EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

22-23 June 2017, EMA, London

Presented by Dr. Jean-Pierre Orand and Dr Faye Ioannou – 22 June 2017

Overview of presentation

- Background to the veterinary vaccine availability action plan
- Background to initiating the focus group meeting with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines -analysis of industry recommendations report
- Scope, Objectives, Outcome of Focus group meeting with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines

EMA/HMA action plan on Availability for veterinary vaccines

- Joint EMA/HMA Workshop 25th March 2015 to improve the availability of veterinary vaccines → 6 recommendations → 13 step action plan
- Action plan to bring together activities from several different initiatives into a single coherent plan to ensure that:
  - resources of the Network as a whole are used to best effect taking into account the recommendations from the EMA/HMA workshop in March 2015
  - efficient and effective cooperation between all of those involved in ensuring the availability of vaccines within the EU (including marketing authorisation holders, regulatory authorities and the European Commission)

EMA/HMA action plan on Availability for veterinary vaccines Actions and progress tracking

green = completed; blue = on-going; black = planned

1. Integrate appropriate elements of action plan into the EU Medicines Agencies Network Strategy to 2020 and the linked multi-annual work plans of the EMA and HMA.
2. Set up a steering group to oversee and monitor progress against the action plan comprised of representatives from HMA and EMA. The EC and EDQM invited as observers. Industry observers invited to participate in relevant topics.
3. **Review the list of issues identified by industry**
4. Explore possibilities for public private partnerships under Horizon 2020
5. Develop guidance on standards for manufacture of autogenous vaccines
6. Identify training opportunities in the area of veterinary vaccines in co-operation with the Network Training Centre (NTC)
7. Set up a webpage to promote communication on veterinary vaccine availability initiative

EMA/HMA action plan on Availability for veterinary vaccines Actions and progress tracking

8. Create a group of CVMP members to identify, prioritise and make public CVMP plans and activities in the area of veterinary vaccine availability
9. CVMP-IWP Party to identify training opportunities for 2016 and 2017 in cooperation with Joint EMA/HMA Network Training Centre
10. Provide support to development of new vaccines and associated technology through existing mechanisms such as scientific advice, innovations task force (ITF)
11. Finalise review of MUMS guidelines and publish
12. CVMP/IWP to reflect on existing measures to promote availability of vaccines for epizootic diseases (FMD, BT,AI) and if new, or review of existing, guidance is required (e.g. multi-strain dossier guideline)

EMA/HMA action plan on Availability for veterinary vaccines Actions and progress tracking

13. CVMP/IWP to reflect on ways to take into account the different types of vaccines (e.g. live/inactivated vaccine, food producing/companion animals) and different situations for authorisation (e.g. normal vs. exceptional situations) as part of guidance on the benefit-risk assessment of veterinary medicinal products.
14. Using appropriate channels, input technical considerations on requirements for vaccines into the process for review of the legal framework for veterinary medicines

Analysis report of recommendations provided by industry in March 2015 on veterinary vaccine requirements

A report aiming to review industry's recommendations and to provide a summary analysis of these recommendations, identifying and prioritising possible actions and main implementers was produced by the EMA/HMA Steering Group (SG) and adopted by HMA and CVMP in 2016.

Main actions proposed to address industry's recommendations in the analysis report

- **Role of efficacy field trials -** Problem statement: conduct of field efficacy trials often too challenging when compared with the added value of the produced data in the context of final dossier, **Proposed action: Focus group meeting with invited stakeholders on field efficacy trials to take place in 2017 (highest priority)**
- ***Role of serology*** *- Problem statement: accepting serology more readily in EU as marker of efficacy , Proposal: Industry to provide a clearer problem statement with examples to be reviewed by CVMP/IWP against current guidance and decide whether space for flexibility and need to follow up with focus group*
- ***Use of PhV data*** *- Problem statement: use of PhV as valid field data; Proposal: Industry to provide refined problem statement with more detailed arguments and examples; CADDVA/SG to decide on further follow up*
- ***SPC simplification*** *- Proposal: Industry invited to provide specific concerns and examples in the form of concept paper - SG to evaluate and decide follow up*

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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.

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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
- ❑Identify possible alternative sources of information on expected efficacy of a vaccine under field conditions
- ❑Make recommendations on the need for field efficacy trials to support efficacy claims.

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Composition:

The focus group aims to bring together stakeholders, experts and regulators from the EU and other regions.

Invited stakeholders include: IFAH-Europe, FVE, and Association of Veterinary Consultants.

Regulators: EMA/HMA Steering Group (SG) & CVMP ad-hoc group on veterinary vaccine availability (CADDVA) members, IWP experts, USDA regulators, EDQM, EC.

Invited academic experts come from the areas of veterinary epidemiology, infectious diseases, statistics, clinical trials

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Final output:

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 (SG) that will then decide the appropriate follow up (e.g SG to consider focus group conclusions and decide whether to request to revise the CVMP guidance on field trials).

Thank you for your attention

Dr. Jean-Pierre Orand,

Dr. Faye Ioannou

faye.ioannou@ema.europa.eu

European Medicines Agency
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

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