Application for Transfer of a Licence for Manufacturing Medicinal Products for Veterinary Use

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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 licence: |
| 1. DECLARATION - CURRENT HOLDER OF THE LICENCE   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 91/412/EEC and Regulation 2019/6, as amended); and * all items (including but not limited to samples)   of whatsoever nature required to be held by the holder of licence **<insert licence 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 LICENCE   I hereby make application for the licence **<insert licence number>** granted to  **<insert name of current holder>** in accordance with the requirements of Regulation 2019/6, as amended by Directive 2004/28/EC, and with the Animal Remedies Regulations 2007 (S.I. No. 786 of 2007), as amended, to be transferred to **<insert name of the proposed holder>**.  From time of transfer of the licence 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 licence.  I hereby confirm that:   * the quality management system in accordance with the principles and guidelines of good manufacturing practice specified by Commission Directive 91/412/EEC and Regulation 2019/6, as amended, which has been operated by **<insert name of current holder>** to time of transferwill 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 licensed under the licenceincluding obtaining approval as required from the Health Products Regulatory Authority for any changes to the licence; * **<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 licensed 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.   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 a licence.  Please refer to the ‘Guide to Fees (Veterinary Products)’ onthe ‘Publications and Forms’ section at [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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