HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Import and Export Licences and Letters of No Objection for Controlled Drugs (including the import of cannabis-based products for medical use)

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~~This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.~~

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1 INTRODUCTION

Operators (manufacturers, wholesalers, authorised persons) require a controlled drugs licence or registration processed by the Health Products Regulatory Authority (HPRA) on behalf of the Department of Health if they wish to produce/manufacture, supply, import, export or possess any controlled drug in the Schedules to the Misuse of Drugs Regulations 2017, as shown below:

Activity	Regulatory requirements
Manufacture of any controlled drugs listed in the schedules	Annual licence, renewed each year
Supply, import, export or possess a controlled drug in Schedules 1 and 2	Annual licence, renewed each year
Supply, import, export or possess a controlled drug in Schedules 3, 4 and 5	Registration, not subject to renewal
In addition:	
Each import or export of controlled drugs in Schedules 1, 2, 3 and Schedule 4 part 1 into or out of Ireland*	Import or export licence (as appropriate), to accompany the product
Each import or export of controlled drugs in Schedule 4 part 2 and Schedule 5 into or out of Ireland	Letter of no objection (LONO)

~~Application forms for annual licences and registrations can be found on the 'Publications and Forms' section of www.hpra.ie or by contacting controlleddrugs@hpra.ie. Details on how to apply for an import/export licence or LONO are outlined below.~~

*The Misuse of Drugs (Prescription and ~~control~~Control of Supply of ~~supply of cannabis~~Cannabis for ~~medical use~~Medical Use) Regulations 2019, as amended, permits cannabis-based products specified in Schedule 1 of the Regulations to be imported for supply via the Medical Cannabis Access Programme (MCAP) in Ireland. There are additional restrictions and requirements relating to the import and supply of such cannabis-based products. See ~~Section~~Appendices 1 and 2.~~11~~ for further details.

Application forms for annual licences and registrations can be found on the HPRA website or requested by contacting the HPRA at controlleddrugs@hpra.ie. Details on how to apply for an import/export licence or LONO are outlined further in this guide.

2 HOW TO APPLY FOR AN IMPORT/EXPORT LICENCE OR LONO

2.1 NDS Web

~~Manufacturers and wholesalers must have a~~The National Drugs Control System (NDS) Web is a highly secure online licence application system for controlled drugs. NDS is designed to improve the processing times for licence and LONO applications and to facilitate electronic data collection for monitoring trade in controlled drugs. Manufacturers and wholesalers must have an NDS Web account to apply for any import/export licences or LONOs, **with the exception of LONOs for Schedule 5 controlled drugs**. ~~NDS Web is a highly secure online licence application system for controlled drugs. It forms part of the National Drugs Control System (NDS) and is designed to improve the processing times for licence and LONO applications and to facilitate the electronic data collection for monitoring trade in controlled drugs~~To obtain a LONO for Schedule 5 controlled drugs, an application form should be requested from the HPRA at controlleddrugs@hpra.ie. See section 2.5 of this guide for further details.

~~All other authorised persons wishing to apply for an import/export licence or LONO should contact the HPRA directly on controlleddrugs@hpra.ie for instructions on how to apply for a NDS Web account.~~

~~In order to obtain a LONO for Schedule 5 controlled drugs, an application form should be requested from controlleddrugs@hpra.ie. See Section 2.5 for further details.~~

~~A 'Guide to NDS Web Extranet' can be found on the 'Publications and Forms' section of www.hpra.ie.~~

2.2 Applying for a NDS Web account

To apply for a NDS Web account, the applicant should firstly provide the following information to the HPRA at controlleddrugs@hpra.ie:

- Name of company
- Name of contact person and email ~~controlleddrugs@hpra.ie to obtain the website link~~address (It is recommended that this is a group email that can be accessed by all staff who will have a role in applying for ~~NDS Web.~~controlled drug licences)
- List of all controlled drugs products/substances to be imported or exported containing the following information:
  - Product name (including brand name if there is one)
  - Name of controlled drug active ingredient
  - Product strength
  - Package size (i.e. how many tablets or capsules per pack)
  - Volume of product (if it is a liquid)
- Names and addresses of foreign companies from/to which drugs or products requiring a licence are to be imported/exported, respectively.

A credit account must be set up with the ~~HPRA~~Department of Health to facilitate the quick processing of licences. Please note that we cannot process any applications until the fee has

been received. Please contact the HPRA at controlleddrugs@hpra.ie to acquire information on how to pay the Department of Health.

