

**Guidance to application form for admission to the Danish Medicines Agency's list of cannabis primary products and cannabis intermediate products comprised by the medicinal cannabis pilot programme.**[[1]](#footnote-1)

**Imported products**

The application form is divided into sections covering information and documentation about

* The intermediate product applied for
* The manufacturer of the intermediate product
* The primary product applied for
* The manufacturer of the primary product

In the following, you will find explanations to the information you should provide under each section in the application form as well as guidance on the type of documentation that you should enclose with the application.

You have to submit an application form per product, however, several pack sizes of the same product can appear from the same application form. If you apply for several strengths, you have to submit an application form for each strength of the product. The same applies to various forms of the product (e.g. tea and capsules). In that case, you also have to submit an application form for each product form.

**Product number:**

When cannabis intermediate products and cannabis primary products are included on the list, a product number will be allocated to the products. If there are several pack sizes of the same product, a product number will be allocated to each pack size.

Consequently, the application form also includes application of product number(s) for the cannabis intermediate products and cannabis products applied for.
When a cannabis product is finished and dispensed by a pharmacy, the cannabis product will have the same product number as the intermediate product.

**Language:**

Both the application form and the enclosed documentation must be in either Danish or English. If the original documents are in a third language, you need to enclose a copy of the original document as well as a translation into either Danish or English.

The enclosed draft labelling for the packaging must be in Danish and any description of the preparation must also be in Danish.

**Information about the cannabis intermediate product:**

In this section, you provide information about the product (intermediate product) that you apply for permission to manufacture on the basis of the imported primary product.

Intermediate product name applied for in Denmark:

Generally, the intermediate product must bear the same name as the primary product followed by the name of the intermediate product manufacturer. However, the name should not mislead or cause confusion with other cannabis intermediate products or cannabis products or any other medicinal products.
The name of the cannabis product is identical with the name of the cannabis intermediate product.

Pack size:

Please state the quantity per pack – e.g. number of grams (powdered or comminuted herbal substance), number of ml (liquid product) or number of pieces (capsules).

You can only apply for the same pack size(s) as that of the primary product applied for. You must not open packs of the primary product or make multi-packs.

Product form:

The product form is the pharmaceutical form or other dosage formulation in which the cannabis intermediate product applied for is available.

The Danish Drug Standards and the European Pharmacopoeia (Ph. Eur.) define various pharmaceutical forms and the related technical requirements.

In the application form, you can find examples of pharmaceutical forms that may be relevant to the application.

If the intermediate product applied for corresponds to one of these pharmaceutical forms, please tick the pharmaceutical form applied for, e.g. capsules, herbal tea, oral drops etc.

The examples in the application form are selected on the basis of ”Standards for pharmaceutical forms and terms that may be used for labelling” (in Danish). A more detailed description of the pharmaceutical forms is available in the applicable version of Danish Drug Standards, annex 4 (available electronically at www.retsinfo.dk in Danish).

Examples of the meaning of the individual pharmaceutical forms:

Granules:

Granules are a solid pharmaceutical form consisting of grain of a uniform size (like washing powder and instant coffee).

Capsules:

Hard capsules have a hard shell and typically contain a powder, granules or a comminuted herbal substance. Soft capsules have a soft shell and typically contain a liquid.

Oromucosal spray:

Oromucosal spray is a term used for the labelling of emulsion, solution and suspension dosed via a spray to the oral cavity.

Oral liquid:
Oral liquid is a term used for very few active substances, e.g. cod-liver oil and castor oil, administered directly into the mouth without any type of formulation. For example, wholly/partially evaporated extracts administered directly as they are.

Oral drops:
Oral drops is a term used for the labelling of oral drops, emulsion, solution and suspension. For example, wholly or partially evaporated extracts that are subsequently dissolved in oil, water or ethanol.

Sachet/bag:
Small sachet of woven paper or synthetic material (such as a tea bag), containing a single dose of the medicine.

Tablets:

The term tablet can be used for the labelling of tablets, coated tablets and film-coated tablets.

If the intermediate product applied for does not have a defined pharmaceutical form, please describe the form.

Declaration applied for (indication of content and strength):

The declaration must be in accordance with “Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products / traditional herbal medicinal products” (EMA/HMPC/CHMP/CVMP/287539).

By following this guideline, it will be ensured that the declaration comprises relevant information about the strength of the product and the applied parent plant, plant part as well as herbal preparation, if any.

When this guideline on declaration is followed, it will provide a good basis for comparing various products.

