Application for Registration (or Variation to Existing Registration) of Broker of Finished Medicinal Products for Human Use

|  |
| --- |
| 1. Applicant Details

Registered company name or name of individual requiring registration:     Company registration office number:     Permanent or legal address of registrant:     Eircode:      Address(es) of site(s) where registered activities take place:      Eircode:      Name and address of applicant (if different from the proposed registration holder):     Eircode:      E-mail address of applicant:     Contact telephone number:     Contact fax number      |

|  |
| --- |
| 1. The following requirements relating to the brokering of medicinal products must be complied with
 |
| 2.1 I confirm that the brokered medicinal products are covered by a marketing authorisation granted pursuant to regulation (EC) No. 726/2004 or by the Competent Authority of an EU Member State.2.2 I confirm that an emergency plan is in place which ensures effective implementation of any recall of a medicinal product from the market ordered by the Competent Authorities or carried out in co-operation with the manufacturer or marketing authorisation holder. A copy of this procedure should be submitted with the application.2.3 I confirm that a system to ensure that records either in the form of purchase/sales invoices, or on computer, or in any other form for any transaction in medicinal products brokered providing at least the following information, is in place:* Date on which the sale or purchase of the product was brokered
* Name of medicinal product
* Quantity brokered
* Name of supplier or consignee as appropriate
* Address of supplier or consignee as appropriate
* Batch number for products bearing the safety features

2.4 I confirm that the records will be retained for a period of five years.2.5 I confirm compliance with the guidelines on good distribution practice (GDP) published by the European Commission in accordance with Article 84 of the 2001/83/EC Directive insofar as those guidelines apply to brokers.2.6 I confirm that a quality system setting out responsibilities, processes and risk management measures in relation to brokering activities are in place and will be maintained.2.7 I am aware of the requirement to immediately inform the licensing authority and where applicable the marketing authorisation holder of medicinal products which I identify as, suspect to be, or have reasonable grounds for knowing or suspecting to be, falsified, and undertake to do so. I am aware that the mentioned premises may be subject to inspection by the Competent Authority.2.8 To the best of my knowledge and belief the particulars I have given in this form are correct, truthful and complete.**I will notify all changes to the above mentioned data without delay to the Competent Authority.** |

|  |
| --- |
| 1. declaration

In the event of the registration being granted, I undertake to ensure fulfilment of the obligations arising by virtue of the terms and conditions of the registration 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 documents have been included with the application.*[ ]  Letter of application[ ]  Completed application form[ ]  Certificate of incorporation[ ]  Emergency plan[ ]  Fee application form[ ]  Signed declaration |

**Send to:**

Licensing Section

Compliance Department

Health Products Regulatory Authority

Earlsfort Centre

Earlsfort Terrace

Dublin 2

D02 XP77

Tel: + 353 1 676 4971

Fax: + 353 1 676 7836

E-mail: compliance@hpra.ie