Order on product numbers for end products of cannabis and the cannabis intermediates used[1]

Pursuant to Section 42(2) and Section 66(2) of Act No 1668 of 26 December 2017 on a pilot scheme for medicinal cannabis and on a scheme for the cultivation, production, etc. of medicinal cannabis, as amended by Acts No 2392 of 14 December 2021 and No 439 of 6 May 2025, the following is laid down:

Section 1. A product number uniquely identifies a cannabis end product and the cannabis intermediate from which the cannabis end product is made. A named cannabis end product and the cannabis intermediate product used in a specific form, strength and package size must thus have a unique product number.

Section 2. An intermediate product manufacturer must apply to the Danish Medicines Agency for a product number for the cannabis end product and the cannabis intermediate product from which the cannabis end product is manufactured.

(2) An application under (1) must be submitted together with an application for inclusion of the cannabis intermediate product on the list of cannabis intermediate products covered by the scheme, cf. Section 7(2) of the Act on the Medicinal Cannabis Pilot Programme and the Scheme for Cultivation, Production etc. of Medicinal Cannabis.

(3) Applications must be submitted electronically using the application form prepared by the Danish Medicines Agency.

Section 3. If a cannabis intermediate product has been removed from the list of cannabis intermediate products covered by the scheme, cf. Section 8 of the Act on the medicinal cannabis scheme and on the scheme for the cultivation, production, etc. of medicinal cannabis, and if an application is subsequently made for inclusion of the cannabis intermediate product on the list again, an intermediate product manufacturer must at the same time apply for a new product number, cf. Section 2.

Section 4. An intermediate product manufacturer must affix the product number to the packaging of the cannabis intermediate product, cf. Section 7 of the Order on the labelling, etc. of cannabis intermediate products, in such a way that it cannot be removed.

Section 5. The Danish Medicines Agency can, in special cases, based on conditions which are set in each individual case, issue exemptions to the regulations stipulated in this notification.

Section 6. Infringements of Section 4 or of conditions laid down pursuant to Section 5 may be punishable by a fine.

(2) Companies, etc., (legal persons) may be held criminally liable in accordance with the regulations set out in Chapter 5 of the Penal Code.

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[1] A draft of this Order has been notified in accordance with Directive (EU) 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)

Section 7. The regulation enters into force on 1 January 2026.

(2) Order No 2522 of 14 December 2021 on product numbers for cannabis end products and the cannabis intermediate products used is hereby repealed.

The Danish Medicines Agency