The following general principles apply to the declaration:

* The declaration is stated per dosage unit, that is per tablet, capsule, sachet etc. In case of a multi-dose pack (for example a pack of herbal tea, 200 grams), the unit of measurement should be indicated – preferably expressed as quantity per weight unit because this is the most exact unit (the volume depends on e.g. temperature).
* The quantity of the active substance (herbal substance or herbal preparation) should be stated as an interval for standardised herbal substances/herbal preparations and as an exact quantity for quantified herbal substances/herbal preparations.
* The quantity of the active substance/active marker should be indicated as the exact quantity in standardised herbal substances/herbal preparations (active substance) and as an interval for quantified herbal substances/herbal preparations (active marker).
* Both the Latin name and the Danish name of both the parent plant and the plant part should be included in the declaration. As regards parent plants like cannabis, where the applied subspecies is important, the relevant subspecies should also be stated.
* If extracts are used, the extraction solvent should be stated in the declaration (because the extraction solvent has an impact on which substances are extracted).

Examples of declarations:

1 sachet contains:
x-y grams *Cannabis sativa* subsp *sativa* L., flos (cannabis flower), corresponding to z mg delta-9-tetrahydrocannabinol (THC).

1 sachet contains:
x grams *Cannabis sativa* subsp *sativa* L., flos (cannabis flower), corresponding to

y-z mg delta-9-tetrahydrocannabinol (THC).

1 sachet contains:

x-y grams granules of *Cannabis sativa* subsp *sativa* L., flos (cannabis flower), corresponding to z mg delta-9-tetrahydrocannabinol (THC) and u mg cannabidiol (CBD).

1 sachet contains:

x-y grams granules of *Cannabis sativa* subsp *indica* L., flos (cannabis flower), corresponding to z mg delta-9-tetrahydrocannabinol (THC) and u mg myrcene.

1 capsule contains:
x-y grams extract (as dry extract) of *Cannabis sativa* subsp *sativa* L., flos (cannabis flower), corresponding to z mg delta-9-tetrahydrocannabinol (THC).

Extraction agent: Ethanol 50% V/V

1 capsule contains:
x grams extract (as soft extract) of *Cannabis sativa* subsp *sativa* L., flos (cannabis flower), corresponding to y-z mg cannabidiol (CBD)

Extraction agent: water.

All of the above examples are fictitious and only serve as examples of various pharmaceutical forms, various parent plants and herbal preparations as well as differences in the way in which the active substance is assayed.

Packaging:

Please indicate the packaging applied for and the material used for the packaging, e.g.:

Container made of plastic (HDPE) with red lid made of HDPE.

Bottle made of brown glass with a screw cap made of HDPE with dropper applicator .

Bag of paper packed in a cardboard box.

The packaging must not cause any confusion with food, beverages and other non-food products or cosmetic products.

Storage conditions:

Please indicate the storage conditions applied for, for example ”No special storage conditions”, ”Do not store above 30°C”, ”Store in refrigerator (2°C to 8°C)” or ”Store in original packaging”.

The wording of the stated storage conditions must be in accordance with the Danish Drug Standards.

The storage conditions of the intermediate product applied for must be based on the storage conditions applicable to the primary product in the country of origin. If no storage conditions apply to the primary product in the country of origin, this should be stated in the application form; the applicant may suggest storage conditions. In that case, argumentation and documentation for the suggested shelf life should be enclosed.

Shelf life:

Please indicate the shelf life of the product before opening and at the indicated storage, e.g. 24 months.

In some cases, a product may have a shorter shelf life after opening, e.g. 2 weeks. If so, this should also be stated.

The shelf life of the intermediate product applied for must be based on the shelf life applicable to the primary product in the country of origin. If no shelf life applies to the primary product in the country of origin, this should be stated in the application form; the applicant may suggest a shelf life. In that case, argumentation and documentation for the suggested shelf life should be enclosed.

Method of administration and method of preparation:

Please state whether the product is intended for oral consumption, for inhalation or any other method.

In the application form, you can find examples of methods of application that may be relevant to this application. The examples are based on the ”List of applicable standards as well as indication of non-technical terms for routes of administration” in the applicable version of Danish Drug Standards (annex 4). If the intermediate product applied for corresponds to one of these methods of application, please tick the method applied for.

You should also state whether the product requires further preparation after dispensing to the patient, e.g. preparation of herbal tea.
The description of the preparation should appear from the outer package, if possible. If this is not possible, the description of the preparation must appear from the enclosed description of the method of preparation that comes with the package.

Dosage unit:

Please state whether the intermediate product manufacturer provides a suitable dosage unit with the package of the cannabis intermediate product applied for.