~~Note:~~ Please see the HPRA guidance document 'Guide to NDS Web Extranet' on the ~~'Publications and Forms' section of www.hpra.ie~~HPRA website for detailed guidance on~~:~~
~~How~~ how to ~~register~~:

- Register an account and log in to NDS Web
- ~~How to add~~Add finished products and establishments to a company's NDS Web account
- ~~How to reset~~Reset a password on NDS Web

2.3 Exportation: licence and LONO applications (excluding Schedule 5 controlled drugs)

Once registration with NDS Web is complete, the authorised operator can submit an application through their account.

Operators wishing to export controlled drugs must obtain a valid import authorisation from the country to which they are exporting, i.e. the importing country. **Export licence applications containing the corresponding import authorisation reference number will only be processed if the corresponding import licence has been attached on NDS Web as a ~~PDF~~pdf file.**

The foreign ~~Competent Authority~~competent authority import authorisation (from the importing country) may contain an expiry date. In such cases, the corresponding export licence/LONO will be issued in accordance with the stated expiry date of the foreign import authorisation, i.e. one day before the foreign import authorisation expires. Each export licence/LONO is valid for one exportation consignment only.

If the foreign ~~Competent Authority~~competent authority import authorisation does not contain an expiry date, the following timelines will be applied to the export licence/LONO:

- Three months from the date of the licence/LONO approval for goods exported to countries within the EU/EEA, Switzerland~~,~~ and the United Kingdom
- Six months from the date of the licence/LONO approval for goods exported to countries outside the EU/EEA, Switzerland~~,~~ and the United Kingdom

Export licence/LONO applications can only be assessed and processed once a complete application has been submitted via NDS Web, the import authorisation has been attached, and the relevant fee has been paid. Inaccurate or incomplete applications will be placed on hold and will not be processed until all required documentation/information has been received. Inaccurate or incomplete applications will be notified as comments via NDS Web or email if necessary.

The estimated turnaround time for applications is approximately four weeks from the date of electronic submission of the completed application and fee. This timeframe is an estimate to

assist with commercial planning; however, it is subject to change, depending on the volume of applications being processed at any one time.

An export licence/LONO is only valid if it bears the official stamp of the Department of Health.

Please see the HPRA guidance document 'Guide to NDS Web Extranet' on the 'Publications and Forms' section of www.hpra.ie for detailed guidance on how to submit a controlled drug export licence application on NDS Web.

2.4 Importation: licence and LONO applications (excluding Schedule 5 controlled drugs)

Registered NDS Web account holders may submit a controlled drugs import licence/LONO application through their NDS Web account.

Once issued, import licences/LONOs are valid for the following time periods:
- Three months for goods imported from countries within the EU/EEA, Switzerland, and the United Kingdom
- Six months for goods imported from countries outside the EU/EEA, Switzerland, and the United Kingdom

Each import licence/LONO is valid for one importation consignment only.

Import licence/LONO applications can only be assessed once a complete application has been submitted and the relevant fee received. Inaccurate or incomplete applications will be placed on hold and will not be processed until all of the required documentation/information has been received.

The estimated turnaround time for licence/LONO applications is approximately four weeks from the date of electronic submission of a complete application and fee. This timeframe is an estimate to assist with commercial planning; however, it is subject to change, depending on the volume of applications being processed at any one time.

An import licence/LONO is only valid if it bears the official stamp of the Department of Health.

Please see the HPRA guidance document 'Guide to NDS Web Extranet' on the 'Publications and Forms' section of www.hpra.ie for detailed guidance on how to submit a controlled drug import licence application on NDS Web.

2.5 LONOs for Schedule 5 controlled drugs

To request a LONO for a Schedule 5 controlled drug, the following information should be provided to the HPRA at controlleddrugs@hpra.ie:

- ~~Name of company~~
- Name of company
- Name of contact person and email address
- List of all controlled drugs preparations/substances to be imported or exported. Information on the strength of product, name of controlled drug active ingredient, pack size, volume of product (liquid preparations) and quantity to be ~~import~~imported/exported should be included.
- Names and addresses of foreign establishments from/to which drugs or preparations requiring a licence are to be imported/exported, respectively
- Foreign import licence/LONO (required per export LONO application)

Operators wishing to export Schedule 5 controlled drugs must obtain a valid import authorisation from the country to which they are exporting, i.e. the importing country. Export LONO applications containing the corresponding import authorisation reference number will only be processed once the HPRA has received a copy of the foreign import authorisation.

