# Executive Order on cannabis bulk and cannabis primary products[1]

Pursuant to sections 5, 6, 7(9), 9(8), 10 and 66(2) of Act No 1668 of 26 December 2017 on a medicinal cannabis pilot programme and on a programme for the cultivation, production, etc. of medicinal cannabis, as amended by Act No 1519 of 18 December 2018, Act No 2392 of 14 December 2021 and Act No 439 of 6 May 2025, the following is laid down:

## Chapter 1

*Scope of the Order*

**Section 1.** This executive order covers the cultivation of cannabis for medicinal use in Denmark and the production of cannabis bulk and cannabis primary products as well as the export of cannabis bulk and cannabis primary products.

**Section 2.** The executive order applies to companies that have received an authorisation from the Danish Medicines Agency to produce cannabis bulk and cannabis primary products under section 9(1) of the Act on the Medicinal Cannabis Programme, and to applicants for such authorisations where this is explicitly stated in the individual provisions.

*(2)* The manufacture of a cannabis intermediate product must comply with the executive order on cannabis intermediate products.

## Chapter 2

*Definitions*

**Section 3.** The following definitions apply for the purposes of this executive order:

1) Mother plant: The name of the cannabis plant that forms the basis for the production of the cannabis drug. The mother plant is defined by its botanical, Latin name, which includes genus, species and author names (*Cannabis sativa* L.).

2) Cannabis drug: The part of the mother plant that is used, e.g. dried flower or leaf. The drug can be whole or fragmented.

3) Herbal preparation: A processed cannabis drug, such as a powdered drug or extract.

4) Excipients: Ingredients that are not active ingredients and are included in the formulation of the finished cannabis bulk or cannabis primary product.

5) Cannabis API: Cannabis, in the form of cannabis drug or herbal preparation, cultivated and processed in an EU/EEA country in accordance with a registration as a manufacturer of active substances, cf. section 50a of the Danish Medicines Act, or a similar registration in another EU/EEA country as covered by Article 46b of Directive 2001/83/EC of the European

[1] A draft of this executive order has been notified in accordance with Directive 2015/1535/EU of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification).

Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

6) Cannabis bulk: Any processed cannabis product, e.g. cannabis drug, extract or other herbal preparation, etc. covered by this executive order, which is not a cannabis primary product or cannabis intermediate product, and which is produced by a company or person with an authorisation pursuant to section 9(1) of the Act on the Medicinal Cannabis Programme for the purpose of further processing or packaging in consumer-ready pack sizes either for the production of a cannabis primary product or for export.

7) Cannabis primary product: A cannabis product covered by the Act on the Medicinal Cannabis Programme that is produced in Denmark in accordance with the rules laid down in this executive order with a view to either being included on the Danish Medicines Agency's list of cannabis intermediate products and cannabis primary products included in the programme, cf. section 7 of the Act on the Medicinal Cannabis Programme, or with a view to export. A cannabis primary product may contain one or more cannabis herbal drugs or one or more herbal preparations as active ingredients. A cannabis primary product may alternatively contain one or more cannabis herbal drugs or one or more herbal preparations as active ingredients. A cannabis primary product is formulated as a pharmaceutical form. The finished primary product is presented in consumer-ready pack sizes.

8) Manufacturer: A company with an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme to produce cannabis bulk and cannabis primary products.

9) Cultivation of cannabis: All processes related to growing, harvesting, drying and grinding of cannabis.

10) Production activities: All cultivation and processing activities, packaging operations, labelling, quality control, storage and release of cannabis bulk and cannabis primary products.

11) Good Manufacturing Practice (GMP): The part of quality assurance ensuring that cannabis bulk and cannabis primary products are produced and controlled in accordance with the quality requirements applicable to the cannabis products in relation to their intended use.

12) Good Agricultural and Collection Practices (GACP): A set of guidelines that regulate the cultivation, harvesting and other subsequent handling and storage of the plant material to ensure consistent and sufficient quality of the plant material.

13) Incoming inspection: Physical receipt and inspection of cannabis plant parts, seeds, cannabis products, cannabis API, excipients, packaging, etc. and inspection of the accompanying documentation required under this executive order.

14) Qualified person: A person appointed by the company to ensure that the company complies with applicable regulations for the manufacture and release of cannabis bulk and cannabis primary products and who fulfils the minimum scientific and technical qualification requirements set out in this executive order.

15) Quality assurance: All measures undertaken to ensure that cannabis API, cannabis bulk and a cannabis primary product is of the quality required in relation to its intended use.

16) Quality control: Procedures and documentation for sampling, inspection and control of received cannabis API, cannabis bulk and cannabis primary products, control and testing of packaging material and release, ensuring that cannabis bulk and cannabis primary

products are not released until their quality is documented as satisfactory in relation to both internal requirements and this executive order.

17) Release: The activity where the qualified person certifies that a batch of the cannabis bulk or cannabis primary product has been produced in accordance with all relevant procedures and that this has the necessary quality to be further processed, distributed or used for the manufacture of cannabis primary products or cannabis intermediate products.

