

## Latest updates regarding medical cannabis

The legal reform in the Danish medicinal field culminated in 2018 to the point that the cultivation of cannabis was allowed for medicinal purposes in Denmark. Two distinct schemes were established and in January 2019 new legislation introduced the possibility to grant authorisation to export Danish medicinal cannabis products.



This month, the Danish Health Minister Magnus Heunicke expressed his opinion that the pilot scheme should be extended for a few more years in order to maintain the development and to secure a proper foundation for the assessment, whether the reform should be made permanent. Even though the launch of the pilot scheme has mainly gone as planned, some issues still remain unclear. However, the interest in entering the medicinal cannabis industry is growing. For that reason, a group of doctors and researchers from the university hospitals across the country have joined their forces to find constructive solutions to overcome the deficiencies they find in the scheme.

Now, let's take a look back on how the reform has influenced the industry and the status of the current situation in the field.

### Recalling the current scheme

To avoid confusion, it is reasonable to take a look at the basics first - there are two distinct schemes concerning the field of medicinal cannabis that run parallel to each other:

1. the special development scheme, and
2. the pilot scheme

As the two established schemes allow entirely different activities, it is essential to understand which one of the schemes is discussed. Therefore, businesses should carefully assess which scheme they wish to apply under. NJORD will provide consultancy services to our clients from the very beginning of the process and assist companies in determining their strategy, and which scheme would serve their goals in the best possible way.

In short, under the development scheme, a licensee can grow cannabis in Denmark to develop cannabis for medicinal use after which they may apply for permission for the growing and handling of cannabis for medicinal purposes. The export of medicinal cannabis produced under the development scheme is only permitted for analysis for which a company must obtain a license for "export for analysis". In other words, this scheme does not yet allow an undertaking to conduct business in this sector.

Under the pilot scheme, it is actually possible to conduct business in the industry. First, the Danish authorities allowed the import of medicinal cannabis products to Denmark. Later, it became possible to apply for a license under the pilot scheme to grow cannabis in Denmark for medicinal purposes. The authorisation to export under the pilot scheme concerns cannabis bulk and Danish-grown primary products. The authorisation under the pilot scheme is made conditional upon the company having previously obtained permission from the Danish Medicines Agency to produce cannabis products.

### Danish-grown cannabis products

"Why does this matter?" might be the first question one may have.

Under the two distinct medicinal cannabis schemes, there is also a distinction between Danish medicinal cannabis products and imported medicinal cannabis products. The pilot scheme recognizes two types of medicinal cannabis products: Danish-grown or Danish-produced medicinal cannabis product and imported medicinal cannabis products. In order to interpret the legislation under the medicinal cannabis pilot scheme correctly, it is necessary to understand what is considered a Danish-grown or Danish-produced product.

The most recently introduced legislation allows companies to export Danish-grown cannabis primary products. A cannabis primary product is defined as a finished cannabis product imported from another country under the pilot scheme. According to the Danish Medicines Agency, the term also covers Danish-grown cannabis packed in consumer-ready packs from cannabis bulk. But there is a notable matter: only the Danish-grown primary products may be exported.

Substantially different rules apply to domestic cannabis products. Therefore, it is essential to distinguish between when cannabis primary products and cannabis intermediate products are based on imported products, and when such products are based on Danish-grown cannabis. Accordingly, the imported cannabis primary product cannot be exported regardless that it is produced from Danish-grown cannabis bulk. If a product based on Danish-grown cannabis bulk has been processed outside of Denmark and is imported to Denmark, it cannot be exported yet again - neither as a cannabis primary product nor as a cannabis intermediate product.

To conclude on the above: the entire process of producing cannabis primary products must take place in Denmark in order to qualify as a Danish-grown primary product that can be exported after obtaining a proper license. The exporter of Danish-grown and Danish-produced medicinal cannabis products should also be aware of the legislation and mandatory licenses required in the country of import.

### The current situation on the field

The Danish Medicines Agency issues a license when a company has satisfied all the requirements. The license ensures that companies producing medicinal cannabis products comply with national rules governing the industry.

Below are the currently issued pilot scheme licensees on the Danish market. The list has been retrieved from the Danish Medicines Agency's webpage.

| Name                      | Type of permission                                 | Number of locations | Date of pe |
|---------------------------|--|---------------------|------------|
| Schroll Medical ApS       | Authorisation to manufacture cannabis bulk         | 1                   | 29-10-2019 |
| Schroll Medical ApS       | Authorisation to manufacture cannabis intermediate | 1                   | 29-10-2019 |
| Canopy Growth Denmark ApS | Authorisation to manufacture cannabis bulk         | 1                   | 30-10-2019 |
|                           | Authorisation to manufacture cannabis intermediate |                     |            |

If a licensed company producing cannabis intermediate products applies to have its products admitted for sale at Danish pharmacies, these products must be admitted to the Danish Medicines Agency's list. Below is the most recent list of medicinal cannabis products published by the Danish Medicines Agency.

| Name                   | Amount of THC        | Amount of CBD       | Product form                  |
|------------------------|----------------------|---------------------|-------------------------------|
| CBD Capsules Stenocare | Less than 1 mg       | 10 mg               | Capsules, hard                |
| Bedica CannGros        | 140 mg / g           | Less than 10 mg / g | Herbal tea / inhalation steam |
| 1:1 Drops Stenocare    | Approx. 12.5 mg / ml | 12.5 mg / ml        | Oral solution                 |
| Bediol "CannGros"      | 63 mg / g            | 80 mg / g           | Herbal tea / inhalation steam |
| Bedrocan "CannGros"    | 220 mg / g           | Less than 10 mg / g | Herbal tea / inhalation steam |
| CBD Drops Stenocare    | Less than 2 mg / ml  | 25 mg / ml          | Oral solution                 |
| THC Drops Stenocare    | 25 mg / ml           | Less than 2 mg / ml | Oral solution                 |

## NJORD and the legal field of medicinal cannabis

We at NJORD provide direct advice in the form of effective solutions. We offer advice in more than 30 areas of expertise. We are able to assist throughout the entire process, from establishing your business and obtaining licenses to developing products and procedures. NJORD's cannabis lawyers have already assisted several clients successfully in starting their operations under the medicinal cannabis pilot scheme in Denmark. Contact our cannabis lawyer Partner Jeppe Brogaard Clausen.

Read more about medicinal cannabis:

The Danish medicinal cannabis programme  
How to obtain Danish licenses for medicinal cannabis



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