The foreign ~~Competent Authority~~competent authority import authorisation (from the importing country) may contain an expiry date. In such cases, the corresponding export LONO will be issued in accordance with the stated expiry date of the foreign import authorisation, i.e. one day before the foreign import authorisation expires. Each export LONO is valid for one exportation consignment only.

If the foreign import authorisation does not contain an expiry date, the following timelines will be applied to the export LONO:

- Three months from the date of the LONO approval for goods exported to countries within the EU/EEA, Switzerland~~,~~ and the United Kingdom
- Six months from the date of the LONO approval for goods exported to countries outside the EU/EEA, Switzerland, and the United Kingdom

Applications can only be assessed once the documentation listed above has been submitted. Inaccurate or incomplete requests will be placed on hold and will not be processed until all the required documentation/information has been received.

The estimated turnaround time for LONO applications is approximately four weeks from date of submission of a complete request. This timeframe is an estimate to assist with commercial planning; however, it is subject to change, depending on the volume of applications being processed at any one time.

A LONO is only valid if it bears the official stamp of the Department of Health.

Once a LONO for a controlled drug preparation in Schedule 5 has been used, the date that the controlled drug consignment was imported/exported and the quantity of units that were imported/exported should be written on the physical LONO. The physical endorsed LONO

should then be returned to the HPRA address (see section 2.7 of this guide for the HPRA address).

LONOs for controlled drugs preparations in Schedule 5 do not need to be endorsed on NDS Web.

2.6 LONOs for non-controlled substances

If a substance is not a controlled drug in Ireland but is a controlled drug in the exporting or importing country, the HPRA may issue a 'non-controlled LONO'. If this documentation is required email, contact the HPRA at controlleddrugs@hpra.ie stating the name and address of the importer/exporter and the quantity and description of each substance.

2.7 Endorsement of import and export licences and LONOs (Schedule 4 part 2)

The licensee must comply with the conditions of the licence/LONO. One such condition is that the licence or LONO, duly endorsed, must be surrendered to the Minister for Health by returning it to the HPRA address stated below within seven days of the date of importation/exportation.

Endorsing a licence refers to the reconciliation of a licence and consignment, i.e. reporting the date that a licence was used and reconciling the quantity of controlled drug that was imported/exported under that given import/export licence.

To endorse a licence/LONO, the endorsement date (i.e. the date that the controlled drugs consignment was received/shipped depending on whether it is an import/export) and the endorsed quantity should be clearly marked on the licence/LONO.

If a licence or LONO is not used it should be endorsed by the licensee, marked as 'UNUSED' and returned to the Controlled Drugs section of the HPRA within seven days of:
- the decision not to use the licence/LONO, or
- the expiry date specified on the licence.

Licences and LONOs for controlled drugs preparations/substances in Schedule 1, 2, 3, or 4 should be endorsed on NDS Web. Please see the HPRA guidance document 'Guide to NDS Web Extranet' on the 'Publications and Forms' section of www.hpra.ie for guidance on endorsing licences and LONOs on NDSWebNDS Web.

The physical copy of all controlled drug licences and LONOs, duly endorsed, should be returned within seven days of date of import/export/expiry/date of the decision not to be used to: the HPRA at the following address:
Controlled Drugs Section,
Health Products Regulatory Authority,

Kevin O'Malley House,
Earlsfort Terrace,
Dublin 2
D02 XP77

The licence/LONO is valid only for the licensee and may be revoked at any time by the Minister for Health, to whom it must be immediately surrendered.

If any alteration is required to a licence/LONO it should be returned to the Controlled Drugs ~~Section~~section of the HPRA with a request for amendment and the reasons for the request. No alteration by the licensee is permitted.

It is an offence under the Misuse of Drugs Acts 1977 to 2016 to contravene a condition of a licence or LONO.

The licence or LONO must be produced for inspection when required by a member of An Garda Síochána or a person duly authorised under section 24 of the Misuse of Drugs Acts 1977 to 2016, for a period of two years from the date of expiry as specified on the licence/LONO.