18) Reference test: A pack or sample of each batch of cannabis API, cannabis bulk, cannabis primary product, excipients, packaging, etc. that is stored for the purpose of subsequently documenting the product's contents, packaging, labelling, etc.

19) Site master file: A part of the quality system that fulfils the criteria for a site master file described by the European Commission in "Rules governing medicinal products in the European Community, Volume 4" and describes the company's quality policies, quality control and the activities performed on the site. A site master file also contains contact information for the company, release procedures, organisation charts, floor plans and a description of premises and equipment, cleaning procedures, the documentation system, handling of complaints and recalls, and a description of self-inspections and the responsibilities of the qualified person.

20) Batch: A defined quantity of cannabis API, cannabis bulk or cannabis primary products produced in a single process and appearing homogeneous.

21) Batch documentation: Documentation related to the manufacturing of cannabis bulk and cannabis primary products carried out for each individual batch.

22) Distribution of cannabis bulk and cannabis primary products: Storage of released cannabis bulk and cannabis primary products and delivery of cannabis bulk and cannabis primary products to companies with authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme.

23) Counterfeit cannabis bulk or cannabis primary product: Any cannabis bulk or cannabis primary product with a false description of:

a) its identity, including its packaging and labelling, its name or its composition in terms of any of its constituents, including active ingredients, excipients and the content of those ingredients,

b) its origin, including its manufacturer; or

c) its history, including records and documents relating to the distribution channels used.

24) Pharmaceutical form: Pharmaceutical form as specified in the European Directorate for the Quality of Medicines and HealthCare's (EDQM) database of standard terms or in the Danish Drug Standards (DLS).

25) Cannabis plant parts: Living plant parts of the mother plant Cannabis sativa L., specifically shoots, stems, material produced by micropropagation and cuttings.

26) Cannabis product: A collective term for cannabis bulk and cannabis primary products.

27) Pesticide: Plant protection products covered by Regulation 1107/2009/EC of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (Pesticides Regulation).

Chapter 3

*Authorisations*

**Section 4.** To obtain authorisation to produce cannabis products under section 9(1) of the Act on the Medicinal Cannabis Programme, the applicant must:

1) specify which cannabis products, including product type and pharmaceutical form, are to be produced and the place of production and storage of the cannabis products,

2) have premises and a quality assurance system that fulfil the requirements of this executive order,

3) have a qualified person available who fulfils the requirements of this executive order, and

4) have a safety officer available who fulfils the requirements of this executive order.

*(2)* The applicant must use the Danish Medicines Agency's electronic application form and provide the application with documentation to indicate that this party fulfils the requirements referred to in paragraph 1, points 2 to 4, including a detailed description of the company in the form of a site master file.

**Section 5.** The Danish Medicines Agency may require the applicant to provide additional information about the matters referred to in section 4.

*(2)* If the Danish Medicines Agency requires further information under paragraph 1, the deadlines in section 7 shall be suspended until this information has been provided.

**Section 6.** Before issuing an authorisation to manufacture cannabis products, cf. section 9(1) of the Act on the Medicinal Cannabis Programme, the Danish Medicines Agency may send the application to the Danish Agricultural and Fisheries Agency to obtain an agricultural assessment from the Danish Agricultural and Fisheries Agency if cultivation is included in the application.

**Section 7.** An application for authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme shall be processed within 90 days of submission of a satisfactory application.

*(2)* If the holder of an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme applies for a change to the information stated in the authorisation, the application shall be processed within 30 days. This period can be extended to 90 days in exceptional cases.

**Section 8.** The Danish Medicines Agency will only issue an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme after having ensured through an investigation by its representatives that the information in the application corresponds to the facts.

**Section 9.** The holder of an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme may not change the conditions on which the authorisation was based without the authorisation of the Danish Medicines Agency, see sections 4(1) and 5(1).

Chapter 4

*Requirements for cannabis products*

**Section 10.** Cannabis bulk and cannabis primary product must fulfil the following requirements:

1) It must not be intended to be used for parenteral administration.

2) The composition of the cannabis primary product must be available, including the names, quantities and quality of the active ingredients and any excipients.

3) The quality of the cannabis drug, herbal preparation and cannabis product must be determined, with information on the manufacturing processes and the analytical methods used with associated acceptance criteria (specifications) and shelf life. The analytical methods must be validated and described in sufficient detail with requirements for the suitability of the method so that they can be transferred and repeated in control analyses performed at the request of the Danish Medicines Agency. If an analytical method described in the European Pharmacopoeia (Ph. Eur.), cf. the Danish Drug Standards, is used, reference may be made to this instead.

4) The mother plant used must be determined. If a cultivar of Cannabis sativa L. is used, its name must be specified.

5) If the cannabis product contains an extract of the cannabis drug, information on the extraction solvent used must be provided.

6) A specification must be established for the cannabis drug, and the specification must apply throughout the entire period of use of the cannabis drug. The specification for the cannabis drug must generally comply with the monograph for it in the European Pharmacopoeia (Ph. Eur.), cf. the Danish Drug Standards. If no suitable drug monograph exists in the European Pharmacopoeia (Ph. Eur.), the specification must comply with another national European pharmacopoeia, or an internal specification must be prepared based on the general monographs in the European Pharmacopoeia (Ph. Eur.).

