Order on medical prices and delivery conditions, etc. for cannabis intermediate products and cannabis end products[1]

The following is laid down pursuant to Section 43(2), Section 45(2) and (3), Section 46(3), Section 47(2), Section 47a(6) and Section 66(2) of Act No. 1668 of 26 December 2017 on the pilot scheme for medicinal cannabis and on the scheme 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:

§ 1. The order encompasses cannabis intermediate products, cf. Section 3(7) of the Medicinal Cannabis Act, and cannabis end products, cf. Section 3(9) of the Medicinal Cannabis Act.

§ 2. An intermediate product manufacturer, cf. Section 3, no. 8, of the Medicinal Cannabis Act, must report the following to the Danish Medicines Agency:

1) Pharmacy purchase price for cannabis intermediate products at the package level when a new package is brought to market or the price of an existing package changes.
2) Delivery capacity (i.e. number of packages that can be delivered at the start of the price period) if the cannabis intermediate product is included in a reimbursement group, cf. Section 4(2) of the legislative decree on reimbursement for cannabis end products, but only in connection with price notification in accordance with no. 1.

§ 3. Notification under Section 2 must be made no later than Monday at 8 pm 14 days before the entry into force of a new medicine price period, cf. section 43(1) of the Medicinal Cannabis Act.

(2) An intermediate product manufacturer must ensure that the notification has reached the Danish Medicines Agency in a timely manner and that the notification has the desired content.

§ 4. The Danish Medicines Agency rejects notification of a pharmacy purchase price in the following cases:

1) A change of less than DKK 1.00 is reported.
2) A pharmacy purchase price is reported without simultaneous reporting of delivery capacity where required under Section 2(2).

§ 5. At least 10 days before the entry into force of a new pharmaceutical price period, the Danish Medicines Agency will inform the intermediate product manufacturer of the status of the notification, including the time of the

notification, the content of the notification, receipt by the Danish Medicines Agency and information on whether the notified price is given the status of 'A', 'B' or 'C' price, cf. paragraph 2.

(2) In a group consisting of intermediate cannabis products containing the same cannabis starting product and which are in the same quantity and strength as the prescribed cannabis end product, cf. Section 30 of the Medicinal Cannabis Act, covered by the scheme, the 'A', 'B' and 'C' prices are understood as follows:

1) The 'A' price is the lowest price of a cannabis intermediate product in the group.
2) The 'B' price is the price in the group when the price difference between the cheapest intermediate cannabis product and the cannabis intermediate product is:
   a) DKK 5 if the cheapest cannabis intermediate product in the group costs DKK 100 or less;
   b) 5% of the price of the cheapest intermediate cannabis product if the cheapest intermediate cannabis product in the group costs more than DKK 100, but less than DKK 400; or
   c) DKK 20 if the cheapest intermediate cannabis product in the group costs DKK 400 or more.
3) The 'C' price refers to the other prices in the group of cannabis intermediate products.

§ 6. The Danish Medicines Agency publishes the following information together with Medicine Prices for Companies:

1) The price of cannabis end products produced from cannabis intermediate products, cf. Section 2(1).
2) Package sizes.
3) Substitutability at the package level, cf. Section 30 of the Medicinal Cannabis Act.
4) Warnings about cannabis end products that affect the ability to drive.
5) Prescription status.
6) Package combinations, cf. Section 31 of the Medicinal Cannabis Act.
7) 'A', 'B' or 'C' price.
8) Reimbursement price, cf. Section 4(1) of the legislative decree on reimbursement for cannabis end products.
9) Shortages, cf. Section 9(1).

(2) In addition to publishing the information in Medicine Prices for Companies, cf. paragraph 1, the Danish Medicines Agency also informs pharmacies about the information.

§ 7. The Danish Medicines Agency publishes the information referred to in Section 6(1) together with other information in Medicine Prices for Companies online at: www.erhverv.medicinpriser.dk.

(2) Medicinal prices are published every second Monday.The information is valid from 12 a.m. on Monday.

*(3)*The information in paragraph 1 is made available electronically to subscribers at 6 pm on the last working day, excluding Saturdays, before the Monday on which the information in Medicine Prices for Companies takes effect.

(4) Anyone can subscribe to Medicine Prices for Companies. The subscription provides access to www.erhverv.medicinpriser.dk and to the information stated in Section 8(1) and (2).

Section 8. Prior to publication in accordance with Section 7(1)-(3), the following preliminary information will be made available to subscribers at www.erhverv.medicinpriser.dk:

1) 11 days before publication: Preliminary information on prices for new packages of cannabis intermediate products and cannabis end products, as well as changes to the range.

