

**Application for admission to the list of cannabis intermediate products and cannabis primary products comprised by the medicinal cannabis pilot programme[[1]](#footnote-1)**

**Imported products**

1. **Information about the cannabis intermediate product**

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| 1.a  Intermediate product name applied for in Denmark: |
| 1.b  Pack size: |
| 1.c  Product form  Granules  Capsules, soft  Capsules, hard  Oromucosal spray  Oral liquid  Oral drops  Oral powder  Oral powder in sachet  Tablets  Herbal tea  Herbal tea in bag  Other, please state |
| 1.d  Applied declaration of content and strength: |
| 1.e  Packaging: |
| 1.f  Storage conditions: |
| 1.g  Shelf life before opening:  Shelf life after opening: |
| 1.h  Method of administration:  For oral use  For inhalation  For use in the oral cavity  For use under the tongue  Other, please state  Preparation after dispensing to the patient, if relevant: |
| 1.i  Dosage unit  The pack contains a relevant dosage unit: Yes  No  If yes, what type of medicine measurer: |
| 1.j  Any medical devices  Are any special medical devices required for the application: Yes  No  If yes, what type of medical device:  This medical device is supplied with the cannabis intermediate product: Yes  No |
| 1.k  **Documentation requirements** (to be enclosed with the application, please tick)  Draft labelling text for inner and outer packaging is enclosed. The product name should also appear from the outer packaging in Braille.  Draft text about use and preparation enclosed with the pack, if applicable.  Copy/photo of relevant medicine measurer, if this is supplied with the pack.  Copy/photo of relevant medical device, if this is supplied with the pack. |

1. **Information about the manufacturer of the cannabis intermediate product**

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| 2.a  Company name:  Company address:  Postal code:  Country:  Company tel. no.:  Company email address:  CVR no. (Danish company):  Reference no., if any, to relevant valid certificates in the Eudra GMDP database:  Responsible contact person:  Name:  Telephone:  Email: |
| 2.b  **Documentation requirements** (to be enclosed with the application, please tick):  Copy of valid company and manufacturing authorisation of the manufacturer of cannabis intermediate products – including authorisation to handle euphoriant substances, if relevant.  Company and manufacturing authorisation of the manufacturer of the cannabis intermediate products is under evaluation and therefore not enclosed. The authorisation will be submitted as soon as possible.  Copy of any other admission to the list of cannabis intermediate products and cannabis primary products.  Enclosed  Not relevant to enclose |

1. **Information about the cannabis primary product**

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| 3.a  Name of primary product in country of origin: |
| 3.b  Country of origin: |
| 3.c  Country of cultivation: |
| 3.d  Latin name of parent plant: |
| 3.e  Herbal substance (please tick)  Cannabis flower  Cannabis leaf  Cannabis herb  Other, please state: |
| 3.f  Herbal preparation, if any (please tick)  Comminuted herbal substance  Powdered herbal substance  Granulated herbal substance  Extract. Please state extraction agent:  Other, please state: |
| 3.g  Pharmaceutical form or other dosage formulation: |
| 3.h  Strength: |
| 3.i  Pack size(s): |
| 3.j  Packaging: |
| 3.k  Storage conditions:  No storage conditions have been stated. |
| 3.l  Shelf life:  Shelf life before opening:       Shelf life after opening:  No shelf life has been stated. |
| 3.m  **Documentation requirements** (to be enclosed with the application, please tick):  Overview of the composition applied for.  Documentation that the primary product was provided in accordance with the UN Single Convention of 30 March 1961, including the provisions on the establishment of a cannabis bureau and licence to cultivate cannabis on specified cultivation areas.  Documentation that the applied cannabis plant is cultivated in accordance with the good agricultural and collection practice (GACP) and that the plant is cultivated without the use of pesticides.  Documentation that the manufacture of the primary product complies with the national rules on cultivation and processing of cannabis products in the country of cultivation.  Documentation that the manufacture of the primary product complies with the national rules on cultivation and processing of cannabis products in the country of origin.  Documentation that the manufacture of the primary product is in accordance with the principles of good manufacturing practice (GMP).  Documentation that the product has been assayed to determine the content of THC and CBD and has been analysed for other quality-related substances and impurities in accordance with a monograph of the relevant pharmacopoeia or national standard. Information on batch numbers must appear from the enclosed certificates of analysis.  Documentation that the primary product can be legally dispensed in the country of origin for medicinal use in the same quality, form and pack size as the intermediate product applied for.  Documentation that the primary product complies with the requirements of the country of origin for packaging, pack size and labelling.  Any other relevant information: |

1. **Information about the manufacturer of the cannabis primary product**

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| 4.a  Company name:  Company address:  Postal code:  Country:  Company tel. no.:  Company email address:  Reference no. to relevant valid certificates in the Eudra GMDP database, if applicable: |
| 4.b  **Documentation requirements** (to be enclosed with the application, please tick):  Copy of valid company and manufacturing authorisation of the manufacturer of the primary product – including authorisation to handle euphoriant substances, if relevant. |

1. **Any comments:**

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| The applicant has the following other cannabis primary products or cannabis intermediate products on the list of cannabis intermediate products and cannabis primary products. Please state item number(s):  The applicant has previously had the following cannabis primary products or cannabis intermediate products on the list of cannabis intermediate products and cannabis primary products. Please state item number(s):  Other: |

**The application also includes an application for an item number for a cannabis product manufactured on the basis of the above-mentioned intermediate product.**

1. **Date and signature**

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| Date:  Click to write a date.  Signature: |

1. See section 7(2) of the legislative proposal L57 2017-18 on the medicinal cannabis pilot programme. The legislative proposal is proposed to be adopted with effect from 1 January 2018. [↑](#footnote-ref-1)