Executive Order on cannabis intermediate products[1]

Pursuant to sections 5, 6(4), 7(9), 9(8), 10, 63(2) 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 429 of 6 May 2025, the following is laid down:

Chapter 1

Scope of the executive order

Section 1. This executive order covers the manufacture of cannabis intermediate products based on imported or manufactured cannabis primary products and the inclusion of cannabis intermediate products on the Danish Medicines Agency's list, covered by the Act on the Medicinal Cannabis Programme.

Section 2. The executive order applies to companies and persons who have received an authorisation from the Danish Medicines Agency to produce cannabis intermediate 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.

Chapter 2

Definitions

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

1) Imported cannabis primary product: A cannabis product covered by the programme and imported into Denmark in accordance with the rules laid down in the Act on the Medicinal Cannabis Programme for the purpose of producing a cannabis intermediate product. A cannabis primary product may contain one or more cannabis herbal drugs or one or more drug preparations as active ingredients. A cannabis primary product may alternatively contain one or more cannabis herbal drugs or one or more drug preparations as active ingredients. A cannabis primary product is formulated as a pharmaceutical form.

2) Manufactured cannabis primary product: A cannabis product covered by the programme and manufactured in Denmark in accordance with the rules laid down pursuant to the Act on the Medicinal Cannabis Programme for the purpose of producing a cannabis intermediate product or with a view to export. A cannabis primary product may contain one or more cannabis herbal drugs or one or more drug preparations as active ingredients. A cannabis primary product may alternatively contain one or more cannabis herbal drugs or

[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).

one or more drug preparations as active ingredients. A cannabis primary product is formulated as a pharmaceutical form.

3) Cannabis intermediate product: A cannabis product covered by the programme that is produced from an imported or manufactured cannabis primary product for the purpose of producing a cannabis finished product.

4) Cannabis finished product: A cannabis product covered by the programme that is manufactured in a pharmacy or hospital pharmacy from a cannabis intermediate following a doctor's prescription for a specific patient.

5) Intermediate product manufacturer: A company authorised under section 9(1) of the Act on the Medicinal Cannabis Programme

6) Production activities: All import activities, packaging operations, labelling, quality control, storage and release of cannabis intermediate products.

7) Imported cannabis primary products: Receipt of a cannabis primary product from an EU/EEA or MRA country that the intermediate product manufacturer has included on the Danish Medicines Agency's list of cannabis primary products and cannabis intermediate products covered by the programme.

8) Labelling: Labelling of packaging (both inner and outer) with the information specified in this executive order and the executive order on the labelling, etc. on cannabis intermediate products.

9) Country of cultivation: The country where the cannabis plant is grown and harvested.

10) Country of manufacture: The country where the cannabis primary product is released for distribution.

11) Country of origin: The country where the cannabis primary product can be legally dispensed to patients for medicinal use.

12) Export country: The country from which the cannabis primary product has been imported.

13) RA land: A country with which Denmark or the EU has entered into an agreement on mutual recognition of other countries' regulatory supervision in the pharmaceutical field.

14) Principles of good manufacturing practice in the country of manufacture: A set of guidelines and rules that regulate cannabis primary product quality, manufacturing procedures, consistent production, documentation, traceability and quality control before cannabis primary products are released to the market.

15) Good Agricultural and Collection Practices (GACP): A set of guidelines and rules that regulate the actual cultivation, harvesting and subsequent handling and storage of the plant material to ensure consistent and sufficient quality of the plant material. Requirements are defined for staff training, production facilities and equipment, documentation of production conditions, etc.

16) Original manufacturer: The producer who has produced the cannabis primary product in accordance with the rules of the country of origin.

17) Incoming inspection: Physical receipt and inspection of cannabis primary products, packaging, etc. and inspection of the accompanying documentation required under this executive order.

18) Qualified person: A person appointed by the company to ensure that the company complies with applicable regulations for the manufacture of cannabis intermediate products

and who fulfils the minimum scientific and technical qualification requirements set out in this executive order.

19) Quality assurance: All measures undertaken to ensure that a cannabis intermediate product is of the quality required in relation to its intended use.

20) Quality control: Procedures and documentation for sampling, inspection and control of received cannabis primary products, control and testing of packaging material and production of cannabis intermediate products and release, ensuring that cannabis intermediate products are not released until their quality is documented as satisfactory in relation to both internal requirements and this executive order.