7) If an active ingredient consists of a herbal preparation, a specification must be established for it and the specification must be valid for the entire period of use of the herbal preparation. If no suitable monograph for the herbal preparation exists in the European Pharmacopoeia (Ph. Eur.), cf. the Danish Drug Standards, an internal specification must be prepared based on the general monographs in the European Pharmacopoeia (Ph. Eur.).

8) Specifications must be established for other cannabis products to ensure the quality of the product, and the specifications must apply throughout the product's entire lifetime. Specifications must include requirements for appearance, tests for ID, quantitative determination (assay), degradation products and any other impurities, microbial purity and any residual solvents and drying losses. In addition, the specifications must include tests for the quality of the pharmaceutical form, e.g. mass variation, actual content, disintegration, dissolution, etc.

9) The cannabis drug, herbal preparation and cannabis product must be assayed for potency with regard to the content of THC and CBD and analysed for identification, impurities and any other relevant quality parameters. The THC content must be calculated as total THC, i.e. the sum of THC ((-)-delta-9-trans-tetrahydrocannabinol (dronabinol)) and

THCA ((-)-delta-9-trans-tetrahydrocannabinolic acid). The CBD content must be calculated as total CBD, i.e. the sum of CBD (cannabidiol) and CBDA (cannabidiolic acid). The analytical methods used must, as far as possible, originate from relevant applicable monographs in the European Pharmacopoeia, cf. the Danish Drug Standards, or other European national pharmacopoeia or standards.

10) The cannabis product must be filled into suitable packaging that prevents absorption into and migration from the packaging and protects against light and moisture. The quality of the packaging used must fulfil pharmaceutical or food requirements.

11) Storage time and storage conditions must be set for the cannabis product before, and if applicable, after opening. The specified storage conditions must be indicated in accordance with Annex 1. The specified storage time and storage conditions must be justified by stability studies performed on the cannabis product.

12) The manufacturer must be able to provide certificates of analysis with traceability to the applicable specifications referred to in points 6 and 8.

## Chapter 5

*General requirements for the manufacture of cannabis products*

**Section 11.** A cannabis bulk manufacturer must ensure the following:

1) That cannabis bulk follows the manufacturing processes and complies with the specifications set for it and fulfils the requirements of the executive order.

2) That all manufacturing processes for cannabis bulk are carried out in accordance with good manufacturing practices for medicinal products and intermediate products and in accordance with the authorisation for cultivation and production of cannabis bulk. For cannabis bulk that is processed only by drying, grinding and packaging of the cannabis drug following cultivation and harvesting of the cannabis plant, these manufacturing processes must be carried out in accordance with good manufacturing practice for active substances.

3) That cannabis bulk used as raw material for the production of other cannabis bulk is distributed in accordance with good distribution practice for active substances. The manufacturer of cannabis bulk must verify that manufacturers from whom the manufacturer purchases cannabis bulk comply with good practices for the distribution and manufacture of medicinal products, intermediate products and active substances by conducting audits at the cultivation, manufacturing and distribution sites for cannabis bulk. The manufacturer of cannabis bulk must verify that manufacturers from whom the manufacturer purchases cannabis bulk have the necessary authorisations issued by the Danish Medicines Agency. The manufacturer must verify the authenticity and quality of the cannabis bulk.

4) That the suitability of all raw materials, including cannabis plant parts, seeds, oil, etc. used in the production of cannabis bulk is assessed.

5) That seeds and cannabis plant parts used as raw materials for the cultivation of cannabis comply with Good Agricultural and Collection Practices (GACP), as published by the European Medicines Agency in their Guide to good agricultural and collection practices for medicinal plants.

6) That the excipients are suitable for use in cannabis bulk by determining what is appropriate good manufacturing practice for excipients. This is determined on the basis of a

formalised risk assessment taking into account the requirements of other appropriate quality systems, the origin of the excipients, their intended use and previous instances of quality defects. The manufacturer shall ensure that the established appropriate good manufacturing practices are applied and document the measures taken in this regard. The manufacturer must check the authenticity and quality of the excipients.

7) That documented incoming inspection is carried out when receiving raw materials including seeds, cannabis plant parts, oil, excipients, etc.

**Section 12.** A cannabis primary product manufacturer must ensure the following:

1) That cannabis primary products used for the production of cannabis intermediate products included in the Danish Medicines Agency's list, cf. section 7(3) of the Act on the Medicinal Cannabis Programme, follow the manufacturing processes and comply with the specifications on which the listing of the cannabis product is based.

2) That cannabis primary products distributed follow the manufacturing processes and comply with the specifications set for them and fulfil the requirements of the executive order.

3) That all manufacturing processes for cannabis primary products are carried out in accordance with good manufacturing practices for medicinal products and intermediate products and in accordance with the authorisation for production of cannabis products.

