Application for products to be considered for inclusion in Schedule 1 of the Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019

**On behalf of the Department of Health**

Misuse of Drugs Act 1977

Misuse of Drugs Regulations 2017

Misuse of Drugs (prescription and control of supply of cannabis for medical use) regulations 2019

**Notes:**

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.

In order for a cannabis based product to be considered by the Minister for Health for inclusion in Schedule 1 of the Regulation, companies must complete this application form. The following conditions of application must be met:

1. The product composition must be aligned with those detailed in the clinical guidance published by the Department of Health (published on [gov.ie - Medical Cannabis Access Programme (www.gov.ie)](https://www.gov.ie/en/publication/90ece9-medical-cannabis-access-programme/).
2. Every application must be accompanied by relevant supporting documents as detailed in section 5 of this form.
3. The application form, labels, leaflet and documentation must be in the English language.
4. A separate application form is required to be completed for each form and each strength of each product; however, several pack sizes of the same product can appear on the same application form.
5. Only cannabis based finished products requiring no further processing or manipulation can be considered for inclusion in Schedule 1 of the Regulations.

Please complete all sections of the application form or mark them ‘Not applicable’ as appropriate. Incomplete application forms, or submissions missing supporting documents, will not be processed and may result in delays to the application process and the return or cancellation of the application.

Complete applications should be submitted to controlleddrugs@hpra.ie. The HPRA may contact the applicant with queries regarding the submission.

All products included in Schedule 1 of the Regulations will be also included in Schedule 2 of the Misuse of Drugs Regulations 2017. A separate annual licence is required to possess, supply or offer to supply, a controlled drug described in Schedule 2 of the Misuse of Drugs Regulations2017. In addition to an annual licence, an import licence is required to accompany each import consignment. The relevant forms with which to apply for these licences are available on the HPRA [website](https://www.hpra.ie/homepage/controlled-substances).

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| Section 1 applicant details | |
| Name |  |
| Address |  |
| Eircode/Postal code (if applicable) |  |
| Legally registered company name and address with the Companies Registration Office (CRO)  *(For companies located outside of Ireland, please provide the relevant national documentation.)* |  |
| CRO number (if applicable) |  |
| Name of contact to whom correspondence should be addressed |  |
| Email address of contact |  |
| Phone number of contact |  |