21) Release: The activity where the qualified person certifies that a batch of the cannabis intermediate product has been produced in accordance with all relevant procedures and that it is of sufficient quality to be distributed.

22) Reference test: A pack of each batch of cannabis intermediate product stored for subsequent documentation of its contents, packaging and labelling, etc.

23) Site master file: Part of the quality system that describes the company's quality policies, quality control and the activities performed on the site. The 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.

24) Batch: A defined quantity of cannabis products that are produced in a single process and appear homogeneous.

25) Batch number (or LOT number): A unique number that identifies a batch.

26) Batch documentation: Documentation related to the manufacturing of cannabis products carried out for each individual batch.

27) Distribution of cannabis intermediate products: Storage of released cannabis intermediate products and delivery of cannabis intermediate products to pharmacies, hospital pharmacies or companies authorised under section 39(1) of the Danish Medicines Act for distribution of medicinal products in accordance with the executive order on distribution of medicinal products.

28) Counterfeit cannabis primary product: Any 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, its country of manufacture, its country of origin or its country of cultivation, or

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

29) Pesticides: 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).

30) 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).

Chapter 3

Authorisation to produce cannabis intermediate products

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

1) disclose the location of their import of cannabis primary products, receipt of manufactured cannabis primary products and manufacturing and storage of cannabis intermediate products,

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

3) have a qualified person 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 the applicant fulfils the requirements referred to in paragraph 1, points 2 and 3, 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 6 shall be suspended until this information has been provided.

Section 6. An application for authorisation to receive or import cannabis primary products and produce cannabis intermediate products will be processed within 90 days from the submission of a satisfactory application.

(2) If the holder of an authorisation to receive or import cannabis primary products and produce cannabis intermediate products 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 7. The Danish Medicines Agency may initially choose to issue an authorisation to receive or import cannabis primary products and produce cannabis intermediate products only after having ensured through an investigation by its representatives that the information in the application corresponds to the facts.

Section 8. The holder of an authorisation to receive or import cannabis primary products and produce cannabis intermediate products 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.

Chapter 4

Quality assurance

Section 9. Every intermediate product manufacturer must establish and operate an effective quality assurance system that actively involves management and employees in the relevant departments of the company. The intermediate product manufacturer must document the quality

assurance system in writing, including a description of responsibilities, procedures and risk measures related to the company.

(2) The intermediate product manufacturer must prepare and maintain a site master file as part of the establishment of the quality system.

(3) The intermediate product manufacturer must carry out adequate and documented supplier qualification prior to any agreement with a supplier.

Organisation and personnel

Section 10. Every intermediate product manufacturer must have a competent and sufficiently qualified staff that is large enough to fulfil the quality assurance objectives of cannabis intermediate products.

(2) The responsibilities of the management and senior personnel, including the qualified person, 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 must be approved in accordance with the intermediate product manufacturer's quality assurance system.

Section 11. 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 pursuant to 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, cannabis primary products or 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 12. Personnel referred to in section 10 must undergo initial and ongoing training that includes theory and practical application of quality assurance and manufacturing of cannabis intermediate products.

Section 13. Personnel referred to in section 10(2) must be given sufficient authority to enable them to fulfil their responsibilities properly.

Section 14. Every intermediate product 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 15. Premises and equipment must be designed, dimensioned, used and maintained in such a way that they are fit for purpose and can be cleaned.

(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 and any other action that may adversely affect the quality of cannabis intermediate products.

Section 16. 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 17. Premises for receipt, production or storage must be designed to prevent unauthorised access.

Section 18. Every intermediate product manufacturer must ensure that equipment and premises to be used for manufacturing processes with a decisive influence on the quality of cannabis intermediate products are subject to appropriate qualification.

Documentation

Section 19. Every intermediate product manufacturer must establish and maintain a documentation system. This system must be based on documentation for the cannabis primary product and for the finished cannabis intermediate product on the main regulations regarding production and control of the finished cannabis intermediate product and on general instructions regarding equipment, hygiene, production and control.

(2) Instructions must be available for each of the pack sizes manufactured.

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

Section 20. If electronic data processing systems are used, the intermediate product manufacturer must validate the systems and ensure that data is stored appropriately and that changes to data are documented. Data must be protected against loss or damage for the required retention period.

