HMA
Heads of Medicines Agencies

Protecting and Promoting Public and Animal Health in Europe

Joint EMA/HMA Workshop on requirements for authorisation of vaccines in the EU

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anses
alimentation, environnement, travail

Introduction

- Vaccines are very useful medicines:
  - To prevent animal diseases
  - As being an alternative for antimicrobials
- But a complete dossier needs time and important investment for the industry and we are confronted with a problem of availability
- for each MA vaccine, corresponding dossier contains sufficient scientific data:
  - Quality data (manufacturing process and controls, consistency of production, stability).
  - Clinical data (safety and efficacy under laboratory and field conditions).

  ⇒benefit-risk assessment (must be positive to grant a marketing authorization).

Rationale

- Already many registrations for vaccines, for which lightweight records are accepted, i.e.
  - Vaccines for limited markets
  - Temporary use (national and EC level only)
  - Multistrain dossiers
  - Vaccines against Influenza in horses
  - Authorizations under exceptional circumstances:
    - Minimum requirements established at EU level: avian Influenza, Bluetongue
    - Sometimes on a case-by-case basis: Coxiella

  → accepted although major diseases, widespread use and long time to get all information to revert to a full marketing authorization (3-4 years)

Rationale

- Large amounts of autogenous vaccines used now useful for MUMS

  → Animals vaccinated with autogenous vaccines are circulating throughout EU

  → Status of autogenous vaccines very different between EU countries:

  - levels of requirements (from zero to maximum)
  - types of autogenous vaccines authorized (bacteria only to all types of active ingredients)….

Background

- HMA meeting in Vilnius Sept 2013:
  - Presentation of issue concerning autogenous vaccines vs vaccines with marketing authorisation
- HMA decisions:
  - HMA TFIL: identification of the need to clarify the definition of autogenous vaccines and develop a harmonized approach throughout the European Union for producing autogenous vaccines
  - EMA is asked to conduct a reflection on level of requirement for delivering vaccine's marketing authorisation taking on board experience from other countries (i.e. US)

Expective Outputs

The main objective of this workshop is:

- to consider if the level of requirements remains proportionate to the risks and benefits of this class of products;
- How can we increase the availability of safe, sure and efficient vaccines in EU?

THANK YOU FOR YOUR ATTENTION

And

Good Work