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| Section 2 Specified controlled drug  *Sufficient information should be supplied to justify inclusion of the product in Schedule 1 of the Misuse of Drugs (Prescription and control of supply of cannabis for medical use) Regulations 2019. Please complete all sections.* | | |
| **2.1** | | |
| Please select which product composition the proposed product aligns to as per the Department of Health clinical guidance (you can select more than one). | | |
| 1. Medical condition: Spasticity associated with multiple sclerosis resistant to all standard therapies. | | |
| * >80% purity full spectrum oral solution THC 10: CBD 10 (1:1) | |  |
| * >80% purity full spectrum oral solution THC 25: CBD 25 (1:1) | |  |
| 1. Medical condition: Intractable nausea and vomiting associated with cancer chemotherapy, despite the use of standard anti-emetic regimes. | | |
| * >80% purity full spectrum oral solution, THC 10mg/ml : CBD 10mg/ml | |  |
| * >80% purity full spectrum oral solution, THC 25mg/ml : CBD 25mg/ml | |  |
| * >80% purity full spectrum oral solution, THC 10mg/ml (CBD 0.2mg/ml) | |  |
| * >80% purity full spectrum oral solution, THC 25mg/ml (CBD 0-4mg/ml) | |  |
| * Vaporised formulation 19% THC:<1% CBD | |  |
| * Vaporised formulation 12% THC:<1% CBD | |  |
| **2.2** | | |
| Full name of cannabis product or preparation *(including brand name and product name)* |  | |
| Dosage form *(e.g. flower, oil, suspension, capsule, etc.)* |  | |
| Concentration of tetrahydrocannabinol (THC) |  | |
| Name and address of manufacturer of the product |  | |
| Name and address of supplier of the product *(if different to the manufacturer)* |  | |
| **2.3** | | |
| Please indicate the product type by checking **one** of the relevant boxes below:  A preparation or other product produced from dried, ground or powdered flower of cannabis  A preparation or product produced from dried, ground or powdered flower of cannabis and which is presented as an oil-based solution  A preparation or product produced from dried, ground or powdered flower of cannabis and which is presented as an oil-based suspension  A preparation or product produced from dried, ground or powdered flower of cannabis and which is presented as an oil-based capsule | | |
| **2.4** | | |
| **2.4.1**  Provide a declaration of content and strength, 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)’.   1. For dried, ground or powdered flower, the declaration should confirm the product contains not more than 230 milligrams of tetrahydrocannabinol per gram and not more than 5 grams total weight per pack.   OR   1. 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.   **2.4.2**  Provide a certificate of analysis for the most recent commercial batch placed on an EEA market. | | |
| **2.5** | | |
| Provide official documentation from the relevant competent authority in a Member State to confirm that the product or preparation:   1. is permitted to be sold or supplied for medical purposes by the relevant public or state body of an EU/EEA Member State, and 2. is currently supplied to patients in the Member State referred to in a) above. | | |
| **2.6** | | |
| Provide a copy of the product labelling which demonstrates compliance with Appendix 2 of AUT-G0127, ‘Guide to import and export licences and LONOs for controlled drugs (including the import of cannabis products)’. | | |
| **2.7** | | |
| Each package must be accompanied by an information leaflet on the Irish Medical Cannabis Access Programme. Leaflets can be downloaded from the Medical Cannabis Access Programme section of the Department of Health website. It is not possible for companies to amend this leaflet.  Provide a description of how the standard product leaflet will be inserted into the product packaging including details of the site that will carry out this activity. | | |
| **2.8** | | |
| Provide 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. | | |
| **2.9** | | |
| Provide a statement from the company and/or manufacturer that currently place the product on another EEA market (if different from the applicant) that they are aware of this application and in agreement with their product being placed on the Irish market under the responsibility of the aforenamed applicant. | | |

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| section 3 operation type and Preparations produced |
| Please include general information on the proposed operations should the product be included in Schedule 1 of the Regulations (e.g. quantity to be imported, nominated supplier/importer). |

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| section 4 Importing |
| Do you plan to import the specified controlled drug to Ireland?  (*Please note that a separate annual licence and import licence are required in order to import into the country.)*  Yes  No  From which country will you be importing the specified controlled drug?    Estimate the total quantity to be imported in this calendar year. |

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| section 5 checklist of documents |
| The following information must be submitted with the application (except where not applicable).  *Please check the boxes to confirm that documents have been included with the application.*  Certificate of incorporation (if applicable)  A declaration of content and strength of the product  Evidence that the exact product is permitted to be sold or supplied for medical purposes by a relevant public or state body of an EU/EEA Member State  Evidence that the exact product is supplied to patients in the Member States referred to above  A copy of the packaging of the specified controlled drug  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  Statement from product owner in original EEA Member State (if different from applicant)  Proof of payment made to the Department of Health. Please note purchase orders and cheques are not acceptable. Please contact [controlleddrugs@hpra.ie](mailto:controlleddrugs@hpra.ie) for queries regarding fees. |

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| section 6 declaration |
| I hereby declare that, to the best of my knowledge and belief, all the particulars given in this application are correctly stated.  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**  **Print name**:       **Title/position:**  **Notes:**  Applications must bear the signature of the applicant. Where the application is on behalf of a limited company the declaration must be signed by a director or the secretary and, in the case of a partnership, by a partner.  **Special attention is directed to section 21(7) of the Misuse of Drugs Act, 1977, which makes it an offence punishable by a fine or imprisonment or both, for any person to make a declaration or statement which is false in any particular for the purpose of obtaining the issue, grant or renewal of a licence, authorisation or permit under the Act.** |

Send to:

Controlled Drugs, Licensing Section

Compliance Department

Health Products Regulatory Authority

Kevin O’Malley House

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Dublin 2

D02 XP77

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Email: [controlleddrugs@hpra.ie](mailto:controlleddrugs@hpra.ie)