Executive order on the production of cannabis finished products by pharmacies[1]

Pursuant to Section 18(3) and Section 66(2) of Act No 1668 of 26 December 2017 on a medicinal cannabis pilot programme and on a scheme for the cultivation, production, etc. of medicinal cannabis, as amended by Act No 2392 of 14 December 2021 and Act No 439 of 6 May 2025, the following is laid down:

Scope and terminology

Section 1. The executive order shall apply to the production by pharmacies of cannabis finished products, as defined in Section 3(9) of the Act on a Medicinal Cannabis Programme.

Section 2. Only pharmacies and pharmacy branches may produce cannabis finished products.
(2) Pharmacy outlets are not permitted to produce cannabis finished products.

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

1) Pharmacy and pharmacy branch: The pharmacy or pharmacy branch, hospital pharmacy or hospital pharmacy branch, as well as private hospital pharmacy or private hospital pharmacy branch, which, in accordance with the Act on a Medicinal Cannabis Programme and related executive orders regulations, produces a cannabis finished product prescribed for a specific patient.
2) Production activities: The production process described in section 18(1) and (2) of the Act on a Medicinal Cannabis Programme and sections 13-17 of this executive order on labelling, quality control and inspection of production before dispensing cannabis finished products.
3) Responsible person: An authorised person who bears overall responsibility for all aspects of the production process, including inspection of production before dispensing, cf. Section 16 of the executive order.
4) Quality assurance: The pharmacy's control system, which contains all documentation and procedures for handling cannabis intermediate products and cannabis finished products in connection with the pharmacy's production activities, and which must ensure consistent production of cannabis finished products and release in accordance with the rules laid down in the Act on the Medicinal Cannabis Programme and this executive order.

Quality assurance and documentation requirements

Section 4. The pharmacy must guarantee the quality of their production of cannabis finished products. The pharmacy must document the quality assurance, including describing responsibilities,

[1] *A draft of this 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).*

document management, workflows and risk management measures associated with the production of cannabis finished products.

(2) The pharmacy must have production procedures.

(3) All procedures must be approved, signed and dated by the responsible person.

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

Section 5. The pharmacy must have a system for dealing with deviations from procedures for the production of the cannabis finished product. The pharmacy must perform root cause analysis in order to investigate deviations and suspected product defects.

(2) The pharmacy must undertake corrective and preventive actions if deviations from the procedures for the production of cannabis finished products are recorded.

Section 6. Every pharmacy must ensure that a documentation system is established and maintained. The system must include documentation for quality assurance, including procedure descriptions for the individual production and inspection of the complete cannabis finished product, as well as general instructions for procedures concerning equipment, production and inspection.

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

(3) All changes must be made so that the change is dated and the original text can still be read.

(4) The documentation relating to quality assurance must be kept for at least 5 years.

Section 7. If electronic, photographic or other data processing systems are used, the pharmacy 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.

Organisation and governance

Section 8. Production activities may only be carried out by pharmacists or other academics with a scientific background or pharmaconomists, who must undergo basic and ongoing training on the production process.

Section 9. The responsible person must have a scientific (academic) background and relevant experience.

Section 10. The responsibilities of the management and the responsible person must be specified in a functional distribution plan.

Requirements for premises and equipment

Section 11. Premises and equipment must be designed, used and maintained so that they are suitable for the production of cannabis finished products and so that they can be cleaned effectively. The pharmacy must document the maintenance and cleaning of premises and equipment.

(2) Premises and workstations must be arranged in such a manner as to reduce the risk of errors as far as possible.

Section 12. Equipment and processes to be used in the production of cannabis finished products and with a decisive impact on the quality of the cannabis finished product must be subject to appropriate qualification and validation by the pharmacy.

Production requirements

Section 13. The pharmacy must ensure that cannabis finished products are produced in accordance with the Act on the Medicinal Cannabis Programme, section 18(1) and (2), and the requirements of this executive order.

Section 14. Prior to production, the person producing a cannabis finished product must ensure that:

1) the cannabis intermediate product to be used in the specific production corresponds to the prescription and what the pharmacy has ordered,
2) the cannabis intermediate product has been inspected upon receipt and that there has been compliance with the storage conditions for the cannabis intermediate product during storage at the pharmacy, and
3) the cannabis intermediate product is intact and undamaged.

Section 15. Labelling of a cannabis intermediate product as part of the production of a cannabis finished product must be positioned appropriately and not cover other essential information on the packaging.

(2) Labelling in the form of text must be written in Danish.

Section 16. Before dispensing cannabis finished products, the responsible person must ensure that an inspection is performed to confirm that they have been produced in accordance with the executive order and the procedures for production specified in section 18(1) and (2) of the Act on the Medicinal Cannabis Programme, and also that the cannabis finished products are labelled in accordance with the rules laid down in the Act on the Medicinal Cannabis Programme.

(2) If possible, the responsible person may conduct their inspection from a location other than the one where the cannabis finished product is produced.

(3) The responsible person may delegate the performance of the inspection referred to in paragraphs 1 and 2 to another employee at the pharmacy with a scientific (academic) background and relevant experience.

Section 17. The pharmacy must ensure that all production processes are carried out in accordance with established instructions and procedures. Appropriate and sufficient resources must be available for inspection of the production process.

(2) Measures must be implemented to avoid confusion.

Requirements for production documentation

Section 18. Every pharmacy must be in possession of documentation for the production of the individual cannabis finished product, which makes it possible to track the production process, including registration of the batch number for the cannabis finished product.

(2) All documentation relating to the produced cannabis finished products must be retained for at least one year beyond the expiry date of the product or at least five years after the inspection of the finished cannabis finished product, cf. section 16, whichever is longer.

Self-inspection

Section 19. Every pharmacy 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.

Exemption

Section 20. The Danish Medicines Agency may grant exemptions from one or more provisions of this executive order in exceptional circumstances.

Penalties

Section 21. Infringement of Section 2(1) and Sections 4–19 of this executive order shall be punishable by a fine or imprisonment for up to eighteen months.

(2) Criminal liability under paragraph 1 shall rest with the pharmacist, the regional council or the owner of the private hospital pharmacy, respectively.

Entry into force

Section 22. The executive order shall enter into force on 1 January 2026.

(2) Executive Order no. 2501 of 14 December 2021 on the production of cannabis finished products by pharmacies is repealed.

Danish Medicines Agency