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Guidelines on project description for an application for a cannabis cultivation and handling licence with a view to producing cannabis for medicinal use

These guidelines describe the requirements for the project description that should be enclosed with an application for a cannabis cultivation and handling licence with a view to producing cannabis for medicinal use.

The project description must include a detailed account of the applicant's plans for cannabis cultivation and production of a consistent and standardised product of the required quality that can form part of the medicinal cannabis pilot programme. The project description must provide evidence that the production will produce cannabis that can form part of the medicinal cannabis pilot programme.

The applicant must aim to produce standardised, consistent and reproducible products so that the content of active substances is the same for every harvest and every manufacturing process and there is full control over all manufacturing activities.

1 Quality assurance

In this part of the project description, the company should describe how it will ensure that the intended cannabis quality is obtained. This could be in the form of a quality manual or the like. The quality manual should describe the procedures and instructions for the applied processes. All processes must be clearly defined and described and must be reviewed regularly. Any non-compliance with these procedures must be documented, the reason for the deviation occurred must be examined, and relevant actions must be taken to avoid that the deviation occurs again.

Moreover, the quality manual should describe how changes to processes and procedures will be handled.

The responsible person in the company must supervise this work. This supervision must be described in the procedures.

2 Staff and qualifications

The persons responsible for the cannabis cultivation and harvest must appear from the product description. This may be illustrated in an organisational chart that also gives an estimate of the number of employees that will be engaged in the cultivation and handling of cannabis. Steps should be taken to ensure that the company has sufficiently qualified and trained staff. The project description should describe how all staff members engaged in cultivation and handling activities are trained in the company's requirements and procedures, and how this will be documented.

The staff must maintain strict personal hygiene and have no open wounds, infections or the like.

3 Buildings and facilities

The area and location of buildings must be described, including a specification of the area expected to be used for cultivation, handling and storage of cannabis. The associated facilities should also be described. Buildings and facilities used for cultivation and drying, if any, must be clean and ventilated, and

temperature, light and humidity must be monitored and controlled. It may be an advantage to use a growth chamber for this purpose. Buildings must be free from insects, rodents and other pests, and the process for ensuring this should appear from the project description.

A description should be made of how the company will ensure that buildings and facilities are only used for the production of cannabis and that the cannabis is not mixed with any other material.

If activities are carried out in leased premises, a contract must be available. The contract must state the name of the landlord, how responsibilities are divided, and whether the landlord can access the premises. It must appear from the project description if leased premises are used.

4 Equipment

Any equipment used for cultivation and handling activities must be described. It must be described how the company will ensure that the equipment is only used for cannabis and that the equipment used is clean and suitable for the purpose, including regular calibration. Equipment made from wood is not suitable for the cultivation and handling of cannabis.

5 Documentation

All documents related to the quality assurance system, including procedures and instructions, must be available to the staff that need to read them. Traceability of documents must be described so that any documentation can be provided when required. It should be documented when the buildings were cleaned and when the staff were trained in working procedures. This could be in the form of a log book.

All processes must be described and documentation for every cultivation/harvest must be available. This includes the date and time of the processes and information about material used.

6 Seeds and reproductive material

The seeds and/or reproductive material used must be described; this includes variety and origin. Traceability to the original seeds and reproductive material from the harvested cannabis must be ensured. It is important that the seeds and reproductive material are suitable for the purpose, including independence, homogeneity, stability and purity.

A description of the variety must be available, supplemented by the relevant DNA profile, if any. Moreover, a chemical profile must be available. The chemical profile must contain values for the content of significant active substances, such as THC and CBD.

The varieties of seeds and other reproductive material must be traceable in relation to origin, quantities, variety and ownership, and documentation for this must be available at all times.

When reviewing the application, the Danish Agricultural Agency will assess whether these matters are sufficiently described and documented.

7 Cultivation

The cannabis cultivation process must be described. Pesticides and plant protection agents must not be used, and mixing with other plant materials should be avoided. Any impurities must be removed.

The selected cultivation medium must be described.

The company must ensure that watering and any fertilisation do not have a negative impact on cultivation. Consequently, it must be free from impurities, such as excrement, heavy metals, pesticides and toxicological impurities.

8 Harvest

The harvest process must be described. Harvest must take place when the plant has obtained the best quality for the intended use. It must be described at what time of the day the harvest is expected to take place, and the plant's expected age at harvest must also be described. Moreover, the description must include information about how mixing with other plant materials will be avoided.

9 Primary processing

Primary processing includes washing, trimming, drying, freezing etc. It must be described how the company will avoid that plant material is exposed to direct sunlight and how the optimal conditions for e.g. drying are to be obtained.

10 Packaging

Packaging of the harvested cannabis must be described. The packaging must be clean and dry, and a label showing the contents must be added to the packaging. The packaging must be stored in a clean, dry area free from insects, rodents and other pests.

11 Storage

Storage of cannabis products must be described. The facilities, who has access to them and how safe accessibility is ensured must also be described. This means safety, alarm system and a description of storage conditions, temperature and humidity.

12 Time frame for achieving the desired product quality

The project description must include expected milestones. This means a plan for cultivation, harvest and primary processing. It must be described when the cannabis products are expected to be ready for the medicinal cannabis pilot programme.

13 Accounts

A procedure for keeping accounts of the cannabis production must be available. On the Danish Medicines Agency's website, you can find guidelines on accounting and annual reporting of euphoriant substances. Accounting and reporting must comply with the requirements in the Danish executive order on euphoriant substances (executive order no. 557 of 31 May 2011, as amended) (in Danish).

The accounts of the cannabis cultivation must be divided into cannabis cultivated for medicinal use and cannabis cultivated for scientific use. The accounts must include information about the area on which cannabis is cultivated, the size of the area sown, and the size of the harvested area. The area must be expressed in hectare. In addition, the accounts should state the quantity of harvested cannabis in kilograms. Any losses during cultivation, both before and after the harvest, must be accounted for.

Moreover, accounts must be kept of cannabis in stock (expressed in grams) and the quantity of cannabis that has been destroyed or lost (grams). The same applies to any inventory shrinkage. If extracts of

cannabis are manufactured, including cannabis resin, accounts must be kept of the quantity of extracts/resin extracted (expressed in grams).

14 Destruction

Destruction of cannabis requires approval by the Danish Medicines Agency subject to section 13 of the Danish executive order on euphoriant substances (executive order no. 557 of 31 May 2011, as amended) (in Danish).

The application form for destruction is available at the Danish Medicines Agency's website.

When authorisation for destruction has been obtained, the material should be sent for incineration. Destruction must be monitored and documented by a note dated and signed by two persons from the cultivation company.

Upon request, the Danish Medicines Agency must be given access to the destruction.

15 Special safety measures

The project description must include a detailed account of any safety measures that will be taken in connection with the cultivation and processing of cannabis.

Special safety measures must be taken. Access to buildings and facilities must be restricted, and it must be ensured that cannabis material is cultivated and stored safely, in safe packaging and inaccessible to unauthorised persons.

In connection with the application, the Danish National Police will assess the commercial value. Thus, personal information about the owner of the company and the responsible manager will be collected.

16 Manufacture for medicinal purposes

Cannabis to be used for the manufacture of marketed medicinal products must comply with the rules governing the manufacture of active substances for medicinal products, see executive order no. 1360 of 18 December 2012 on manufacture, import and distribution of active substances for manufacturing of medicinal products (in Danish). Manufacture of active substances intended for manufacturing of medicinal products (API) also requires registration as a manufacturer of APIs

Cannabis to be used for the manufacture of magistral medicinal products must as a minimum comply with the requirements in the Danish Drug Standards