Application for a Licence for Controlled Drugs (other than to Import or Export)

Misuse of Drugs Act 1977

Misuse of Drugs Regulations 2017

**Notes:**

Licences are required to manufacture controlled drugs described in Schedules 1 to 5 of the Misuse of Drugs Regulations 2017 (the Regulations). Licences are also required to supply, offer to supply and/or to possess controlled drugs described in Schedules 1 and 2 of the Regulations.

A registration is required for the possession, supply and offer to supply controlled drugs described in Schedules 3, 4 and 5 of the Regulations; separate application forms for registrations are also available.

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 of licences and a copy must be submitted with every application. Certificates issued by An Garda Síochána relating to safe custody provisions of controlled drugs remain in force for a period of two years.

Every application for a licence 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 with any queries regarding the submission.

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| 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 licensed  |       |
| Address of premises to be licensed |       |
| Eircode |       |
| Name of manager or person in charge |       |
| E-mail address |       |
| Contact number |       |
| Section 2 Purpose and type of licence required*Sufficient information should be supplied to justify the granting of the licence.*  |
| Please indicate the operation type by checking the relevant box below: [ ]  Manufacturer *(Licence type e.g. possession, production, supply       )*[ ]  Wholesaler *(Licence type e.g. possession, supply      )*[ ]  University or laboratory *(Licence type e.g. possession      )*[ ]  Private hospital, clinic or tissue establishment *(Licence type e.g. possession, for use at licenced location      )*[ ]  Advanced paramedic / paramedic *(Licence type e.g. possession, limited authority to supply      )* |
| For **all** licences please give a brief statement identifying the purpose for which the controlled drugs will be used:*(e.g. retain samples, forensic/chemical analysis, research and development of ……, wholesale distribution)*      |
| For private hospitals, clinics, 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 facility.  |
| For renewal licences please advise if you are adding/removing any drugs on the licence.     If removing drugs from the licence please confirm that these are no longer held on the premises.      |

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| For activities in respect of controlled drugs described in Schedules 1 to 5 of the Regulations, please indicate by marking in the tables below the drugs and activity type for which licences are required.*Note: separate licences are required for production, for supply and for possession under specific circumstances; therefore please indicate all activities for which a licence is required.*For **all possession** licences (except private hospitals, clinics or tissue establishments) please indicate in the tables below the approximate quantity of each controlled drug to be held at the licenced premises on an annual basis.*Note*: For advanced paramedics/paramedics please state both the maximum quantity to be in their possession and the maximum quantity to be held at the premises.  |

| **Part A : Schedule 1 and 2 drugs** |
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| **Drugs** | **To produce base drug (including salts)** | **To produce preparations** | **To supply**  | **To possess** | **Quantity Held (grams/mls) *(possession licences only)*** |
| **Schedule 1\****Please specify below:* |  |  |  |  |  |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
| **Schedule 2** | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Alfentanil | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Buprenorphine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Cocaine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Codeine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Dihydrocodeine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Dipipanone | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Etorphine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Fentanyl | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Hydrocodone | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Hydromorphone | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Levorphanol | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Medicinal Opium (this includes papveretum) | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Methadone | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Methylphenidate | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Morphine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Nalbuphine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Oxycodone | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Pethidine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Pholcodine | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Remifentanil | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Quinalbarbitone | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Tapentadol | [ ]  | [ ]  | [ ]  | [ ]  |       |
| Others *(Please specify)*      | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |
|       | [ ]  | [ ]  | [ ]  | [ ]  |       |

*\* Please note that licences may be granted in respect of these drugs in limited circumstances which include use in research, forensic science applications and as an essential starting material or intermediate in an industrial manufacturing process in accordance with the Misuse of Drugs (Designation) Order 1998, as amended..*

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| **Schedule 3, 4 and 5 drugs Licence to produce only** |
| **Part B : Schedule 3 drugs**  |
| **Licence to produce***(For possession and/or supply only of Schedule 3, 4 and 5 drugs, a separate registration is required. Please see registration application form on* [*www.hpra.ie*](http://www.hpra.ie)*)* |
|  | Base drugs (including salts) | Preparations |
| Amylobarbitone | [ ]  | [ ]  |
| Flunitrazepam | [ ]  | [ ]  |
| Ketamine | [ ]  | [ ]  |
| Methylphenobarbitone | [ ]  | [ ]  |
| Pentazocine | [ ]  | [ ]  |
| Pentobarbitone | [ ]  | [ ]  |
| Phenobarbitone | [ ]  | [ ]  |
| Phentermine | [ ]  | [ ]  |
| Temazepam | [ ]  | [ ]  |
| Others *(Please specify)*      | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |

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| **Part C : Schedule 4 drugs** |
| **Licence to produce***(For possession and/or supply only of Schedule 3, 4 and 5 drugs, a separate registration is required. Please see registration application form on* [*www.hpra.ie*](http://www.hpra.ie)*)* |
|  | Base drugs (including salts) | Preparations |
| Alprazolam | [ ]  | [ ]  |
| Bromazepam | [ ]  | [ ]  |
| Chlordiazepoxide | [ ]  | [ ]  |
| Clobazam | [ ]  | [ ]  |
| Clonazepam | [ ]  | [ ]  |
| Diazepam | [ ]  | [ ]  |
| Flurazepam | [ ]  | [ ]  |
| Lorazepam | [ ]  | [ ]  |
| Lormetazepam | [ ]  | [ ]  |
| Midazolam | [ ]  | [ ]  |
| Nitrazepam | [ ]  | [ ]  |
| Prazepam | [ ]  | [ ]  |
| Selegiline | [ ]  | [ ]  |
| Triazolam | [ ]  | [ ]  |
| Zolpidem | [ ]  | [ ]  |
| Zopiclone | [ ]  | [ ]  |
| Others *(Please specify)*      | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |
|       | [ ]  | [ ]  |

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| section 3 operation type and Preparations produced*In the space provided below or via a separate referenced attachment, give a brief description of the operation(s) for which the licence(s) are required and, if applicable, provide a list and details of all the preparations to be produced under the authority of the licences for which application is made (i.e. preparations in Schedule 2, 3, 4 or 5).*      |
| 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) and who will have access to it. A declaration from An Garda Síochána must also be submitted in addition to this information.*      |
| 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 licence is sought (e.g, details of a registered pharmacy business, wholesale distributor).*      |
| section 6 ImportingWill you be importing controlled drugs in Ireland? (*Please note that a separate import licence may be required for each import into the country.)*[ ]  Yes [ ]  No |
| section 7 checklist of documentsThe 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, **signed by a superintendent**, stating that the safe holding the controlled drugs has been inspected and has been deemed appropriate. This certificate is valid for two years from date of issue and a copy of it must be submitted with every application for a controlled drugs licence. [ ]  Proof of payment made to the Department of Health (if applicable). Please note purchase orders and cheques are not acceptable. Please contact controlleddrugs@hpra.ie for queries regarding fees. |
| section 8 declarationI 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:

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Compliance Department

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