Application for Registration of Manufacturer, Importer or Distributor of Active Substances

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| **APPLICANT DETAILS**  **For internal use only:**  Draft registration no:  Registration reference no:  Fee codes:  Name or corporate name of registrant:  Organisation Management Service ID (ORG ID):  Company registration office number:  If applicable, alternative name under which the company conducts its business (e.g. business name/trading style):  Organisation Management Service ID (ORG ID) for alternative name:  Company registration office number for alternative name:  Permanent or legal address of registrant:  Eircode:  Organisation Management Service Location ID (LOC ID):  Address of site where registered activities take place in Ireland:  Eircode:  Organisation Management Service Location ID (LOC ID):  If the site where registered activities take place already holds a manufacturing or wholesale authorisation for human medicines, please provide the authorisation number(s):  Name and address of applicant to whom correspondence should be addressed:  Eircode:  Contact telephone number:  Email address of applicant: |

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| 1. **Type of Registration requested**   Active Substance Registration for human use  Active Substance Registration for veterinary use  **Note: separate applications are required for each type of registration identified above.**   1. **SCOPE OF REGISTRATION REQUESTED**   *Identify all activities for which registration is being sought.*  *Note:*   * *If the registrant is a manufacturer of an active substance then it must also register as a distributor of that active substance unless the active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.* * *If the registrant is an importer of an active substance then it must also register as a distributor of that substance unless the imported active substance is only used for manufacture of a medicinal product by the registrant at the address listed above.* * *Please review the ‘HPRA Guide to Registration Requirements for Active Substance Manufacturers, Importers and Distributors in Ireland’ prior to completing this form, as it provides worked examples on how to complete it correctly.*   Registration for a manufacturer of an active substance  Registration for an importer of an active substance  Registration for a distributor of an active substance |

SCOPE OF REGISTRATION

Name and address of the site:

Organisation Management Service Location ID (LOC ID):

1. MANUFACTURING OPERATIONS

Active substance(s):

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|  | **Manufacture of active substance by chemical synthesis** |
|  | 1. Manufacture of active substance intermediates  2. Manufacture of crude active substance  3. Salt formation/purification steps: <free text> (e.g. crystallisation)  4. Other <free text> |

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|  | **Extraction of active substance from natural sources** |
|  | 1. Extraction of substance from plant source  2. Extraction of substance from animal source  3. Extraction of substance from human source  4. Extraction of substance from mineral source  5. Modification of extracted substance <specify source 1,2,3,4>  6. Purification of extracted substance <specify source 1,2,3,4>  7. Other <free text> |

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|  | **Manufacture of active substance using biological processes** |
|  | 1. Fermentation  2. Cell culture <specify cell type> (e.g. mammalian/bacterial)  3. Isolation/purification  4. Modification  5. Other <free text> |

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|  | **Manufacture of sterile active substance** *(note Parts A, B and C, to be completed as applicable)* |
|  | 1. Aseptically prepared  2. Terminally sterilised |

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|  | **General finishing steps** |
|  | 1. Physical processing steps <specify> (e.g. drying, milling/micronisation, sieving)  2. Primary packaging (enclosing/sealing the active substance within a packaging material which is in direct contact with the substance)  3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance.)  4. Other <free text> (for operations not described above) |
|  | **Quality control testing**  *Complete this section only if any parts of sections A, B, C, D, E are completed.* |
|  | 1. Physical/chemical testing  2. Microbiological testing (excluding sterility testing)  3. Microbiological testing (including sterility testing)  4. Biological testing |

1. IMPORTATION AND DISTRIBUTION OPERATIONS

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| **A** | **Importation**  *(List all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)* | | |
|  | Active substance | Third-country manufacturer  (name, address and OMS location ID if available) | Distributor  (name, address and OMS location ID if available) |
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|  | Clarifying remarks related to the scope of these registered operations:  *Tick all relevant operations which apply to the importation activities.*  1. Procurement (purchase of active substance from sites outside the EEA for the purpose of importation)  2. Site of physical importation (site receiving active substance from outside the EEA)  3. Other <free text> | | |

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| **B** | **Distribution** |
|  | Active substance(s) *(list all active substances for which distribution operations apply):* |
|  | Clarifying remarks related to the scope of these registered operations:  *Tick all relevant operations which apply to the distribution activities.*  1. Procurement (purchase of active substance from sites in the EEA)  2. Holding (i.e. storage)  3. Supply (to registered sites e.g. distributors, or authorised sites (MIA holders), located in the EEA)  4. Export (to sites outside the EEA)  5. Other <free text> |

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| declaration  I declare that the above particulars are, to the best of my knowledge and belief, correct.  Signature:  Date:  Print name:  Title/position: |

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| Checklist of Documents  The following information must be submitted with the application (except where not applicable).  *Please tick the checkboxes below to confirm the documents have been included with the application.*  Letter of application  Completed application form  Certificate of incorporation  Site master file if available (active substance manufacturers only)  Signed declaration  Relevant fee |
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**Send to:**

Licensing Section

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

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