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Veterinary Medicines Division

Focus group meeting with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines - Concept note

Background

Industry has repeatedly expressed the view that field trials pose considerable difficulties when compared with the added value they bring to the final dossier and in particular with regard to the efficacy claims in the context of an EU authorisation for veterinary vaccines. Reproducing the challenge model under field conditions is claimed to be particularly difficult to achieve as often there is inadequate circulation of infectious agent for an effective challenge. The incidence of disease may be limited due to overall improvements in biosecurity on farms identified for the field trial. In contrast, challenge can overwhelm the protection afforded by the vaccine when the disease is not under control. On this basis industry wishes to keep field trials for safety evaluation and to perform efficacy trials only to support specific claims associated with more complex field evaluation such as body weight gain or when the laboratory trials have not provided an adequate challenge model for the pathogenesis of the natural disease. Industry have also expressed the view that results from field trials from non EU regions can be considered as valid in an application dossier for a marketing authorisation in the EU. In addition, it has been suggested that, for marketed products, pharmacovigilance data can replace field data when applying for a marketing authorisation in other Member States using the mutual recognition procedure.
It is important to note that Council Directive 2009/9/EC states that: “unless justified, the results from laboratory trials shall be supplemented with data from field trials; when efficacy cannot be demonstrated by laboratory trials, field efficacy trials alone may be acceptable”. The Directive therefore provides some space for flexibility. The CVMP note for guidance on field trials with veterinary vaccines (EMEA/CVMP/852/99) provides a good justification for the requirement for field trials for vaccine applications but also allows for deviations should there be a scientifically acceptable justification. Notwithstanding the legal flexibility, Industry is concerned that if they don’t include field trials in an application dossier, the dossier will not be validated or the application will be delayed during assessment.

Industry has therefore requested a review of the requirement for field data to support efficacy and an updated position on when such studies need to be provided in order that companies have a clear understanding how the field efficacy requirements will be applied for new MA applications. IFAH-Europe

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provided a position paper on field trials and outlined specific proposals for consideration by regulators on the issue.
On the basis of the above considerations the organisation of a focus group on field efficacy trials in the context of an EU MA application for veterinary vaccines was decided as the highest priority for 2017 by the Joint EMA/HMA Steering Group on veterinary vaccine availability. This proposal was endorsed by both CVMP and HMA and was included in the 2017 work programmes for both CVMP and IWP. The focus group will take place at the end of June 2017 (a 2 half day meeting is proposed: 22nd of June afternoon to 23rd June 1pm). The outcome of the focus group meeting will be a brief report including conclusions and recommendations to be considered by the EMA/HMA Steering Group that will then decide the appropriate follow up.

Scope

To explore the specific challenges faced by industry in performing field trials to support efficacy claims and how these challenges might be overcome whilst still obtaining adequate assurances of the expected efficacy of a vaccine under field conditions.

Objectives

- Identify specific challenges faced by industry in performing field trials to support efficacy claims
- Identify the value that field efficacy data may bring to the dossier for marketing authorisation of a veterinary vaccine i.e. identify those situations where field trials do and those situation where field trials do not provide valuable data to support a robust benefit risk assessment and/or enhance the content and value of the SPC.
- Identify possible alternative sources of information on expected efficacy of a vaccine under field conditions (For each alternative source of information elaborate the challenges to acceptance that currently exist and recommend practical measures as to how these challenges could be overcome).
- Make recommendations on the need for field efficacy trials to support efficacy claims.

Participants

The focus group should bring together stakeholders and experts from EU and other regions with a maximum level of attendees of approximately 30-35 people.

Stakeholders should include: IFAH-Europe, FVE, and Association of Veterinary Consultants.

Regulators: Steering Group and CADDVA members, IWP experts, USDA regulators, EDQM, EC.

Proposed academic experts from the areas of: epidemiology, statisticians, clinical trials (profiles of experts to be defined by CADDVA).

Agenda

attached

Annex

Profiles of experts: experts participating in the focus group must have a veterinary background and/or good understanding of animal health

a) **Epidemiologists / infectious diseases experts:** veterinary epidemiologists or infectious diseases experts with experience on infection dynamics i.e. being able to interprete results from small experiments (e.g. clinical studies) to larger populations. Knowledge of EU requirements for veterinary vaccine authorisation should be an advantage.

b) **Statisticians:** statisticians with experience in evaluating results of animal health trials & understanding animal health population dynamics. Knowledge of EU requirements for veterinary vaccine authorisation an advantage.

c) **Clinical experts:** veterinary scientists with experience in setting up (design, monitoring) & interpreting results from clinical trials for animal health purposes and ideally for vaccines.