Application for Registration of Category 2 Scheduled Substances (Precursor Chemicals)

*Applications are made in accordance with:*

* *Regulation (EC) No. 273/2004 (as amended) laying down the rules governing the monitoring of intra-Community trade.*
* *Regulation (EC) No. 111/2005 (as amended) laying down rules for the monitoring of trade between the Community and third countries in drug precursors.*

*The rules for the implementation of the above legislation are contained in:*

* *Commission Delegated* [*Regulation (EU) No 2015/1011*](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_162_R_0003&from=EN) *repealing Commission Regulation (EC) No 1277/2005,*
* *Commission Implementing* [*Regulation (EU) No 2015/1013*](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_162_R_0005&from=EN)*, and*
* *Commission Delegated* [*Regulation (EU) No 2016/1443*](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1443&from=EN) *amending Regulations (EC) No 273/2004 and 111/2005.*

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| **SECTION 1: APPLICANT DETAILS** | | |
| **1.1** | | **Applicant contact details**  Name:  Address:  Company registered address (if different):  Company registration number:  Telephone:  Fax:  Email: |
| **SECTION 2: RESPONSIBLE OFFICER** | | |
| **2.1** | **Responsible Officer contact details**  Name:  Address:  Telephone:  Fax:  Email: | |
| **2.2** | **Details of relevant professional qualifications and/or experience in dealing with the sale, supply and exportation of scheduled substances** | |
| **2.3** | **Description of the position and tasks of the Responsible Officer** | |

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| **SECTION 3: PREMISES** | |
| **3.1** | **Business premises address** |
| **3.2** | **Have you previously held a registration for category 2 scheduled substances at the premises listed in 3.1?**  No  Yes  If yes, please list the licence number of the last licence held and its expiry date:  Licence number:  Expiry date: |
| **3.3** | **Is the business premises in 3.1 listed on any other licence, registration or authorisation issued by the HPRA?** *(e.g. medicinal product manufacturers or wholesale authorisation, controlled drugs licence or registration, scheduled substance registration, active substance registration or medicinal product broker registration)*    No  Yes  If yes, please list all licence, registration and authorisation numbers: |
| **3.4** | **Description of all places the activities of storage, manufacture, production, processing, trade, distribution, brokering, possession, import, export, placing on the market and/or intermediary activities involving scheduled substances** *(attach separate document if necessary)* |

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| **SECTION 4: ACTIVITIES** | |
| **4.1** | **Purpose for which the registration is required**  *(State briefly, e.g.* *storage, manufacture, production, processing, trade, distribution, brokering, possession, import, export, placing on the market and/or intermediary activities. Sufficient information should be supplied in order to justify obtaining a licence.)* |
| **4.2** | **Control of supplies**  Details of the precautions to be taken to prevent supply of scheduled substance(s) to unauthorised persons: |
| **4.3** | **Scale of usage**  Anticipated annual scale of usage of the scheduled substance(s): |
| **4.4** | **Preparations produced**  List any preparations or other products to be produced under the authority of the registration for which application is made: |

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| **SECTION 5: TYPE OF REGISTRATION REQUIRED**  *(Indicate with a tick the scheduled substances and primary activities for which registration is required.)* | | | | | | |
| ***Scheduled Substance***  *(including their salts wherever such exist)* | ***CN Code as per Annex I to Regulation (EC) No 273/2004 (as amended and 111/2005 (as amended)*** | ***TRADE WITHIN THE EU*** | | ***TRADE BETWEEN THE EU AND THIRD COUNTRIES*** | | |
| ***To place on the market (a)*** | ***To possess (as end user)***  ***(b)*** | ***Import***  ***(c)*** | ***Export***  ***(d)*** | ***Intermediary activities***  ***(e)*** |
| **Subcategory 2A** |  | | | | | |
| Acetic anhydride | 2915 24 00 |  |  |  |  |  |
| Red Phosphorus | 2804 70 00 |  |  |  |  |  |
| **Subcategory 2B** |  | | | | | |
| Phenylacetic acid | 2916 34 00 |  | N/A |  |  |  |
| Anthranilic acid | 2922 43 00 |  | N/A |  |  |  |
| Piperidine | 2933 32 00 |  | N/A |  |  |  |
| Potassium permanganate | 2841 61 00 |  | N/A |  |  |  |

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| Operators are exempt from registration where the quantities supplied or placed on the market within the EU do not exceed those indicated below, over the period of one year. Please inform the Controlled Drugs section of any recipients exceeding these annual thresholds.   |  |  |  | | --- | --- | --- | | **Substance** | **Annual threshold** | **Annual estimated quantity** | | Acetic anhydride | 100 litres |  | | Red Phosphorous | 0.1 kg |  | | Potassium permanganate | 100 kg |  | | Anthranilic acid and its salts | 1 kg |  | | Phenylacetic acid and its salts | 1 kg |  | | Piperidine and its salts | 0.5 kg |  |   Please note this exemption does not apply to the above scheduled substances when involved in external trade (i.e. imports, exports and/or intermediary activities outside the EU).  Please note when the above quantities are exceeded with the current calendar year, the operator must contact the Health Products Regulatory Authority immediately to comply with the registration requirement.   1. **Placing on the market** means any supply, whether in return for payment or free of charge of scheduled substances in the Union; or the, storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Union. 2. **To possess** means the possession of a scheduled substance by a user who is engaged in the processing, formulation, consumption, storage, keeping treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances. A ‘user’ defines persons possessing scheduled substances for purposes other than placing them on the market. 3. **Import** means any entry of scheduled substances having the status of non-Union goods into the customs territory of the Union, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Council Regulation (EEC) No 2913/92. 4. **Export** means any departure of scheduled substances from the customs territory of the Community, including the departure of scheduled substances that requires a customs declaration and the departure of scheduled substances after their storage in a free zone of control type I or free warehouse within the meaning of Council Regulation (EEC) No 2913/92. 5. **Intermediary activities** means any activity to arrange purchase and sale or supply of these precursor chemicals carried out to obtain agreement between two parties or to do so through acting on behalf of at least one of these parties without taking these substances into its possession or taking control of the carrying out of such transaction. This definition shall also include any activity involving purchase and sale or supply without the precursor chemicals being introduced into the customs territory of the Union. |

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| **SECTION 6: CERTIFICATES AND FEES** | | |
| **6.1** | Authenticated copy of the company’s Certificate of Incorporation  *(tick to confirm attachment)* |  |
| **6.2** | Certificate of good conduct of the applicant and Responsible Officer  OR  Document showing that they offer the necessary guarantee for the proper conduct of operations  *(tick to confirm attachment)* |  |
| **6.3** | Proof of payment made to the Health Products Regulatory Authority. Please note purchase orders and cheques are not acceptable. Please contact [controlleddrugs@hpra.ie](mailto:controlleddrugs@hpra.ie) for queries regarding fees.  *(tick to confirm attachment)* |  |

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| SECTION 7: declaration  In the event of the licence being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the licence and declare that the above particulars are, to the best of my knowledge and belief, correct.   |  |  | | --- | --- | | Signature: | Date: |   *(Applications must bear the signature of the Responsible Officer)* |

**Note:**

This application should be sent to:

Controlled Drugs Section

Compliance Department

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

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