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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 FORM – NEW**  ANIMAL TEST CERTIFICATE (ATC)  APPLICATION TYPES: **S**  SMALL-SCALE CLINICAL TRIALOF A MEDICINAL PRODUCT IN ANIMALS  **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. **Name of Test Product:**

**1.2** **Name and Address of Proposed ATC holder[[1]](#footnote-1):**

Name:

Company Name:

Address:

Email Address:

Telephone No:

**1.3** **Name and Address of Sponsor[[2]](#footnote-2) (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:

**1.7 Previous ATC Authorisation No. (if applicable[[3]](#footnote-3)):**

**1.8 Name and address of previous ATC holder (if applicable):**

Name:

Address:

**SECTION 2 – PRODUCT DETAILS**

**2.1 If the investigational or control product has a Marketing Authorisation[[4]](#footnote-4) in the UK, EEA, USA, Canada, Japan, New Zealand or Australia, please provide the following details:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product name / designation** | **Country/Region where authorised** | **MA no.[[5]](#footnote-5)**  **(Vm no. in UK)** | **Target Species** | **Dosage and Route of administration** | **Withdrawal Period, if applicable** |
|  |  |  |  |  |  |

If the product does not have a UK marketing authorisation (MA), please attach a copy of the MA and the product SPC (in English translation) from the country where the product is authorised.

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

1. Name and address of manufacturer, MA holder, or product licence holder:

1. Name and address of authorised importing wholesale dealer:

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

**SECTION 3 – CLINICAL TRIAL DETAILS**

**3.1** **Nature and purpose of the clinical trial (objectives):**

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

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

**3.4 Test product:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product name / designation** | **Pharmaceutical form** | **Method of administration** | **Dose rate / Dose** | **Duration of administration / Treatment schedule** |
|  |  |  |  |  |

**3.5 Control (positive or negative / placebo) product(s):**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product name / designation** | **Pharmaceutical form** | **Method of administration** | **Dose rate** | **Duration of administration** |
|  |  |  |  |  |

**3.6 Detail the type of individual who will administer the product to the animal (investigator, owner, other):**      

**3.7 Procedure used in preparation of the products prior to administration and to achieve accuracy of dosing (where relevant)[[6]](#footnote-6):**

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

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

**3.10 Authorised or statutory withdrawal periods for food producing species (or their products) intended to enter the food chain[[7]](#footnote-7):**

**3.11 Where relevant, provide confirmation that food producing species (or their products) will not enter the food chain:**

**3.12 Provide details of disposal or fate of food producing species (not intended to enter the food chain):**

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

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

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

Please statistically justify your sample size (as appropriate).

**3.15** **Estimated duration of trial:**

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

1. Inclusion criteria:
2. Exclusion criteria:

**3.17 Description of safety monitoring for animals:**

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

**3.18 Name and qualifications (including RCVS registration number) of the Investigator(s)[[8]](#footnote-8):**

**3.19 Details of test site(s) if known[[9]](#footnote-9), indicating the name of the Investigator with responsibility at each individual test site if multiple sites are named:**

**3.20 Name and qualifications (including RCVS registration number) of the individual acting as trial Monitor, if applicable[[10]](#footnote-10):**

**3.21 Name and qualifications of the individual with responsibility for pharmacovigilance, i.e. reporting suspected adverse reactions to the VMD:**

**3.22** **Please provide the Home Office Project License number and a brief description of the associated procedure(s) if any clinical trial procedures are authorised and regulated in accordance with the ASPA (i.e. Animals (Scientific Procedures) Act 1986, as amended):**

**SECTION 4 – TARGET SPECIES SAFETY**

For ALL applications, please provide evidence to support the safety of the test product in the proposed target species, when used for the proposed indication and in accordance with the clinical trial protocol. Safety in the target species may, in some cases, be possible to extrapolate from the existing marketing authorisation(s) for the test product, if justified.

VMD assessors will review evidence supporting safety in the target species to confirm that it is acceptable at the proposed dosage and for the proposed route and duration of administration. There should also be evidence supporting a reasonable margin of safety for the test product.

A critical summary of the evidence submitted in support of target species safety should be provided (refer to Annex 2 for further guidance).

Evidence to support the safety of the control product(s) in the target species, when used in accordance with the clinical trial protocol, may also be required in certain cases. For example, when a positive control veterinary medicinal product with a UK marketing authorisation will be used, but this use will not be in accordance with the product’s summary of product characteristics, and this raises safety concerns.

Support for target species safety:

**SECTION 5 – EFFICACY INFORMATION**

For ALL applications, please provide evidence to support a reasonable expectation of efficacy (i.e. that the test product will produce the desired effect) when used in accordance with the clinical trial protocol. Reference to laboratory and/or pilot studies may be necessary.

A critical summary of the data submitted in support of efficacy should be provided (refer to Annex 2 for further guidance).

