require guidance on or information about company authorisations, please contact Authorisations & Security of supply at virksomhedstilladelse@dkma.dk.

The Danish Medicines Agency issues company authorisations to companies domiciled in Denmark only. The handling of, for example, medicinal products outside Denmark requires an authorisation from a corresponding regulatory authority in the country concerned.

An address at which activities are performed is considered a 'site' by the Danish Medicines Agency. A company can have several sites, which will appear from the company authorisation. All companies must have a legally registered address (a main address). This address can also be a site if activities are performed at the address. If no activities take place at the legally registered address, the address will be considered an administrative address by the Danish Medicines Agency.

2. Submission of applications to the Danish Medicines Agency

The application forms are available under their respective areas under Company authorisations and registrations in either Word format with locked fields or as e-forms.

Companies that use the Word format must submit the form duly signed as a PDF file (scanned and preferably in OCR format) by email to virksomhedstilladelse@dkma.dk. The Danish Medicines Agency can receive up to 50 MB per email.

The application must be submitted with a detailed cover letter or cover email, describing the reason for the application and must contain relevant additional material.

Guidance on how to apply for the different types of authorisation, including instructions on how to complete the application form and requirements for additional material, can be found under each individual area under Company authorisations and registrations.

The e-forms must be completed online using a digital signature.

We advise applicants not to send company authorisations by ordinary post.

3. Application types

There are four different types of applications for a company authorisation:

1. Application for new company authorisation (first application)
2. Application for change of an existing authorisation
3. Application for renewal of an existing authorisation (if duration is restricted)
4. Application for a termination of a company authorisation

3.1 Application for a new company authorisation

Before a company submits an application for a new company authorisation, the company must be ready for an inspection by the Danish Medicines Agency. Being ready for an inspection means that the company must be able to document the required competencies and that the required premises, facilities, equipment, processes and procedures to be used on all sites are ready. The legislation regulating the specific area must furthermore be implemented. When an application for a new company authorisation is submitted, the company must complete the entire application form, so that the application reflects a snapshot of the activities that the company wants to perform.

Before the Danish Medicines Agency grants a company authorisation, we will in most cases inspect the applicant's premises. We will contact the company to schedule an inspection.

3.2 Application for change of an existing authorisation

When we receive an application to change an existing company authorisation, we distinguish between whether or not the change requires an inspection. Changes such as new activities, new site or relocation of existing sites often require an inspection, whereas changes to the company's name or persons associated with the company generally do not require an inspection. The Danish Medicines Agency decides on a case-by-case basis whether or not an inspection is required.

Within six months before the date of expiry of a current company authorisation, applications to change and renew an authorisation can be combined. To do so, both "change" and "renewal" must be ticked, and the entire application form must be completed in pursuance of item 3.3 Application for renewal of existing authorisation.

If a company submits an application to change an authorisation and during the review decides to apply for yet another change, it must submit a new application which specifies all changes. The Danish Medicines Agency will then disregard the first application and base its review on the last application submitted.

3.3 Application for renewal of an existing authorisation

Most types of company authorisations are issued without an expiry date. It means that company authorisations will only bear an effective date, implying that the authorisation is valid until it is changed or terminated. Note, however, that the authorisation of activities with euphoriant substances regarding the activities cultivation or synthesis and other chemical changes or isolation as well as the authorisations to manufacture cannabis intermediate products will still be issued with an expiry date.

Applications for renewal of a company authorisation can be submitted to the Danish Medicines Agency within six months before the expiry of the current authorisation, but no later than three months before expiry. It is the responsibility of the company to apply for renewal no later than three months before the expiry of a current company authorisation.

In case of renewals, the entire application form must be completed with all required information. Previously submitted additional material that has not changed, should not be resubmitted.

3.4 Application for termination of a company authorisation

If a company wishes to terminate their authorisation, the Danish Medicines Agency must always be informed in writing. Cancellation must be made before the end of the year if payment of the annual fee for the following year is to be avoided.

A company authorisation may be terminated only after the company has ceased all activities which require a company authorisation. In the case of an authorisation for the manufacture and importation of medicinal products and intermediate products, authorisation for the manufacture of cannabis bulks and cannabis primary products and authorisation for the manufacture of cannabis intermediate products, there are special requirements for the subsequent conduct of activities where the authorisation must be maintained for a certain period of time in accordance with the applicable legislation. More information on this can be found in the relevant guides to the application forms under each area at Company authorisations and registrations.

In the event of bankruptcy, the Danish Medicines Agency shall also be informed in writing.

4. Assessment times

Companies should expect the following assessment times for the processing of applications for a new company authorisation or changes or renewal of an existing authorisation:

- 90 calendar days for new applications, renewals, termination as well as changes that require an inspection
- 30 calendar days for changes that do not require an inspection

The assessment times are the maximum time allowed for us to review applications, and we endeavor to review applications in the shortest possible time.

The assessment time starts from the time we receive a valid application (duly completed application form) together with the required material as provided by the requirements applicable to the application type concerned. All relevant pages of the application form must be duly completed, and any required documents must be available.

