| Logo des BASG (Bundesamt für Sicherheit im Gesundheitswesen) | BASG/AGES Medizinmarktaufsicht Traisengasse 5, A-1200 Wien |
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**APPLICATION FORM - Request for approval of a clinical trial on a veterinary medicinal product**

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| --- | --- | --- | --- |
| **TITLE OF THE STUDY** | |  |  |
|  | | |  |
| **APPLICANT** | | | |
| **Name of the applicant** | | | |
| Address | | | |
| Phone No. | E-mail | | |
| **HEAD OF THE STUDY / PRINCIPAL INVESTIGATOR** (list other investigators participating in the study in Appendix 1) | | | |
| **Name of the study leader** | | |  |
| Address | | |  |
| Phone No. | E-mail | |  |
| Name of the responsible veterinarian (if the study leader is not a veterinarian) | | |  |
| Address | | |  |
| Phone No. | E-mail | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **MANUFACTURER AND IMPORTER OF THE INVESTIGATIONAL VETERINARY MEDICINAL PRODUCT** | | | |  |
| **Manufacturer** | | | |  |
| **Contact person of the manufacturer** | | | |  |
| Address | | | |  |
| Phone No. | | E-mail | |  |
| **Importer** (if the investigational veterinary medicinal product is not manufactured in the EU/EEA) | | | |  |
| Address | | | |  |
| Phone No. | | E-mail | |  |
| **SPONSOR** | | |  | |
| **Sponsor** | | |  | |
| Address | | |  | |
| Phone No. | E-mail | |  | |
| **Contact person of the sponsor** | | |  | |
| Address | | |  | |
| Phone No. | E-mail | |  | |

|  |  |  |
| --- | --- | --- |
| **PREPARATIONS USED IN THE STUDY** |  |  |

|  |  |
| --- | --- |
| **INVESTIGATIONAL VETERINARY MEDICINAL PROCUCT / AUTHORISED VETERINARY MEDICINAL PRODUCT**  Name of the investigational product and pharmaceutical form    ATCvet-Code (if available) | **CONTROL PRODUCT**  **PLACEBO**  Name of the control product and pharmaceutical form    ATCvet-Code (if available) |
| Qualitative and quantitative composition | Qualitative and quantitative composition |
| Route of administration, dosage and duration of treatment | Route of administration, dosage and duration of treatment |
| MRL status of the active substance(s)/excipients (if necessary) | MRL status of the active substance(s)/excipients (if necessary) |
| Withdrawal periods for food-producing species and scientific justification (if applicable) | Withdrawal periods (if applicable) |
| Source of the investigational veterinary medicinal product for the study (production site, wholesaler or pharmacy) | Source of the control product/placebo for the study (production site, wholesaler or pharmacy) |
| Is the investigational veterinary medicinal product authorised in Austria or in another EU member state/EEA/third country?  Yes  No  If yes, country and authorisation/registration number: | Is the control product authorised in Austria or in another EU member state/EEA/third country?  Yes  No  If yes, country and authorisation/registration number: |
| GMP-certificate  QP-declaration  GMP-conformity | GMP-certificate  QP-declaration  GMP-conformity |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **CLINICAL TRIAL** | | |  | | |
| Study number | | | | | |
| Planned duration of the study (date of start and end) | | | | | |
| Objective of the trial and brief summary of the study plan | | | | | |
| Type of the trial (GCP-compliant, controlled or uncontrolled, randomised, blinded etc.) | | | | | |
| Animal species | Test group | | |  | |
| Total number of study animals: | Control group | |
| Number of animals by gender: | | | Number of animals by gender: | |
| ♀ | ♂ | | ♀ | ♂ |
| Has this trial already been submitted to the responsible Ethics Committee?  Yes  No, it will be submitted simultaneously.  In any case, please provide us the opinion of the Ethics Committee as soon as it is available. | | | | | |
| If clinical trials with the investigational veterinary medicinal product have been conducted in Austria earlier, please provide the title(s) and study number(s): | | | | | |
| Has this study already been submitted in another EU member state/EEA/third country?  Yes  No  If yes, country/countries and, in case of a positive outcome the date of approval/in case of a negative outcome date of rejection:    Is this study submitted simultaneously in another EU member state/EEA/third country?  Yes  No  If yes, country/countries: | | | | | |

