Holst, Newsletter

Licence to import, develop and cultivate cannabis

The Danish medicinal cannabis pilot programme runs until 31 December 2021. The programme entails that licences can be issued for the import of cannabis for Danish patients, and companies may apply for a license to cultivate, produce and distribute medicinal cannabis in Denmark. In parallel to the pilot programme, a development scheme has been introduced making it possible to apply for a cannabis cultivation and handling licence with a longterm view to producing cannabis suitable for medicinal use.

The market for medicinal cannabis is developing rapidly, but which type of licence should you apply for if you wish to go with the flow? And which requirements from the Danish Medicines Agency must your company comply with?

Which licence should you apply for?

The Danish Medicines Agency is the authority in Denmark competent to process applications. The Danish Medicines Agency can issue different types of licences:

Licence to produce cannabis bulk

If your company wants to cultivate cannabis and produce cannabis bulk, you must apply for a license to produce cannabis bulk (i.e. processed cannabis ready for further processing).

Licence to produce cannabis intermediate products

If your company wants to import cannabis for the pilot programme or to produce intermediate or primary products, you must apply for a licence to produce cannabis intermediate products. Cannabis primary products and intermediate products are finished cannabis products that are imported into or produced in Denmark in order to produce an end-product which may be dispensed to a specific patient.

Companies licenced to produce cannabis intermediate products may apply for having a product admitted on the Danish Medicines Agency's list of products admitted for the pilot programme. Once specific product details have been disclosed to the Danish Medicines Agency – among others product price – the products will be available for prescription by Danish doctors.

Licence to cultivate and handle cannabis with a view to producing cannabis suitable for medicinal use

Under the pilot programme, it is possible for companies to apply for a cannabis cultivation and handling licence with a view to producing cannabis suitable for medicinal use. Cannabis cultivated under the development scheme cannot be used in the pilot programme, however, may solely be handled for the purpose of developing the product with a view to achieving such quality that it may be applied in the pilot programme.

Authorisation to handle euphoriant substances

Apart from the above licenses, the company must also apply for an authorisation to handle euphoriant substances; such is also issued by the Danish Medicines Agency.

Which requirements must your company comply with?

The requirements imposed on your company will depend on the activity, your company wants to engage in. Hence, the requirements for producing cannabis bulk or cannabis intermediate products are stricter than the requirements provided

if your company solely attends at development or test level and in the longer run wants to obtain a license for cultivating and handling cannabis with a view to developing medicinal cannabis.

Licences to produce cannabis bulk and intermediate products

If your company wants to obtain a licence for the production of cannabis bulk or cannabis intermediate products, you must fill in an application form from the Danish Medicines Agency and submit it together with relevant annexes. The application form for cannabis bulk is accessed through this link and the application form for cannabis intermediate products is accessed through this link.

The application form shall be accompanied by a Site Master File, which, among others, contains detailed information on the activities that your company wishes to engage in, including a detailed description of your company's quality policies, quality controls and activities performed. The file must also contain plan drawings and descriptions of your business premises and equipment, procedures for release, cleaning, handling of complaints and cancellations, and description of self-inspections, contact information and an organisation chart of your company.

In respect of both applications, it is also important that your company states a specific competent person who is related to the company either as a permanent employee or who in another way has concluded an agreement with the company. Furthermore, your company must submit documentation of relevant educational background and practical experience of the competent person.

The Danish Medicines Agency must also be notified about an appointed safety responsible person and the company's responsible manager. If the company produces cannabis primary products, such persons must give consent that the Danish Medicines Agency may obtain personal data on them from the Danish National Police.

Upon submission of application to the Danish Medicines Agency, your company must be prepared for an inspection, as the Agency decides whether to inspect the applying company prior to issuing any licence. In addition, the Danish Medicines Agency supervises that companies having obtained a licence, comply with the requirements set out by the Danish Medicines Agency and with the company's own procedures.

If your company wants to cultivate cannabis products, you must in addition to the above comply with the Danish code of good agricultural practices ("GACP"), which determines guidelines for cultivation, harvesting and other subsequent handling and storage of the plant matter.

If your company wants to produce cannabis products, you must also comply with the Danish code of good manufacturing practices ("GMP").

Licence to cultivate cannabis under the development scheme

If your company solely is engaged in the development or test scheme and wants to develop medicinal cannabis which is not yet to be dispensed to patients, you must apply for a licence to cultivate cannabis under the development scheme. The application form for licences under the development scheme is accessed through this link.

In addition to the application form, your company must submit a project description to the Danish Medicines Agency describing plans for cultivation and development of cannabis with a view to obtaining such quality that it may be applied under the pilot programme. In addition, the project description must include a presentation of your company's quality assurance system, company staff, buildings, facilities and equipment of your company, the process for cultivation, harvesting, processing, etc., and there must be a procedure on how an account will be kept on the cannabis production.

Furthermore, it is a condition for issuing any licence that the Danish Agricultural Agency does not object to the agricultural conditions in the company, as well as it is a condition that the Danish National Police - on the grounds of the applicant's personal data - is not hesitant in accommodating the application.

As a rule, companies applying for a licence to cultivate and handle cannabis with a view to developing medicinal cannabis are not inspected in connection with processing the application. However, as a company you must expect that the Danish Medicines Agency will visit you for inspection at a later time.

Can we assist you?

Our specialists are ready to assist if you wish to learn more or need sparring when applying for a license to import, develop or cultivate medicinal cannabis.

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