Application for a Variation to a Veterinary Clinical Field Trial Licence under Animal Remedies Legislation

SECTION A: CLINICAL FIELD TRIAL LICENCE HOLDER AND LICENCE NUMBER

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| Holder of the clinical field trial licence:  Address 1:  Address 2:  Address 3:  Telephone number:  E-mail:  Clinical field trial licence number: |

SECTION B: PROPOSED VARIATION

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| Proposed variation  *(Select all that apply and* *enter details in relevant section C ( 1- 6) below):*  1. Time extension of clinical field trial licence  2. Change to test product(s) (including quantities of test product) to be used in this trial  3. Change to principal investigator/study director  4. Change to species of animal authorised for use  5. Change to total number(s) of animal(s) authorised for use |

SECTION C: PROPOSED VARIATION DETAILS (if applicable)

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| **C1: Time extension of clinical field trial licence**  Date of expiry of current clinical field trial licence:  Time extension sought (months):  Justification for request for time extension: |

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| **C2: Change to test product(s) including quantities of test product to be used in this trial**  Provide details of any changes to test product(s) for example changes to the product name, changes to product composition, changes to the route of administration, or changes to the quantities of test product required:    Provide justification as to why any changes listed above are necessary: |

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| **C3: Change to principal investigator/study director**  Name of existing principal investigator/study director:  Enter the details of the proposed principal investigator/study director below:  Title:  First name:       Surname:  Address 1:  Address 2:  Address 3:  County:  E-mail:       Telephone:  Please append the CV of the proposed principal investigator/study director with this application. |

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| **C4: Change to species of animal authorised for use**  Species of animal currently authorised:  Species of animal for which authorisation is now being sought:  Justification for the use of an additional species under the clinical field trial licence: |

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| **C5: Change to total number of animals**  Total number of animals currently authorised for use:  Number of additional animals required:  Justification for requirement for additional animal numbers:  Are these additional animals owned by the clinical field trial licence holder/study sponsor?  Yes  No  If the animals are not owned by the clinical field trial licence holder/study sponsor will the consent of the owner of the animals be obtained?  Yes  No  Fate of these animals following the completion of the trial: |

SECTION d: DECLARATION AND UNDERTAKING

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| *The declaration and undertaking below should be signed by or on behalf of the applicant, or the person who is responsible for the overall execution of the trial and its compliance with the trial licence*.  I hereby **declare** that:   * The information contained in this application is true and correct.   I hereby **undertake** that in the event of the trial licence being granted:   * To ensure fulfilment of the obligations arising by virtue of the terms and conditions of the trial licence. * To submit an application for an amendment if any substantial changes to the trial are required. * To report any trial deviations that have an adverse effect on animal health or welfare, and to report any adverse effects on animal health or welfare to the responsible veterinarian. * To keep written records of all animals used under this clinical field trial licence for a minimum of five years, and to make all written records or trial documentation available to the HPRA upon request or as part of an inspection. * To ensure that the test products are kept securely and used only for the purpose of the trial conduct.   Signature of applicant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print/type name:  Date: |

**CHECKLIST**

Trial protocol (if different to currently approved protocol)

Ethics approval and documentation (where relevant)

CV (if new principal investigator/study director proposed)

Certificate confirming composition of test products without a marketing authorisation (if different to those currently licensed)

SPCs for each product with a marketing authorisation to be used during the trial (if different to those currently licensed)

Statements regarding compliance of test products (if different to those currently licensed) regarding freedom from GMOs, TSE and extraneous agents (where relevant) or EPA licence approval (where relevant)

Relevant summaries of safety and efficacy data on test products without a marketing authorisation (if different to those currently licensed)

If an unauthorised vaccine or biological product (and not currently licensed), information on the controls employed in production to ensure product is not contaminated with other agents

Evidence of fee payment