LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guide to applying for a licence to produce cannabis bulk

This guide describes how to complete the application form for a licence to produce cannabis bulk.

In the following, a licence to produce cannabis bulk will be referred to as a bulk manufacturer's licence.

For information on general requirements and guidelines for applications for a company authorisation, please see the Guidelines on requirements and deadlines for applications for company authorisations.

For information on requirements for the production of cannabis bulk, see the executive order on the cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products.

This guide starts with general information on the bulk manufacturer's licence and then goes through the application form with guidance on how to complete the individual annexes.

For information on the requirements and details of the competent person, please see the guide Requirements for and expectations of the competent person in a cannabis company (in Danish only).

The application must be submitted with relevant supplementary material as described in this guide. Please send the application electronically to virksomhedstilladelse@dkma.dk in compliance with our Guidelines on requirements and deadlines for applications for company authorisations.

Contents

1. General information

1.1 The bulk manufacturer's licence

With the Act on a Medicinal Cannabis Pilot Programme, which entered into force on 1 January 2018, a four-year pilot programme was launched allowing companies with an intermediate product manufacturer's licence to import cannabis primary products and produce cannabis intermediate products. With the issue of the executive order on cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products, it has also become possible for companies in Denmark to cultivate and process cannabis (cannabis bulk) as well as produce cannabis primary products from Danish-grown medicinal cannabis.

You can read more about applying for a licence to produce and import cannabis primary products and produce cannabis intermediate products in our Guide to applying for a licence to produce cannabis intermediate products.

Any cultivation, production and distribution of cannabis bulk may only take place if authorised by the Danish Medicines Agency.

All bulk manufacturer's licences will be issued with an expiry date as the above-mentioned pilot programme runs for a limited period. Towards the end of the pilot programme, the Danish Medicines Agency will provide guidance to the companies on the potential renewal or termination of the licences.

1.2 Simultaneous authorisation of activities with euphoriant substances
The Danish Medicines Agency only issues bulk manufacturer's licences to companies that have also been granted an authorisation from the Danish Medicines Agency to handle euphoriant substances if the product is covered by the executive order on euphoriant substances. However, cultivation of cannabis in the pilot programme will always require an authorisation to handle euphoriant substances (including Schedule A). Consequently, the company must also submit an application for authorisation to handle euphoriant substances no later than the submission of the application for a bulk manufacturer's licence. If the company already has such authorisation, the company must ensure that the relevant activities regarding cannabis (Schedule A) appear on the authorisation. If this is not the case, a variation application must be submitted to update the authorisation.

1.3 Distribution of produced cannabis bulk
The holder of a bulk manufacturer's licence has permission to distribute own-produced cannabis bulk. Cannabis bulk may be distributed to Danish companies either holding a licence to produce cannabis bulk or a licence to produce cannabis primary products. Production of cannabis primary products appears from a licence to produce cannabis intermediate products in Annex 1, Part 2.

Cannabis bulk may furthermore be exported to countries permitting the import of cannabis for medicinal use and only to companies holding the required authorisations to handle cannabis for medicinal use according to the legislation of the import country.

1.4 Companies' relationships with a proprietary pharmacist or doctor
The companies comprised by the medicinal cannabis pilot programme have a reporting obligation and a duty to inform when they establish a relationship with a proprietary pharmacist or a doctor. Read more here.

2. Step by step guidance to complete the application form and the requirements for documentation

The application form for a bulk manufacturer's licence is divided into six Annexes:

Annex 1: Cultivation and production of cannabis bulk

Annex 2: Contract acceptors

Annex 3: Competent person

Annex 4: Safety responsible person

Annex 5: Responsible manager (the company's owner or managing director)

Annex 6: Consent forms

The following sections describe how to complete Annexes 1-6 of the application form.

2.1 Annex 1 - Cultivation and production of cannabis bulk
In Annex 1, please list the activities related to cannabis bulk which the company wishes to perform. Annex 1 relates to one single site, which means you have to complete an Annex 1 for each of the company's sites that handle cannabis bulk. State the address of the relevant site at the top of Annex 1.

Annex 1 has five parts:

- Part 1: Cultivation of cannabis
- Part 2: Processing/production
- Part 3: Quality control
- Part 4: Release
- Part 5: Other activities (including export)

The individual parts should only be completed if the activity concerned is to be carried out in the company. Subcontracted activities must appear on the contract acceptor's licence.

