EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Summary of interim results from analysis of field efficacy data for Centrally Authorised Products

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Focus group meeting with invited stakeholders on field efficacy trials for veterinary vaccines

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Approach adopted

- Analysis performed on publicly available data in European Assessment Reports (EPARs) and SPCs of 91 IVMPS authorised through the Central Authorisation Procedure
- Summary results presented here on 63 vaccines reviewed to date (June 2017)
- Objective was to review the field efficacy data described in the EPAR and determine how this data influenced the wording of the SPC with particular attention given to the indication section (4.2)
- Consideration given to impact also in other areas
  - 4.4 Special warnings for each target species
  - 4.5 Special precautions for use
  - 4.8 Interaction with other medicinal products and other forms of interaction
  - 4.9 Amounts to be administered and administration route
  - 5. Immunological Properties
- Aim to complete an objective report on findings during 2017

Summary for MUMS vaccines: 9 MUMS/ 63 MAs reviewed

- MUMS applications frequently include field efficacy studies
- The need for field efficacy data is primarily influenced by the nature of the disease:
  - E.g. for leishmania and coxiella vaccines critical efficacy data derived from field study
- Field efficacy studies can result in warnings:
  - E.g. 4.5 (Special precautions for use) and 4.4 (Special warnings for each target species)

(e.g. rabbit vaccine: serological efficacy field trials in pregnant animals and offspring conducted – Results were taken into account in a warning in Section 4.5 of SPC concerning poor antibody responses to myxomatosis)

Summary for vaccines against epizootic diseases: 12/63 MAs

- FMD vaccine. No field studies provided/required
- BTV vaccines (1, 2, 4, & 8) serotypes:
  - Vaccines were used in several countries in some MSs in a very large number of animals including specific field trials before extensive use as part of national campaigns
- Critical data from laboratory challenges used to establish OOI and DOI
  - CVMP expressed some concern relating to the use of homologous challenge for some lab studies
- Use under national authorisations provided important information on safety and efficacy under field conditions

Summary for ‘Standard’ vaccine MA applications: 42/63

Field data in a number of centrally authorised veterinary vaccine applications influenced the indication or other sections of the SPC

Examples

- Porcine circovirus:
  - Reduction in daily weight gain loss plus interaction with mycoplasma vaccines
  - Repeated doses of no benefit from field study ; section 4.9 of SPC reflected this accordingly and recommended single dose
- Canine leptospirosis:
  - Statement on SPC concerning serological responses/protection in animal model (hamster: passive protection)
  - Presence of MDA to leptospira does not significantly reduce response: No MDA warning on SPC
- Canine rabies: poor immune response against rabies after a single vaccination in field (8% no seroconversion, 25% did not reach 0.5 IU). Section 4.9 of SCP: veterinary surgeons may wish to give additional rabies vaccination
- Infectious laryngotracheitis: Section 4.8 of SPC based on field data to reflect delayed response to MD vaccine by 10 weeks
- E.coli: Reduction in moderate to severe post-weaning D+ observed in field studies and reflected in SPC
- Equine influenza: Efficacy of a booster dose reflected in SPC wording based on field data.

Closing remarks

- Summary presented of interim results of analysis of field data reported in EPARs of 63 centrally authorised vaccines
- Work ongoing to complete analysis for all centrally authorised vaccines and validate/quality check interim results
- Final report will inform the discussion on the value of field trials by analysing evidence of use made of field efficacy data in assessment of centrally authorised vaccines

Thank you!