

Danish Medicinal Cannabis Pilot Programme

2018-2021

Anna Skat Nielsen
Head of Division
October 2018

THE SITUATION IN DENMARK

2016: A lot of interest and questions about medicinal cannabis in Denmark from:

- Patients and interest groups
- Politicians

→ November 2016: Political agreement: More ways to prescribe medicinal cannabis

→ October 2017: Act on a Medicinal Cannabis Pilot Project put forward

→ 1 January 2018: Medicinal Cannabis Pilot Project Programme, 4 years

THE DANISH PILOT PROGRAMME

- Not legalisation of cannabis in general
- The purpose of the pilot programme is to offer patients a lawful way of testing treatment with medicinal cannabis if they have not benefitted from authorised medicines.

THE DANISH PILOT PROGRAMME - PRESCRIPTION

Medicinal cannabis can be prescribed by any doctor.

- The responsibility for medical treatment of a patient lies with the treating doctor at any time
- Relevant authorised marketed medicines should be tried prior to medical cannabis treatment
- Patient must be involved actively

THE DANISH PILOT PROGRAMME – GUIDELINE TO DOCTORS

Guideline for doctors to consult if they are considering to prescribe medicinal cannabis

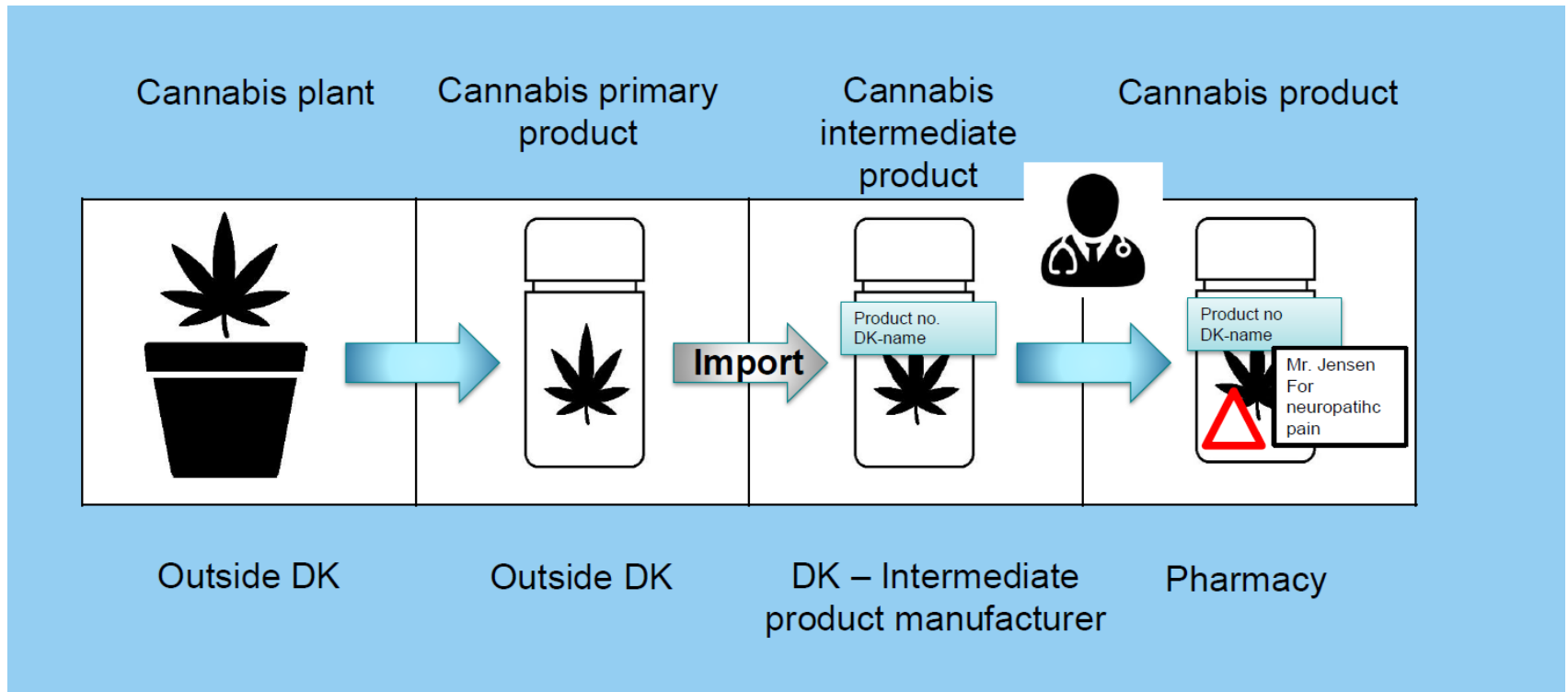
- Danish Medicines Agency assesses that medicinal cannabis should be considered only for the following indications that are supported by some evidence that medicinal cannabis could have an effect:
 - Painful spasms caused by multiple sclerosis
 - Painful spasms caused by spinal cord damage
 - Nausea after chemotherapy
 - Neuropathic pain, i.e. pain due to a disease of the brain, spinal cord or nerves.