4) That cannabis bulk used as raw material for the production of cannabis primary products is distributed in accordance with good distribution practice for active substances. The manufacturer of a cannabis primary product must verify that manufacturers from whom the manufacturer purchases cannabis bulk comply with good practices for the distribution and manufacture of medicinal products, intermediate products and active substances by conducting audits at the cultivation, manufacturing and distribution sites for the cannabis bulk. The manufacturer of a cannabis primary product must verify that manufacturers from whom the manufacturer purchases cannabis bulk have the necessary authorisations issued by the Danish Medicines Agency. The manufacturer must verify the authenticity and quality of the cannabis bulk.

5) That the suitability of all raw materials, including oil, etc. used in the production of cannabis primary products is assessed.

6) That the excipients are suitable for use in cannabis primary products by determining what is appropriate good manufacturing practice for excipients. This is determined on the basis of a formalised risk assessment taking into account the requirements of other appropriate quality systems, the origin of the excipients, their intended use and previous instances of quality defects. The manufacturer shall ensure that the established appropriate good manufacturing practices are applied and document the measures taken in this regard. The manufacturer must check the authenticity and quality of the excipients.

7) That documented incoming inspection is carried out when receiving raw materials including oil, excipients, etc.

**Section 13.** Detailed guidelines on good manufacturing practices for medicinal products, intermediate products and active substances are published by the European Commission in "Rules governing medicinal products in the European Community, Volume 4".

**Section 14.** Every manufacturer must periodically review the manufacturing methods used in the light of scientific and technical progress.

*Quality assurance*

**Section 15.** Every manufacturer must establish and operate an effective quality assurance system that actively involves management and employees in the relevant departments of the company. The manufacturer must document the quality assurance system in writing, including a description of responsibilities, procedures and risk management measures related to the company.

*Organisation and personnel*

**Section 16.** Every manufacturer must have a competent and sufficiently qualified staff that is large enough to fulfil the quality assurance objectives of cannabis bulk and cannabis primary products.

*(2)* The responsibilities of management and senior personnel, including the qualified person responsible for the implementation and execution of good manufacturing process must be defined in job descriptions. The hierarchical relationships must be defined in an organisation chart.

*(3)* The job descriptions and organisation chart referred to in paragraph 2 and section 35(2) must be approved in accordance with the manufacturer's quality assurance system.

**Section 17.** The qualified person must have completed a university education of at least 4 years in pharmacy, medicine, pharmaceutical chemistry and technology, chemistry or biology.

*(2)* The qualified person must have received instruction in the basic subjects of general and inorganic chemistry, organic chemistry, analytical chemistry, pharmaceutical chemistry, general and applied biochemistry (medical), physiology, microbiology, pharmacology, pharmaceutical technology, toxicology and pharmacognosy during their university education, cf. paragraph 1.

*(3)* The person referred to in paragraph 1 must have at least 2 years of practical experience in the fields of production, quality assurance or quality control of cannabis products or medicinal products from one or more companies authorised to produce cannabis bulk and cannabis primary products, to produce cannabis intermediate products, or authorised to produce and import medicinal products and intermediate products.

*(4)* The practical experience requirement set out in paragraph 3 shall be reduced to 1 year if the university programme extends over at least 5 years.

**Section 18.** Personnel covered by section 16 must undergo basic and continuous training that includes theory and practical application of the concepts of quality assurance and good manufacturing practice.

**Section 19.** The personnel referred to in section 16(2) and section 34(1) must be given sufficient authority to fulfil their responsibilities properly.

**Section 20.** Every manufacturer must establish and comply with hygiene instructions adapted to the activities to be carried out.

*(2)* These instructions must include procedures for staff health, hygiene and attire.

*Premises and equipment*

**Section 21.** Every manufacturer must ensure that premises and equipment are designed, dimensioned, used and maintained so that they are fit for their purpose and so that effective cleaning can be carried out.

*(2)* The layout and design of premises and equipment and work operations must be carried out in such a way as to minimise the risk of error and to avoid confusion, contamination, cross-contamination and any other action that may adversely affect the quality of cannabis products.

**Section 22.** Storage facilities must be large enough to enable good order to be maintained and an appropriate flow of goods to be observed. A special area must be designated for goods for destruction.

**Section 23.** Every manufacturer must ensure that equipment and premises to be used for manufacturing processes with a decisive influence on the quality of products are subject to appropriate qualification and validation.

*Documentation*

**Section 24.** Every manufacturer must establish and maintain a documentation system. The system must be based on specifications for raw materials used, including seeds, cannabis plant parts, cannabis API, cannabis bulk, excipients and the finished cannabis bulk and cannabis primary product, on main regulations regarding composition, production and control of the finished cannabis bulk and cannabis primary product, and on general instructions for procedures regarding equipment, hygiene, production and control.

*(2)* Main instructions must be available for each of the batch sizes manufactured.

*(3)* The documents must be clear, error-free and up-to-date.

**Section 25.** Every manufacturer must be in possession of documentation for the production of the individual batch, which makes it possible to track the production process.

*(2)* All documentation relating to the batch produced must be kept for at least one year beyond the expiry date of the batch or at least 5 years after release of the cannabis bulk or distribution or the release of the cannabis primary product for distribution for the manufacture of cannabis intermediate products, whichever is longer.

