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.

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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\*)*  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** |
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| 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](mailto: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\*)*

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| 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\*)*

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| **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: |

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| **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’). |

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| fees  An 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. |
| declaration  I 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](mailto: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)