Application to Withdraw an Authorisation, Licence, Approval or Registration

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| 1. type of authorisation\* requested to be withdrawn (*Tick as appropriate*)

[ ]  Manufacturer’s authorisation for medicinal products for human use [ ]  Manufacturer’s licence for medicinal products for veterinary use [ ]  Manufacturer’s authorisation for investigational medicinal products [ ]  Wholesaler’s authorisation [ ]  Laboratory approval [ ]  Blood establishment authorisation[ ]  Tissue establishment authorisation[ ]  Organ authorisation[ ]  Broker of medicinal products for human use registrationActive substance registrations:[ ]  Manufacturers [ ]  Importers [ ]  Distributors**\***For the purpose of this document the term ‘authorisation’ is used to collectively refer to any of the above mentioned categories of authorisation, licence, approval or registration granted by the HPRA. |
| 1. Applicant details

Legally registered name of authorisation holder:      Organisation Management Service ID (ORG ID):      Organisation Management Service Location ID (LOC ID):      Legally registered address of the authorisation holder:      Eircode:      Address of premises where activities take place (if different from that of the holder):      Organisation Management Service Location ID (LOC ID):      Eircode:      Authorisation/licence/registration number:      Name and address of applicant to whom correspondence should be addressed:       |

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| 1. REASON FOR WITHDRAWAL

[ ]  Commercial      [ ]  Quality, including GMP issues      [ ]  Safety issues      [ ]  Efficacy issues      [ ]  Other       |
| 1. PLEASE PROVIDE THE FOLLOWING DOCUMENTATiON WITH THIS APPLICATION FORM:
	1. For manufacturers, provide:

[ ]  Most recently issued manufacturer’s authorisation.[ ]  Most recently issued GMP certificates.[ ]  Information on how your company plans to comply with conditions of the licence or authorisation.[ ]  Details of how GMP documentation will be retained. [ ]  Confirmation that you have informed any manufacturers for whom you carry out contract manufacturing activities. Please provide a list of any Irish sites affected and their authorisation activities. * 1. For wholesalers and brokers of medicinal products for human use (as appropriate), provide:

Information on how your company plans to comply with conditions of licence/authorisation in relation to:[ ]  Retention of GDP documentation[ ]  Storage of retain and stability samples[ ]  Distribution records[ ]  Handling of recallsAlso provide:[ ]  Most recently issued wholesale authorisation.[ ]  Most recently issued GDP certificates.[ ]  Confirmation that you have informed any companies for whom you carry out contract wholesale/storage activities. Please provide a list of any Irish sites affected and their authorisation numbers. [ ]  Confirmation if there is any stock remaining on site or in a contract wholesale distribution storage site. [ ]  Confirmation that the IMVO has/will be informed of the withdrawal, if applicable. * 1. For laboratories, provide:

[ ]  Most recently issued laboratory approval.[ ]  Most recently issued GMP certificates.[ ]  Information on how your company plans to comply with conditions of the laboratory approval.[ ]  Details of how GMP documentation will be retained. [ ]  Confirmation that you have informed any manufacturers for whom you carry out contract analysis. Please provide a list of any Irish sites affected and their authorisation activities.* 1. For blood, tissue or organ authorisations, provide:

Information on how your company plans to comply with conditions of licence/authorisation for example:[ ]  Retention of traceability records for 30 years.[ ]  Retention of information relating to serious adverse reactions and events.[ ]  Transfer of prescribed activities to another authorised site.[ ]  Return the most recent authorisation issued.Please note, further information may be requested upon receipt of this application. * 1. For active substance manufacturers, distributors and importers, provide:

[ ]  Most recently issued registration document.[ ]  Most recently issued GMP/GDP certificates.[ ]  Information on how your company plans to comply with conditions of the registration.[ ]  Details of how GMP/GDP documentation will be retained. |

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| 1. declaration

I hereby make application for the above authorisation to be withdrawn in accordance with the proposals given above. I declare that the information provided is correct and that appropriate measures have been put in place to ensure continued compliance of products handled under the authorisation being withdrawn.

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| Signature:       | Date:        |
|  |  |
| Print name:        | Title/position:        |

*Notes:* Applications must bear the signature of the applicant. Where the application is on behalf of a limited company, the declaration must be signed by a director or the secretary and, in the case of a partnership, by a partner. |

1. RETURN ADDRESS

Send to:

Licensing 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: compliance@hpra.ie