Storage of reference samples and batch documentation as well as handling of complaints and withdrawals belong to the other activities in Annex 1. If only storage of reference samples and batch documentation and/or the handling of complaints and withdrawals are performed, these activities should be specified in section "1.5 Other" in Annex 1, Part 1, and section "2.9 Other" in Annex 1, Part 2, as appropriate.

At the end of each part of Annex 1, it is possible to add comments as necessary. You can use this field if some of the selected activities need further elaboration.

Part 1: Cultivation of cannabis

Complete this part if your company wishes to cultivate cannabis. The harvesting, drying, dividing finely and storage of cultivated cannabis belong under the activities of this part and must be ticked off as appropriate.

Part 2: Processing/production

Please complete this part if the company processes Danish-grown cannabis, e.g. through extraction and/or produces finished product forms in bulk. The drying and dividing finely of harvested cannabis are not considered processing; instead they are activities that appear from the cultivation part of the application (Part 1).

The production of finished product forms in bulk includes primary packaging of the concerned product form, if relevant, e.g. the packaging of capsules in blister packs. It is important to note that this must not involve packaging of products in consumer-ready packs since this is the definition of cannabis primary products. If a company wishes to produce cannabis primary products, this is to be applied for separately by applying for a licence to produce cannabis intermediate products in which production of cannabis primary products is included. Find out more here.

Part 3: Quality control

Complete this part if the company performs analysis of cannabis bulk.

Part 4: Release

Complete this part if the company releases cannabis bulk.

Part 5: Other activities

Complete this part if the company carries out other activities than those in parts 1-4. Export of cannabis bulk is to be ticked off in Part 5.

2.2 Annex 2 – Contract acceptors

In Annex 2, please state the company's contract acceptors.

Activities can be subcontracted to contract acceptors in Denmark, cf. section 33 of the executive order on the cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products. The activities that may be subcontracted are production, analysis, receipt, storage and/or supply. Please note that release cannot be subcontracted. Analysis is the only activity that may be subcontracted to companies in other EU/EEA countries, cf. section 34 of the above-mentioned executive order.

Contract acceptors are to be listed by name and address. If the subcontracted activities are carried out at several sites of the same company, all relevant addresses of the contract acceptor must appear from the application form. All relevant addresses must be comprised by the contract, and all relevant site addresses must have been audited.

Please state the activities to be carried out by contract acceptors in Annex 2. The list of contract acceptors may also be enclosed as an appendix.

A **contract acceptor in Denmark** must hold one of the following company licences granted by the Danish Medicines Agency from which the relevant activities appear:

- Licence to produce cannabis bulk
- Authorisation to manufacture or import medicines and intermediate products

Please note that a contract acceptor with an authorisation to manufacture and import medicinal products and intermediate products may only carry out quality control of cannabis products. All other activities require a licence to produce cannabis bulk.

If the cannabis product(s) concerned are covered by the executive order on euphoriant substances, the contract acceptor must also hold an authorisation to undertake activities with euphoriant substances.

A **contract acceptor in another EU/EEA country** must hold a manufacturing authorisation pursuant to the concerned country's legislation corresponding to a Danish manufacturing authorisation pursuant to section 39 of the Danish Medicines Act.

When applying for an addition of a contract acceptor or a new site of an already approved contract acceptor on the bulk manufacturer’s licence, the contract acceptor must be stated in Annex 2, and the following documents must be submitted with the application:

- Valid licence of the contract acceptor covering the concerned sites and activities.
- Conclusion of audit report based on an audit of the contract acceptor. It must appear from the conclusion if the contract acceptor is assessed to comply with the rules of the executive order on the cultivation, production and distribution of cannabis bulk and production of cannabis primary products or the executive order on the manufacture and import of medicinal products and intermediate products depending on which licence the contract acceptor holds.
- The front page of the concluded contract (or other page listing the names and addresses of contract acceptor and contract giver) as well as a page from the contract with the signatures of all relevant parties (i.e. representative of the contract giver and representative of the contract acceptor). The submission of a draft contract is accepted for applicants applying for a new licence.

Not before the Danish Medicines Agency has approved a contract acceptor may the company start using that contract acceptor. When we approve a contract acceptor, the contract acceptor will appear from the company's bulk manufacturer’s licence under Annex 2.

2.3 Annex 3 – Competent person

In Annex 3, please state the competent person in the company. The requirements for the competent person appear from the guide Requirements for and expectations of the competent person in a cannabis company (in Danish only).