If the product is available in doses (e.g. tablets and capsules, sachets in measured doses etc.), a dosage unit should not be provided.

Products that are not available in doses, such as herbal tea in large package size or solution for drinking, may be provided with a dosage unit that matches the product’s form and dosage, for example a measuring spoon, measuring glass, dosing syringe, dropper applicator or the like.

If the cannabis intermediate product is supplied with a relevant dosage unit, please enclose a copy/photo of the dosage unit.

Medical devices:

Please state whether the intake requires any special medical device, and if so, which device, e.g. an inhaler.

If the cannabis intermediate product is supplied with a relevant medical device, please enclose a copy/photo of the device.

The application of the medical device must be described in the enclosed description of the method of preparation.

Labelling:

Labelling includes the information appearing from the outer and inner packaging. A draft text for this purpose must be enclosed.

The labelling must include the following information, see section 52 of the special legislation:

The packaging of a cannabis intermediate product must contain the following information:

Name of cannabis intermediate product

Content and strength of cannabis intermediate product (corresponding to the declaration)

Form of the cannabis intermediate product

Pack size (content)

Method of application

Preparation, if any

Storage conditions and shelf life

Name and address of the intermediate product manufacturer

Product number of the cannabis product

Batch number

The labelling must be easy to read, easy to understand and indelible.

The text must be in Danish. This also applies to any description of the method of preparation.

Since the products are imported, the labelling may contain text in the original language. This labelling in the original language must not contain other information than the information appearing from the Danish labelling.

The labelling must not contain elements of a promotional nature.

The labelling must not be misleading or cause confusion with other medicinal products, pharmaceutical forms or strengths.

The information should, to the extent possible, be stated on both the inner and outer package.
If it is not possible to describe the preparation on the package, the description should be provided with the package.

The name of the product (cannabis intermediate product and cannabis product) should also appear in braille text on the outer package.

Moreover, it must be possible to see if the final package has been opened. It should appear from the draft labelling how this anti-tampering device works.

**Information about the manufacturer of the cannabis intermediate product:**

In this section, please provide information on the manufacturer of the cannabis intermediate product – this means the company that submits the application for admission to the list of cannabis intermediate products and cannabis primary products comprised by the medicinal cannabis pilot programme.

Information about the company’s name and geographical location as well as contact details of the responsible contact person must be stated in the application form.

As documentation, please enclose a copy of a valid authorisation to manufacture cannabis intermediate product for the intermediate product manufacturer as well as authorisation of activities with euphoriant substances. If the product applied for is not covered by the executive order on euphoriant substances, the manufacturer does not need to hold an authorisation of activities with euphoriant substances.

If the intermediate product manufacturer has or has had other cannabis products on the lists, please enclose relevant documentation for this. This information should be provided in the application form under ”Any comments”. See the section below.

**Information about the cannabis primary product:**

In this section, please provide information about the product you want to import for the purpose of manufacturing the intermediate product applied for.

Name of the primary product in the country of origin:

Please state the name of the product in the country in which the product can be dispensed to patients for medicinal use.

Country of origin:

Please state the country in which the primary product can be dispensed to patients for medicinal use.

Products can only be imported from countries in which the products are accepted for medicinal use and with which Denmark or the EU has signed an agreement on mutual recognition of the country’s regulatory supervision in the pharmaceutical area.

The agreements are available on the EMA’s website: [www.ema.europa.eu](http://www.ema.europa.eu) → Human regulatory → Research and development → Compliance → Good manufacturing practice → Mutual recognition agreements

The application can only concern one country of origin.

Country of cultivation:

Please state the country in which the used cannabis plant (parent plant) of the primary product applied for has been cultivated and harvested.

The application can only concern one country of cultivation.

Latin name of parent plant:

Please provide information about the parent plant used in the form of the Latin name of the plant. The name must contain both the generic name, name of the species as well as the subspecies (e.g. indica, sativa or ruderalis) and it must be stated whether this is a special variety or type of the plant.

In addition to the Latin name of the plant, the author of the plant name must also be mentioned (e.g. Linné).

Example: *Cannabis sativa* L. ssp.indica

Herbal substance:

A herbal substance is the part of the parent plant that is used, e.g. leaf (folium), flower (flos) or the above-ground part of the plant, which is termed herb (herba).

A herbal substance may be fresh or dried, whole or cut into smaller pieces, making it easy to handle.

Herbal preparation:

A herbal preparation is the further processing of the herbal substance, for example comminuted or powdered.