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

Chapter 5

Requirements for imported cannabis primary products

Section 21. An imported cannabis primary product must fulfil the following requirements:

1) It must be provided in accordance with the UN Single Convention on Narcotic Drugs of 30 March 1961, including its provisions on the establishment of a cannabis agency and authorisation for cultivation on designated cultivation areas,

2) The cannabis drug used must be cultivated in accordance with Good Agricultural and Collection Practices (GACP),

3) The production of cannabis primary products must comply with national regulations on the cultivation and processing of cannabis products in the country of cultivation and country of origin,

4) It must be manufactured and quality controlled in accordance with principles of good manufacturing practice,

5) It must be 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. Danish Drug Standards, or in accordance with another national pharmacopoeia or standard,

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

7) It must be legally available in the country of origin for medicinal use in the same form and pack size that the intermediate product manufacturer wants to import,

8) It must be manufactured in and imported from an EU/EEA country or a country with which Denmark or the EU has entered into an agreement on mutual recognition of other countries' regulatory supervision in the pharmaceutical field, and

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

Section 22. An imported cannabis primary product may be produced from cannabis cultivated with the use of pesticides, without prejudice to paragraph 2, if:

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, and

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.

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

Chapter 5

Inclusion in the Danish Medicines Agency's list of cannabis primary products manufactured in Denmark and associated cannabis intermediate products

Section 23. The Danish Medicines Agency assesses the application submitted under section 7(2) of the Act on the Medicinal Cannabis Programme and makes an overall professional assessment of the quality of the cannabis primary product, cf. the Act on the Medicinal Cannabis Programme and the executive order on cannabis bulk and cannabis primary products. If the Danish Medicines Agency assesses that the requirements for inclusion on its list are met, the cannabis primary product shall be

included on the list together with the corresponding cannabis intermediate product, cf. section 7(3) of the Act on the Medicinal Cannabis Programme.

(2) The cannabis primary product and cannabis intermediate product must be labelled in such a way that it is not misleading and there is no risk of confusion. The name must not be identical to a name of an exported cannabis primary product.

(3) The cannabis intermediate product must comply with the labelling requirements set out in the executive order on the labelling etc. of cannabis intermediate products.

(4) In an assessment under paragraph 1, first sentence, the Danish Medicines Agency may assign a storage time and storage conditions if there is insufficient documentation for the storage time and storage conditions stipulated by the manufacturer, cf. section 10(12) of the executive order on cannabis bulk and cannabis primary products. The Danish Medicines Agency may also require the manufacturer to initiate stability studies and submit the results thereof.

(5) An application for inclusion on the list of cannabis primary products must be submitted electronically using the Danish Medicines Agency's application form. The Danish Medicines Agency shall make the application form available on the website of the Danish Medicines Agency. The Danish Medicines Agency may lay down more detailed requirements for the content and form of the application and the documentation accompanying the application for inclusion in the Agency's list.

(6) An application must be submitted if the documentation on which inclusion is based is subsequently changed. The requested change and documentation for this must be submitted electronically to the Danish Medicines Agency. The change may not be implemented until it has been accepted by the Danish Medicines Agency.

Chapter 7

Receipt of cannabis primary products

Receipt of imported cannabis primary products

Section 24. The company must establish a system that ensures the authenticity of received cannabis primary products.

Section 25. The intermediate product manufacturer must ensure that documented incoming inspections are performed for all shipments of cannabis primary products that are imported, including:

1) That each delivery is accompanied by documentation showing the date, the name or designation of the primary product, the quantity imported, the pharmaceutical form, strength and pack size, the expiry date (if applicable), the names and addresses of the supplier and recipient and the batch numbers.
2) That the cannabis primary products delivered correspond to what was ordered and have been transported safely, in accordance with the storage conditions and in such a way that the quality of the cannabis primary 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 to distribute the cannabis primary product according to the rules of the exporting country.
5) That the cannabis primary products supplied can be legally dispensed in the country of origin for medicinal use in the same form and pack size as received.

6) That the cannabis used in the cannabis primary product 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.

7) That the cannabis used in the cannabis primary product has been cultivated according to good agricultural practices and that any use of pesticides is compliant with section 22.

8) That the production of the cannabis primary product has complied with national regulations on the cultivation and processing of cannabis products in the country of cultivation and country of origin and by duly authorised producers in the country of origin.

9) That the cannabis primary products supplied are quality controlled in accordance with principles of good manufacturing practice in the country of origin.

