LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Guide to applying for a licence to produce cannabis intermediate products

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

In the following, a licence to produce cannabis intermediate products will be referred to as an intermediate product 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 the requirements for the import of cannabis primary products and the production of cannabis intermediate products, please see the executive order on the import of cannabis primary products and production of cannabis intermediate products and the relevant guideline. For information on requirements for the production of cannabis primary products, 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 intermediate product 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. 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 intermediate product 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 to produce cannabis primary products from Danish-grown medicinal cannabis.

Any import and production of a cannabis primary product and any production of a cannabis intermediate product may only take place if authorised by the Danish Medicines Agency.

All intermediate product 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 intermediate product 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. Consequently, the company must also submit an application for authorisation to handle euphoriant substances no later than the submission of the application for an intermediate product 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 Cannabis primary products

A distinction is made between cannabis primary products produced in other countries and subsequently imported to Denmark and cannabis primary products produced in Denmark. Thus, the activities allowed for the two types are different. This is reflected in the application form, which has a part specifically for the import of cannabis primary products and another part specifically for the production of cannabis primary products.

1.4 Distribution of cannabis products

The holder of an intermediate product manufacturer's licence has permission to distribute its own produced and/or released cannabis intermediate products. The distribution of released cannabis intermediate products which the company has not itself produced and/or released is subject to an authorisation for wholesale distribution of medicinal products.

Danish-produced cannabis primary products may be distributed to other companies with a cannabis intermediate product manufacturer's licence and be exported to countries permitting the import of cannabis for medicinal use and only to companies holding the required licences to handle cannabis for medicinal use according to the legislation of the import country.

Imported cannabis primary products may not be sold to other companies or exported to other countries.

1.5 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 an intermediate product manufacturer's licence is divided into six Annexes:

Annex 1: Import and production of cannabis primary products and production of cannabis intermediate products

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 – Import and production of cannabis primary products and production of cannabis intermediate products

In Annex 1, please list the activities related to cannabis products 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 primary products and cannabis intermediate products. State the address of the relevant site at the top of Annex 1.

Annex 1 has three parts:

- Part 1: Import of cannabis primary products
- Part 2: Production of cannabis primary products
- Part 3: Production of cannabis intermediate products

Please tick all activities that are carried out at the company's own sites. For example, if your company imports cannabis primary products and produces cannabis intermediate products, parts 1 and 3 must be completed, but not Part 2 as no production of cannabis primary products takes place. Do not tick off any subcontracted activities as these activities must instead appear from the relevant licence of the contract acceptor.

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 either section "2.8 Other" or section "3.3 Other" for cannabis primary products and cannabis intermediate products, respectively, in Annex 1.

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.

<u>Part 1: Import of cannabis primary products</u>

Complete this part if your company wishes to import cannabis primary products for production of cannabis intermediate products.

<u>Part 2: Production of cannabis primary products</u>

Complete this part if your company wishes to produce cannabis primary products from Danish-grown cannabis.

All relevant activities in relation to production of primary products must be ticked off in this part. For example, if your company wishes to produce capsules, "capsules" must be ticked off both in relation to production and packaging, and if secondary packaging takes place, this must also be ticked off. Quality control, release, storage and export must be ticked off as relevant.

<u>Part 3: Production of cannabis intermediate products</u>

This part is completed if the company wishes to produce cannabis intermediate products either from imported cannabis primary products or Danish-produced cannabis primary products.

The storage of released cannabis intermediate products belongs under the activities "3.1 Production of cannabis intermediate products" and "3.2 Release of cannabis intermediate products". If the cannabis intermediate products are stored at another site, or at a company where it was not produced or released, the company must hold an authorisation for wholesale distribution of medicinal products and an authorisation to handle euphoriant substances on the relevant site.

2.2 Annex 2 – Contract acceptors

In Annex 2, please state the company's contract acceptors. Activities can be subcontracted to Danish contract acceptors under section 33 of the executive order on the cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products and section 40 of the executive order on the import of cannabis primary products and production of cannabis intermediate products. The activities that may be subcontracted are production, analysis, receipt, storage and/or supply. Please note that release cannot be subcontracted. Analysis of Danish-produced cannabis is the only activity that may be subcontracted to companies in other EU/EEA countries, cf. section 34 of the executive order on the cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products.

Contract acceptors are to be listed by name and address. If several activities are carried out at several sites of the same company, all relevant addresses of contract acceptors 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 for import and production of cannabis primary products and production of cannabis intermediate products.
- Authorisation to manufacture or import medicines and intermediate products
- Authorisation for wholesale distribution of medicinal products within the EU/EEA.

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, whereas a company with an authorisation for wholesale distribution of medicinal products within the EU/EEA may solely store and release cannabis intermediate products. All other activities require a licence to produce cannabis intermediate products.

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 for analysis 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 intermediate product manufacturer’s licence, the contract acceptor must be stated in Annex 2, and the following documents must be submitted with the application:

- Valid licence(s) 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 subject to which the contract acceptor's licence was granted, e.g. that the company producing cannabis primary products complies with the requirements of the executive order on the cultivation, production and distribution of cannabis bulk and production of cannabis primary products.

- 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 intermediate product 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 approval of a new competent person on the intermediate product 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

Annex 4 is only relevant for companies producing cannabis primary products under Annex 1, Part 2.

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

Annex 6 is only relevant for companies producing cannabis primary products under Annex 1, Part 2.

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 intermediate product 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 regarding Annex 3

3.2 Variation application

When an application to change an existing intermediate product 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 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 authorised 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 an intermediate product 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 intermediate products subject to the executive order on the import of cannabis primary products and production of cannabis intermediate products and/or responsibility for cannabis primary products subject to the executive order on the cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products, the company must continue to hold an intermediate product manufacturer's licence.

The termination of an intermediate product 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. Sections 34 and 35 of the executive order on the import of cannabis primary products and production of cannabis intermediate products as well as sections 27 and

32 of the executive order on the cultivation, processing and distribution of medicinal cannabis and production of cannabis primary products specify for how long reference samples and batch documentation for the different products should be kept.

A company that wishes to terminate its intermediate product manufacturer's licence but remains 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 intermediate product 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 remains 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 intermediate product manufacturer's licence.