Another typical herbal preparation is an extract where the active substance of the herbal substance is extracted by means of an extraction solvent (e.g. water or ethanol). The extraction solvent used has an impact on which substances will be extracted. Consequently, the extraction solvent used should also be stated.

Extracts are also termed dry extract, soft extract or liquid extract – depending on whether the extract is subsequently dried fully or partially.

In this section, please state if an extract is dissolved in e.g. oil.

Pharmaceutical form:

Please state the primary product’s pharmaceutical form as in the country of origin.

See the above section on pharmaceutical form.

Strength:

Please state the strength as in the country of origin.

See the above section on strength.

Pack size:

Please state the pack size(s), in which the primary product can be legally dispensed for medicinal use, in the country of origin. See the above section on pack size.

Packaging:

Please state the packaging, in which the primary product can be legally dispensed for medicinal us, in the country of origin.

See the above section on packaging.

Storage conditions:

Please state the storage conditions of the product in the country of origin.

See the above section on storage conditions.

If the primary product has not been allocated any storage conditions in the country of origin, it should be stated instead.

Shelf life:

Please state the shelf life of the primary product in the country of origin.

See the above section on shelf life.

If the primary product has not been allocated any shelf life in the country of origin, it should be stated instead.

**Documentation requirements for the primary product:**

Composition:

Please state all the ingredients of the primary product – both the herbal substance/herbal preparation applied for (active substance) as well as any excipients.

The composition is particularly relevant to primary products consisting of herbal preparations and/or a dosage formulation – that is products, which also contain other substances (excipients) than the active substance.

As regards primary products where an extract is mixed with oil, both the quantity of the extract and all the excipients used (including the oil(s) used) must be stated in this section. As regards dried, powdered herbal substances in a capsule, please state all the excipients in both the capsule filler and the capsule itself.

Names of any excipients should, to the extent possible, be stated in accordance with the Danish Drug Standards. Table of terms for raw materials is available at [www.dkma.dk / Licensing and supervision / Supervision and inspection / Danish Drug Standards](https://laegemiddelstyrelsen.dk/en/licensing/supervision-and-inspection/danish-drug-standards/).

The quantity of the active substance and all excipients must also appear. The quantity should be expressed in grams or milligrams per dosage unit in case of a dosage formulation. As regards products in a non-solid form available in doses, e.g. 100 grams of herbal tea, it would be relevant to state the quantities per 1 gram or per 100 grams, depending on what appears to be most relevant.
The function of the individual ingredients must also be stated (e.g. extraction solvent, solvent, capsule shell, filler, lubricating agent etc.).

Please state the quality (e.g. Ph. Eur. quality) for all ingredients.

This guidance includes a composition form in appendix 1, in which you can specify the composition.

UN Single Convention:

Please enclose a letter/certificate/declaration from the relevant national authority in the country of origin and/or the country of cultivation that the country in question has acceded to the UN Single Convention of 30 March 1961 on control with narcotic drugs, including the provisions on the establishment of a cannabis bureau and licence to cultivate cannabis on specified cultivation areas.

Documentation for good agricultural and collection practice (GACP):

Please provide documentation that the plant material for the manufacture of the primary product has been cultivated in accordance with good agricultural and collection practice. For example, a letter/certificate from the relevant national authority in the country of cultivation.

Alternatively, a GACP statement from the manufacturer of the primary product may be enclosed, from which it appears that the manufacturer of the primary product declares that the cultivation of the used plant material took place in accordance with GACP.

Moreover, it must appear from the documentation submitted that the plant material was cultivated without the use of pesticides. For example, a declaration from the relevant authority in the country of cultivation or a declaration from the relevant cultivator.

Documentation that manufacturing and cultivation comply with the national rules in the country of cultivation:

Please provide documentation that cultivation of the plant material used for the manufacture of the primary product complies with the national rules on cultivation and processing of cannabis in the country of cultivation. For example, a letter/certificate issued by the relevant national authority in the country of cultivation or a declaration from the manufacturer of the primary product.

Documentation that manufacturing of the primary product complies with the national rules in the country of origin:

Please provide documentation that the manufacture of the primary product complies with the national rules on the manufacture of cannabis products in the country of origin. For example, a letter/certificate/declaration issued by the relevant national authority in the country of origin, from which it appears that the primary product in question can be distributed for medicinal use in the country concerned. It could also be a copy of the manufacturer’s authorisation issued by the national authority in the country of origin as well as a declaration from the manufacturer of the primary product that the requirements in the authorisation are complied with.