10) That the primary products 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. Danish Drug Standards, or in accordance with a national pharmacopoeia or standard

11) That the primary products supplied have been manufactured in and imported from an EU/EEA country or a country with which Denmark or the EU has entered into an agreement on mutual recognition of other countries' regulatory supervision in the pharmaceutical field (MRA country).

(2) The information referred to in points 5 to 9 and 11 of paragraph 1 may be ensured by obtaining declarations from the original manufacturer certifying that the conditions are fulfilled. These declarations must be verified and documented.

(3) Every delivery must be accompanied by the information referred to in paragraph 1(10) in the form of certificates of analysis with traceability to applicable specifications.

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

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

Receipt of manufactured cannabis primary products

Section 26. The intermediate product manufacturer must ensure that documented incoming inspections are performed for all deliveries of manufactured cannabis primary products, including:

1) That each delivery is accompanied by documentation showing the date, the name or designation of the primary product, the quantity received, the pharmaceutical form, strength and pack size, the expiry date, the names and addresses of the supplier and recipient and the batch numbers.

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

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

4) That the cannabis used in the cannabis primary product has been cultivated in accordance with Good Agricultural and Collection Practices (GACP) and that any use of

pesticides is compliant with section 42 of the executive order on cannabis bulk and cannabis primary products.

5) That the manufacturer of the cannabis primary product has complied with and released the cannabis primary product in accordance with the executive order on cannabis bulk and cannabis primary products.

6) That the primary products 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, cf. section 10(9) of the executive order on cannabis bulk and cannabis primary products.

7) That the supplier is in possession of an authorisation pursuant to section 9(1) of the Danish Act on the Medicinal Cannabis Programme for the production of cannabis bulk and cannabis primary products, as well as a relevant authorisation pursuant to the Act on Euphoriant Substances, if the cannabis primary products are covered by the executive order on euphoriant substances.

(2) The information referred to in points 5 and 6 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 accompanied by the information referred to in paragraph 1(7) in the form of certificates of analysis with traceability to applicable specifications.

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

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

Storage of cannabis primary products

Section 27. Cannabis primary products must be stored under the specified storage conditions. The temperature in storage premises and refrigeration equipment must be validated, controlled and documented.

Section 28. Cannabis primary products must be stored separately from other products and must be protected from the harmful effects of light conditions, temperatures, humidity levels and other external factors.

Counterfeit cannabis primary products

Section 29. An intermediate product manufacturer must ensure that cannabis primary products that are or may be counterfeit are stored separately. Cannabis primary products that are or may be counterfeit must also be labelled to make it clear that they are not for distribution.

Documentation for received cannabis primary products

Section 30. All documentation must be kept by the intermediate product manufacturer for at least 1 year beyond the expiry date of the batch or at least 5 years after release for sale or distribution, whichever is longer.

Chapter 7

Preparation of cannabis intermediate products

Section 31. A cannabis intermediate product must be produced by labelling the corresponding cannabis primary product, cf. the executive order on the labelling, etc. of cannabis intermediate products.

(2) An intermediate product manufacturer can package the cannabis primary product in an outer packaging. The packaging must be suitable for the purpose.

Section 32. The intermediate product manufacturer may only produce cannabis intermediate products that the intermediate product manufacturer has had included on the Danish Medicines Agency's list pursuant to section 7(3) of the Act on the Medicinal Cannabis Programme. Cannabis intermediate products may only be produced from the cannabis primary products included in the list.

Section 33. Every intermediate product 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 confusion.

(3) Any process deviation or defect in the cannabis intermediate product must be documented and investigated thoroughly.

Section 34. Cannabis intermediate products that have not been released must be stored in accordance with sections 26 and 27.

Quality control

Section 35. Every intermediate product 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 facilities with sufficient personnel and equipment to carry out the necessary examination of cannabis primary products and cannabis intermediate products and the examination and testing of all parts of the outer packaging.

Section 36. The intermediate product manufacturer must ensure that reference samples of each individual batch of released cannabis intermediate products are stored for at least one year after the set expiry date.

Documentation for the manufacturing of cannabis intermediate products

Section 37. Every intermediate product manufacturer must be in possession of documentation for the production of the individual batch (batch documentation), 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 intermediate product for sale or distribution, whichever is longer.

Release

Section 38. Prior to the release of any batch, the qualified person must issue a release certificate and certify in this that the batch has been produced in accordance with this executive order and the Act on the Medicinal Cannabis Programme.