Evidence to support a reasonable expectation of efficacy for the control product(s) in the target species, when used in accordance with the clinical trial protocol, may also be required in certain cases (please refer to section 4).

Support for efficacy:

**SECTION 6 – DECLARATIONS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **To be completed by the 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 unauthorised 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 undertake 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 the 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 ‘recognised veterinary practice’. | | | | |
| Signature |  | Job Title |  |  |
|  |  | |  | |
| Name in BLOCK LETTERS |  | Date |  |  |
| **RCVS registration number:** | | | | |
| **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 |  |  |
| **RCVS registration number:** | | | | |
| **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 |  |  |
| **RCVS registration number:** | | | | |

**Annex 1**

**Guidance on user and target species safety warnings to be used for product labelling, product 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 an ATC, issued following a type‑S ATC application, 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 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:

* 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 must be included in the product literature (package leaflet/product labels). 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 (labelling and package leaflet) 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 inform the user about the following aspects:

A. The concerned risk.

B. What exposure must be avoided to minimise the concerned risk.

C. How to avoid that exposure.

D. What to do in the event of exposure (if relevant).

Example: A liquid product that is administered by the farmer using a spray gun to a flock of sheep, is irritant to eyes. The user safety information would be:

* This product can cause eye-irritation. (A)
* Avoid contact with the eyes. (B)
* Wear protective glasses. (C)
* When the product comes into contact with the eyes, rinse immediately with plenty of water. (D)

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 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 the VMD. If the product 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 requirements (sections 4 and 5):**

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, and the public assessment reports of regulatory agencies) may also be submitted and will be judged on merit.

The submitted literature should provide evidence supporting the safety and efficacy of the active substance, when used in accordance with the study’s proposed dosage regimen and route of administration in the target species. It is essential that a critical summary of this evidence is also provided. This summary should provide a review the submitted literature and should explain how the sources individually or collectively support the data requirements set out in sections 4 and 5 of the application form.

It may not be necessary to provide target species safety data where an existing marketing authorisation is for:

* the same target species,
* the same route of administration, and
* the dose proposed for the trial is the same or lower than the authorised dose.

HOWEVER, if based on the particular characteristics of the study population, the risks associated with administration of the test product cannot be extrapolated from the existing marketing authorisation (e.g. due to the reproductive status of study animals) then appropriate target species safety data should be submitted.

For applications concerning a minor species it may be acceptable 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 ATC holder is the individual who takes overall legal responsibility for the trial. This is usually the sponsor or the person / organisation to which the Sponsor has legally delegated this responsibility. [↑](#footnote-ref-1)
2. 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-2)
3. For example, a case where an existing ATC, issued following a type‑S ATC application, requires a change to its terms that cannot be authorised by way of an ATC variation application and a new type‑S ATC application is required. [↑](#footnote-ref-3)
4. If a product has a marketing authorisation (MA) in the UK this information should be provided. If the product has an MA in multiple countries, details of only one MA are required unless the information is of particular relevance to this ATC application. [↑](#footnote-ref-4)
5. For UK authorised products 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 MA. SPCs for most UK-authorised veterinary products are available on the Product Information Database at <https://www.gov.uk/check-animal-medicine-licensed>, and for human products at <http://www.medicines.org.uk/emc/>. For products authorised in non-UK countries (e.g. EEA member countries) the SPC should be available from the MA holder or the relevant national regulatory agency. For products authorised in countries outside the EEA, different terminology may be used for 'MA' and 'SPC'. [↑](#footnote-ref-5)
6. For example, appropriate information would include:

   Details of specialist equipment to be used for preparation of chemotherapy drugs

   Details of the safeguards for the administrator

   Clarification of whether tablets are to be divided to allow administration of the correct dose, or if tablets are to be crushed, and how this will be undertaken.

   Please note: Products should not be modified or manipulated (e.g. diluted), except as advised in the SPC and products should not be mixed unless supported by compatibility data [↑](#footnote-ref-6)
7. 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-7)
8. The Investigator is the individual responsible for all aspects of study conduct at a study site; see VICH Topic GL9 (GCP). If details are not available when the ATC application is submitted, any additional Investigator details should be submitted for consideration once known by way of an ATC variation application. [↑](#footnote-ref-8)
9. If not available at the point of application, an estimated maximum number of sites should be provided. Confirmation of the exact number of sites plus site details must be given in writing before the trial starts; please note if final numbers exceed the estimated maximum an ATC variation application must be submitted for consideration before the trial commences. [↑](#footnote-ref-9)
10. See VICH Topic GL9 (GCP) for the definition of the Monitor. For some small-scale clinical trials conducted by veterinary researchers it may not be necessary to appoint a monitor (e.g. single site study); please state 'not applicable' where this is the case. [↑](#footnote-ref-10)