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 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.

CONTENTS

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 of supply of cannabis for medical use) Regulations 2019 permits cannabis based products specified in Schedule 1 of the Regulations to be imported for supply via the Medical Cannabis Access Programme in Ireland. There are additional restrictions and requirements relating to the import and supply of such cannabis based products. See Section 2.11 for further details.

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

2.1 PharmaTrust

Manufacturers and wholesalers must have a PharmaTrust account to apply for any import/export licences or LONOs, with the exception of LONOs for Schedule 5 controlled drugs. PharmaTrust is an electronic application system which allows companies to apply online. 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.

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 PharmaTrust 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 PharmaTrust Extranet' can be found on the 'Publications and Forms' section of www.hpra.ie.

2.2 Applying for a PharmaTrust account

To apply for a PharmaTrust account, the following information should be provided in email to controlleddrugs@hpra.ie:

- Name of company
- Name of contact person and email address
- List of all controlled drugs the company intends to import or export, including raw material and finished products.
  - In the case of finished products, include information on strength of product, name of controlled drug active ingredient, pack size and volume of product (liquid preparations) on this list.
  - In the case of raw material, include the estimated quantity of material to be imported/exported each year.
- List of all establishments the company is importing/exporting from or to and the full address of each company.

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

Note: Finished products and establishments must be added to a company's PharmaTrust account by the HPRA. It is not possible for a company to add products or establishments to their own account and any attempt to do so will result in an unsuccessful application.

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

Once registration with PharmaTrust 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 once the HPRA has received a copy of the import licence. Electronic copies of the import licences should be submitted to controlleddrugs@hpra.ie. The HPRA will also accept

submissions made via Eudralink to controlleddrugs@hpra.ie. For Eudralink registration and information contact the Eudralink helpdesk via eudralink@ema.europa.eu.

The foreign 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 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 EEA and Switzerland.
- six months from the date of the licence/LONO approval for goods exported to countries outside the EEA and Switzerland.

Export licence/LONO applications can only be assessed and processed once a complete application has been submitted via PharmaTrust, the import authorisation has been received, 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 has been received.

The estimated turnaround time for applications is approximately four weeks from the date of electronic submission of the completed application, which includes receipt of the foreign import authorisation and the appropriate 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.

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

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

Once issued, import licences/LONOs are valid for the following time periods:

- three months for goods imported from countries within the EEA and Switzerland.
- six months for goods imported from countries outside the EEA and Switzerland.

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 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.

2.5 LONO for Schedule 5 controlled drugs

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

- Name of company
- Name of contact person and e-mail address
- List of all controlled drugs products/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/exported should be included.
- Names and addresses of foreign companies from/to which drugs or products 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 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 EEA and Switzerland
- six months from the date of the LONO approval for goods exported to countries outside the EEA and Switzerland

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 has been received.

The estimated turnaround time for LONO applications is approximately four weeks from date 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.

~~2.5~~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 e-mail controlleddrugs@hpra.ie stating the name and address of the importer/exporter and the quantity and description of each substance.

~~2.6~~2.7 Endorsement of import and export licences and LONOs

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 within seven days of the date of importation/exportation.
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.

These endorsed licences and LONOs should be returned to:
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 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 ~~the~~ 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.

~~2.7~~2.8 Licence fees

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 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 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 per consignment	Department of Health

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

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.

~~2.8~~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' must accompany urgent requests, along with supporting documentary evidence and it is available on the 'Publications and Forms' section of www.hpra.ie.

~~2.9~~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.

~~2.10~~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:

- 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 PharmaTrust application to export any of these drugs outside the EU.

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 1 of this guidance document, and the product is:

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

~~a)~~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,

~~b)~~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 PRODUCTS OR PREPARATIONS TO BE CONSIDERED FOR INCLUSION IN SCHEDULE 1 OF THE MISUSE OF DRUG (PRESCRIPTION AND CONTROL OF SUPPLY OF CANNABIS FOR MEDICAL USE) REGULATIONS 2019

The Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019 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.ie or by contacting controlleddrugs@hpra.ie. Details on the requirements to be fulfilled in order for a cannabis 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 documentation for cannabis products and preparations

1 Evidence 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 of the Misuse of Drugs Regulations 2017.

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 should confirm the product contains not more than 230 milligrams of tetrahydrocannabinol 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 per millilitre (3% w/v) per unit dose and the total volume is not more than 60 millilitres.