(2) When releasing the cannabis intermediate product, the qualified person must ensure that there is a reference sample of each batch and that the cannabis intermediate product based on an imported cannabis primary product fulfils the requirements set out in sections 21 and 22, or the cannabis intermediate product based on a manufactured cannabis primary product fulfils the requirements in the executive order on cannabis bulk and cannabis primary products.

(3) When releasing the cannabis intermediate product, the qualified person must ensure that the cannabis intermediate product is compliant with the documentation submitted by the intermediate product manufacturer when applying for inclusion of the cannabis product on the Danish Medicines Agency's list of cannabis intermediate products covered by the programme.

(4) The certification must also be recorded in a register or similar which has been established for this purpose and is updated regularly. The register must be kept for at least 5 years after the cannabis intermediate product is released for sale or distribution.

Complaints and recalls

Section 39. Every intermediate product manufacturer must establish an effective system for recording and investigating complaints and a system that allows cannabis intermediate products in the distribution network to be recalled immediately and at any time.

(2) The intermediate product 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.

Returns and destruction

Section 40. Imported cannabis primary products may not be returned to the distributor from the cannabis product's country of origin.

(2) Imported cannabis primary products that are not used in the production of cannabis intermediate products must be destroyed unless otherwise authorised by the Danish Medicines Agency.

(3) Cannabis primary products and cannabis intermediate products to be destroyed must be stored separately until the time of destruction.

Self-inspection

Section 41. Every intermediate product manufacturer must regularly carry out self-inspections as part of the quality assurance system in order to check the implementation of and compliance with

applicable regulations, detailed guidelines and internal procedures, and also 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 evaluation and auditing of any contract acceptors.

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

Contractual relationships

Section 42. Every intermediate product manufacturer (contract giver) can outsource activities to others (contract acceptors) in Denmark if:

1) the contract acceptor has a comprehensive authorisation for the outsourced activities pursuant to section 9(1) of the Act on the Medicinal Cannabis Programme, 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 tasks. If there are several contractual relationships between the contract giver and the contract acceptor, these can be combined into one contract,

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 this executive order,

6) 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

7) 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) However, every intermediate product manufacturer (contract giver) may store, receive and distribute released cannabis intermediate products to others (contract acceptor) in Denmark if the contract acceptor has a comprehensive authorisation for wholesale distribution under section 39(1) 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 Denmark in accordance with the provisions of this executive order.

(4) An intermediate product manufacturer (contract giver) may not contract out the release of a cannabis intermediate product to others pursuant to paragraph 1.

Section 43. A regional company established under section 78(3) of the Danish Health Act that obtains authorisation under section 9(1) of the Act on the Medicinal Cannabis Programme in the event of a prolonged supply shortage may, with the authorisation of the Danish Medicines Agency, entrust the receipt of cannabis primary products (including incoming inspection), production of cannabis intermediate products and storage to others (contract acceptors) if:

1) the contract acceptor has a comprehensive authorisation in accordance with section 9(1) of the Act on the Medicinal Cannabis Programme,

2) there is a written contract between the contract giver and the contract acceptor for each task,

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 this executive order,

5) the contract states that the contract acceptor cannot delegate the performance of tasks to a third party, and

6) the contract states that the contractor must release all cannabis intermediate products for sale or distribution.

(2) The Danish Medicines Agency must be informed of any change in the contractual relationship between the contract giver and the contract acceptor.

(3) The contract giver may not contract out the release of a cannabis intermediate product to others pursuant to paragraph 1.

Chapter 8

Penalty provisions and entry into force

Section 44. The Ministry of the Interior and Health may grant exemptions from one or more provisions of this executive order in exceptional circumstances.

Penalties

Section 45. Unless a higher penalty is warranted by other legislation, anyone who violates section 8, sections 9 to 10, sections 12 to 20, 24, section 25(1), (2), second sentence, and (3 to 5), section 26(1), (2), second sentence, and (3 to 5), sections 27 to 30, section 31(1) and (2), second sentence or sections 32 to 43(2) shall be fined.

(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

Section 45. The executive order shall enter into force on 1 January 2026.

(2) Executive Order no. 2538 of 14 December 2021 on the import of cannabis primary products and production of cannabis intermediate products is repealed.

Ministry of the Interior and Health, (date)