DENMARK

I. Introduction

1. Identify the geographic scope and limits of your answers to the questions below.

Denmark.

II. Legislation

2. Please provide links to applicable statutes and regulations.

Act no. 1668/2017 on the Medicinal Cannabis Pilot Programme, as amended

Executive Order no. 695/2019 on cultivation, manufacturing and distribution of cannabis bulk and manufacturing of cannabis primary products, as amended

Executive Order no. 694/2019 on import of cannabis primary products and manufacturing of cannabis intermediate products, as amended

Executive Order no. 1334/2019 on euphoriant substances, as amended

In addition to the aforesaid legislation, the Danish Medicines Agency (the Authority) has published several guidelines covering specific topics under the Programme and development scheme. The said guidelines are available (in Danish only) on the website of the Agency.

A. Is there any pending legislation that could materially alter applicable statutes or regulations?

On January 1, 2018, a four-year medicinal cannabis pilot program (the Programme) was introduced. The Programme is governed by the Danish Act no. 1668/2017 on the Medicinal Cannabis Pilot Programme, as amended (the Act). Parallel to the Programme, a four-year development scheme was also introduced. According to the development scheme, the Authority authorizes research and development activities in terms of cultivating and handling cannabis, which may form part of the Programme at a later stage. The Programme will be evaluated throughout its duration to determine whether it should be extended or made permanent.

Expectations are that the Danish medicinal cannabis industry will grow and evolve. At this point, however, we are not aware of any draft regulations and, accordingly, do not expect any immediate legal changes.

B. Is there any proposed legislation that could materially alter applicable statutes or regulations?

No legislation has been proposed that could materially alter applicable statutes or regulations.

3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?

The cannabis laws in our jurisdiction is pretty well settled, though we are still within the four-year pilot Programme.

III. General information (e.g., governing bodies, licenses, import/export)

4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?

The governing and competent national authority for implementing the Programme is the Authority, which is an agency under the auspices of the Health Ministry.

The Authority has powers to draft and oversee the implementation of the legislation, i.e. granting authorizations for cultivation, import, production and export of cannabis primary products and production of cannabis intermediate products as well as research and development activities concerning cannabis cultivation and handling.

5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

Under the Programme, the following activities may be authorized:

- Import, production and export of cannabis primary products and production of cannabis intermediate products
- Cannabis cultivation for medicinal use and producing cannabis bulk and cannabis primary products from Danish-grown cannabis
- Cannabis cultivation and handling with a view to producing at a later stage cannabis suitable for medicinal use according to the Programme (includes import, receipt, cultivation, possession, producing preparations for analyses, distribution, export, etc.)

All of the above-mentioned activities require authorization.

6. What sales or use is allowed in your jurisdiction? E.g., edibles, vaping, tinctures, food additives, etc.

Cannabis for medicinal use is allowed in our jurisdiction: Any medicinal cannabis product that is to be comprised by the Programme must be admitted to a list that is published on the website of the Authority. For more information, please see this page on Admission of products to the Programme.

A. Are the rules different for medical vs. adult recreational use?

The rules for medicinal vs. adult recreational use differ as cannabis for recreational use is not permitted in Denmark.

B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.

In Denmark, the retail sale of medicinal cannabis is restricted to specific retail channels. Accordingly, medicinal cannabis may only be dispensed by a pharmacy based on a doctor's prescription.

C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?

No zoning restrictions apply, please see above under 6.a.

7. What import and export is allowed in your jurisdiction?

Import allowed into Denmark:
A company intending to import cannabis primary products must obtain authorization to manufacture cannabis intermediate products. It is not possible, by itself, to distribute imported cannabis primary products. Furthermore, it is not possible to import cannabis bulk with a view to producing products to be included in the Programme.

Export allowed from Denmark:
Export activities relating to cannabis bulk or primary products must be in accordance with the requirements laid down in Chapter 8 of Executive Order no. 695/2019. Cannabis bulk or primary products must be exported to countries only which permit import of medicinal cannabis. The company in the import country must have the necessary local permits in place to handle the cannabis bulk or primary products according to local laws.

The export of medicinal cannabis under the development scheme is permitted only for analysis purposes. Any export of euphoriant substances, cannabis included, is subject to import and export certificates, and the company must have been granted an authorization pursuant to the rules on euphoriant substances, which covers export for analysis purposes.