2.8 Licence fees

~~*Controlled*~~For controlled drug annual licence:

Operation	Application fee	Payable to:
Possess (Schedule 1 and2)	€31.75 per drug	Department of Health
Supply (Schedule 1 and 2)	€63.50 per drug	Department of Health
Produce preparations containing any controlled drugs	€127.00 per drug	Department of Health
Produce any raw drugs	€190.50 per drug	Department of Health

~~*Controlled*~~For controlled drug registration:

Operation	Application fee	Payable to:
Possess (Schedule 3,4 and 5)	No fee	N/A
Supply ~~-~~(Schedule 3,4 and 5)	No fee	N/A

~~*Controlled*~~For controlled drug import and export licences (Schedule 1, 2, 3):

Operation	Application fee	Payable to:
Export licence	€63.50 per consignment	Department of Health
Import licence	€63.~~30~~50 per consignment	Department of Health

~~*Controlled*~~

For controlled drug import and export ~~LONO~~licences (Schedule 4 part ~~2, Schedule 5~~1):

Operation	Application fee	Payable to:
Export ~~LONO~~licence	N/A	N/A
Import ~~LONO~~licence	N/A	N/A

~~Controlled~~For controlled drug import and export LONO (Schedule 4 part 2, Schedule 5):

Operation	Application fee	Payable to:
Export LONO	N/A	N/A
Import LONO	N/A	N/A

For controlled drug applications for products to be considered for inclusion as a 'specified controlled drugs' in Schedule 1 of the Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019:

Operation	Application fee	Payable to:
Application for product to be considered as a 'specified controlled drug'	€63.50 per application	Department of Health

Fees must be paid prior to or at the time of application. All fees must be received by credit transfer to the Department of Health. Any fees received payable to the HPRA will be returned and this may result in a delay to the application process.

2.9 Exceptional circumstances

In the case of urgent requests for expedited processing of licences and LONOs, operators must provide details of the exact nature of this urgency. The HPRA operates a queuing system for the very high number of import/export licences and LONO applications from operators. In the interests of fairness to all operators, licence applications can only be prioritised in extremely urgent cases, e.g. medicines shortages directly impacting patients. The form 'Request for an expedited import/export licence or letter of no objection' ~~which is~~ available on the ~~'Publications and Forms' section of www.hpra.ie,~~HPRA website, along with supporting documentary evidence must be ~~emailed~~sent to the HPRA at controlleddrugs@hpra.ie. The form must be signed by the Responsible Person/Qualified Person at the establishment.

2.10 Contact information

Operators should appoint a designated person as point of contact for controlled drugs licensing matters. A deputy can also be appointed if necessary. This point of contact should be notified to the HPRA and any changes to these arrangements should be provided in writing to the HPRA within seven days of the change in personnel.

2.11 Restrictions on exports of certain controlled drugs

There are additional controls in place for operators wishing to export any of the following controlled drugs outside the ~~European Union~~EU/EEA:

- Amobarbital (CAS RN 57-43-2)
- Amobarbital sodium salt (CAS RN 64-43-7)
- Pentobarbital (CAS RN 76-74-4)
- Pentobarbital sodium salt (CAS 57-33-0)
- Secobarbital (CAS RN 76-73-3)
- Secobarbital sodium salt (CAS RN 309-43-3)
- Thiopental (CAS RN 76-75-5)
- Thiopental sodium salt (CAS RN 71-73-8), also known as thiopentone sodium

Operators must contact the HPRA prior to the submission of ~~a~~an NDS Web application to export any of these drugs outside the EU/EEA.

2.12 Restrictions on imports of certain controlled drugs

The HPRA will only accept import licence applications for cannabis-based products that are received from a company that holds the relevant controlled drug annual licence as outlined in ~~Section~~section 1 of this guidance document, and where the product is:

a) A medicinal product that has a medicines marketing authorisation for Ireland, or

b) A medicinal product that has a medicines marketing authorisation for another country and has been prescribed in accordance with article 5(1) of EU Directive 2001/83/EC or,

c) A product included in Schedule 1 of the Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019*

*The requirements to be fulfilled ~~in order~~ for a cannabis product ~~or preparation~~ to be considered for inclusion in Schedule 1 of these Regulations can be found in Appendices 1 and 2 of this document.

