Application for Registration of Schedules 3/4/5 Controlled Drugs

Misuse of Drugs Act 1977

misuse of drugs regulations 2017

**Notes:**

For controlled drugs described in Schedules 3, 4 and 5 of the Misuse of Drugs Regulations 2017 (the Regulations), a registration is required for possession, supply and offering to supply. A company registered to supply or offer to supply a controlled drug described in Schedule 3, 4 or 5 of the Regulations will also by virtue of the Regulations be entitled to possess the drugs to which the registration relates.

The production or manufacture of controlled drugs requires a licence. Application forms for such licences are available on request.

The adequacy of the arrangements for the safe custody of controlled drugs described in Schedules 1, 2 and 3 of the Regulations, held under licence or registration, may from time to time be the subject of inspection by An Garda Síochána. This inspection report or certificate will be taken into account in the granting or renewal of licences or registrations and a copy must be submitted with every application. Certificates issued by An Garda Síochána relating to the safe custody of controlled drugs remain in force for a period of two years.

Every application for a registration must be accompanied by all the associated supporting documents as detailed in section 7 of the application.

Please complete all sections of the application form or mark ‘Not applicable’ as appropriate. Incomplete application forms or those missing supporting documents may not be processed and may result in delays to the application process and return or cancellation of the application. Please contact [controlleddrugs@hpra.ie](mailto:controlleddrugs@hpra.ie) with any queries regarding the submission.

|  |  |
| --- | --- |
| Section 1 Applicant Details | |
| Name of applicant |  |
| Address of applicant |  |
| Eircode |  |
| Legally registered company name **and** address with the Companies Registration Office  *(Please ensure the name and address matches the details held by the CRO.)* |  |
| CRO number |  |
| Name of premises to be registered |  |
| Address of premises to be registered |  |
| Eircode: |  |
| Name of manager or person in charge |  |
| Email address |  |
| Contact number |  |
| Wholesale distribution authorisation number, if applicable |  |

|  |
| --- |
| Section 2 Purpose and type of registration required  *Sufficient information should be supplied to justify the granting of the registration.* |
| Please indicate the operation type by checking the relevant box below:  Manufacturer *(Registration type e.g. possession, supply       )*  Wholesaler *(Registration type e.g. possession, supply      )*  University or laboratory *(Registration type e.g. possession      )*  Private hospital, clinic or tissue establishment *(Registration type e.g. possession, for use at registered location      )*  Advanced paramedic / paramedic *(Registration type e.g. possession, limited authority to supply      )* |
| For **all** registrations please give a brief statement identifying the purpose for which the drugs will be used:  *(e.g. retain samples, forensic/chemical analysis, research and/or development of ……, wholesale distribution)* |
| For private hospitals, clinics and tissue establishments please provide the following information: *(Only provide roles and job titles, not names of personnel)*   1. Role of responsible person *(i.e. medical practitioner or pharmacist)*      1. Job title of responsible person *(e.g. Clinical Director/Chief Pharmacist)*      1. Job title of principal prescriber *(e.g. Clinical Director, Chief Medical Officer or equivalent)*       Note: the role of the responsible person is to ensure conditions of the licence are complied with; the principal prescriber has overall responsibility for prescribing practices in the facility. |

|  |  |  |  |
| --- | --- | --- | --- |
| For activities in respect of controlled drugs detailed in Schedules 3, 4 and 5 of the Regulations, please indicate by marking in the tables below, the controlled drugs and activity type for which registrations are required.  If the registration is for possession **only** please indicate maximum quantity of each substance that would be held on site at any one time. | | | |
| Part A: Schedule 3 drugs | | | |
| **Drug** | **To supply** | **To possess** | **Max. quantity on site** |
| Amylobarbitone |  |  |  |
| Flunitrazepam |  |  |  |
| Ketamine |  |  |  |
| Methylphenobarbitone\* |  |  |  |
| Pentazocine |  |  |  |
| Pentobarbitone |  |  |  |
| Phenobarbitone\* |  |  |  |
| Phentermine |  |  |  |
| Temazepam |  |  |  |
| Others *(Please specify)* |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| \* Certain preparations of these controlled drugs are in Schedule 4 (i.e. those containing not more than 100mg calculated as base) | | | |
| **Part B: Schedule 4 drugs** | | | |
| **Drug** | **To supply** | **To possess** | **Max. quantity on site** |
| Alprazolam |  |  |  |
| Bromazepam |  |  |  |
| Chlordiazepoxide |  |  |  |
| Clobazam |  |  |  |
| Clonazepam |  |  |  |
| Diazepam |  |  |  |
| Flurazepam |  |  |  |
| Lorazepam |  |  |  |
| Lormetazepam |  |  |  |
| Midazolam |  |  |  |
| Nitrazepam |  |  |  |
| Prazepam |  |  |  |
| Selegiline |  |  |  |
| Triazolam |  |  |  |
| Zolpidem |  |  |  |
| Zopiclone |  |  |  |
| Others *(Please specify)* |  |  |  |
|  |  |  |  |
|  |  |  |  |
| **part c: schedule 5 drugs** | | | |
| **Drug** | **To supply** | **To possess** | |
| Codeine \* |  |  | |
| Pholcodeine\* |  |  | |
| Others *(Please specify)* |  |  | |
|  |  |  | |
| \**Please note that these substances are described in Schedule 5 of the Regulations if they meet the criteria that they are not for administration through injection, not more than 100mg (calculated as base) per dosage unit or in the case of an undivided preparation, has a total concentration of not more than 2.5% (calculated as base). If the substance or preparation does not meet this criteria, the provisions of a controlled drug described in Schedule 2 of the Regulations apply (such as the requirement for a licence instead of a registration).* | | | |

|  |
| --- |
| section 3 operation type  *In the space provided below or via a separate referenced attachment, give a brief description of the operation(s) for which registration is required.* |
| section 4 safe custody arrangements  *Give a brief description in the space provided below or in a separate referenced attachment. Applicants are reminded of their responsibility to ensure that all controlled drugs held under licence or registration are kept in a manner so as to prevent unauthorised access to the drugs. Please include details of the safe (if applicable for controlled drugs described in Schedule 3 of the Regulations) and who will have access to it. A declaration from An Garda Síochána must be submitted in addition to this information for controlled drugs described in Schedule 3 of the Regulations.* |
| section 5 Suppliers  (For private hospitals/tissue establishments and university/lab only)  *In the space provided below or via a separate referenced document please provide information on the suppliers of the drugs for which a registration is sought (e.g. the registered pharmacy business details.).* |
| section 6 Importing  Will you be importing controlled drugs?  Yes  No |
| section 7 checklist  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). This must be provided for first time applicants and for renewals where the company name and/or address has changed.  Declaration from An Garda Síochána (applicable for controlled drugs described in Schedule 3 of the Regulations), signed by a superintendent, stating that the safe holding the controlled drugs has been inspected and has been deemed appropriate. |

|  |
| --- |
| SECTION 8 DECLARATION  In the event of the registration being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the registration and declare that all the particulars given in this application are, to the best of my knowledge and belief, correct.  **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

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

E-mail: [controlleddrugs@hpra.ie](mailto:controlleddrugs@hpra.ie)