EXPLANATORY NOTES FOR APPLICATION OF A LICENSE FOR THE APPROVAL OF A CLINICAL TRIAL WITH A VETERINARY MEDICINAL PRODUCT

Data to be supplied

When applying for an approval , you must fully complete this form.
In addition, you are requested to provide the following information as attachments:

Appendix 1: General information

* Permits
    - If the intended trial falls within the scope of the Animal Experiments Act (WOD), *a copy of the WOD permit* for this trial must be provided.
    - For a live genetically modified vaccine, *a copy of the permission of the COGEM* as referred to in Directive 90/220 / EEC must be provided.
* Summary
    - A summary of the clinical trial (maximum 1 page) must be provided.

Appendix 2: Test protocol

* An extensive trial protocol must be submitted, containing at least the following information:
    - *Purpose of the test*: this should indicate which data is to be obtained and which regulatory requirement this is to fulfill (which dossier part).
    - *Start and end date of the trial*, if the trial is intended to last longer than one year, please provide a justification.
    - *The name* of the investigational veterinary medicinal product to be tested.
    - *The nature and class* of the investigational veterinary medicinal product to be tested (pharmaceutical: antimicrobial, etc .; immunobiological: live, dead, etc.).
    - *The complete qualitative and quantitative composition* of the investigational veterinary medicinal product to be tested, including active ingredients, any adjuvants and excipients.
    - *The therapeutic indication* of the investigational veterinary medicinal product to be tested.
    - *The pharmaceutical form* of the investigational veterinary medicinal product to be tested.
    - *Method of administration* (e.g. oral, intramuscular) and treatment method (dose, duration of application / vaccination schedule).
    - *The quality of the investigational veterinary medicinal product* (including sterility, purity).
    - *Target animal safety data*, including data from pre-clinical and any clinical safety studies, relevant chemical, pharmaceutical, animal pharmacological and toxicological data.
    - *Consumer safety data*, including data on residues and MRLs, and a proposal for the withdrawal period(s) based on experimental data.
    - *Safety data for the operator*, including a proposal for the safety measures to be taken.

- *The route of delivery and return of the veterinary medicinal product*: description of the distribution channel, storage, etc., and description of the procedure for the return of unused investigational veterinary medicinal products.
- *Information on the distribution* (only for live vaccines) of the vaccination strain to unvaccinated and / or non-target animals.
- *Target animals and scope of the experiment*: The species, age, sex, inclusion / exclusion criteria, the number of animals and the number of experimental groups must be argued in relation to the stated objective of the experiment, if necessary with a statistical substantiation.
- *Farms/clinics involved*: all involved farms/clinics must be reported and described (name, address, business type, housing). If at the time of the application not all participating farms/clinics are known, the list may be supplied later in a separate appendix, but at the latest before the specified start date of the trial.
- *Veterinarians involved*: The names and addresses of the veterinarians involved must be provided.
- *Adverse effects*: If already known, adverse effects should be reported.
- *Rescue treatment*: Any alternative treatment(s) for animals that do not or insufficiently respond to the treatment under investigation should be indicated.
- *Organization chart*, in which the responsibilities of those involved are indicated.

<u>Appendix 3: Participating companies</u>

* This appendix is not necessary if the participating farms/clinics are already fully indicated in the trial protocol.

* All farms/clinics involved must be listed and described (name, address, business type, housing). If not all participating farms/clinics are known at the time of the application, this appendix (appendix 3) may be supplied later, but at the latest before the specified start date of the trial.