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| |  |  |  | | --- | --- | --- | | **R:\Logos\VMD Logos\4 Detailed Colour - light green.png** |  | **Veterinary Medicines Directorate**  Woodham Lane, New Haw  Addlestone, Surrey  KT15 3LS  United Kingdom  Tel: +44 (0)1932 336911  Search for VMD on GOV.UK |   **APPLICATION FOR AN ANIMAL TEST CERTIFICATE (TYPE S)**  **An incomplete application form may delay the application process.**  *Where a section of the application form refers to data supplied within the data package, please clearly indicate the location of this data within the data package, e.g. attachment / PDF name, page number etc.*  **Further guidance about this application type is available on GOV.UK** |

**SECTION 1 – ADMINISTRATIVE DETAILS**

**1.1 Product Name:**

**1.2** **Name and Address of Proposed ATC Holder:**

Name:

Company Name:

Address:

Email Address:

Telephone No:

**1.3** **Name and Address of Sponsor[[1]](#footnote-1) (if different to 1.2 above):**

Name:

Address:

Email Address:

Telephone No:

**1.4** **Contact Details for this Application:**

Name:

Email Address:

Telephone No:

**1.5** **Invoice Details:** Email address of where the invoice should be sent to.

Email Address:

**1.6** **e-Issuing Details:** Email address of where the authorisation documentation should be sent to (if different from 1.4 above).

Email Address:

**SECTION 2 – APPLICATION DETAILS**

**2.1 Previous ATC Authorisation No. (If applicable):**

**2.2 Name and address of previous ATC holder (if applicable, and if different to 2.1 above):**

Name:

Address:

**2.3 If using a UK-authorised investigational or control product, please give the details of the UK Marketing Authorisation(s) (same formulation)[[2]](#footnote-2):**

**Product Name:**

**Vm No:**

**Other details:**

**2.4 If using an EU or EEA authorised investigational or control product, please give details of EU or EEA Marketing Authorisation(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member State** | **MA No. (equivalent to Vm no. in UK)** | **Species** | **Dosage / Route** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |

* please attached a copy of the marketing authorisation and SPC for the product (in English translation)

**2.5 If using an investigational or control product authorised in a third country (USA, Canada, Japan, New Zealand and Australia only), please give details of the Marketing Authorisation(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Member State** | **MA No. (equivalent to Vm no. in UK)** | **Species** | **Dosage / Route** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |

* Please attached a copy of the marketing authorisation and SPC for the product (in English translation)

**2.6 For products to be imported into the UK, please provide the following:**

1. Name and address of manufacturer or MA or PL holder:

1. Name and address of authorised importing wholesale dealer:

1. Country from where the import is to be made:

**2.7 If any trial procedures are covered by A(SP)A, the Home Office Project License number should be provided:**

**SECTION 3 – TRIAL DETAILS**

**3.1** **Nature and purpose of the test (objectives):**

**3.2** **Target Species (only one per trial):**

**3.3** **Indication(s) or outcomes / endpoints to be investigated:**

**3.4 Details of the pharmaceutical form / method of administration / dose rate / duration of administration:**

1. Investigational treatment (test article):
2. Positive control:
3. Negative / placebo control:

**3.5 Maximum no. of animals treated with:**

1. Investigational treatment (test article):
2. Positive controls:
3. Negative/ placebo controls:

**3.6** **Estimated duration of trial:**

**3.7 Description of eligibility criteria for animals:**

1. Inclusion criteria:
2. Exclusion criteria:

**3.8 Who will administer the product to the animal (investigator, owner, other)?:**

**3.9 Procedure used in preparation of the product prior to administration and to achieve accuracy of dosing (where relevant)[[3]](#footnote-3):**

**3.10 Details of user safety warnings to be used for labelling, package leaflets, owner information sheets, etc (refer to Annex 1):**

**3.11 Statement of target species safety warnings to be used for labelling, package leaflets, owner information sheets, etc (refer to Annex 1):**

**3.12 Description of safety monitoring. For example, advise on the following points:**

* When, and by whom, clinical examinations will be performed
* Any investigations to be performed to monitor safety, e.g. blood profiles, anaesthetic monitoring
* Provision for monitoring investigations and reporting adverse events
* Provisions for access to 24th emergency veterinary care
* Provision of rescue treatment for animals administered placebos or failing to respond to treatment

**3.13 Name and qualifications of the overall test monitor or senior investigator (see VICH guideline on Good Clinical Practices for definition of monitor):**

