9 November 2017
EMA/548726/2017
Veterinary Medicines Division

Recommendations from the Joint EMA/HMA Steering Group on veterinary vaccine availability to CVMP based on the outcome of the Focus Group meeting with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines

The Joint EMA/HMA Steering Group on veterinary vaccine availability has considered the findings of the final report from the Focus Group meeting with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines in June 2017 and agreed on the appropriate follow up, in the form of the specific recommendations outlined below. The recommendations are addressed to those regulatory bodies considered most relevant for undertaking the proposed follow up actions. In this context the Steering Group recommends that:

1. CVMP should consider how best to provide predictability to applicants as to those situations in which a justification to omit field efficacy data will be accepted by regulators. The possibility of defining transparent and objective criteria that can be applied in reaching a decision should be explored. The Committee may also wish to investigate whether or not it is possible to establish and publish lists of diseases/indications/species for which field efficacy data will/will not be required. If appropriate, CVMP should consider revision of the CVMP Guidelines on Field Trials for Veterinary Vaccines (EMA/CVMP/852/99) and of any other affected guideline to provide guidance to applicants on the grounds on which omission of field trials can be justified.

2. CVMP should consider how best to reflect in the SPC of veterinary vaccines the efficacy data that have been provided. For reasons of fairness and transparency, the SPC should reflect the efficacy data provided and the source of the data on which the indication is based. However, in situations where confirmatory field efficacy data are not available (either not provided based on an acceptable justification or when data from field trials do not provide conclusive evidence of efficacy), negative statements in the SPC should not generally be included.

3. As a follow-up to the preliminary data presented at the Focus Group meeting, the EMA should complete its analysis of the contribution of field data to the overall conclusions on efficacy for veterinary vaccines authorized through the centralized procedure. Objective data on the extent to which field data contributed to the overall conclusions on efficacy for individual veterinary vaccines can potentially assist with establishing specific criteria by which omission of field data can be justified in the context of a veterinary vaccine application for an EU authorisation.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

4. EMA should bring to the attention of EDQM the discussion and conclusions made during the Focus Group meeting with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines.

5. EMA should explore possibilities for further engagement with academia on the subject of efficacy of veterinary vaccines within the Framework for Collaboration between EMA and Academia, also taking into account the conclusions of the Focus Group on epidemiological modelling.