Application for Transfer of an Authorisation for Manufacturing Investigational Medicinal Products

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| 1. Details of CURRENT authorisation holder

Name of authorisation holder:      Authorisation number:      Legally registered address of authorisation holder:       Eircode:       Organisation Management Service ID (ORG ID):       Organisation Management Service Location ID (LOC ID):        Site address of premises subject to the authorisation:      Eircode:      Organisation Management Service Location ID (LOC ID):      Companies Registration Office number:      Contact person:      Contact telephone:      Email address:       |
| 1. Details of Proposed authorisation holder

Name of proposed authorisation holder:      Legally registered address of proposed authorisation holder:      Eircode:      Organisation Management Service ID (ORG ID):       Organisation Management Service Location ID (LOC ID):       Site address of premises subject to the proposed authorisation:       Eircode:      Organisation Management Service Location ID (LOC ID):       Companies Registration Office number:      Contact person:      Contact telephone:      Email address:       |
| 1. BaCKGROUND

Please give a brief background explanation for the proposed transfer of the authorisation:       |
| 1. DECLARATION - CURRENT HOLDER OF THE AUTHORISATION

I hereby confirm that on transfer **<insert name of current holder>** will furnish to **<insert name of the proposed holder>**:* all records and documentation, including but not limited to the site master file and all documents related to and in accordance with the principles and guidelines of good manufacturing practice specified by Commission Directive 91/356/EEC (repealed and replaced by Directive 2003/94/EC), Article 47 of Directive 2001/83/EC\*, and Medicinal Products (Control of Manufacture) Regulations 2007\*; and
* all items (including but not limited to samples)

of whatsoever nature required to be held by the holder of authorisation **<insert authorisation number>**.*\*as amended*I declare that all information supplied and supporting documentation is correct and I am authorised to make this declaration on behalf of the applicant.Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name:      Capacity in which this declaration is made by or on behalf of the applicant:      Telephone no:      Email:      Witnessed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name and address of witness:       |
| 1. DECLARATION - PROPOSED HOLDER OF AUTHORISATION

I hereby make application for the authorisation **<insert authorisation number>** granted to **<insert name of current holder>** in accordance with the requirements of Commission Directive 91/356/EEC (repealed and replaced by Directive 2003/94/EC), Article 47 of Directive 2001/83/EC\*, and with the Medicinal Products (Control of Manufacture) Regulations 2007\*, to be transferred to **<insert name of the proposed holder>**.From time of transfer of the authorisation by the Health Products Regulatory Authority to **<insert name of the proposed holder>** I hereby undertake to ensure fulfilment by **<insert name of the proposed holder>** of the obligations arising from the authorisation. I hereby confirm that:* the quality management system in accordance with the principles and guidelines of good manufacturing practice specified by Commission Directive 91/356/EEC (repealed and replaced by Directive 2003/94/EC), Article 47 of Directive 2001/83/EC\*, and with the Medicinal Products (Control of Manufacture) Regulations 2007\*, which has been operated by **<insert name of current holder>** to time of transfer will continue to be implemented by **<insert name of the proposed holder>** from time of transfer;
* from time of transfer **<insert name of the proposed holder>** will have the sole responsibility for the activities authorised/under the authorisation including obtaining approval as required from the Health Products Regulatory Authority for any changes to the authorisation;
* **<insert name of the proposed holder>** has procedures in place to permit the recall of any product manufactured and released for sale or supply from the authorised/premises subsequent to the transfer and a copy of the procedure is attached to this application;
* the site master file will be amended to reflect the transfer and it will be submitted to the Health Products Regulatory Authority within one month of the transfer;
* the transfer will not adversely affect the quality, efficacy or safety of any medicinal product issued from the premises.

*\*as amended*I declare that all information supplied and supporting documentation is correct and I am authorised to make this declaration on behalf of the applicant.Signed: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name:      Capacity in which this declaration is made by or on behalf of the applicant:      Telephone no:      Email:      Witnessed by: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:      Print name and address of witness:       |
| 1. fees

An application fee must be submitted with each request for a transfer of an authorisation.Please refer to the ‘Guide to Fees for Human Products’ on the ‘Publications and Forms’ section of [www.hpra.ie](http://www.hpra.ie) and complete the fee application form. |
| 1. CHECKLIST OF DOCUMENTS

The following documentation 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 [ ]  Certificate of Incorporation for proposed holder [ ]  If any current key personnel are to change, provide CVs and training records in relation to the changing personnel. |

Send to:

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