EXPLANATORY STATEMENT FOR APPLICATIONS FOR AN EXEMPTION FOR TESTS WITH VETERINARY MEDICINAL PRODUCTS

Data to be supplied

When applying for an exemption, 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 'Bureau GGO'* 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.