4 Official documentation from the relevant State Authorities 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 of an EU/EEA Member State, and

b) is currently supplied to patients in the Member State referred to in a) above.

5 A sample of the packaging and labelling for the product or preparation must be submitted. This must be in English and in accordance with guidance on labelling and packaging as set out in Appendix 2 below.

6 A description of how the 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.

A self-declaration from the company confirming that it will inform the HPRA if there are any changes to the supply status of the product or if the company becomes aware of any issue of concern.

7

APPENDIX 2 PACKAGING AND LABELLING REQUIREMENTS FOR SPECIFIED CONTROLLED DRUGS

Mock ups of all labels 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 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

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 Product form: The pharmaceutical form or other dosage formulation. The European Pharmacopoeia (Ph. Eur.) define various pharmaceutical forms and the related technical requirements. 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
- e) Oromucosal spray: emulsions, solutions and suspensions designed for administration via a spray to the oral cavity
- f) Dried herb.

4 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).

5 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.

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

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

8 Name and contact details of the finished product manufacturer

9 Batch number

10 Highlight any potential allergens/excipients that may be allergenic

11 A special warning to keep the product out of the sight and reach of children

12 A special precaution for disposal of unused product

13 A special warning to read the leaflet provided.

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

1 Product name
2 Content and strength of active ingredient(s)
3 Product form
4 Method of administration
5 Shelf life/expiry date
6 Batch number
7 Special storage conditions
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 leaflet can be downloaded from the Medical Cannabis Access Programme section of the Department of Health website.

~~**APPENDIX 1**~~
~~**APPLICATIONS FOR CANNABIS PRODUCTS OR PREPARATIONS TO BE ENTERED ON TO THE SPECIFIED CONTROLLED DRUG LIST**~~

~~**The proposed Misuse of Drugs (prescription and control of supply of cannabis for medical use) Regulations 2019 will outline the legal framework and details of the functioning of the Medical Cannabis Access Programme in Ireland. It will permit the importation, prescribing and supply of specified cannabis based controlled drugs in Ireland which are not authorised medicines but limits it to those that meet the requirements set out in Part**~~

~~1 or Part 2 of Schedule 2 of the Regulations and have been placed on a Specified Controlled Drug List.~~

~~As this legislation has yet to be published, the guidance below is subject to change. Applications will not be accepted until such time that the legislation is published. This guidance is being published in advance of the legislation to permit companies time to gain a general understanding of the proposed Medical Cannabis Access Programme so that they may begin preparing applications in advance of the legislation if they so wish.~~

~~A company may apply to the HPRA to have their product added to the Specified Controlled Drug List and to do so they must meet the requirements set out in Part 1 or Part 2 of Schedule 2 of The Misuse of Drugs (prescription and control of supply of cannabis for medical use) Regulations 2019, and as currently drafted, provide the documentation outlined below.~~

~~If the application is complete and it is considered to meet the requirements of the above referenced legislation, the cannabis product or preparation for medical use shall be included with its name and the name of the related supplier on the Specified Controlled Drug List. An application to be listed on the Specified Controlled Drug List may be refused if the HPRA is not satisfied that the requirements of Parts 1 or 2 of Schedule 2 of the Regulations have been met. The Specified Controlled Drug List shall be published on the website of the HPRA.~~

~~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 or delisted from the Specified Controlled Drug List.~~

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

~~Application documentation for Part 1 (dried cannabis herb products)~~

~~Evidence that the product must be a preparation or other product that is produced from dried, comminuted or powdered flower of Cannabis, and is not a medicinal product with a marketing authorisation specified in Schedule 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2017 and not being a preparation or product specified in Part 2 of Schedule 2 of the Regulations.~~

~~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)'. This should confirm that the finished dried herb product contains not more than 230 milligrams of tetrahydrocannabinol per gram and not more than 5 grams total weight per pack.~~

~~Official documentation from the relevant State Authorities must be submitted to confirm that the product or preparation:~~

~~is permitted to be sold or supplied for medical purposes by the relevant public or state body of an EU/EEA Member State, and~~
~~it is currently supplied to patients in the Member State referred to in a) above~~

~~A sample of the packaging and labelling for the product or preparation. This must be in English and in accordance with guidance on labelling and packaging as set out in Appendix 2.~~