**MULTICENTRE TRIAL**

|  |  |
| --- | --- |
| Number of clinics participating in the study trial: | Total number of study animals: |
| Research centres in Austria, their principal investigators and number of the study animals. Also give information on the dosage if it differs between centres. | |

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| **SIGNATURES** | |  |
| I have read the reports issued by the sponsor on the investigational veterinary medicinal product.  I will keep a research dairy during the veterinary clinical trial and ensure that all suspected adverse events observed in course of the trial are reported to the pharmacovigilance database or Federal Office for Safety in Health Care (BASG). I will also notify the Federal Office for Safety in Health Care (BASG) of any substantial changes to be made to the study plan without delay. I have read the relevant EU guidelines on veterinary clinical trials. | | |
| Place and date: | Principal investigator’s signature and name in block letters: | |
| I hereby affirm that the information given above on the investigational veterinary medicinal productis correct and complete. I will notify the Federal Office for Safety in Health Care (BASG) about the end of the study or immediately if the trial is discontinued or never begun, and why. Upon completion of the study trial, I will submit to BASG a report on the findings of the veterinary clinical trial and will immediately.  Furthermore, I hereby confirm that the documents are attached as set out in the Annex. All documents legitimised by a signature are original and may be submitted upon request. All enclosed translations and copies are entirely consistent with the original. | | |
| Place and date: | Sponsor’s signature and name in block letters: | |
| Place and date: | Applicant’s signature and name in block letters: | |

|  |  |
| --- | --- |
| **ANNEXES TO THE APPLICATION FORM[[1]](#footnote-1)** |  |
| Cover letter  Current Summary of Product Characteristics (SPC) of the investigational veterinary medicinal product (if the investigational (veterinary) medicinal is authorised)  Current Summary of Product Characteristics (SPC) of the control product (for controlled study/ies with positive control group)  Documentation on pharmaceutical quality and manufacturing of the investigational (veterinary) medicinal product (including GMP, GMP equivalent or QP declaration)  Clinical Trial Study Plan (incl. GCP compliance according to VICH GL 9 Good Clinical Practice)  Preclinical documentation (pharmacology, toxicology, user safety data)  Scientific justification of the proposed withdrawal period (if necessary) and data on residue studies (if available)  Information on the target animal safety  Information on the dose justification  Statistical protocol according to the EMA/CVMP/EWP/81976/2010-Rev.  Information for the principal investigator/head of study (“investigator’s brochure”): including Reference Safety Information (RSI) on the investigational medicinal product, if no SPC exists  Proof of qualification of the head of study  Recruitment methodology  Information letter for the pet owner  Declaration of consent of the pet owners or holders of the study animals  Opinion of the responsible Ethics and Animal Welfare Committee (ETK)/Animal testing permit  Other investigators involved in this study (see Appendix 1)  Others, please specify (e.g. BMSGPK import certificate for investigational veterinary medicinal products with addictive or psychotropic substances; or opinion of the BMSGPK in studies with GMOs or investigational veterinary medicinal products against animal diseases pursuant to § 16 Austrian Tierseuchengesetz (if applicable). | |

# APPENDIX 1

# DETAILS ON OTHER INVESTIGATORS

|  |  |  |
| --- | --- | --- |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Phone No. | E-mail | |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Phone No. | E-Mail |  |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Phone No. | E-mail |  |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Phone No. | E-mail |  |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Tel.Nr. | E-mail |  |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Phone No. | E-mail |  |
| **Name of investigator** | | Degree or qualification |
| Address | |  |
| Phone No. | E-mail |  |

1. Please tick the items for which attachments are included in the application. This facilitates the assessment of the application for completeness. [↑](#footnote-ref-1)