But doctors may prescribe for other indications.

THE DANISH PILOT PROGRAMME - IMPORT

The cannabis products can be imported or produced in Denmark

IMPORT



THE DANISH PILOT PROGRAMME - IMPORT

Import, production and export of cannabis primary products and production of cannabis intermediate products are all activities appearing on the authorisation to produce cannabis intermediate products

- 3 companies have applied authorisation as cannabis intermediate product manufacturers

PRODUCTS IN THE PILOT PROGRAMME- PRODUCTS

The list of admitted cannabis products allows doctors to gain an overview of the cannabis intermediate products comprised by the programme.

This list describes the strength, product form and pack size of each product.

PRODUCTS IN THE PILOT PROGRAMME - PRODUCTS

The following products can be prescribed (8 October 2018):

- **Bedrocan CannGros**
 - Product: Tea
 - Strength: 220 mg/g THC
- **Bediol Cannngros**
 - Product: Tea
 - Strength: 63 mg/g THC + 80 mg/g CBD
- **1:1 DROPS STENOCARE**
 - Product: Oil
 - Strength: 12,5 mg/g THC + 12,5 mg/g CBD
- **CBD DROPS STENOCARE**
 - Product: Oil
 - Strength: 25 mg/g CBD
- **THC DROPS STENOCARE**
 - Product: Oil
 - Strength: 25 mg/g THC

THE DANISH PILOT PROGRAMME - PRODUCTION

Medicinal cannabis produced in Denmark by using cannabis plants cultivated in Denmark

1 January 2018: Development scheme for the cultivation of cannabis in Denmark

1 July 2018 legislation on:

- Cultivation of cannabis for medicinal use in Denmark or export
- Production of Danish cannabis product

THE DANISH PILOT PROGRAMME - PRODUCTION

The development scheme runs in parallel with the four-year medicinal cannabis pilot programme.

The Danish Medicines Agency issues cannabis cultivation and production licences with the purpose of supplying cannabis intermediate products to the pilot programme.

THE DANISH PILOT PROGRAMME - PRODUCTION

Companies to have (as at 8 October 2018) applied for permission to cultivate and handle cannabis with the intention of developing cannabis for medicinal use:

- 20 companies have permission
- 7 companies are in process
- 2 companies have not been giving permission

THE DANISH PILOT PROGRAMME – INFORMATION TO DOCTORS ON PRODUCTS

Information about the cannabis products can be found:

- on the list of cannabis products (website of the Danish Medicines Agency)
 - The list describes the strength, product form and pack size
- in the product sheets (website of The Danish Medicines Agency)
 - Completed by the company and contains information about the name of the cannabis product, declaration, product form, pack size, method of administration, including dosing recommendations, method of preparation, storage conditions and product number
- in the local medical systems
 - Vary between the systems used by the doctors. Information about name, strength, pack size, route of administration and the indications covered by the Danish Medicines Agency's guidelines for doctors on the medicinal cannabis pilot programme
- on medicinpriser.dk (medicine prices)

THE DANISH PILOT PROGRAMME - ADVERTISING

Advertising is not allowed for the cannabis products.

In this context, advertising means any presentation of the product, i.e. product designation, the way it is displayed, product recommendations on packaging, product description supplied with the product, mention of the product on the company website, etc.

THE DANISH PILOT PROGRAMME -REIMBURSEMENT

A political agreement has made cannabis products in the pilot programme eligible for reimbursement from 1 January 2019.

- Under the agreement, terminally ill patients will be reimbursed at 100% when buying cannabis products in the pilot programme whereas other patients will be reimbursed at 50% up to an annual reimbursement amount of DKK 10,000.
- Retroactive allowing for reimbursement of cannabis products bought in 2018.
- The reimbursement will be paid on a current basis to terminally ill patients from 1 September 2018 and to other patients from the 1st quarter of 2019.

THE DANISH PILOT PROGRAMME - NUMBERS

- 883 patients have been prescribed medicinal cannabis from 1 January to the end of September
- 202 doctors have prescribed medicinal cannabis from 1 January to the end of September

→ The numbers are still rising

THE DANISH PILOT PROGRAMME – ACCUMULATION OF SCIENTIFIC KNOWLEDGE, FUNDS

The pilot programme is intended to provide a better basis to assess the use of medicinal cannabis at the end of the trial period

- 2 funds (DKK 5 mio. each) to accumulate scientific knowledge
 - 2 projects to increase our knowledge about the use and effect of medicinal cannabis
 - 3 projects to monitor the treatment of patients across therapeutic indications based on registry data and patient interviews

THE DANISH PILOT PROGRAMME - EVALUATION

The Danish Pilot Programme is being monitored

- Half way
- End

Future arrangements → Political decision

Thank you for your attention!

