Application Form for Renewal of a Manufacturer’s / Wholesaler’s Authorisation / Licence

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| 1. Type of renewal authorisation / licence requested

*(tick as appropriate)*Manufacturer’s authorisation for medicinal products for human use [ ] Manufacturer’s authorisation for medicinal products for veterinary use [ ] Wholesaler’s authorisation [ ]  |
| 1. Applicant Details

Name and address of authorisation / licence holder:      Eircode:      Legally registered address of the authorisation / licence holder (if different from above):      Eircode:      Company office registration number:      Name and address of manufacturing or wholesaling premises (if different to that of the holder):      Eircode:      Name and address of applicant (if different from the proposed approval holder):      Licence / authorisation number:      Contact person:      Contact telephone:      Contact fax:      E-mail address of contact:       |

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| 1. Personnel (required for manufacturer’s authorisation / licence only)

Detail by department the numbers of personnel involved directly in GMP operations (e.g. production, quality control, engineering, quality assurance, compliance etc.)

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| **Department** | **No. of personnel** |
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| 1. Approved or pending variation applications since granting of the licence / authorisation or last renewal

Note: This information can also be supplied as an attachment to the application form.Any proposed variation to the licence cannot be submitted as part of this renewal application. Any proposed variation must be submitted separately and should be accompanied by the appropriate variation form and fee.

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| **Date of submission** | **Date of approval** | **Variation number** | **Brief description of change** |
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| 1. Documentation

Please enclose the current recall procedure with the application.Please state the current Site Master File revision number and date of issue (manufacturer only):       |
| 1. declaration

I hereby make application for the above manufacturer’s / wholesaler’s authorisation be renewed. I declare that all information supplied and supporting documentation is correct.**Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**      **Print name**:       **Title / position:**       |

Send to:

The Compliance Department, Health Products Regulatory Authority,

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Fax: + 353 1 676 7836

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