Documentation that the manufacture of the primary product is in accordance with the principles of good manufacturing practice (GMP):

For example, you could enclose a valid authorisation/registration, covering the manufacture of APIs (active product ingredients) or a valid GMP certificate, covering the relevant activities.

Alternatively, please enclose any other type of valid manufacturing authorisation as well as a declaration from the manufacturer that the manufacture takes place in accordance with the principles of good manufacturing practice (GMP).

Documentation for determination of strength:

Please enclose certificates of analysis, from which all analytical parameters, the related acceptance criteria as well as results of analyses must appear. Information on batch number must appear from each certificate of analysis.
It must appear from the certificates of analysis whether analyses were made in accordance with a monograph in e.g. the German pharmacopoeia, the European Pharmacopoeia, the United States Pharmacopeia, another national pharmacopoeia, such as the Japanese pharmacopeia or a well-established national standard. The analytical parameters and methods described in the monograph must be used.

As regards quality-related substances as well as impurities, analyses must be made according to the analysis parameters and methods described in the relevant pharmacopoeial monograph.

Quality-related substances mean THC, CBD and any other declared substances in the primary product.

Impurities mean analyses such as ”foreign matter”, ”Loss on drying”, degradation products (e.g. cannabinol (CBN)), pesticides, heavy metals, ”total ash”, aflatoxins, microbial purity etc. If the selected monograph does not contain such tests, additional general tests must be made for herbal substances in the European Pharmacopoeia (Ph. Eur.).

To document a consistent production, the above-mentioned certificates of analysis must be enclosed for at least 3 batches, and the analytical results must be within the acceptance criteria of declared content and impurities, respectively. If the product applied for consists of e.g. cannabis flower, analyses should be made according to a monograph for cannabis flower, e.g. of the German pharmacopoeia. This means that the content of THC and CBD must be in the range of + 10% of the declared content and that the content of cannabinol (CBN) must not exceed 1%.

If the product applied for contains an extract, it may be more relevant to make the analysis according to a monograph for extracts, if possible.

If it is not possible to submit certificates of analysis for 3 batches when you submit the application, please enclose at least one certificate of analysis and submit the remaining certificates of analysis to the Danish Medicines Agency later on. In this case, the individual batches must not be released by the intermediate product manufacturer for prescription and dispensing at a pharmacy until you have received acceptance from the Danish Medicines Agency. An explanation justification on why it is not possible to submit certificates of analysis for 3 batches should be enclosed.

Documentation that the primary product can be legally dispensed in the country of origin for medicinal use in the same quality, form etc. as the intermediate product applied for:

Please provide documentation that the primary product applied for can be legally dispensed to patients for medicinal use in the same quality, form and pack size(s) in the country of origin. It should also appear from the documentation that the primary product applied for complies with the requirements of the country of origin for packaging and labelling (the text on the package).

For example, a letter/certificate issued by the relevant national authority in the country of origin, from which it appears that the primary product in question can be distributed for medicinal use in the country concerned. If such documentation is not available on product level, please enclose documentation that the company is authorised to manufacture products that can be legally dispensed as well as a declaration from the manufacturer that the product complies with the requirements of the country of origin.

**Information about the manufacturer of the cannabis primary product:**

Please provide information about the manufacturer of the cannabis primary product.

Information about the company’s name and address (including country) as well as contact details should be stated in the application form.

For example, you could enclose a valid manufacturing authorisation/registration, covering the manufacture of APIs (active product ingredients) or a valid GMP certificate, covering the relevant activities.

Alternatively, please enclose any other type of valid manufacturing authorisation as well as a declaration that the manufacture of the primary product takes place in accordance with the principles of good manufacturing practice (GMP).

See the above section on documentation for the manufacturing of the primary product.

**Any other comments:**

Please provide any other information that may be relevant to the application, for example, more documentation about a certain topic.

If the applicant has other cannabis primary products or cannabis intermediate products on the lists of cannabis primary products or cannabis intermediate products for medicinal use, this should also be stated and a copy of the admission letter should be enclosed – including information about case no. and the previously issued product number(s). This also applies if the applicant has previously had cannabis products included on the lists or applied for admission to the lists. This information should be enclosed as documentation related to the intermediate product manufacturer.

**Submission of application:**

The applicant completes and signs the application form. Please print your name below your signature and the date.

Please send the application form to the Danish Medicines Agency by email to medicinskcannabis@dkma.dk. In the subject field, please write ”Application for admission to list”.

**Appendix 1**

**Composition form** for

The quantities stated are per

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| Active substance(s) | Quantity | Quality / specification | Function |
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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)