APPENDIX 1- APPLICATIONS FOR CANNABIS-BASED PRODUCTS OR PREPARATIONS TO BE CONSIDERED FOR INCLUSION IN SCHEDULESCHEDULE 1 OF THE MISUSEMISUSE OF DRUG (PRESCRIPTIONDRUGS (PRESCRIPTION AND CONTROLCONTROL OF SUPPLYSUPPLY OF CANNABISCANNABIS FOR MEDICAL USE) REGULATIONSMEDICAL USE) REGULATIONS 2019

The Misuse of Drugs (Prescription and controlControl of supplySupply of cannabisCannabis for medical useMedical Use) Regulations 2019, as amended, outline the legal framework and details of the Medical Cannabis Access Programme (MCAP) in Ireland. These Regulations enable the importation, prescribing and supply of cannabis-based products or preparations, known as 'specified controlled drugs' in Ireland to those that meet the requirements of the Regulations and have been included in Schedule 1 of the Regulations.

A company may apply to the HPRA (who process the application on behalf of the Minister for Health), to have their product added to Schedule 1 of the Regulations. The application forms can be found on the 'Publications and Forms' section of www.hpra.ieHPRA website or requested by contacting controlleddrugs@hpra.ie.the HPRA at controlleddrugs@hpra.ie. Details on the requirements to be fulfilled in order for a cannabis-based product or preparation to be considered for inclusion in Schedule 1 are outlined below.

If the Department of Health or HPRA becomes aware of any safety or quality issues relating to a specified controlled drug, the product or preparation may be refused an import licence.

A specified controlled drug imported for the purpose of these Regulations cannot subsequently be exported outside of the State.

Application documentationrequirements for cannabis-based products and preparations

1 EvidenceDetails of product name, brand name, dosage form, content and pack size/volume.

2 Confirmation that the product is a preparation or other product that is produced from dried, ground or powdered flower of cannabis, and is not a medicinal product with a marketing authorisation specified in Schedule 2, 3, 4 or 5.

13 Confirmation of content and strength, in accordance with Part 1 definitions of the Misuse of Drugs (Prescription and Control of Supply of Cannabis for Medical Use) Regulations 2017. 2019:

2 Details of product name, brand name and dosage form/presentation should be submitted.

3 A declaration of content and strength must be provided, in accordance with the EMA 'Guideline on declaration of herbal substances and herbal preparations in herbal

~~medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/287539)';~~

a) For dried, ground or powdered flower ~~this~~ the declaration should confirm the product contains not more than 230 milligrams of tetrahydrocannabinol (THC) per gram and not more than 5 grams total weight per pack.

b) For oil-based solutions, suspensions and capsules, the declaration should confirm that the product does not contain more than 30 milligrams of tetrahydrocannabinol (THC) per millilitre (3% w/v) per unit dose and that the total volume is not more than 60 millilitres.

4 Certificate of analysis for the most recent commercial batch placed on an EU/EEA market and confirm the name of the EU/EEA country.

5 Confirmation that the proposed product composition and formulation is not equivalent to a medicinal product with a marketing authorisation within the meaning assigned to that term in Regulation 3(1) of the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. no. 540 of 2007).

~~4~~6 Official documentation from the relevant ~~State Authorities~~national competent authority must be submitted to confirm that the product ~~or preparation: :~~

a) is permitted to be sold or supplied for medical purposes by the relevant ~~public or state body~~national competent authority of an EU/EEA Member State~~, and~~ (An official document or statement by the competent national authority or a link to their website confirming the product is approved for supply may be accepted).

b) is currently supplied to patients in the EU/EEA Member State referred to in ~~a~~6a) above~~.~~ (e.g. a copy of a recent prescription issued for the product in the EU/EEA Member State).

~~5~~7 ~~A sample of the packaging and labelling for the product or preparation~~Mock-ups of all labels (immediate label and outer carton, if applicable) must be submitted~~. This~~ for the product. These must be in English and in accordance with guidance on labelling and packaging as set out in Appendix 2 ~~below.~~ of this document.

~~6~~8 A description of how the MCAP information leaflet will be inserted into the product packaging, including details of the site that will carry out this activity. This leaflet can be downloaded from the Medical Cannabis Access Programme section of the Department of Health website.

9 A ~~self-declaration~~statement from the company ~~confirming~~and/or manufacturer who currently place the product on another EU/EEA market (if different from the applicant) that they are

aware of this application, are in agreement with their product being placed on the Irish market under the responsibility of the aforenamed applicant and will inform the applicant of any substantial changes to the particulars of the product or supply of product.

~~7~~10 The applicant must confirm that it will inform the HPRA if there are any ~~changes to the~~ future changes to the particulars provided in this application to include the product on the MCAP, e.g. changes to product composition, formulation, packaging, supply status ~~of~~in the ~~product~~EU/EEA Member State, or ~~if the company becomes aware of~~ any ~~issue~~other issues of concern.

