**Application form for approval of clinical trial of Veterinary Medicinal Products according to the Regulation (EU) 2019/6 in several EU Member States**

***Note: clinical trials are defined in the article 4(17) of the Regulation and their approval is described in Article 9 of this Regulation. Some EU Member States may use this application form for national application for clinical trial applications and as well for other studies. Please consult national competent authorities.***

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| **List of the EU Member States where the clinical trials application is submitted:** | | | | |
| □ AUSTRIA | □ BELGIUM | □ BULGARIA | □ CROATIA | □ CYPRUS |
| □ CZECH REPUBLIC | □ DENMARK | □ ESTONIA | □ FINLAND | □ FRANCE |
| □ GERMANY | □ GREECE | □ HUNGARY | □ ICELAND | □ IRELAND |
| □ ITALY | □ LATVIA | □ LITHUANIA | □ LUXEMBOURG | □ MALTA |
| □ NETHERLANDS | □ NORWAY | □ POLAND | □ PORTUGAL | □ ROMANIA |
| □ SLOVAK REPUBLIC | □ SLOVENIA | □ SPAIN | □ SWEDEN | □ UNITED KINGDOM (NI) |

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| **The application concerns:** | |
|  | A VMP other than biologicals |
|  | A VMP biological – non immunological |
|  | A VMP immunological |

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| **Name of the coordinating person in EU\* / Delegation to the CRO:** | |
| Name: |  |
| Contact person: |  |
| Address: |  |
| Country: |  |
| Telephone: |  |
| E-mail address: |  |

\* this person is authorised to communicate on behalf of the sponsor

|  |  |
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| **Sponsor** | |
| Name: |  |
| Contact person: |  |
| Address: |  |
| Country: |  |
| Telephone: |  |
| E-mail address: |  |

|  |  |
| --- | --- |
| **Investigator(s)**\*\* | |
| Name: |  |
| Contact person: |  |
| Address: |  |
| Country: |  |
| Telephone: |  |
| E-mail address: |  |

\*\* if necessary, additional investigators can be added

|  |  |
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| **Monitor(s)\*\*\*** | |
| Name: |  |
| Contact person: |  |
| Address: |  |
| Country: |  |
| Telephone: |  |
| E-mail address: |  |

\*\*\* if necessary, additional monitors can be added

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| **Application / study protocol\***  **\*** The list provided is not exhaustive nor is every item included applicable to all study protocols but it is intended to give guidance | |
| Title of the study |  |
| Identifier of the study  (study protocol number, the status of the study protocol (i.e.the final version of the application and any subsequent versions or additions) and the date of the version and the date of the signature of the study protocol) |  |
| GCP conform (y/n)  If No: justification should be provided | □ Yes  □ No |
| Objective(s) and justification of the study |  |
| Schedule of events:  (including expected date of commencement of the animal phase, the period of administration of the product(s), the post administration observation period, the withdrawal period (when applicable) and the termination date where known) |  |
| Study design (e.g. a placebo controlled clinical field effectiveness study or a randomized blocked design versus a positive control, with blinding) |  |
| Target species |  |
| Animal selection and identification: specification of the source, number, identity and type of study animal to be used, such as species, age, gender, breed category, weight, physiological status and prognostic factors |  |
| Inclusion/exclusion criteria and post-inclusion removal criteria |  |
| Animal management and housing |  |
| Animal Feeds |  |
| Treatment including   * Route of administration, * Dose(s), * dosing regimen (IVP/control), * withdrawal period (if applicable) * special precautions to be observed when administering the product(s) including user safety |  |
| Disposal of study animals, products |  |
| Assessment of efficacy   * primary endpoint, * secondary endpoint(s) |  |
| Assessment of safety   * local tolerance, * systemic tolerance * others |  |
| Statistics / Biometrics  (according to guideline EMA/CVMP/EWP/81976/2010-Rev.1 for non-biological VMPs only)   * randomisation * blinding * justification of sample size * statistical methods |  |
| Handling of records |  |
| Description of the handling of adverse events (e.g. routing and time frames of serious adverse event and human reaction reporting) |  |
| Supplements to be appended to the protocol |  |

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| **Study site where the trial will be conducted\*** | |
| Name: |  |
| Contact person: |  |
| Address: |  |
| Country: |  |
| Telephone: |  |
| E-Mail address: |  |

\* if necessary, additional test facilities can be added

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| **Information on the VMP used for the clinical trial**  **(if the VMP is not authorised, not all fields should be filled)** | | |
| Product | Product concerned by the clinical trial | Comparator product (if any) |
| Name of product |  |  |
| Composition (full composition in active substance(s) an in excipient(s) |  |  |
| Is it a new active substance not included in any authorised VMP? | □ Yes  □ No |  |
| Is the investigational VMP authorised in an EU member state/EEA/third country?  If yes,   * name of country * authorisation/registration number * Name of the Marketing Authorisation Holder | □ Yes  □ No |  |
| Was the product either refused, withdrawn or suspended before the application of the clinical trial?  If yes mention the grounds for the refusal / withdrawal /suspension | □ Yes  □ No |  |
|  |  |  |
| Target Species |  |  |
| ATC-vet code |  |  |
| Pharmaceutical form |  |  |
| Route(s) of administration |  |  |
| Dosing regimen |  |  |
| Duration oft he treatment/medication |  |  |
| Indications |  |  |
| MRL status (set or not) with a scientific justification (if applicable) |  |  |
| Proposed withdrawal period |  |  |
| Does the product contain a GMO? |  |  |
| Is the product compliant with EU requirements for TSE? |  |  |
| Is the product free from extraneous agents? |  |  |
| Is the batch used is GMP compliant ? |  |  |

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| **MANUFACTURER AND IMPORTER OF THE PRODUCT** | |
| **Manufacturer** | |
| Manufacturer’s contact person |  |
| Address |  |
| Country |  |
| Telephone |  |
| E-mail address |  |
| **Importer** | |
| Address |  |
| Country |  |
| Telephone |  |
| E-mail address |  |

Please refer to "VICH Topic GL 9 (GCP) Guidance on Good Clinical Practices" available at: . <http://www.vichsec.org/component/attachments/attachments/142.html?task=download>

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| **I hereby certify that,** | |
|  | the attached electronic data contain the documents that are the subject of the submitted application. |
|  | all attached translations and copies fully correspond to the original. |
|  | the trial will be conducted in compliance with the protocol and applicable regulatory requirements/legislation. |

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| **SIGNATURES** |
| I hereby affirm that the information given above on the medicine is correct. The sponsor will inform National Competent Authority if the trial is discontinued or never begun, and why. |
| Place and date |
| Sponsor’s signature and name in block letters (or signature of coordinating person in EU/person authorize to communicate on behalf of the sponsor) |