NOTIFICATION OF ESTABLISHMENT OF A CLINICAL TRIAL	**REF:** ANMV/AMM/P005 **VERSION: 6 MARCH 2020**

PURPOSE

Describe the procedures for notifying establishment of a clinical trial of a veterinary medicinal product.

REGULATORY REFERENCES

Articles R.5141-8 *et seq* of the Public Health Code

PRACTICAL ASPECTS

Content of the notification

a) A notification letter including:

- **The parties involved**

- Sponsor: name and address of the company initiating the trial
- The contact point (if different from the applicant)
- The investigator(s): name and address of the veterinarian(s) directing and supervising implementation of the trial

- **Framework of the trial**

- The sponsor's reference for the clinical trial
- The trial's title, objective and therapeutic indication
- Trial justification: new MA, amendment of an MA
- The site(s) of the trial, if already known, or at least the *département(s)* concerned (N.B. for trials on pets, the contact details of the investigating veterinarians are sufficient)
- The dates of the trial: start date and duration
- The animals:
    - species
    - number
    - breakdown by group
    - (specify the number of animals in France for international trials)

- **Regarding the medicinal product to be tested**

- The medicinal product:
    - name or code
    - full qualitative and quantitative composition
    - pharmaceutical form
    - route of administration
    - dosage and treatment duration
- Registration status of the medicinal product: if the drug has been refused an MA or its MA has been suspended or withdrawn at international level in the five years preceding the application; state the reasons for this decision.
- Withdrawal period: for livestock, in the absence of sufficient documentation justifying a specific withdrawal period, the overall withdrawal period provided for in the regulations must be applied.
- "TSE" status: whether or not the medicinal product is concerned by the Ministerial Order of 24/01/01 on preventing transmission of animal spongiform encephalopathies.
- For narcotics and psychotropic drugs: a copy of the authorisation for use granted by the ANSM must be provided.
- Pharmaceutical establishments: manufacturer, importer, distributor:
    - manufacturer's name and address
    - if necessary, name and address of the importing establishment
    - name and address of the French distributor of veterinary medicinal products undergoing clinical trials

- In addition, when the manufacturer and/or importer are not French establishments, provide the opening authorisation or a GMP certificate (see table below).

If the manufacturer is located in a country of the EU or party to the EEA agreement (outside France)	a recent document (less than three years old) issued by the competent authorities certifying that the establishment is authorised to manufacture for the pharmaceutical form in question.
If the manufacturer is not in a country of the EU or party to the EEA agreement:	a recent document (less than three years old) issued by the competent authorities certifying that the establishment is authorised to manufacture for the pharmaceutical form in question. the name and address of the importing establishment; If the importer is European (outside France): a recent document (less than 3 years old) issued by the competent authorities mentioning the authorisation to import veterinary medicines

- **For a reference drug* (if applicable)**

(* This medicinal product must have an MA in Europe for the claimed species and indication)

- The medicinal product:
  - name
  - qualitative and quantitative composition in active ingredient
  - pharmaceutical form
  - dosage and treatment duration
  - withdrawal period
- For medicinal products not benefiting from an MA in France, if possible, provide a copy of the MA obtained in Europe accompanied by the SPC.

- **For a placebo (if applicable)**

- The medicinal product:
  - full qualitative and quantitative composition
  - pharmaceutical form
- Pharmaceutical establishments: same information as for the drug to be tested

b) The trial protocol

c) A technical document: "summary of prerequisites"

- **For a chemical drug**

If a withdrawal period that differs from the standard withdrawal period (see Article 11(2) of Directive 2001/82/EC) is proposed, it must be duly justified by appropriate documentation.

Specific data may be requested when notifying establishment of particular clinical trials (e.g. user safety data for a new external antiparasitic, ecotoxicity data for a medicinal product intended for farmed fish and administered in water).

- **For an immunological drug**

- the qualitative and quantitative composition of the product, specifying whether or not the active ingredient is live and whether or not the product contains an adjuvant.
- a brief description of the manufacturing process.
- the list of checks for possible contaminants (viral, bacterial, fungal, mycoplasmic and parasitic agents screened for and an indication of the techniques used) carried out on all raw materials of biological origin

and the corresponding standards of acceptability, accompanied by the corresponding certificates of analysis[1].

- a description of the safety and potency tests carried out on the finished product and the corresponding standards of acceptability, accompanied by a statement from the manufacturer certifying that the tests comply with the standards laid down. In particular, the manufacturer should compare the compliance of the immunological product with the monograph of the European Pharmacopoeia, if such a monograph exists[2].
- laboratory demonstration of the product's safety after a dose or overdose.
- if necessary, a study of reproductive function and an examination of immunological functions.
- in the case of an immunological substance containing at least one live organism, a study to assess the spread and stability (reversion to virulence) of the strain used as the vaccine.

Recipient of the application

The application must be sent by post to:

Anses-Agence nationale du médicament vétérinaire

Licensing department

14 rue Claude Bourgelat – Parc d'Activités de la Grande Marche – Javené CS 70611 - 35306 FOUGERES, France

Contact for information

Licensing Unit, Tel: +33 (0)2 99 94 66 65 – e-mail: enreg@anses.fr

AMENDMENTS TO THE TRIAL

The Agency must be notified in advance (letter and protocol if necessary) of any amendment to the trial (date and duration of the trial, number of animals, investigators, trial sites, dosage, withdrawal period, etc.).

The letter must refer to the trial in question and explicitly state what is being amended.

TIMEFRAME

ANSES-ANMV has two months to oppose establishment of the trial. One month in the case of an amendment.

If the application complies with the regulations in force, a letter confirming that the Agency has no objection to establishment of the trial is systematically sent to the applicant.

If any information is missing, a request for additional information is sent to the applicant with a deadline for reply. In the absence of any reply by the specified deadline, opposition to establishment of the trial shall be considered final.

LINK WITH AN IMPORT APPLICATION

The clinical trial notification may be submitted jointly with the import application.

Note: the imported quantities must be in line with the quantities needed to establish the trial.

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1 This information is only requested if relevant.
2 If applicable, justify any non-compliance with the existing monograph.