Application form for a Wholesale Distribution Authorisation

Refer to the ‘Guide to New Applications and Variations to Wholesale Distribution Authorisations’, available on [www.hpra.ie](http://www.hpra.ie), when completing this application form.

**General notes:**

* All sections of the application form must be completed in order for the application to be accepted.
* Supporting information and documentation as specified in this guidance is required in order for the application to be deemed complete.
* Please note this application will be deemed incomplete if the applicant is not **ready for inspection** at the time of submission of this application.
* Please note any proposed variation to a current authorisation must not be implemented until formal approval has been provided by the HPRA.

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| Applicant Details  *(Relating to Schedule 1 of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*  Legally registered name of proposed authorisation holder:  Legally registered address of proposed authorisation holder:  Eircode:  Organisation Management Service ID (ORG ID):  Organisation Management Service Location ID (LOC ID):  Trading style (if applicable):  *(Please provide business document from the Companies Registration Office if using a trading style.)*  Company Registration Office number:  *(Please include certificate of incorporation.)*  Company Registration Office number for ‘Trading As’ company (if applicable):  Address of the proposed wholesaling site in Ireland:  Eircode:  Organisation Management Service Location ID (LOC ID):  Is this application for a wholesaling distribution authorisation of general sale medicines only?  Yes  No |

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| Do wholesaling activities occur at the legally registered address of the proposed authorisation holder? (Refer to the section ‘Guidance on addresses’ in the guidance document.)  Yes  No  Name and address of applicant (if different from the proposed authorisation holder):  Eircode:  Contact telephone number:  Email address of applicant: |

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| SCOPE OF WHOLESALE DISTRIBUTION   1. Medicinal products   1.1 with a Marketing Authorisation in EEA country(ies)  1.2 without a Marketing Authorisation in the EEA and intended for EEA market  1.3 without a Marketing Authorisation in the EEA and intended for exportation   1. authorised wholesale distribution operations   *(Relating to Schedule 1 of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*  2.1 Procurement  2.2 Holding  2.3 Supply  2.4 Export   1. medicinal products with additional requirements   *(Relating to Schedule 1 of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*  3.1 Products according to Art. 83 of 2001/83/EC[[1]](#footnote-1)  3.1.1 Narcotic or psychotropic products  3.1.2 Medicinal products derived from blood  3.1.3 Immunological medicinal products  3.1.4 Radiopharmaceuticals (including radionuclide kits)  3.2 Medicinal gases  3.3 Cold chain products (requiring low temperature handling)  3.4 Other products  3.4.1 Prescription only medicinal products  3.4.2 Medicinal products for general sale  3.4.3 Over the counter medicinal products for sale through pharmacies only  3.4.4 Unauthorised medicinal products (refer to guide for more information)  3.4.5 Vaccines  3.4.6 Parallel imported medicinal products authorised by Parallel Product Authorisation (PPA)  3.4.7 Parallel imported medicinal product authorised by Dual Pack Registration (DPR)  3.4.8 Parallel distributed centrally authorised medicinal products  3.4.9 Traditional herbal medicinal products  3.4.10 Homeopathic medicinal products (HOR and HOA)  3.4.11 Exempt medicinal products (refer to guide for more information))  3.4.12 Biological products  3.4.13 Advanced therapy medicinal products |

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| Annex 2 Contract Wholesale distribution sites  *(Relating to Schedule 1- 4 (3) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*  Please provide the details specified below for **each** contract wholesale distribution site.   |  | | --- | | Name: | | Address:  Organisation Management Service Location ID (LOC ID): | | WDA/MIA number: | | Located outside Ireland but within the EEA? Yes  No | | If yes, copy of the authorisation/licence issued by the relevant national Competent Authority (NCA) (where applicable) supplied? Yes  No | | Confirm if a technical agreement will be available for review during inspection.  Yes  No | | Confirm if details of the following regarding transportation vehicles, containers and/or routes, for both cold-chain and ambient conditions, will be available during inspection:   * Details of validated temperature control measures Yes  No * Details of ongoing temperature verification systems Yes  No | |

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| Annex 3 Responsible Person/Deputy responsible person  *(Relating to Schedule 1 – 5(1&2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*  Please provide the details specified below for **each** responsible/deputy responsible person.   |  | | --- | | Name:  Proposed role: Responsible person or deputy responsible person:  Direct email address of RP/deputy RP:  Direct contact mobile telephone (available 24 hrs):  Additional information: | |

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| Additional supporting information  Proposed wholesale distribution model  Proposed supplier types (refer to guidance document for required content):  Confirm if a technical agreement will be available for review during inspection.  Yes  No  Proposed customer types (refer to guidance document for required content):  Proposed transport model(s) (refer to guidance document for required content):  Premises and equipment  *(Relating to Schedule 1, 4 (2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*  Please refer to guidance document for required content and for holding sites ensure details of temperature mapping are provided if applicable:  Quality system  List of the procedures in quality system submitted with application  Yes  Additional personnel  Please provide the details specified below for **each** additional personnel. Additional personnel can be named on an appendix to the application if required.  Name:  Qualifications:  Experience:  Role:  Confirmation of inspection readiness  I confirm that the proposed authorisation holder and relevant sites are ready for inspection at the time of submission of this application Yes  No  Brokers  If a wholesaler of medicinal products uses the service of a broker, that broker is required by the Falsified Medicines Directive to register with the HPRA.  Do you use the services of a broker?  Yes  No  Broker name:  Broker address:  Eircode: |

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| 1. fees/classification of facility   An application fee must be submitted with each request for a wholesale distribution authorisation. An annual maintenance fee is also payable in respect of each authorisation and is related to the size of the facility. Please refer to the ‘Guide to New Applications and Variations to Wholesale Distribution Authorisations’ for guidance on selection of a site category.  *(please tick)*  **Large site**  **Medium site**  **Small site**  **Minor site**  **Procurement and supply only site**  Please refer to the ‘Guide to Fees for Human Products’ on the ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie) and complete the fee application form. |
| 1. declaration   In the event of the authorisation being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the authorisation and declare that the above particulars are, to the best of my knowledge and belief, correct.  **Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**:  **Print name**:       **Title/position**: |
| 1. Checklist of Documents   The following information must be submitted with the application (except where not applicable).  *Please tick the checkboxes below to confirm the information and supporting documents have been included with the application.*  Letter of application  Certificate of incorporation  Business document from Companies Registration Office if using a trading style  Completed application form  Statement on premises and equipment  Overview of documents and records  Statement on quality system  Details relating to Responsible Person(s)  Written confirmation relating to contract RP  Classification of facility size  Proof of payment of relevant fee  Signed declaration |

*\*as amended*

**Send to:**

Compliance Department,

Health Products Regulatory Authority,

Kevin O’Malley House,

Earlsfort Centre,

Earlsfort Terrace,

Dublin 2,

D02 XP77.

Tel: + 353 1 676 4971

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

1. Without prejudice to further authorisations as may be required according to national legislation [↑](#footnote-ref-1)