**3.14 Details of investigator(s): Name and professional qualification of investigating veterinarians:**

**3.15 Details of test site(s) (if known[[4]](#footnote-4)) indicating the identity of the named Investigator with responsibility at each individual test site where multiple sites are named:**

**3.16 Name and qualifications of the person responsible for pharmacovigilance, i.e. reporting suspected adverse reactions to the VMD[[5]](#footnote-5):**

**3.18 Where relevant, provide confirmation that food species will not enter the food chain:**

**3.19 Disposal or fate of test food producing animals (not intended to enter the food chain):**

**3.20 Authorised or statutory withdrawal periods for food producing species intended to enter the food chain[[6]](#footnote-6):**

**3.21 Please confirm that any waste product and empty containers will be disposed of in accordance with current regulations:**

**SECTION 4 – TARGET SPECIES SAFETY**

**Please provide the following for all applications EXCEPT where an existing UK, EU or EEA authorisation is for the same species and the same dosing regimen.**

**4.1** **Published literature references to provide supportive evidence for safety in the proposed species using the proposed dose regimen (refer to Annex 2):**

**SECTION 5 – EFFICACY INFORMATION**

**5.1 For ALL applications, please provide evidence that there is reasonable expectation that the test product will produce the desired effect. Refer to Annex 2 for further information about using published literature references:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section 6 – Declaration**  **To be completed by proposed ATC holder:**  I apply for the application as described above. I confirm that the information given in support of this application is correct at the time of submission.   * Informed owner consent will be obtained for any off-label or unauthorized use of the product * All adverse events (including lack of efficacy) will be reported to the VMD; serious adverse events, i.e. involving human, or which have caused increased mortality or serious ill health in treated animals, must be reported within 15 days   I undertake to abide by the terms and conditions of any ATC issued in response to this application. I also undertaken to inform the VMD of:   * Any matter coming to our attention which might affect the safety in use of the product * The discontinuation of the test with an explanation | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **If any information provided in this application is later found to be false or incorrect, the Secretary of State may suspend or revoke the authorisation.** | | | | |
| **To be completed by senior investigator:**  The study protocol has been reviewed by the senior investigator and at least two other veterinary surgeons who are independent of the trial and, in our opinion, it is ethical and is to be conducted in accordance with the RCVS Guide to Professional Conduct and ‘recognized veterinary practice’.. | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
|  | | | | |
| **To be completed by first veterinary surgeon who has reviewed the protocol and is independent of the trial:** | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **Qualifications:** | | | | |
| **To be completed by second veterinary surgeon who has reviewed the protocol and is independent of the trial:** | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **Qualifications:** | | | | |

**Annex 1**

**Guidance on user and target species safety warnings to be used for labelling, package leaflets, owner information sheets etc.**

Please refer to the VMD’s published guidance 'Apply to run a clinical trial using an animal medicine', available at <https://www.gov.uk/government/publications/apply-to-run-a-clinical-trial-using-an-animal-medicine>.

For trials conducted under a Type S ATC, it is the responsibility of the ATC holder to ensure that the labelling/package leaflets conform to the requirements laid out in the ['product literature standard](https://www.gov.uk/government/publications/product-literature-mock-ups-for-an-animal-medicine-licence)'. An 'ATC label proforma' is also available from our website.

The investigating veterinary surgeon, at the time of dispensing, is also responsible for ensuring that products are labelled in accordance with Schedule 3, paragraph 13(2) of the Veterinary Medicines Regulations (Supply of veterinary medicinal products for use under the cascade), with the exception that the name of the product may be omitted for the purposes of “blinding” the trial.

For the following products, no further information is required in the application form:

* EU (incl. UK) or EEA authorised veterinary medicinal products for which the labels and product literature are in English
* Products which are to be administered directly by the investigator, if there is no subsequent risk to other persons and adverse effects are not likely to occur after the animal has left the investigator’s direct supervision.

For all other products a statement of user and target species warnings, to be included in the product literature/labels, should be provided. Examples are given below:

**Target species safety warnings**

These should be divided into:

* Contraindications: (circumstances under which use of the product may have serious consequences for target species safety, and therefore the product should NOT be used), and
* Special precautions for use in the target species: (warnings to ensure safe use of the product in animals).

These warnings may relate to:

* particular routes of administration,
* concomitant disease conditions, e.g. renal, cardiac or hepatic failure
* age or weight (a minimum age, or weight based on accuracy of dosing, may need to be given)
* warnings not to use during pregnancy or lactation if there are inadequate reproductive safety data
* interactions with other drugs
* sensitive sub-populations (e.g. related to breeds such as collies)
* known adverse effects

Where to find the information

The sources of information which could be taken into consideration are:

* The product literature authorised in another country
* Published scientific references including texts such as Plumb’s Veterinary Drug Handbook and the BSAVA Small Animal Formulary.