**Section 26.** If electronic, photographic or other data processing systems are used, the manufacturer must validate the system and demonstrate that data will be stored appropriately, that data is protected against loss or damage during the expected storage period, and that changes in data are documented.

*(2)* Data stored in these systems must be readily available to the Danish Medicines Agency in readable form.

*Production*

**Section 27.** Every manufacturer must ensure that all production processes are carried out in accordance with established instructions and procedures. Appropriate and sufficient resources must be available for process control.

*(2)* Measures must be implemented to avoid cross-contamination and confusion.

*(3)* Any new production process or substantial modification of the production process must be validated. Critical steps in any production process must be regularly validated.

*(4)* Any process deviation or defect in the cannabis bulk or cannabis primary product must be documented and investigated thoroughly.

*(5)* Every batch must be assigned a unique batch number to enable traceability of the cannabis products.

*Quality control*

**Section 28.** Every manufacturer must establish and maintain a quality control system which is managed by a person who has the necessary qualifications and is independent of production.

*(2)* The person referred to in paragraph 1 must have, or have access to, one or more quality control laboratories with sufficient personnel and equipment to carry out the necessary examination and testing of seeds and cannabis plant parts, cannabis API, cannabis bulk, cannabis primary products, excipients and all parts of the packaging.

*(3)* Laboratories outside the company may be used in accordance with the rules of this executive order on contract analyses.

**Section 29.** In the final quality control of the finished cannabis bulk or cannabis primary product before release for distribution or production of cannabis intermediate, the manufacturer must ensure that an assessment is made of all essential information in the batch documentation, such as production history, process control results, analysis results, compliance of the products with the finished product specification and the final packaging.

**Section 30.** The manufacturer must ensure that reference samples of each individual batch of cannabis bulk or cannabis primary product are stored for at least one year after the set expiry date.

*(2)* Reference samples of used cannabis API, cannabis bulk, excipients, packaging, etc. must be stored by the manufacturer for at least two years after the release of the product. This period may be shortened if their shelf life is shorter. Storage of reference samples may be omitted for certain volatile solvents, gases and water, as well as other raw materials where there are significant reasons to do so.

*(3)* The samples referred to in paragraphs 1 and 2 must be available to the Danish Medicines Agency.

*Outsourcing of activities in contract*

**Section 31.** Every manufacturer (contract giver) can outsource activities to others (contract acceptors) in Denmark if:

1) the contract acceptor has a comprehensive authorisation for the activity contracted out pursuant to section 9(1) of the Act on the Medicinal Cannabis Programme for the production of cannabis bulk and cannabis primary products, without prejudice to paragraph 2,

2) the contract acceptor has a relevant authorisation under the Act on Euphoriant Substances,

3) there is a written contract between the contract giver and the contract acceptor relating to all activities,

4) the responsibilities of the contract giver and the contract acceptor are clearly set out in the contract,

5) the contract states that the contract acceptor is obliged to comply with good manufacturing practice,

6) the contract contains a description of the manner in which the responsible person, who is accountable for the proper execution of the given activities, is to perform their duties, and

7) the contract states that the contract acceptor cannot delegate the performance of activities to a third party without the consent of the contract giver.

*(2)* However, any manufacturer (contract giver) may entrust the analysis to others (contract acceptors) in Denmark if the contract acceptor has an adequate authorisation for the activity contracted out under section 39(1) or (2) of the Danish Medicines Act. The conditions set out in points 2 to 7 of paragraph 1 shall continue to apply.

*(3)* The contract acceptor may only subcontract tasks to a third party in accordance with the provisions of this executive order.

*(4)* Licensing requirements for enterprises with narcotics referred to in paragraph 1, point 2 shall not apply if the enterprise exclusively carries out activities with cannabis products that are not subject to the Order on Narcotics.

*(5)* A manufacturer giver may not contract out the release of a cannabis bulk or cannabis primary product to others pursuant to paragraph 1.

**Section 32.** Any manufacturer (contractor) can outsource analysis to others (contractors) in another EU/EEA country if:

1) the contract acceptor has a manufacturing authorisation under the legislation of another EU/EEA country that corresponds to a Danish company authorisation under the Danish Medicines Act,

2) there is a written contract between the contract giver and the contract acceptor relating to all analysis tasks,

3) the responsibilities of the contract giver and the contract acceptor are clearly set out in the contract,

4) the contract states that the contract acceptor is obliged to comply with good manufacturing practice,

5) the contract contains a description of the manner in which the responsible person, who is accountable for the proper execution of the given task, is to perform their duties, and

6) the contract states that the contract acceptor cannot delegate the performance of tasks to a third party without the consent of the contract giver.

*(2)* The contract acceptor may only subcontract tasks to a third party in accordance with the provisions of this executive order.

*Security*

**Section 33.** Cannabis bulk and cannabis primary products must always be stored out of reach of unauthorised persons.

*(2)* Premises for receipt, production or storage of cannabis must be designed to prevent unauthorised access.

**Section 34.** To ensure compliance with section 33, every manufacturer must appoint a safety officer who is responsible for the development and implementation of any relevant safety measures. These safety measures must be determined on the basis of a risk assessment of the manufacturer's own circumstances.