APPENDIX 2 ~~PACKAGING~~ PACKAGING AND LABELLING REQUIREMENTS FOR SPECIFIED CONTROLLED DRUGS

Mock-~~-~~ups of all labels (immediate label and outer carton, if applicable) should be submitted with the application.

Labelling must be in plain English, be easy to read, easy to understand and indelible. It must not include any information of a promotional nature. The information must not be misleading or imply that the product is a medicinal or herbal product.

It is recommended that the name of the product should appear in Braille text on the outer packaging.

It must be possible to identify if the final pack has been opened. Mock-ups should demonstrate how the anti-tampering device works.

The requirements listed below cover information to be included on the immediate label ~~of the primary container~~ and on the outer package label. The information should, to the extent possible, be stated on both.

The product package labels (immediate label and outer carton)

1 Product name.
2 Content and strength of main ingredients, to include tetrahydrocannabinol (THC) and cannabidiol (CBD). This is to be expressed in weight/weight or weight/volume, or percentage concentration.
3 The names of the ingredients tetrahydrocannabinol (THC) and cannabidiol (CBD) should be spelt out in full at least once (ideally under the product name) on the immediate product label and on the outer carton label.

~~3~~ Product form: The pharmaceutical ~~form or other~~ dosage ~~formulation. The European Pharmacopoeia (Ph. Eur.) define various pharmaceutical forms and the related technical requirements.~~form should be defined. Examples include~~:~~

~~a) Granules: a solid pharmaceutical form consisting of grain of a uniform size~~
~~b) Capsules: gel capsules which may contain a solution, suspension or emulsion~~
~~c) Oral drops:~~ 'oral ~~drops, emulsions, solutions and suspensions, e.g. wholly or partially evaporated extracts that are subsequently dissolved in a vehicle such as oil, water or ethanol~~
~~d) Oral liquid: examples include wholly or partially evaporated extracts not dissolved in a vehicle~~

1 ~~Oromucosal spray: emulsions, solutions and suspensions designed for administration via a spray~~solution', 'oil', 'capsule', 'dried flower', etc. For an exhaustive list, please refer to the ~~oral cavity~~European Pharmacopoeia Standard Terms.

~~f) Dried herb~~

~~1~~2 Pack size: the quantity per pack, e.g. number of grams (powdered or ground herbal substance), number of millilitres (liquid product), or number of units (e.g. capsules).

3 Method of administration: the route of administration should be detailed, e.g. oral, inhalation, or other. Any specific information on the ~~preparation of the~~ product prior to administration should also be included.

- For a product administered orally, if the product is supplied with a dosing device, e.g. a syringe, confirm the graduations of the syringe (e.g. 0.1 ml graduations) and justify that the syringe/dosing device supplied with the product is fit for purpose. State if the dosing device has a CE mark.
- For an inhalation product, the label should state the route of administration as 'To be administered by inhalation (vaporisation) only'. Provide details of the type of device to be used for inhalation.

~~1~~4 Storage conditions. If no specific storage conditions apply, include a statement to reflect same such as 'No special storage conditions'.

~~1~~5 Shelf life/expiry date: Both the shelf life at the indicated storage conditions and the shelf life after opening should be listed, if different.

~~1~~6 Name and contact details of the finished product manufacturer.

~~1~~7 Batch number.

8 List of all ingredients contained in the product.

~~1~~9 Highlight any potential allergens/excipients that may be allergenic.

~~1~~10 A special warning to keep the product out of the sight and reach of children.

~~1~~11 A special precaution for disposal of unused product.

~~1~~12 A special warning to read the leaflet provided.

Where there is insufficient space on ~~primary pack~~the immediate product label, e.g. vial, and the complete information listed above is provided on ~~secondary/~~the outer ~~labelling~~carton, the following minimum particulars must be included on the ~~primary pack~~immediate product label:

1 Product name

~~1~~2 Content and strength of active ingredient(s)

~~1~~3 Product form

~~1~~4 Method of administration

~~1~~5 Shelf life/expiry date

~~1~~6 Batch number

~~1~~7 Special storage conditions

~~1~~8 A special warning to keep the product out of the sight and reach of children

Each package must be accompanied by an information leaflet on the Irish Medical Cannabis Access Programme. This MCAP leaflet can be downloaded from the Medical Cannabis Access Programme section ~~of~~published by the Department of Health ~~website.~~ at www.gov.ie.