**User safety warnings**

User safety warnings are the precautions and special instructions for handling and administering the product. These warnings should:

(i) give precautions to take when handling the product, e.g. avoid accidental contact with eyes.

(ii) give advice on what to do in the event of accidental occurrence, e.g. in case of accidental contact with eyes, wash immediately with plenty of water. If irritation persists seek medical advice.

What user warnings to use and where to find the information:

* If the product you are using is a veterinary medicine:

Use the precautions and warnings on the label or given in the package leaflet; if the product is from outside the EU and/or the labels or package leaflet are not in English, you should get these translated to provide the information.

* If the product is a human medicine:

Refer to the label and package leaflet for guidance and any information that is specifically related to the handling of the product and precautions to take; it should be noted that warnings relating to effects to humans from “taking” the product are not usually relevant to "handling" and are not required on the labels of ATCs. If you are unsure, you should seek advice from VMD. If the product is from outside the EU and/or the labels or package leaflet are not in English, you should get these translated to provide the information.

* If there is no information available:

Seek advice from the VMD on the user warnings that will be required.

**Annex 2**

**Target Species Safety and Efficacy data**

Scientific literature should be presented. Ideally, the literature should be derived from publications in peer-reviewed journals or textbooks, but alternative sources may be taken into consideration, for example, papers presented at conferences which have been reviewed by a committee. Other data (e.g. unpublished studies, specialist group email discussion lists) may also be submitted and will be judged on merit. For some EU-authorised veterinary medicines, information on safety and efficacy of the product is available in the Scientific Discussion part of the European Public Assessment Report (EPAR), available on the European Medicines Agency website ([www.ema.europa.eu](http://www.ema.europa.eu)).

The literature should provide supportive evidence for the safety and efficacy of the active substance, when used in accordance with the study’s proposed dosage regimen, in the target species.

If there is an existing EU or EEA authorisation for the product in the same species and using the same dosing regimen, target species safety data are not required.

For an “exotic” species, it may be possible to present literature from a related species if its relevance can be justified by the applicant.

**Full copies of all references should be submitted; citations alone are not sufficient.**

1. The Sponsor is the individual, company or organisation who takes responsibility for the initiation, management and, usually, the financing of the clinical trial. [↑](#footnote-ref-1)
2. The Marketing Authorisation (MA) number (or Product Licence number) is available in the Summary of Product Characteristics (SPC). The SPC describes the approved conditions of use of a product in accordance with its Marketing Authorisation. SPCs for most UK-authorised veterinary products are available on the Product Information Database at [www.vmd.defra.gov.uk](http://www.vmd.defra.gov.uk), and for human products at <http://www.medicines.org.uk/emc/>. For veterinary medicinal products that have an EU-wide MA (“centralised authorisations”) the SPC is available on the EMA website: [www.ema.europa.eu](http://www.ema.europa.eu). The MA number will carry the prefix “Vm”, “EU” or “PL”, depending on the authorisation route.

   For products authorised in non-UK EU member states only, or third countries, the SPC should be available from the Marketing Authorisation Holder, the relevant national regulatory agency, or, for some products at [www.eudrapharm.eu](http://www.eudrapharm.eu). For products authorised in third countries, different terminology may be used for “MA” and “SPC”. [↑](#footnote-ref-2)
3. For example, advise on:

   specialist equipment to be used for preparation of chemotherapy drugs

   safeguards for the administrator

   If tablets are scored to allow administration of the correct dose; if tablets may be crushed.

   Products should not be altered in such a way as to change the pharmaceutical form, or by dilution etc except as advised in the SPC. [↑](#footnote-ref-3)
4. If not available, an estimated maximum number of sites should be provided with confirmation of the exact number plus details given in writing before the trial starts; please note if final numbers exceed the estimated maximum a variation must be submitted for consideration before the trial commences. [↑](#footnote-ref-4)
5. This person may be the monitor or senior investigator [↑](#footnote-ref-5)
6. If there is no authorised withdrawal period for the target species, or the product is being administered using a higher dose regimen than that authorised, then withdrawal periods should be in accordance with those given in the Veterinary Medicines Regulations, Schedule 4. If the product is to be used for the treatment of horses, and the active substance is listed as “essential for the treatment of equidae” according to regulation (EC) 1950/2006, a 6-month withdrawal period should be applied [↑](#footnote-ref-6)