In connection with the authorisation of a new competent person on the bulk manufacturer's licence, the following material should be enclosed with the application:

- CV listing relevant practical experience, relevant courses, etc.
- Diploma
- Training plan if the competent person is newly employed in the company
- For consultants, the contract concluded between the company and the competent person must be enclosed.

When using consultants, the scope of the consultant's presence in the company should be considered so that the competent person's knowledge of the products, the production etc. can be maintained. The scope of the consultant's presence must appear from the application, for example from the cover letter.

2.4 Annex 4 – Safety responsible person

In Annex 4, the name of the company's safety responsible person is stated, i.e. the person responsible for preparing and implementing any relevant safety measures.

2.5 Annex 5 – Responsible manager (the company's owner or managing director)

In Annex 5, the name of the company's responsible manager is stated, defined as the company's owner or managing director.

2.6 Annex 6 – Consent forms

In Annex 6, the safety responsible person and the responsible manager must fill out a consent form, giving the Danish Medicines Agency permission to obtain information about their personal circumstances from the Danish National Police. If the Danish National Police cannot issue a certificate of good conduct, the person concerned will be heard in the matter before a decision is made. The company will usually be given the possibility to assign another responsible person whose conduct is then also to be assessed, in which case we will need to obtain a consent form from that person also.

The consent form is only to be completed the first time a safety responsible person or a responsible manager is to be approved on the licence.

3. Requirements for applications

3.1 Application for new licence

When an application for a new bulk manufacturer's licence is submitted, the entire application form must be completed. In case of activities on several sites, please complete an Annex 1 for each site. Moreover, you should enclose the following:

- Site Master File
- Documentation for authorisation of any contract acceptors. See section 2.2. on contract acceptors
- Documentation for approval of a competent person. See section 2.3 on the competent person

3.2 Variation application

When an application to change an existing bulk manufacturer's licence is submitted, the first two pages of the application form should always be completed. Depending on the type of variation, you only have to complete some of the application form's annexes, please see the descriptions below.

Please also see the Guidelines on requirements and deadlines for applications for company authorisations.

If you apply for a **name change**, it is sufficient to submit the first two pages of the application form.

If you apply for a **change of address or addition of a new site**, please submit a duly completed application form as well as a Site Master File.

If you apply for a **change of activities in Annex 1**, please complete the entire part (parts 1-5) in Annex 1 for the site (all tick marks must be put – activities to be added and activities to be continued). If changes only involve one site, it is sufficient to complete Annex 1 for the relevant site.

If you apply for a **change of contract acceptors**, all contract acceptors must be indicated in Annex 2. Documentation of a new contract acceptor must furthermore be submitted pursuant to section 2.2 on contract acceptors.

If you apply for a **change of the competent person**, please complete Annex 3. Documentation of the competent person must also be enclosed, according to section 2.3 regarding Annex 3.

If you apply for a **change of the safety responsible person**, please complete Annex 4 and Annex 6 with respect to the safety responsible person.

If you apply for a change of the **responsible manager**, please complete Annex 5 and Annex 6 with respect to the responsible manager.

3.3 Termination of licence

If a company applies for a termination of a bulk manufacturer's licence, the company will normally be contacted by an inspector who will schedule a close-down inspection to ensure that the handling of complaints, withdrawals, storage of reference samples, batch documentation etc. are adequately dealt with.

If the company continues to have responsibility for cannabis bulk subject to the executive order on the cultivation, production and distribution of cannabis bulk and production of cannabis primary products, the company must maintain its bulk manufacturer's licence.

The termination of a bulk manufacturer's licence cannot be effected until the day the company no longer carries out related activities and no longer has responsibilities for storage of reference samples as well as batch documentation. It is specified in section 27 of the executive order on the cultivation, production and distribution of cannabis bulk and production of cannabis primary products that all batch documentation shall be retained for at least one year after the expiry date of the batch to which it relates or at least five years after the release of the cannabis bulk product for sale or distribution whichever is the longer.

A company that wishes to terminate its bulk manufacturer's licence but is still responsible for storing reference samples and batch documentation must therefore first submit an application to change the licence, notifying the Danish Medicines Agency that all production activities are being stopped. The Danish Medicines Agency will then issue an altered bulk manufacturer's licence from which it appears that the company exclusively stores reference samples and batch documentation at the address. The same applies if the company is still responsible for complaints and withdrawals. As soon as the company is no longer obliged to comply with the rules above, the company must inform the Danish Medicines Agency in writing to effect an absolute termination of the bulk manufacturer's licence.