A. Are there restrictions in relation to the countries of origin, i.e. which countries of origin are permitted?

Denmark has restrictions as to the countries of origin of certain cannabis products. Import of cannabis primary products must be in accordance with Chapter 5 of Executive Order no. 694/2019 on import of cannabis primary products. The cannabis intermediate products manufacturer must e.g. ensure that the cannabis used in the primary product is grown and obtained in accordance with the 1961 United Nations Single Convention on Narcotic Drugs and is cultivated in a country which is party to the Convention.

B. Please describe restrictions on the import of cannabis seeds.

Seeds from the cannabis plant are not regulated as euphoric substances. An import certificate is therefore not required to import seeds. However, companies importing seeds must ensure that the seeds are free from quarantine pests, but it is our understanding that no further phytosanitary requirements are imposed on the import of cannabis seeds. The Danish Agricultural Agency is the authority responsible for the rules on phytosanitary requirements.

8. Does your region distinguish between different types of cannabis products? (E.g., high or low concentrations of THC.)

A. If so, what distinctions exist?

B. If so, briefly describe the differences.

C. Identify any related laws that should be considered when answering this question.

As of July 1, 2018, the tetrahydrocannabinol (THC) limit was changed in the executive order on euphoriant substances. As a consequence, cannabis products with a content of 0.2% THC or less are no longer subject to the rules on euphoric substances in Denmark. Hence, it is possible to produce and sell cannabis-based products containing up to 0.2% THC without contravening the executive order on euphoriant substances.

9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?

It is possible to market cannabidiol (CBD) products with a THC content below 0.2% in Denmark without contravening the executive order on euphoriant substances. CBD products may, however, be covered by the rules on medicinal products, food products, cosmetic products, etc., and such rules must still be observed.

Hemp may be used in foods, including in food supplements. However, the EU novel food legislation must be respected. The following products of hemp are not considered novel food: Hemp seeds, seed flour, protein powder from seeds and seed oil from varieties of the hemp plant (cannabis sativa L.) listed in the EU Community catalogue of varieties, which are free from or contain low levels of THC. Other parts of the hemp plant, including extracts of hemp products, are considered novel food as a history of consumption has not been demonstrated. This applies to both the extracts themselves and any products to which they are added as an ingredient, such as hemp seed oil. The Danish Veterinary and Food Administration (DVFA) therefore considers such products as novel foods, and the placing on the market requires prior EU risk assessment and authorization under the EU novel food regulation.

A process is ongoing in the EU to identify whether other parts of the hemp plant (leaves, flowers, extracts of different plant parts, etc.) have been lawfully placed on the market as a food in the EU before 15 May 1997. The DVFA recommends contacting the Danish Medicines Agency prior to notification of a food supplement containing CBD in order to clarify that the product is not a medicinal product.

IV. Patients and prescriptions

10. What specific medical conditions, if any, are recognized for treatment with cannabis?

The Authority assesses that medicinal cannabis should be considered only for the following indications supported by some evidence that medicinal cannabis could have an effect. The relevant indications are:

- Painful spasms caused by multiple sclerosis;
- Painful spasms caused by spinal cord damage;
- Nausea after chemotherapy;
- Neuropathic pain, i.e., pain due to a disease of the brain, spinal cord or nerves.

The Danish Medicines Agency has selected the above indications after studying and assessing the relevant scientific studies conducted worldwide to investigate the effect of medicinal cannabis. According to the Authority, the specific products comprised by the Programme have not necessarily been investigated. Nor have the possible side effects in the short and long term been sufficiently identified, which is something doctors and patients must be aware of and accept.

11. Is there a licensed practitioner requirement in order to prescribe cannabis for medical purposes?

All doctors are authorized to prescribe the products included in the Programme. They may also prescribe magistral preparations of cannabis, whereas only neurologists are allowed to prescribe the pharmaceutical product Sativex.

12. Are there patient registration or cardholder requirements?

It is our understanding that no mandatory patient registration or cardholder requirements exist. However, a prescription is needed in order to obtain medicinal cannabis. Prescriptions for medicinal cannabis must be registered in the Shared Medicine Card *(in Danish: det Fælles medicinkort (FMK)*) according to Executive Order No. 1615 of 18 December 2018 (in Danish only) concerning access to and registration of drugs and information on vaccines. The Shared Medicine Card works as a national prescription server.

V. Special requirements

13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?

In Denmark, requirements of traceability and accounting rules are in place.

