Application to Vary a Wholesale Distribution Authorisation

General Notes:

* Please note this application will be deemed invalid if the applicant is not **ready for inspection** at the time of submission of this application.
* Please refer to the ‘Guide to New Applications and Variations to Wholesale Distribution Authorisations’ for information on variation type, timelines and supporting documentation required to accompany variation application.
* Provide a brief background statement regarding the variation application in the background section.
* Delete sections that are not applicable to the variation application.

|  |
| --- |
| Applicant Details *(Relating to Schedule 1 of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*Authorisation number:      Legally registered name of authorisation holder:     Legally registered address of authorisation holder:      Eircode:      Organisation Management Service ID (ORG ID):      Organisation Management Service Location ID (LOC ID):      Company Registration Office number:      *(Please include certificate of incorporation.)*Address of the wholesaling site in Ireland:      Eircode:      Organisation Management Service Location ID (LOC ID):      Name and direct email address of RP named on the authorisation:      Contact telephone of RP named on the authorisation:      Name and address of applicant to whom correspondence should be addressed:      Eircode:      Contact telephone number:      Email address of contact:       |

Proposed variation to the authorisation

**Variations to general information**

[ ]  Minor corrections/typographical errors to authorisation (administrative variation)

[ ]  Change in the name of authorisation holder (administrative variation)

[ ]  Change in the legally registered address of the authorisation holder (administrative variation)

[ ]  Change in the name of the wholesale site (administrative variation)

[ ]  Change in the address of a wholesaling premises (technical variation)

| **Present Wording** | **Proposed Wording** |
| --- | --- |
|       |       |
|       |       |
|       |       |

|  |
| --- |
| Variations to Annex 1 Scope of Wholesale Distribution |
| All additions are technical variations and all removals are administrative variations. |
| 1. Medicinal products
 | **Addition** | **Removal** |
| [ ]  1.1 with a marketing authorisation in EEA country(ies)  | [ ]  | [ ]  |
| [ ]  1.2 without a marketing authorisation in the EEA and intended for the 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\*)* | **Addition** | **Removal** |
| [ ]  2.1 Procurement (obtaining, acquiring, purchasing or buying medicinal products from manufacturers or other wholesale distributors) | [ ]  | [ ]  |
| [ ]  2.2 Holding (storing medicinal products) | [ ]  | [ ]  |
| [ ]  2.3 Supply (all activities of providing, selling or donating medicinal products to wholesalers; pharmacists; or persons authorised or entitled to supply medicinal products to the public) | [ ]  | [ ]  |
| [ ]  2.4 Export (all activities relating to the supply of a medicinal product to a state other than an EU Member State or a Contracting State of the European Economic Area) | [ ]  | [ ]  |
| 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\*)* | **Addition** | **Removal** |
| [ ]  3.1 Products according to Art. 83 of 2001/83/EC[[1]](#footnote-2) | [ ]  | [ ]  |
| **[ ]**  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 (see note 1) | [ ]  | [ ]  |
| [ ]  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 (see note 2) | [ ]  | [ ]  |
| [ ]  3.4.12 Biological products | [ ]  | [ ]  |
| [ ]  3.4.13 Advanced therapy medicinal products | [ ]  | [ ]  |
| **Note 1**: Unauthorised medicinal products are products which do not hold a marketing authorisation in Ireland. A wholesaler may supply such products only to markets outside of Ireland where the products are authorised. Unauthorised medicinal products are not for supply on the Irish market.**Note 2**: An exempt medicinal product is a medicinal product which does not hold a marketing authorisation. It is supplied in response to a *bona fide* unsolicited order formulated in accordance with the specification of a practitioner for use by their individual patients on their direct personal responsibility. Guidance on exempt medicinal products can be found on the ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie/).**Note 3**: Please be aware that a separate licence/registration is required to wholesale controlled drugs. Please contact the HPRA Compliance Department (compliance@hpra.ie) for more information. |

Variations to 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\*)*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **[ ]** Addition of contract wholesale distribution site (technical variation)

|  |
| --- |
| Name:       |
| Address:       |
| Organisation Management Service Location ID (LOC ID):       |
| WDA number:       |

**[ ]** Removal of contract wholesale distribution site (administrative variation)

|  |
| --- |
| Name:       |
| Address:       |

**[ ]** Change in name or authorisation number of contract wholesale distribution site (administrative variation)

|  |  |
| --- | --- |
| **Present wording** | **Proposed wording** |
|       |       |

**[ ]** Change in address of contract wholesale distribution site (technical variation)

|  |  |
| --- | --- |
| **Present wording** | **Proposed wording** |
|       |       |

 |

Variations to Annex 3 Personnel (Relating to *Schedule 1 – 5(1&2) of S.I. No. 538 of 2007, Medicinal Products (Control of Wholesale Distribution) Regulations 2007\*)*

|  |
| --- |
| [ ]  **Addition of a Responsible Person** (technical variation)Name:      Direct email address of RP:      Direct contact telephone:       |
| **[ ]  Addition of a deputy Responsible Person** (technical variation)Name:        |
| **[ ]  Removal of Responsible person (RP) or deputy Responsible Person** (administrative variation)Name:      Current position (RP/deputy RP):       |
| **[ ]  Change in role from Responsible Person to deputy Responsible Person** (administrative variation)Name:       |
| **[ ]  Change in role from deputy Responsible Person to Responsible Person** (technical variation)Name:      Direct email address of RP:      Direct contact telephone:       |

|  |
| --- |
| **Background**Please give a brief background explanation for the proposed changes to your authorisation/ licence (attach additional supporting data as detailed in the ‘Guide to New Applications and Variations to Wholesale Distribution Authorisations’).      |

|  |
| --- |
| feesAn application fee must be submitted with each request for variation to an authorisation/ licence. Please refer to the ‘Guide to Fees for Human Products’ Section 3 or the ‘Guide to Fees for Veterinary Products’ Section 2 on the ‘Publications and Forms’ section at [www.hpra.ie](http://www.hpra.ie). Complete and submit only the relevant section of the fee application form. |
| declarationI hereby make application for the above authorisation/licence to be varied in accordance with the proposals given above, and certify that the changes will not adversely affect the quality, efficacy or safety of any medicinal product tested. I declare that amended documents have been supplied and that the supporting information is correct. I declare that all changes have been identified and that there are no other changes in the amended documentation.**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:**      **Print name:**       **Title/position:**       |

Send to:

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

Please do not submit applications more than once.

\*as amended

1. Without prejudice to further authorisations as may be required according to national legislation [↑](#footnote-ref-2)