

# How to obtain Danish licenses for medicinal cannabis

The Danish Medicines Agency is granting licenses for cultivating, manufacturing, and distributing medical cannabis as the four-year medicinal cannabis pilot programme was established on 1 January 2018.



## A license for each process

In order to cultivate cannabis bulk, manufacture primary and intermediate products, and to distribute the products in Denmark, it is necessary to obtain separate licenses for each process. Furthermore, the manufacturer may distribute the cannabis products when the products have been admitted to the list published by the Danish Medicines Agency. The list allows everyone to see which cannabis products are comprised by the pilot programme. The list shows which products that lawfully may be prescribed by doctors and lawfully dispensed by pharmacies in Denmark.

The executive order applies to cultivating cannabis for medical use in Denmark. However, there are different rules applicable to medical cannabis production in Denmark. The executive order establishes that manufacturing of a cannabis intermediate product must comply with the Act on the medicinal cannabis pilot programme.

Read more about the rules on medical cannabis production in Denmark

## License to cultivate cannabis

The executive order on the cultivation, manufacturing, and distribution of cannabis bulk, and manufacturing of cannabis primary products allows cultivation of cannabis in Denmark. Furthermore, the executive order makes it possible to apply for a cannabis cultivation license only for medical use. The manufacturers can now choose to cultivate, manufacture, and distribute medical cannabis. Before the provisions in the executive order commenced, it was not allowed to cultivate cannabis bulk with an intent to distribute it to pharmacies.

## License to manufacture cannabis

In order to manufacture cannabis primary and intermediate products, a manufacturer must obtain a license. A license to import and manufacture cannabis products can only be issued by the Danish Medicines Agency. A manufacturer does not need to apply for a cultivation license if the manufacturer prefers to acquire primary products from another party.

## License to distribute cannabis

In order to distribute cannabis primary products that are cultivated and manufactured in Denmark, the product must be admitted to the Danish Medicines Agency's list of cannabis intermediate products and cannabis primary products. However, it should be noted that cannabis intermediate products are distributable, as long as they comply with the Danish Medicines Act and the stipulations established in accordance with the executive order on euphoriant substances. The manufacturer of cannabis intermediate products can only distribute cannabis intermediate products to pharmacies, hospital pharmacies, and manufacturers with a license to distribute drugs. In addition, cannabis intermediate products are not allowed to be distributed to manufacturers and persons outside of Denmark.



### How to export medical cannabis

The Danish Medicines Agency is granting authorisations to companies to export medical cannabis after the introduction of new legislation.

The Danish Medicines Agency's list allows everyone to see which cannabis products are comprised by the pilot programme. Additionally, the list shows which products that lawfully may be prescribed by doctors and lawfully dispensed by pharmacies in Denmark. When a cannabis intermediate product is admitted to the list, it can be prescribed by doctors and dispensed by pharmacies in accordance with the pilot programme.



## **The Danish medicinal cannabis pilot programme**

The Danish four-year medical cannabis pilot programme along with additional regulations have opened the markets for cultivation, manufacturing and distribution of medical cannabis in Denmark and created new business opportunities for companies.

## **How can we help?**

NJORD's lawyers assist throughout the entire process. Furthermore, we advise you on, which licenses for medicinal cannabis that are necessary. Additionally, we also assist with the application process. We have all ready assisted clients to successfully start their operations under the pilot programme. Contact our cannabis lawyers, Partner Jeppe Brogaard Clausen and Assistant Attorney Heikki Selin, if you want to know more about how to get started.

## **Relevant provisions**

- "The Act on the medicinal cannabis pilot programme" (Act no. 1668 of 26 December 2017)
- "The executive order on the cultivation manufacturing, and distribution of cannabis bulk and manufacturing of cannabis primary products" (Executive order no. 943 of 28 June 2018)
- "The executive order on euphoriant substances" (Executive order no. 557 of 31 May 2011)



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