*(2)* The safety officer's area of responsibility must be defined in a job description and must appear in the organisation chart, cf. section 16.

*(3)* All safety measures, including the risk assessment, must be described and documented in the manufacturer's quality assurance system.

**Section 35.** The Danish Medicines Agency shall issues an authorisation to manufacture cannabis products only after examining the personal circumstances and past conduct of the company's owners, director and safety officer, and only if no information exists that would make it questionable to grant the application.

*(2)* The Danish Medicines Agency shall obtain information from the police for the assessment of good character in paragraph 1.

*(3)* In the event of a change of the company's owner or director and the safety officer, the Danish Medicines Agency will carry out a new assessment pursuant to paragraph 1. The outcome of the investigation may have an impact on the manufacturer's continued authorisation.

*(4)* The Danish Medicines Agency may revoke an authorisation at any time if information emerges concerning personal circumstances and past conduct that makes it questionable to maintain the authorisation.

*Release*

**Section 36.** Upon release of each batch of cannabis bulk or cannabis primary products, the qualified person must certify that the batch has been produced in accordance with this executive order.

*(2)* When releasing cannabis primary products to be used in the production of cannabis intermediate products included in the Danish Medicines Agency's list, cf. section 7(3) of the Act on the Medicinal Cannabis Programme, the qualified person must also certify that the cannabis primary product fulfils the requirements on which the inclusion is based.

*(3)* The certification must be recorded in a register or similar which has been established for this purpose and is updated regularly. The register must be stored for at least 5 years and be accessible to the Danish Medicines Agency during this period.

**Section 37.** Cannabis bulk and cannabis primary products must be released according to their manufacturing processes and specifications before they can be distributed.

*Counterfeit cannabis products*

**Section 38.** Every manufacturer must ensure that cannabis API, cannabis bulk or cannabis primary products that are or may be counterfeit are stored separately from other products. These products must also be labelled to make it clear that they are not for distribution.

*Self-inspection*

**Section 39.** Every manufacturer must regularly carry out self-inspections as part of the quality assurance system in order to check the implementation of and compliance with the principles of good manufacturing practice and to propose any changes that may be necessary.

*(2)* Records of completed self-inspections and corrective actions must be kept.

*(3)* The self-inspection programme must include auditing of any contract acceptors.

*(4)* Self-inspection must be carried out in an independent and detailed manner by a designated competent person.

Chapter 6

*Cultivation of cannabis*

**Section 40.** In addition to section 11(1) point 2, when cultivating cannabis, the manufacturer must comply with Good Agricultural and Collection Practices (GACP), as published by the European Medicines Agency in their Guide to good agricultural and collection practices for medicinal plants.

**Section 41.** The manufacturer must use standardised cultivation parameters for the cultivation of cannabis insofar as these affect the quality of the cannabis plant. All processes and procedures that may affect the quality of the cannabis plant must be documented for each batch.

*(2)* If the manufacturer is able to document that a given cultivation parameter does not affect the quality of the cannabis plant, standardisation may be omitted.

**Section 42** The use of pesticides in the cultivation of cannabis is permitted, provided that the following conditions are met:

1) pesticides have been used, all active substances of which are authorised in the EU under Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (Pesticides Regulation),

2) all active substances of the pesticides are listed in Annex IV of Regulation 396/2005/EC of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin,

3) all active substances of the pesticides are included in the list of products that can be used for plant protection in special cases in Appendix 1 of the Danish Agricultural and Fisheries Agency's guidelines on organic agricultural production, and

4) the pesticides are authorised by the Danish Environmental Protection Agency for the specific application.

*(2)* If pesticides have been used in the cultivation of cannabis, the manufacturer of the cannabis product must ensure that there is documentation for the use of the pesticides and that the pesticide residue limits are set taking into account the pharmaceutical form of the cannabis product and patient safety. The Danish Medicines Agency will assess the documentation to the extent deemed necessary.

## Chapter 7

## Buying and receiving cannabis API

**Section 43.** A manufacturer may use cannabis API, in the form of cannabis drug and herbal preparation, produced from cannabis cultivated and processed in EU/EEA countries, in the programme's cannabis products.

**Section 44.** The manufacturer must ensure that documented incoming inspections are performed for all deliveries of cannabis API, including:

1) That the supplier is in possession of a relevant and valid Danish registration, issued in accordance with section 50a of the Danish Medicines Act, for the distribution of active substances.

2) That the cannabis used has been cultivated and procured in accordance with the United Nations Single Convention on Narcotic Drugs of 30 March 1961 and originates from a country of cultivation that is a party to the Single Convention.

3) If pesticides have been used in the cultivation of the cannabis used, only pesticides that fulfil the requirements in section 42(1), points 1 to 3 and point 4 have been used if the cannabis used has been cultivated in Denmark.

