

**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.aIntermediate product name applied for in Denmark:       |
| 1.bPack 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.dApplied declaration of content and strength:       |
| 1.ePackaging:       |
| 1.fStorage conditions:       |
| 1.gShelf life before opening:      Shelf life after opening:       |
| 1.hMethod of administration: [ ]  For oral use[ ]  For inhalation[ ]  For use in the oral cavity[ ]  For use under the tongueOther, please state      Preparation after dispensing to the patient, if relevant:       |
| 1.iDosage unitThe pack contains a relevant dosage unit: Yes [ ]  No [ ] If yes, what type of medicine measurer:        |
| 1.jAny medical devicesAre 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.aCompany 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.aName of primary product in country of origin:       |
| 3.bCountry of origin:       |
| 3.cCountry of cultivation:       |
| 3.dLatin name of parent plant:       |
| 3.eHerbal substance (please tick)[ ]  Cannabis flower[ ]  Cannabis leaf[ ]  Cannabis herb[ ]  Other, please state:       |
| 3.fHerbal preparation, if any (please tick)[ ]  Comminuted herbal substance[ ]  Powdered herbal substance[ ]  Granulated herbal substance[ ]  Extract. Please state extraction agent:      [ ]  Other, please state:       |
| 3.gPharmaceutical form or other dosage formulation:       |
| 3.hStrength:       |
| 3.iPack size(s):       |
| 3.jPackaging:       |
| 3.kStorage conditions:      [ ]  No storage conditions have been stated. |
| 3.lShelf 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.aCompany 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)