EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on data requirements for vaccines March 2015 – Impact on availability

EMA/IFAH-Europe InfoDay 17-18 March 2016

Conclusions of workshop and follow-up actions

Presented by Dr. Faye Ioannou on 17 March 2016
Development and Evaluation of Veterinary Medicines, EMA

Overview of presentation

- Background to the veterinary vaccine availability initiative
- Current state of play
- Outlook and impact

Joint EMA/HMA Workshop 25th March 2015 at EMA, London
Key questions addressed by regulators and industry:

How can we improve the availability of veterinary vaccines whilst maintaining a high level of protection of animal and public health and the environment?

Are requirements for marketing authorisation of vaccines in the EU proportionate to the benefits and risks of this type of product?

Joint EMA/HMA Workshop 25th March 15 -Recommendations:

1. *Increase communication, cooperation and transparency in the development of scientific and administrative guidelines*
2. *Specific training for assessors to enhance consistency of assessment and share experience*
3. *Develop lists of diseases for which vaccines are not available, and therefore required, together with clear expectations of what would be needed for their authorisation*
4. *Examine in more depth the list of factors prepared and prioritised that industry consider constraining the availability of vaccines within the EU.*
5. *Maximise the existing opportunity for the revision of the MUMS guidelines*
6. *Reflect lessons to be learnt from other regulatory areas in terms of the approach to assessment of vaccines and level of requirements in current revision of the legislation governing veterinary medicines.*

Joint EMA/HMA Workshop 25th March 2015
Next steps

- ✓ Recommendations were placed within the context of a wider HMA Network Strategy and **an EMA/HMA action plan on Availability for veterinary vaccines** to ensure efficient and effective cooperation between all of those involved in ensuring the availability of vaccines within the EU was drafted. The plan was adopted in the HMA February 2016 meeting in Amsterdaam.
- ✓ **A Steering Group (SG) on Joint EMA/HMA Action Plan on Availability of Veterinary Vaccines** was created to provide strategic oversight on the implementation of the action plan. The ToR of the Steering Group was adopted in February 2016 HMA meeting in Amsterdaam.
- ✓ An **ad hoc group on veterinary vaccine availability of the CVMP** was created and the ToR were endorsed by CVMP in its March 2016 meeting

EMA/HMA action plan on Availability for veterinary vaccines- **Objectives**

- Bring together activities from several different initiatives into a single coherent plan to ensure that the 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.

- To ensure 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**

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).

EMA/HMA action plan on Availability for veterinary vaccines

7. Set up a webpage to promote communication on veterinary vaccine availability initiative
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

13. CVMP/IWP to reflect on ways to take into account the different types of vaccine (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

EMA/HMA action plan on Availability for veterinary vaccines

- 14 actions agreed
- Actors include: EMA, HMA, CVMP, IWP, CMDv, industry
- 3 already implemented (integration of action plan to Network Strategy, HMA/EMA SG, CVMP ad-hoc group on veterinary vaccine availability established)
- 8 on-going (review of industry list, guidance on autogenous vaccines, webpage, training, ITF, revision of MUMS guideline, multi-strain dossier)

Impact of action plan on veterinary vaccine availability- **Outlook**

Short term: next 6-12 months

oSG meetings with industry participation

oWebsite launch

oRevision of scientific overview and LoQ guidance template for immunologicals to increase consistency and clarity of assessments

Medium term: next 12-24 months

oActions that require updating/revision of guidelines

odiscussion already initiated on multi-strain dossier, autogenous vaccines, public/private partnerships, MUMs

Long term: next 24 months +

oPropose actions to EC requiring legislative amendments for next revision opportunity

Impact of action plan on vaccine availability

✓Accelerate market accessibility of suitable new and/or improved veterinary vaccines for the protection and promotion of animal and public health and animal welfare within the EU

[Working definition subject to agreement]

Thank you for your attention

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