4) That active substances used in the production of cannabis bulk are manufactured by an API manufacturer with a registration issued pursuant to section 50a of the Danish Medicines Act, or an equivalent registration in another EU/EEA country as covered by Article 46b of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and in accordance with good manufacturing practice for active substances, and distributed in accordance with good distribution practice for active substances. The manufacturer of cannabis bulk must also verify that the manufacturer and distributor of the active substances comply with good practices for the distribution and manufacture of active substances by conducting audits at the cultivation, manufacturing and distribution sites for the active substances.

The manufacturer of cannabis bulk must finally verify the authenticity and quality of the active ingredients.

5) That the active substances supplied have been assayed for potency with regard to the content of THC (tetrahydrocannabinol) and CBD (cannabidiol) and analysed for identification, impurities and any other relevant quality parameters, in accordance with the European Pharmacopoeia (Ph. Eur.), cf. the Danish Drug Standards. In cases where the European Pharmacopoeia does not have a suitable monograph, a suitable monograph from another national European pharmacopoeia may be used instead, or an internal specification based on the general monographs of the European Pharmacopoeia may be applied.

6) That each delivery is accompanied by documentation showing the date, the name or designation of the active substance, the quantity, the strength, the expiry date (if applicable), the names and addresses of the supplier and recipient and the batch numbers,

7) That the active substances delivered correspond to the order and have been transported safely in accordance with good distribution practices for active substances.

8) That the packs are intact and undamaged and that the shipment is sealed.

(2) The information referred to in points 2 to 4 of paragraph 1 may be ensured by obtaining declarations from the manufacturer certifying that the conditions are fulfilled. These declarations must be verified and documented.

(3) Every delivery must be verified and accompanied by the information referred to in paragraph 1(5) in the form of certificates of analysis, including from the original manufacturer.

(4) Active substances supplied must be quarantined until the incoming inspection is performed and documented. The active substances must be destroyed if the inspections referred to in paragraphs 1 to 3 are not carried out or the documentation cannot be verified.

**Section 45.** Cannabis API is regarded as cannabis bulk and may be used in the production of cannabis products when the qualified person has certified for each batch that quality control has been carried out in accordance with section 44.

*(2)* The certification must be recorded in a register or similar which has been established for this purpose and is updated regularly. The register must be stored for at least 5 years and be accessible to the Danish Medicines Agency during this period.

*(3)* Cannabis API that is not regarded as cannabis bulk in accordance with paragraph 1 may not be used in the production of cannabis products or distributed.

## Chapter 8

*Complaints and recalls*

**Section 46.** Every manufacturer must establish an effective system for recording and investigating complaints and a system that allows cannabis bulk and cannabis primary products in the distribution network to be recalled immediately and at any time.

*(2)* The manufacturer must register and investigate any complaints regarding errors or defects and inform the Danish Medicines Agency of any error or defect that may result in recalls or extraordinary supply restrictions in the distribution network.

## Chapter 9

*Distribution*

**Section 47.** Cannabis bulk must be distributed in accordance with good distribution practices for active substances. Detailed guidelines on Good Distribution Practice for active substances can be found in the European Commission's "Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use".

**Section 48.** Cannabis primary products must be distributed in accordance with good distribution practices for medicinal products. Detailed guidelines on Good Distribution Practice for medicinal products can be found in the European Commission's "Guidelines on Good Distribution Practice for medicinal products for human use".

**Section 49.** A manufacturer with an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme may only supply cannabis bulk to companies with an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme for the production of cannabis products and a relevant authorisation under the Danish Act on Euphoriant Substances, without prejudice to section 53.

*(2)* A manufacturer with an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme may only supply cannabis primary products to companies with an authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme for the production of cannabis products or cannabis intermediate products and a relevant authorisation under the Danish Act on Euphoriant Substances, without prejudice to section 53.

*(3)* The requirement for authorisation to operate with euphoriant substances as referred to in paragraphs 1 and 2 does not apply if the company exclusively carries out activities with cannabis products that are not covered by the executive order on euphoriant substances.

*Incoming inspection of cannabis products*

**Section 50.** The manufacturer must ensure that documented incoming inspections are performed for all deliveries of cannabis products, including:

1) That each delivery is accompanied by documentation showing the date, the designation of the cannabis product, the quantity, the pharmaceutical form, strength, the batch number, the expiry date (where applicable) and the names and addresses of the supplier and recipient.

2) That the cannabis product delivered correspond to what was ordered and have been transported safely, in accordance with any storage conditions and in such a way that the quality of the cannabis product has not been impaired.

3) That the packs are intact and undamaged and that the shipment is sealed.

4) That the Supplier is in possession of all relevant authorisations pursuant to section 9(1) of the Act on the Medicinal Cannabis Programme and the Danish Act on Euphoriant Substances if the products supplied are covered by the executive order on euphoriant substances.

5) That the cannabis used in the cannabis bulk is cultivated according to Good Agricultural and Collection Practices (GACP).

6) That the manufacturing of the cannabis product complies with good manufacturing practice.

7) That the cannabis product delivered is quality controlled in accordance with good manufacturing practice.

8) That the cannabis product supplied has been assayed for potency with regard to the content of THC (tetrahydrocannabinol) and CBD (cannabidiol) and analysed for identification, impurities and any other relevant quality parameters, cf. section 10(9).