Companies with an authorization to grow cannabis must, in their accounts, be able to account for the area where the cannabis is grown. This includes information on how many hectares they have planted and how many hectares they have harvested, as well as the amount of cannabis resulting from the production. This information must be included in the annual reporting of the accounts to the Danish Medicines Agency.

The rules on traceability concern seeds and propagating material. Traceability to the original seed and propagating material from the harvested cannabis must be ensured. This means that varieties of seeds or other propagating material must be traceable to origin, quantities, variety and ownership. The companies should be able to provide this information at all times.

Please see the Danish Medicines Agency's guidelines on traceability and accounting (only in Danish).

14. Are special taxes imposed? On what and when?

N/A

15. Are there any special rules or limitations that apply to the industry? E.g., banking, patent or trademark protection, labeling requirements.

Labeling requirements exist and they are described in Chapter 7 of Act no. 1668/2017 on the Programme.

Moreover, it is illegal to advertise for cannabis products covered by the Programme. This follows from section 57 of the Act. Advertisements are prohibited for cannabis end-products, cannabis intermediate products included on the published list of cannabis intermediate products and cannabis primary products included on the published list of cannabis primary products.

16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?

N/A.

17. Is data collected to determine the social or health impact of the rules in your jurisdictions? E.g.,

A. Impact on use by under age/minors.

Yes, such data is collected by the Crime Prevention Council.

B. Impact on beer, wine and spirit sales.

Not by the government.

C. Tax revenue.

N/A.

D. Impact on crime, including drug and alcohol addiction.

Yes, by the Crime Prevention Council.

VI. Risks and enforcement

18. What are the most critical issues currently facing the industry in your jurisdiction?

There has been a great deal of debate about the Programme. The debate includes criticism by health professionals of the premises for the implementation and evaluation of the Programme, which are claimed not to be sufficiently clear. The Programme is, for example, accused of not giving the patients necessary access to medicinal cannabis contrary to the political intentions behind the Programme. This is due to the fact that doctors - as part of the Programme - must take full responsibility for the product they prescribe and determine the dose for the individual patient. Consequently, only a few doctors prescribe medicinal cannabis, although the demand from patients is great. It will be interesting to see whether the controversies will affect the decision to extend the Programme for additional years

19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.

A rather new four-year Programme on medicinal cannabis has been implemented. The legislation may be revised in light of the coming evaluation of the Programme. Cannabis for recreational use is illegal.

A. Does enforcement differ based on quantity?

Only possession of medicinal cannabis which has been prescribed by a doctor is allowed.

For all other types of cannabis, the enforcement does not differ based on quantity. Possession of cannabis is prohibited no matter the amount, and it is also prohibited to buy, sell, receive, supply and produce cannabis.

B. Does enforcement differ based on product type?

Cannabis for recreational use is illegal, i.e. possession of cannabis is prohibited no matter the amount, and it is also prohibited to buy, sell, receive, supply and produce cannabis. Only possession of medicinal cannabis which has been prescribed by a doctor is allowed.

VII. Your practice and useful links

20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does your firm have to grow its cannabis practice?

Bech-Bruun's life sciences team offers our clients legal and strategic expert advice in the areas where the life sciences (including the medicinal cannabis sector) industry and investors need it. Our size and industry experience allow us to provide legal advice for many Danish and non-Danish pharmaceutical and biotech enterprises, medical device companies and venture funds and others who want to invest in or acquire life sciences enterprises. Our passion, expertise, availability and number of dedicated life sciences lawyers ensure our clients a technological, legal and commercial understanding that is unique within the Danish law industry.

We know the industry, including the political and administrative decision-making levels, which allows us to optimize your position and ensure you the best possible solution for a technological, legal or commercial issue.

Our services within the medicinal cannabis sector include, among other things:

- Acquisition of green houses
- Corporate assistance, including drafting shareholders agreements, letters of intent – joint ventures etc.
- Building permits
- Leasing contracts
- Management and technical agreements
- Assistance on the Danish Cannabis Pilot Programme and the development scheme, including on
    - Project descriptions
    - Application for licences
    - Import/export matters
    - Competent person (QP)

21. Please provide links to any firm website, blogs, reputable trade publications, or attorneys that would help others understand the state of the law in your jurisdictions.

Main Site for Bech-Bruun's Life Sciences Team

A. Are there any relevant trade organizations?

N/A

B. Are there any relevant lobbying organizations?

Cannabis Danmark

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