

Executive Order on the labelling, etc. on cannabis intermediate productsⁱ

Pursuant to Section 49 and Section 66(2) of Act No 439 of 6 May 2025 on amendment of the Act on a Medicinal Cannabis Pilot Programme and on a programme for the cultivation, production, etc. of medicinal cannabis, the following is laid down:

Chapter 1

Scope and definitions

Section 1. This executive order covers the labelling, product sheets, patient information sheets, and packaging of cannabis intermediate products included in the Medicinal Cannabis Programme, cf. section 7 of the Act on the Medicinal Cannabis Programme and on a programme for the cultivation, production, etc. of medicinal cannabis.

(2) This executive order does not cover the labelling of cannabis finished products, cf. section 18 of the Act on the Medicinal Cannabis Programme and on a programme for the cultivation, production, etc. of medicinal cannabis.

Section 2. Labelling means all text and graphics on the outer and inner packaging of a cannabis intermediate product, including product sheets and patient information sheets, cf. paragraphs 2 and 3. Graphics also include QR codes, if affixed by the company.

(2) Product sheet means a document containing an overview of the labelling information of the cannabis intermediate product. The purpose of the product sheet is to make the labelling information available to the prescribing physician so that the information may be used in the physician's prescription and guidance of the patient, cf. section 8.

(3) Patient information sheet means a document containing relevant information for the patient about excipients, method of preparation and use of the cannabis intermediate product. The purpose of the patient information sheet is to inform the patient about relevant information concerning the cannabis intermediate product, cf. section 9.

Chapter 2

General provisions

Section 3. The labelling of a cannabis intermediate product must be legible, easily understandable and indelible.

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

Section 4. The labelling of a cannabis intermediate product must not contain elements of an advertising nature.

Section 5. The labelling of a cannabis intermediate product must not be misleading or likely to cause confusion with other cannabis intermediate products, cannabis finished products or other medicinal products.

(2) The packaging of a cannabis intermediate product must not give rise to confusion of the product with foodstuffs or luxury items.

Section 6. When a cannabis intermediate product is included in the Medicinal Cannabis Programme, the producer of the cannabis intermediate product is responsible for keeping the labelling up to date in accordance with this executive order.

(2) Amendments to the labelling of a cannabis intermediate product must be submitted to the Danish Medicines Agency as an amendment request, cf. section 7(6) of the Act on the Medicinal Cannabis Programme and on a programme for the cultivation, production, etc. of medicinal cannabis. Amendments relating solely to layout need not be submitted to the Danish Medicines Agency.

Chapter 3

Labelling and packaging

Section 7. The packaging of a cannabis intermediate product must contain the following information:

1) The name of the cannabis intermediate product, cf. Section 48(3) of the Act on the Medicinal Cannabis Programme and on a programme for the cultivation, production, etc. of medicinal cannabis.

2) A declaration of the active constituents of the cannabis intermediate product. The declaration of active constituents may be stated as set out in the EMA Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products.

In addition, the quantitative content of THC (dronabinol) and CBD (cannabidiol) must be stated immediately after the product name.

3) All excipients must be listed qualitatively. Excipients with known effect must be stated with a warning. Warnings for excipients with known effect may be given as set out in the Annex to the European Commission guideline on Excipients in the labelling and package leaflet of medicinal products for human use.

4) The pharmaceutical form.

5) The pack size.

6) The method of administration, including recommended medical devices for administration of the product, where applicable.

7) The method of preparation, if applicable.

8) The method of storage and the expiry date. Storage conditions must be stated as set out in Annex 1.

9) The name and address of the manufacturer of the cannabis intermediate product.

10) The product number of the cannabis finished product.

11) The batch number.

12) The following must appear on the packaging: "Medicinal cannabis".

13) The following must appear on the packaging: "Smoking of the cannabis product is discouraged".

14) The following must appear on the packaging if the product is not included in the programme permitting use by inhalation: "Inhalation of the cannabis product is discouraged".

15) For products where a dosing device must be used to measure the cannabis product, and where such a dosing device is included in the package, the packaging must state which dosing device is provided.

16) For products where a dosing device must be used to measure the cannabis product, but where no dosing device is included in the package, the packaging must state that no dosing device is provided and must also indicate which standard dosing device is suitable for dosing the product.

(2) The labelling information referred to in paragraph 1, nos. 1, 2, 4, 5, 8, 9, 11, 13 and 14 must be stated both on the inner packaging and on any outer packaging of the cannabis intermediate product.

(3) The labelling information referred to in paragraph 1, nos. 3, 6, 7, 10, 12, 15 and 16 must be stated on the outer packaging of the cannabis intermediate product. If the package consists only of inner packaging, the information must be stated on the inner packaging. The producer of the cannabis intermediate product may choose to state the information on both the inner and the outer packaging.

(4) If it is not possible to include all details concerning excipients, use or method of preparation, cf. paragraph 1, nos. 3, 6 and 7, on the packaging, cf. paragraph 3, the information must instead be provided in the package in the form of a patient information sheet, cf. section 9.