~~A description of how the 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.~~

~~A self-declaration from the company confirming that it will inform the HPRA if there are any changes to the supply status of the product or if the company becomes aware of any issue of concern.~~

~~Application documentation for Part 2 (oil based cannabis solution, suspension or capsule)~~

~~Evidence that the preparation or product is produced from dried, comminuted or powdered flower of Cannabis, is not a medicinal product with a marketing authorisation specified in Schedule 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2017 and is presented as an oil-based solution, suspension or capsule.~~

~~Details of product dosage form/presentation should be submitted.~~

~~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)'. This should confirm that the finished preparation or product contains not more than 30 milligrams of tetrahydrocannabinol per millilitre (3% w/v) per unit dose and a total volume of not more than 60 millilitres.~~

~~Official documentation from the relevant State authorities must be submitted to confirm that the product or preparation:~~

~~is permitted to be sold or supplied for medical purposes by the relevant public or state body of an EU/EEA Member State, and~~
~~it is currently supplied to patients in the Member State referred to in a) above~~

~~A sample of the packaging and labelling for the product or preparation. This must be in English and in accordance with guidance on labelling and packaging as set out in Appendix 2.~~

~~A description of how the 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~~

~~A self-declaration from the company confirming that it will inform the HPRA if there are any changes to the supply status of the product or if the company becomes aware of any issue of concern.~~

APPENDIX 2
PACKAGING AND LABELLING REQUIREMENTS FOR CANNABIS PRODUCTS OR PREPARATIONS TO BE ENTERED ON TO THE SPECIFIED CONTROLLED DRUG LIST

Mock ups of all labels 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.

The name of the product is also recommended to appear in Braille text on the outer packaging.

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

The requirements listed below cover information and documentation to be included for immediate and outer package labels. The information should, to the extent possible, be stated on both the inner and outer package.

The product package labels

Product name
Content and strength of active ingredients, to include THC and CBD. This is to be expressed in weight/weight or weight/volume, or percentage concentration.
Product form: The pharmaceutical form or other dosage formulation. The European Pharmacopoeia (Ph. Eur.) define various pharmaceutical forms and the related technical requirements. Examples include:
Granules: a solid pharmaceutical form consisting of grain of a uniform size.
Capsules: hard shell which may contain powder, granules or comminuted herbal substance; soft shell or gel capsules which may contain a solution, suspension or emulsion.
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.
Oral liquid: examples include wholly or partially evaporated extracts not dissolved in a vehicle.
Tablets: tablets, coated tablets and film-coated tablets.
Oromucosal spray: emulsions, solutions and suspensions designed for administration via a spray to the oral cavity.
Dried herb.
Pack size: the quantity per pack, e.g. number of grams (powdered or comminuted herbal substance), number of millilitres (liquid product), or number of units (e.g. capsules).

~~Method of administration: the route of administration should be detailed, e.g. oral, inhalation, or other. Any specific preparation information should also be included.~~
~~Storage conditions. If no specific storage conditions apply, include a statement to reflect same such as 'No special storage conditions'.~~
~~Shelf life/expiry date: Both the shelf life at the indicated storage and the shelf life after opening should be listed if different.~~
~~Name and contact details of the finished product manufacturer.~~
~~Unique identifier of the product, e.g. batch number.~~
~~Highlight any potential allergens/excipients that may be allergenic.~~
~~A special warning to keep the product out of the sight and reach of children.~~
~~A special precaution for disposal of unused product.~~
~~A special warning to read the leaflet provided.~~

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

~~Product name~~
~~Shelf life/expiry date~~
~~Method of administration~~
~~Content and strength of active ingredient(s)~~
~~Product form~~
~~Unique identifier of the product, e.g. batch number~~
~~Special storage conditions~~
~~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 leaflet can be downloaded from the Medical Cannabis Access Programme section of the Department of Health website.~~

APPENDIX 3
CONDITIONS OF APPLICATION TO BE ENTERED ON TO THE SPECIFIED CONTROLLED DRUG LIST

One application must be submitted for each form and each strength of each product; however, several pack sizes of the same product can appear on the same application form.
Only cannabis finished products requiring no further processing or manipulation can be added to the list.
The application form, labels, leaflet and enclosed documentation as outlined above must be in the English language.