2) 10 days before publication: The information referred to in Section 6(1), points 2 to 7, which is provisional at that time.

§ 9. Companies with wholesale distribution authorisation, cf. Section 39(1) of the Medicines Act, must report to the Danish Medicines Agency on all working days, except Saturdays, before 12 p.m. if it is not possible to meet pharmacies' orders for an intermediate cannabis product (a package) up to and including the next working day, except for Saturdays (shortages).

(2) Companies with wholesale distribution authorisation, cf. Section 39(1) of the Medicines Act, may not report shortages for cannabis intermediate products that it does not distribute.At the request of the Danish Medicines Agency, the company must document that it has a distribution agreement or similar arrangement for cannabis intermediate products that are reported in short supply.

*(3)*Reporting of shortages must be done as specified in Annex 1.

§ 10. If, on the last working day, excluding Saturdays, before a new price period enters into force, all companies that are required to report a supply shortage under Section 9 report a supply shortage for a cannabis intermediate product (a package) that in the coming price period will form the basis for the reimbursement price in a reimbursement group, the Danish Medicines Agency will not include information about the package in Medicine Prices for Companies, without prejudice to Section 11.

*(2)*Anyone who places a cannabis intermediate on the market must, at the request of the Danish Medicines Agency, disclose the name of the distributor the cannabis intermediate to pharmacies.

§ 11. Anyone who places an intermediate product of cannabis on the market may with 14 days' notice inform the Danish Medicines Agency that a package is under resolution.When a package is being processed, information about it is included in Medicine Prices for Companies, even if the conditions laid down in Section 10(1) are met.

*(2)*A package that is under resolution cannot form the basis for the subsidy price.

*(3)*The resolution period may be a maximum of three consecutive price periods, after which the package is permanently deleted from Medicine Prices for Companies.

§ 12. If the Danish Medicines Agency fails to include information about a package in Medicine Prices for Companies in accordance with Section 10(1), the information is resumed when an intermediate product manufacturer reports a price in accordance with Section 2(1), cf. Section 3(1).

§ 13. If at least one company with wholesale distribution authorisation, cf. Section 39(1) of the Medicines Act, reports shortages under Section 9(1) for a package that is part of a subsidy group and forms the basis for the subsidy price, the Danish Medicines Agency will establish a new subsidy price on the basis of the price of the cheapest package in the group that has not been reported in short supply.

(2) Subsidy prices in Medicine Prices for Companies are updated daily on the basis of shortage notifications.Updated subsidy prices are valid from 12 a.m. on the following working day, excluding Saturdays.

*(3)*If a cheaper cannabis intermediate can be delivered again after a shortage during the price period, the subsidy price will not be recalculated unless it is a 'C' price that forms the basis for the current subsidy price.

Section 14. Communication between an intermediate product manufacturer and the Danish Medicines Agency pursuant to Sections 2, 3-5 and 11(1) must take place electronically via the Danish Medicines Agency's online extranet system at www.dkmanet.dk, without prejudice to paragraph 2.

(2) Communication pursuant to paragraph 1 may, in agreement with the Danish Medicines Agency, be made by means other than via the Danish Medicines Agency's online extranet at www.dkmanet.dk if exceptional circumstances so warrant.

§ 15. In special cases, the Danish Medicines Agency may grant exemptions from Sections 2-5, Section 9, Section 10(1) and Section 11 of this legislative decree, including for reasons of patient safety.

§ 16. Violations of Sections 2, 9 and 10(2) are punishable by fine.

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

§ 17. The order enters into force on 5 January 2026.

*(2)*Order No. 994 of 28 June 2023 on medicinal prices and delivery conditions, etc. for cannabis intermediate products and cannabis end products is hereby repealed.

Ministry of the Interior and Health,

Annex 1

Reporting of shortages of cannabis intermediate products

Reporting of shortages is done by email. The email must include an XML file containing the information provided in the field overview below. Information about the e-mail address to be used can be obtained from the Danish Medicines Agency.

Field overview

Description	**Indicative type/ length N = Numerical AN = Alphanumeric**	**Typical value quantities/validations/ comments**
CVR no.	N 10	CVR number of the company reporting
Submitter	AN32	Name of the company reporting
Reporting date	N8	Reporting in format YYYYYYMMDD
Item number	N6	
Product name	AN50	
Product form	AN7 if code AN50 if text	Product shape specified as either code or text
Strength	AN100 if text	Strength specified either as a decimal number plus a unit or as a text string
Package size	AN100 if text	Package size specified either as a decimal number plus unit or as a text string
Shortage	–	Shortages are indicated as actual type

[1] A draft of this legislative decree has been notified in accordance with Directive (EU) 2015/1535 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).