Application for Transfer of a Blood Establishment Authorisation

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| 1. Details of CURRENT authorisation holder

Name of blood establishment:      Authorisation number:      Legally registered address of authorisation holder:      Eircode:      Site address of premises subject to the authorisation:       Eircode:       Companies Registration Office number:      Contact person:      Contact telephone:      Email address:       |
| 1. Details of Proposed authorisation holder

Name of proposed blood establishment:      Legally registered address of proposed authorisation holder:      Eircode:      Site address of premises subject to the proposed authorisation:       Eircode:       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 related to and in accordance with the principles and guidelines of Commission Directive 2002/98/EC (as implemented by Commission Directives 2004/33/EC, 2005/61/EC and 2005/61/EC), and with the Quality and Safety of Human Blood and Blood Components Regulations 2005, Human Blood and Blood Components Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations 2006 and Quality System for Blood Establishments Regulations 2006; and
* all items of whatsoever nature required to be held by the holder of authorisation **<insert authorisation number>**.

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 2002/98/EC and with the Quality and Safety of Human Blood and Blood Components Regulations 2005, 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 Commission Directive 2005/62/EC and with the Quality System For Blood Establishments Regulations 2006 , 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 human blood and/or blood component intended for transfusion released from the authorised premises subsequent to the transfer and a copy of the procedure is attached to this application;
* the transfer will not adversely affect the quality or safety of any human blood and/or blood component intended for transfusion issued from the authorised premises.

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 [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 of proposed holder [ ]  Fees [ ]  If any current key personnel are to change, please provide CVs and training records in relation to the changing personnel. |

Send to:

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