

Executive Order on fees for medicinal cannabis and cannabis-producing companies, etc.¹

Pursuant to section 64a(1) 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 1519 of 18 December 2018, Act No 2392 of 14 December 2021 and Act No 439 of 6 May 2025, and pursuant to section 2(b) of the Act on Euphoriant Substances, cf. Consolidated Act no. 1334 of 9 December 2019, the following is laid down:

Fees for business authorisations

Section 1. Anyone applying for an authorisation for the production of cannabis bulk and cannabis finished products must pay a fee to the Danish Medicines Agency for the processing of the application.

(2) The holder of an authorisation under paragraph 1 must pay an annual fee to the Danish Medicines Agency for regular company inspections (annual fee).

Section 2. Anyone applying for an authorisation for the production of cannabis intermediate products must pay a fee to the Danish Medicines Agency for the processing of the application.

(2) The holder of an authorisation under paragraph 1 must pay an annual fee to the Danish Medicines Agency for regular company inspections (annual fee).

Section 3. Anyone applying for an authorisation for the cultivation and handling of cannabis with a view to developing cannabis for medicinal use must pay a fee to the Danish Medicines Agency for the processing of the application.

(2) The holder of an authorisation under paragraph 1 must pay an annual fee to the Danish Medicines Agency for regular company inspections (annual fee).

Section 4. If a company holds a number of authorisations, it must pay the full annual fee for each individual authorisation.

Section 5. If the Danish Medicines Agency issues an authorisation to a company within the first 9 months of the year, after which the company must pay the annual fee, cf. sections 1 to 3, the company must pay the full annual fee for that year. If the authorisation is issued within the last 3 months of the year, the company does not have to pay an annual fee for that year.

(2) A company which, at the beginning of the year, is in possession of a business authorisation for which an annual fee is payable, cf. sections 1 to 3, must pay the full annual fee for the year in question.

Section 6. The amount of the fees referred to in sections 1 to 3 is set out in Annex 1. The fees apply for one geographical location. If a company is divided

¹ A draft of this order 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).

over several geographical locations, the company must pay a fee for each location.

Fees for cannabis product registration

Section 7. Anyone applying for inclusion of a cannabis intermediate product made from an imported cannabis primary product on the Danish Medicines Agency's list of cannabis intermediate products and associated cannabis primary products included in the medicinal cannabis programme must pay a fee for the processing of the application.

Section 8. Anyone applying for inclusion of a cannabis intermediate product made from a manufactured cannabis primary product on the Danish Medicines Agency's list of cannabis intermediate products and associated cannabis primary products included in the medicinal cannabis scheme must pay a fee for the processing of the application.

Section 9. The company that has a product included in the list must pay an annual fee for regular product monitoring and inspection.

Section 10. If a company has several products included in the list, it must pay the full annual fee for each cannabis intermediate product and associated cannabis primary product.

Section 11. If the Danish Medicines Agency places a product on the list within the first 9 months of the year, after which the company must pay the annual fee, cf. sections 7 to 9, the company must pay the full annual fee for that year. If the product is included within the last 3 months of the year, the company does not have to pay an annual fee for that year.

(2) A company which, at the beginning of the year, has a product on the list for which an annual fee is payable, cf. section 9, must pay the full annual fee for that year.

Section 12. The amount of the fees referred to in sections 7 to 9 is set out in Annex 1.

Payment and adjustment of fees

Section 13. The Danish Medicines Agency shall announce the procedure for payment of fees in accordance with this executive order. The fee shall be paid to the Danish Medicines Agency no later than one month after a demand for payment.

(2) The Danish Medicines Agency may refrain from initiating the processing of an application or terminate such processing if the fee for the processing of the application is not paid on time.

Section 14. The fees laid down in this executive order shall be adjusted once a year on 1 January in accordance with the rate set for the general price and wage index by the Ministry of Finance. The resulting amount shall then be rounded to the nearest whole krone.

(2) The current fees are published on the Danish Medicines Agency's website (lmst.dk).

Entry into force provision

Section 15. The regulation shall enter into force on 1 January 2026.

(2) Executive Order No 2553 of 20 December 2021 on fees for medical cannabis and cannabis-producing companies, etc. is repealed.

Ministry of the Interior and Health,

Annex 1

Fees

The Annex sets out the fee rates for application and annual fees under the executive order on fees for medical cannabis and cannabis-producing companies, etc.

Application type	Explanation	Danish Medicines Agency product number	Fee
Application for producer authorisation with cultivation activity	Production of cannabis bulk and cannabis primary product with cultivation activity	7001/7002	130,301 DKK
Application for producer authorisation without cultivation activity	Production of cannabis bulk and cannabis primary product without cultivation activity	7012	125,291 DKK
Application for intermediate product producer authorisation	Preparation of cannabis intermediate products	7003	70,432 DKK
Application for authorisation under the development programme	Cultivation and handling of cannabis for the purpose of developing cannabis for medicinal use	7004	43,690 DKK
Annual fee for producer authorisation with cultivation activity	Production of cannabis bulk and cannabis primary product with cultivation activity	7005/7006	53,606 DKK
Annual fee for producer authorisation without cultivation activity	Production of cannabis bulk and cannabis primary product without cultivation activity	7013	41,579 DKK
Annual fee for intermediate product producer authorisation	Preparation of cannabis intermediate products	7007	41,579 DKK
Annual fee for authorisation under the development programme	Cultivation and handling of cannabis for the purpose of developing cannabis for	7008	13,304 DKK

	medicinal use		
Application for inclusion of a cannabis intermediate product produced from an imported cannabis primary product		7009	49,385 DKK
Application for inclusion of a cannabis intermediate product produced from a produced cannabis primary product		7010	126,533 DKK
Annual fee for a listed cannabis intermediate product and associated primary product		7011	35,371 DKK