EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Focus group meeting
Revision of the reflection paper on anthelmintic resistance

Pharmacovigilance system
Regulatory tools: report on lack of efficacy

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Peter Ekström on 13 June 2016
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Pharmacovigilance system

Monitoring veterinary medicinal products marketed

Pre-authorisation information from

TAS studies

Clinical studies

Limitations

- Duration of studies – chronical treatment, disease progression
- Off-label use – outside indication – lack off efficacy
- Population, young – old, different species (cascade use), different breeds
- Size of population – number exposed during clinical studies, we detect usually the more common adverse event
- Concomitant products

Post authorisation

Safety

Animal safety – adverse event

User safety – precautionary measures

Violation of withdrawal periods – dosage, health of animal

Environmental reports

Efficacy

Lack of efficacy

Today no positive biomarkers yet !

Post authorisation

If we detect rare and very rare adverse events only, with the very rough incidence calculation used today we think that the preauthorisation procedure has worked.

But rare event can be serious enough to shift the positive benefit risk analysis

Lack of Expected Efficacy/ Lack of Efficacy Examples

- Product for Ectoparasites
  - number of ticks on dogs
- Product for Euthanasia
  - animal do not die
- Product for abortion
  - no abortion
- Vaccine
  - number of animal sick despite of vaccination

Lack of Efficacy of anthelmintics

- Few reports - yes
- Individual treatments - happens
- Herd treatments – happens
  - Clinical trials – reports to NCA if in procedure !- clinical trial approval – no directive !
  - Best reports from academia driven studies comparing different anthelmintic treatment.
  - Promote clinical trials/academia studies – depending on National legislation clinical trial
  - literature search
  - PSURs

Promotion

- New legislation proposal
  - The agency and the competent authorities may organise meetings or network for groups of veterinarians or other healthcare professionals , where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.
  - PhVWP, Focus group on promotion of pharmacovigilance reporting on food producing animals (23 November 2016)

Thank you for your attention