When the Danish Medicines Agency has finished reviewing an application for a company authorisation, we decide whether or not we can issue a company authorisation to the applicant on the available basis. If we can accommodate the application, we issue a company authorisation electronically and submit it to the company by email, see section 7.

5. When is it necessary to apply for a change?

If a company wishes to implement a change of a company authorisation, the change must be authorised by the Danish Medicines Agency before implementation. It is the responsibility of the company to make sure to apply in time.

When the company submits the application, it must be ready for an inspection of the new areas.

6. The Agency's administrative procedures, including the term 'clock stop'

When the Danish Medicines Agency receives an application for a company authorisation, we consider whether or not the application requires an inspection. In the affirmative, we initiate an inspection, and before we can issue a company authorisation, a satisfactory follow-up on the inspection must be in place. If we consider that an inspection is not required, the review process is merely administrative.

The Danish Medicines Agency's assessment time is stopped (the so-called 'clock-stop' days) if one of the following deficiencies are identified:

- The application form is not filled out correctly
- Adequate material is not enclosed
- The company is not ready for inspection
- Assessment awaits satisfactory follow-up on inspection

If the applicant does not return to us within six months from clock-stop, we reserve the right to refuse the application and to close the case without further notice. If the company subsequently decides to resume the application, the company must submit a new application as well as pay a new application fee if the application is subject to the payment of a fee, see section 9.

7. Electronic issuance

We issue company authorisations as electronic PDF files only. Company authorisations will be sent to the companies by e-mail. If the company authorisations are to be sent to another person in the company than the person who applied for the authorisation, please specify this in the application.

The individual company can distribute the issued authorisation electronically. Paper copies of the company authorisation can only be obtained in special circumstances. Enquiries and questions regarding the granting of company authorisations can be submitted to virksomhedstilladelse@dkma.dk.

8. Validity

The Danish Medicines Agency issues most company authorisations without expiry. This means that company authorisations will have a date of entry into force only and that the authorisation is valid until it is changed or terminated. However, in exceptional cases, it may be decided during the evaluation of the application that a specific authorisation is issued with an expiry date. Please note that the authorisation of activities with euphoriant substances regarding the activities cultivation and synthesis and other chemical changes or isolation as well as the authorisations to manufacture cannabis intermediate products will still be issued with an expiry date.

9. Fees

The size of the fee for company authorisations is determined by the Danish Ministry of Health in "the executive order on fees payable for medicinal products and pharmaceutical companies etc." and "the executive order on fees payable for medicinal cannabis and cannabis producing companies etc.".

A fee is payable for first-time applications, relocation to a new address or expansion of activities to cover several, geographically separated addresses. The application fee is a one-off fee, which is charged on receipt of applications. No application fee is charged for changes not involving address changes, nor for renewal applications.

In addition, an annual fee is charged, which is payable in advance. Annual fees are paid per site approved by the Danish Medicines Agency. The annual fee will be charge to the company designated as the holder of the authorisation at the turn of the year. In case of change of ownership of a company, no new annual fee will be charged to the company taking over the company authorisation. Whether the companies choose to distribute the annual fee proportionately, the Danish Medicines Agency does not address.

No annual fee is charged for company authorisations issued after 1 October in a given year.

If a company holds an authorisation to manufacture and import medicinal products and intermediate products and is registered as a manufacturer of active substances intended for the manufacture of medicinal products, the company must pay a full annual fee for the authorisation to manufacture and

import medicinal products and intermediate products and a half annual fee to be registered as a manufacturer of active substances.

The application fee/annual fee are adjusted on 1 January every year.

9.1 Specific conditions for individual authorisation
No fees are charged for the issuance of company authorisations for activities with euphoriant substances with the exception of authorisation for cultivation and handling of cannabis for the development of cannabis for medical use.

9.2 Additional fee for location with more than 500 employees
Pharmaceutical companies holding the below authorisation or registration from the Danish Medicines Agency will be charged an additional fee for all locations with more than 500 employees:

- Authorisation to manufacture and import medicinal products and intermediate products
- Registration to manufacture active substances
- Authorisation to conduct toxicological and pharmacological trials (GLP)

The additional fee will be charged if the company employs more than 500 employees at one location on the application date (application fee) or at 1 January (annual fee). The additional fee will only be charged once per location, even though there is more than one authorisation/registration at the location.

Companies have an obligation to inform us if they have more than 500 employees at one location.

10. Change log

Date	Version	Change
01-01-2022	08	General update including addition of table of contents and change log. Updated which authorisations are issued with expiry. New reference to the Order on fees for medical cannabis and cannabis producing companies, etc. Changes to inform that there are now fees for authorisations relating to the cultivation, handling and manufacture of cannabis products and authorisations for the handling of radiopharmaceuticals. Clarified that the annual fee is charge to the company holding the authorisation at the turn of the year. Removed that only half an application fee is paid for registration as a manufacturer of active substances if the company holds a manufacturer's authorisation for medicinal products or applies for it at the same time.