(5) The name of a cannabis intermediate product must also be stated in Braille on any outer packaging. If the package consists only of inner packaging, the information must be stated on the inner packaging.

(6) The producer of the cannabis intermediate product may not label the cannabis intermediate product with the information referred to in section 18 of the Act on the Medicinal Cannabis Programme and on a programme for the cultivation, production, etc. of medicinal cannabis.

Section 8. A product sheet must be prepared for all cannabis intermediate products included in the programme. The product sheet must contain the information specified in section 7(1).

(2) The product sheet shall be prepared by the producer of the cannabis intermediate product in connection with the application for inclusion of the product in the Medicinal Cannabis Programme.

(3) The Danish Medicines Agency shall verify the product sheet on the basis of the information in the application for inclusion of the cannabis intermediate product in the programme and shall make the product sheet available on the website of the Danish Medicines Agency.

(4) In the event of changes to the labelling of the cannabis intermediate product, the producer of the cannabis intermediate product shall be responsible for updating the product label, cf. Section 6. The Danish Medicines Agency shall make the amended product sheet available on the website of the Danish Medicines Agency.

Section 9. A patient information sheet must be prepared where the necessary information on use, method of preparation and/or declaration of excipients, as well as any associated warnings, cannot be stated on the packaging, cf. section 7(4). The patient information sheet must be included in the packaging of the cannabis intermediate product.

(2) The patient information sheet must contain, as a minimum, the necessary information on use and, where relevant for the individual product, information on method of preparation, declaration of excipients, and any warnings concerning excipients with known effect.

(3) The patient information sheet shall be prepared by the producer of the cannabis intermediate product in connection with the application for inclusion of the product in the Medicinal Cannabis Programme.

(4) The Danish Medicines Agency shall verify the patient information sheet on the basis of the information in the application for inclusion of the cannabis intermediate product in the programme and shall make the patient information sheet available on the website of the Danish Medicines Agency.

(5) In the event of changes to the use, method of preparation, excipients, etc. of the cannabis intermediate product, the manufacturer of the cannabis intermediate product shall be responsible for updating the patient information sheet, cf. section 6. The Danish Medicines Agency shall make the amended patient information sheet available on the website of the Danish Medicines Agency.

Section 10. A cannabis intermediate product must be packaged in such a way that any tampering with the packaging can be easily detected.

Chapter 4

Derogations and right of appeal

Section 11. The Danish Medicines Agency may, in special cases and under conditions determined in each individual case, grant derogations from the provisions of this executive order.

Section 12. Any person who contravenes sections 3-10 shall be liable to a fine.

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

Chapter 5

Provisions for entry into force

Section 13. The regulation would enter into force on 1 January 2026.

(2) Executive Order no. 2521 of 14 December 2021 on the labelling, etc. of cannabis intermediate products is repealed.

Danish Medicines Agency,

Storage conditions

The following applies to labelling on packaging and text in product sheets and patient information sheets for the cannabis intermediate product:

Stability data	Text in product sheets and patient information sheets	Labelling of packaging	Addendum to text in product sheets and patient information sheets and labelling on packaging*
The cannabis intermediate product is stable at temperatures above 30 °C	No special storage conditions or This cannabis intermediate product requires no special precautions for storage. or There are no specific requirements regarding storage temperatures for this cannabis intermediate product.	No labelling	May be labelled: Do not freeze or Do not refrigerate or freeze.
The cannabis intermediate is stable at temperatures up to 30 °C	Do not store at temperatures above 30 °C or Store at temperatures below 30 °C	May be labelled: Do not store at temperatures above 30 °C or Store at temperatures below 30 °C	May be labelled: Do not freeze or Do not refrigerate or freeze.
The cannabis intermediate is stable at temperatures up to 25 °C	Do not store at temperatures above 25 °C or Store at temperatures below 25 °C	Must be labelled: Do not store at temperatures above 25 °C or Store at temperatures below 25 °C	May be labelled: Do not freeze or Do not refrigerate or freeze.
The cannabis intermediate product is stable at temperatures up to 5 °C ±3 °C	Store in a refrigerator (2 °C–8 °C) or Store in a refrigerator and transport refrigerated (2°C–8°C)**	Must be labelled: Store in a refrigerator or Store in a refrigerator and transport refrigerated	May be labelled: Do not freeze
The cannabis intermediate is stable only when frozen	Store in a freezer ({{temperature range}}) or Store and transport frozen ({{temperature	Must be labelled: Store in a freezer or Store and transport frozen**	

	range})**		
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- * If relevant, the general storage conditions shall be supplemented with additional labelling, which must also appear in the product sheet and patient information sheet, and on the packaging.
- ** This text should only be used where critically necessary.

Other supplementary storage conditions:

	Storage problems	Supplementary text for the product sheet and patient information sheet, as well as labelling on the packaging, depending on the type of packaging*
1	Moisture-sensitive	Store in the original <container>** , tightly closed or 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 in the product sheet and the patient information sheet, and 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 submitted with the application 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.

ⁱ 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).