*(2)* The information referred to in points 5 and 7 of paragraph 1 must be ensured by obtaining a release certificate from all parts of the chain, certifying that the conditions are fulfilled.

*(3)* Every delivery must be accompanied by the information referred to in paragraph 1(8) in the form of certificates of analysis.

*(4)* Products supplied must be quarantined until the incoming inspection is performed and documented.

*(5)* The cannabis product received must be checked against a verified version of the cannabis product.

## Chapter 9

*Export of cannabis products*

**Section 51.** Cannabis bulk and cannabis primary products may only be exported by companies authorised under section 9(1) of the Act on the Medicinal Cannabis Programme to manufacture cannabis products.

*(2)* Cannabis primary products exported under paragraph 1 must not be included in the Danish Medicines Agency's list pursuant to section 7(3) of the Act on the Medicinal Cannabis Programme or share a name with a cannabis primary product included in the list.

**Section 52.** Cannabis products may only be exported to countries that allow the import of cannabis for medicinal use.

**Section 53.** The manufacturer must ensure that cannabis products are only exported and delivered to companies that have the necessary authorisations to handle cannabis for medicinal use according to the legislation of the importing country **section 54.** A manufacturer must ensure that exported cannabis products are traceable and any defects or deficiencies in exported cannabis bulk or cannabis primary products intended for export are investigated and recorded in the company's complaints and recall system.

*(2)* The manufacturer must notify the importer of the cannabis product, the Danish Medicines Agency and the relevant authority in the importing country of any product defects that may result in a recall.

## Chapter 10

*Exemption*

**Section 54.** The Ministry of the Interior and Health may grant exemptions from one or more provisions of this executive order in exceptional circumstances.

## Chapter 11

*Penalty provisions and entry into force*

*Penalty provision*

**Section 55.** Unless a higher penalty is warranted under other legislation, a fine or imprisonment of up to 18 months shall be imposed on anyone who:

1) violates section 9, sections 11–12, sections 14–16, sections 18–27, section 28(1–2), section 29, section 30(1), (2), first sentence, and (3), section 31(1–3), sections 32–34, sections 36–40, section 41(1), and sections 43–55

2) disregards conditions set out in an authorisation under the executive order, or

3) fails to comply with an order or information obligation authorised by the executive order.

*(2)* Criminal liability may be imposed on enterprises etc. (legal entities) within the meaning of the rules in Chapter 5 of the Penal Code.

*Entry into force provision*

**Section 56.** The executive order shall enter into force on 1 January 2026.

*(2)* Executive Order no. 2539 of 14 December 2021 on cannabis bulk and cannabis primary products is repealed.

*Ministry of the Interior and Health*,

## Annex 1

***Storage conditions***

***The following applies to labelling on packaging for the cannabis product:***

| **Stability data** | **Labelling of packaging** | **Supplement for labelling on packaging*** |
|---|---|---|
| The cannabis product is stable at temperatures above 30 °C | No labelling | May be labelled:<br>Do not freeze<br>*or*<br>Do not refrigerate or freeze. |
| The cannabis product is stable at temperatures up to 30 °C | May be labelled:<br>Do not store at temperatures above 30 °C<br>*or*<br>Store at temperatures below 30 °C | May be labelled:<br>Do not freeze<br>*or*<br>Do not refrigerate or freeze. |
| The cannabis product is stable at temperatures up to 25 °C | Must be labelled:<br>Do not store at temperatures above 25 °C<br>*or*<br>Store at temperatures below 25 °C | May be labelled:<br>Do not freeze<br>*or*<br>Do not refrigerate or freeze. |
| The cannabis product is stable at temperatures up to 5 °C ±3 °C | Must be labelled:<br>Store in a refrigerator<br>*or*<br>Store in a refrigerator and transport refrigerated | May be labelled:<br>Do not freeze |
| The cannabis product is stable only when frozen | Must be labelled:<br>Store in a freezer<br>*or*<br>Store and transport frozen** | |

* If relevant, the general storage conditions shall be supplemented with additional labelling, which must also appear on the packaging.

** This text should only be used where critically necessary.

***Other supplementary storage conditions:***

| | Storage problems | Supplement for labelling on packaging, depending on packaging type* |
|---|---|---|
| 1 | Moisture-sensitive | Store in the original <container>**, tightly closed<br>*or*<br>Keep the <container>** tightly closed |
| 2 | Moisture-sensitive | Store in the original <outer packaging>** |
| 3 | Light-sensitive | Store in the original <outer packaging>** |
| 4 | Light-sensitive | Keep the <container>** in the outer carton*** |

* An explanation of the supplementary labelling must appear on the packaging:
to protect from light
*or*
to protect from moisture
*or*
to protect from light and moisture

** The current standard term for the container must be used (e.g. bottle, blister, etc.).

*** Alternative designations may be used where relevant.

The above supplementary storage conditions may only be applied where the stability documentation demonstrates that there are actual problems with sensitivity to moisture or light, and that these problems cannot be resolved through the use of more suitable packaging.

If the cannabis product is intended solely for export, the required text may be written in a relevant language other than Danish. Similarly, other relevant additional labelling may be added as required by the importing country.