EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

CVMP work programme 2013

Including reports on the scientific challenges facing the CVMP and the Working Parties of CVMP

Presented by: Anja Holm
Chairperson of Committee for Medicinal Products for Veterinary Use (CVMP)

Joint CHMP/CVMP Quality Working Party highlights from Work plan 2013 and challenges

Consolidation of 2012 priorities (all below are Joint CHMP/CVMP GLs):

- GL on Near Infrared Spectroscopy - finalisation of revision
- GL on Process Validation - finalisation of revision
- GL on Stability Testing for Applications for Variations to a MA - finalisation of revision

Process Analytical Technology:

- Joint QWP/BWP/GMDP IWG process analytical technology team – continued contribution at, increasing numbers of applications using new technologies such as Quality by Design, etc

Safety Working Party
highlights from Work Plan 2013 and challenges

- Development of guidance on limits of genotoxic impurities in veterinary medicinal products – concept paper currently out for consultation (multidisciplinary involving also EWP and QWP)
- Development of guidance on assessing the toxicological risk to humans and the environment of VMPs in groundwater – concept paper to be published for consultation in Q2
- Revision of guidance on determination of withdrawal periods for milk – draft revision to be published for consultation in Q3
- Finalisation of guidance on risk characterisation and assessment of MRLs for biocides following consultation – ongoing

Safety Working Party
highlights from Work Plan 2013 and challenges

- Support EU regulatory experts at VICH on safety and residues topics:
  - Guideline on the Acute Reference Dose
  - Guideline on residue studies in fish
  - Revision of guideline on genotoxicity testing
  - Guideline on bioequivalence
- Preparation of comments on draft Codex MRLs

Environmental Risk Assessment Working Party highlights from Work Plan 2013 and challenges

- *Assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicine*
  - Many comments received. ERAWP revising the guideline.
- *Antimicrobial resistance (AMR) due to presence of veterinary medicines with antimicrobial properties in the environment*
  - Literature review, focus on EU situation
  - Challenge: to produce considerations applicable to the risk assessment of marketing authorisations
- *Environmental risk assessment of ivermectin*
  - Reflection paper from ERAWP to be sent to CVMP for consideration

Environmental Risk Assessment Working Party highlights from Work Plan 2013 and challenges

- *Guideline on higher tier testing of antiparasitics to dung organisms*
  - Challenges: further development of dung organisms models required
- *Concept paper on assessing the toxicological risk to humans and the environment of veterinary pharmaceuticals in groundwater* (prepared with SWP-V)
  - Challenges: the approach must balance both the environmental safety and the human safety, when veterinary medicines are used.

Efficacy Working Party
highlights from Work Plan 2013 and challenges

- public consultation:

Deadline: 31 May 2013

- Draft (new) guideline: *Demonstration of palatability* of veterinary medicinal products
- Draft (revised) guideline: *Conduct of efficacy studies for NSAIDs*

Deadline expected: Oct 2013 - *tbc*

- Draft (revised) guideline: *Efficacy for veterinary medicinal products containing antimicrobial substances* – jointly with AWP. Focus Group meeting intended mid 2013.

Efficacy Working Party
highlights from Work Plan 2013 and challenges

- revision of GL (on-going):

- *Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats*
  – only few comments received on CP (deadline 31 Jan)
  Work started on revision, exp. release for consultation: 2014

- *Conduct of efficacy studies for intramammary products for use in cattle*
  - exp. release for consultation: July (September) CVMP

Antimicrobials Working Party
highlights from Work Plan 2013 and challenges

- Smooth transition from the Scientific Advisory Group on Antimicrobials to the Antimicrobials Working Party – nearly same members, new Chair
- Reflections on AMR risk assessment for marketing authorisations of antimicrobials – concept paper published for consultation
  - Challenges: risk assessment of e.g. old preparations, 2nd line antimicrobials, antimicrobials for pets, new antimicrobials
- Data requirement for new veterinary medicinal products for companion animals with respect to antimicrobial resistance - draft reflection paper – nearly finished at AWP

Antimicrobials Working Party
highlights from Work Plan 2013 and challenges

- Revision of the GL demonstration of efficacy for veterinary medicinal products containing antimicrobial substances (EMA/CVMP/627/01) together with EWP
  - Deadline expected for public consultation: Oct 2013 – tbc
  - Focus Group meeting intended mid 2013.
- AMR risks related to off label use of antimicrobials in veterinary medicine
  - Challenges: slow progress due to scarce data
- Follow-up of previous recommendations re. Antimicrobial Resistance
  - Challenges: referrals to be prioritised according to its relevance to minimise antimicrobial resistance

Pharmacovigilance Working Party highlights from Work plan 2013 and challenges

Consolidation of 2012 priorities

- Prioritisation and signal detection for pharmacovigilance surveillance of veterinary medicinal products
  - Recommendation → public consultation
- Causality assessment
  - Consideration of approach as part of surveillance procedure
- Pharmacovigilance communication

Immunologicals Working Party

- Update in Session II of the Info Day -

Joint Ad Hoc Expert Group on application of 3Rs

- Update in Session II of the Info Day -

CVMP
highlights and challenges for 2013

• Review of the Veterinary legislation – scientific support and comments to the Commission

• Injection sites issue - collection of further scientific evidence and consideration of current approach

• Quality of assessment reports – harmonised output across all products and better use of the Benefit-Risk section

CVMP
highlights and challenges for 2013

Antimicrobial resistance – major focus area.

- A harmonised approach and further guidance are needed for Industry.
- Many large referrals to CVMP with the grounds related to antimicrobial resistance.
- Scientific opinion on AMR has been requested by the Commission

Thank you for your attention

Questions?