

Guidelines on requirements and deadlines for applications for company authorisations

These guidelines describe the requirements and deadlines for applications for company authorisations. The Danish Health and Medicines Authority issues company authorisations for the following activities:

- Manufacture and/or import of medicinal products and intermediate products (split on two authorisations for human and veterinary use, respectively)
- Wholesale distribution of medicines within the EU/EEA
- Retail sale of non-pharmacy restricted medicines outside pharmacies, including over-the-counter medicines (HF, HX, HX18), V-marked medicines (HV), medicinal gases (GH) and medicines for production animals (HP, HPK)
- Blood bank activity
- Handling of tissues and cells
- Handling of euphoriant substances
- Handling of radiopharmaceuticals in hospitals
- Conduct of toxicological and pharmacological trials (non-clinical trials)

These guidelines cover all types of company authorisations and are divided into the following sections:

1. General
2. Submission of applications to the Danish Health and Medicines Authority
3. Application types
4. Assessment times
5. When is it necessary to apply for a change?
6. The Danish Health and Medicines Authority's administrative procedures, including explanation of 'clock stop'
7. Electronic issuance
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1. General

The handling of medicines, euphoriant substances, tissues/cells and blood as well as the conduct of toxicological and pharmacological tests (non-clinical tests) must only take place upon authorisation from the Danish Health and Medicines Authority. 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 Company Authorisations and Distribution 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 Company Authorisations and Distribution on +45 4488 9779 or virksomhedstilladelse@dkma.dk. If you have questions about activities with tissues and cells please contact vaevogceller@dkma.dk.

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

A company at which activities are performed is considered a 'site' by the Danish Health and Medicines Authority. A company can have several sites, which will appear from the company authorisation. All companies must have a main company (main address). The main company can also be a site if activities are performed at the address. If no activities take place at the main address, the main address is only an administrative address for the Danish Health and Medicines Authority.

2. Submission of applications to the Danish Health and Medicines Authority

The application forms are available under their respective areas under [Company authorisations and registrations](#) on dkma.dk 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 Health and Medicines Authority 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. The requirements for relevant additional material are stated in the guidelines for the company authorisation concerned.

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 three 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)

1) Application for 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 Health and Medicines Authority. 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 Health and Medicines Authority grants a company authorisation, we inspect the applicant's premises. We will contact the company to schedule an inspection.

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 Health and Medicines Authority 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) 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 Health and Medicines Authority will then disregard the first application and base its review on the last application submitted.

3) Application for renewal of an existing authorisation

As of 1 September 2012, the Danish Health and Medicines Authority implemented a new practice by which company authorisations are no longer issued with 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 activity synthesis and other chemical change will still be issued with an expiry date. Companies holding a company authorisation with an expiry date, must still apply for renewal according to the above rules until they hold a company authorisation with no expiry date. Applications for renewal of a company authorisation can be submitted to the Danish Health and Medicines Authority 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.

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 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 endeavour 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 Health and Medicines Authority 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 Health and Medicines Authority 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 Danish Health and Medicines Authority's administrative procedures, including explanation of 'clock stop'

When the Danish Health and Medicines Authority 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 assessment time is stopped (the so-called 'clock-stop' days) if one of the following deficiencies is identified (clock-stop days begin the day the Danish Medicines Agency informs the applicant of the deficiency):

- 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

As of 1 June 2011, we issue company authorisations as electronic PDF files only. Therefore, we will no longer be sending a company authorisation in paper by ordinary post. Company authorisations will instead be sent to the companies by email to the contact person indicated on the application form. If the company authorisations are to be sent to another person in the company, please specify this in the cover letter or email.

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

As of 1 September 2012, the Danish Health and Medicines Authority implemented a new practice by which company authorisations are no longer issued with 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 activity synthesis and other chemical change will still be issued with an expiry date.

9. Fees

The fees payable for company authorisations are determined by the Ministry of Health and laid down in the "Danish Executive Order on Fees Payable for Medicinal Products, etc." and in the "Danish executive order on authorisation, control, and reporting of severe adverse reactions and events regarding handling of human tissues and cells (the latter of which is only available in Danish and titled: 'Bekendtgørelse nr. 1410 af 20. december 2012 om tilladelse til, kontrol med samt indberetning af alvorlige bivirkninger og alvorlige uønskede hændelser ved håndtering af humane væv og celler).

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. In addition, an annual fee/control fee is charged, which is payable in advance. An annual fee/control fee is charged for each of the company's sites authorised by the Danish Health and Medicines Authority. No application fee is charged for changes not involving address changes, nor for renewal applications.

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

The application fee for new applications can be refunded if a company does not wish to maintain its application, provided that a site inspection has not yet taken place. If at the time when the application is cancelled the site has already been inspected, the application fee will not be refunded.

If both a manufacturer's and importer's authorisation and a wholesale dealer's authorisation are issued for the same address, only one fee is due, corresponding to the most expensive activity registered on the address. This also applies to simultaneous retail distribution.

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

Special situations for individual authorisations

New retail distributors are not charged an annual fee in the year of issuance. The application fee for new applications is not refunded when the retail authorisation has been granted.

No fees are charged for the issuance of company authorisations for activities with euphoriant substances, radiopharmaceuticals or blood bank activity.

10. Termination of company authorisation

Companies that no longer wish to maintain their company authorisation must always notify the Danish Health and Medicines Authority in writing. Requests for termination of an authorisation must be submitted before year-end to avoid payment of the annual fee for the next year.

A company authorisation cannot be terminated until the company has ceased all activities subject to company authorisation. Special rules apply to the discontinuation of activities resulting from the termination of an authorisation to manufacture and import medicines and intermediates, in that the

authorisation must be maintained for a specified period according to applicable law. Further information is available in [Guidelines on applications for authorisation to manufacture and import medicines and intermediates](#).

In case of bankruptcy, the Danish Health and Medicines Authority must also be notified in writing.

Version: Guidelines-Company-authorisations-03

Last updated February 2013