EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guidance on user safety evaluation for pharmaceutical veterinary medicinal products – development of existing and future guidance

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Presented by Nicholas Jarrett
Animal and Public Health

Guideline on user safety for pharmaceutical VMPs

- Annex I of Directive 2001/82/EC includes a requirement for documentation on user safety:
- *"the safety documentation shall show the potential risks which may result from the exposure of human beings to the veterinary medicinal product, for example during its administration to the animal."*
- => original GL on user safety adopted by CVMP in January 2005 and came into force 6 months later

Controversial beginnings

- At the November 2006 EMA/IFAH-Europe Info day industry representatives raised strong concerns over the guideline:
  - Serious shortcomings: vague, target reader uncertain, in some areas too specific, in other areas lacked focus, confusion over rate, extent and duration of exposure, strayed too far into toxicity assessment, lacks guidance on quantitative risk assessment, professional versus non-professional users (?)

  => specific focus group meeting between industry experts and SWP experts, to clarify concerns over the guideline

Focus group meeting – December 2007

- Industry concerns discussed in detail
- A great deal of common ground between industry experts and SWP experts
- A considerable amount of misunderstanding between industry experts and SWP experts
- SWP agreed to recommend revision of the GL to CVMP
- Joint industry/SWP presentation feeding back from the focus group meeting given at EMA/IFAH-Europe Info day in 2008, at which value of focus group meeting was acknowledged by all

Revision of user safety guideline

- Concept paper (April 2008), revised draft guideline (April 2009), final guideline adopted in March 2010 and come into force in October 2010
- Increased clarity
- Specific industry concerns addressed
- Examples provided

User safety – the need for more specific guidance

- Overarching guideline is general and does not provide specific guidance on particular product types or routes of administration
- Need for more specific guidance first highlighted in relation to anticancer products:
  - The guideline on dossier requirements for anticancer medicinal products for dogs and cats was developed to cover user safety issues (as well as quality, TAS, efficacy and environmental risk issues)
  - User safety concerns were again raised by industry following publication of the draft guideline for consultation

  ⇒ focus group meeting held (March 2009)

⇒ Final anticancer products guideline adopted in April 2009

Need for additional specific guidance

- Demand for specific guidance on the user safety evaluation of **topically applied products**
  - lack of a harmonised approach for evaluation of user safety of topically applied products highlighted following withdrawal of a number of antiparasitic collars from market in one member state
  - number of applications for topically administered (particularly spot on) products is increasing

User safety of topically applied products

- Various non EMA guidance documents available but not harmonised

  =>led to different approaches being taken by different companies and different competent authorities
- December 2013: CVMP agreed to ask its SWP to prepare guidance on user safety evaluation of topically applied products
- February SWP: concept paper formally proposing development of the guidance agreed => CVMP for adoption
- Concept paper intended for publication for 3 month consultation period beginning in March or April

Summary

- Development of guidance on user safety for pharmaceutical VMPs has proved to be challenging
- General guideline is now well accepted and used
- Specific guidance exists for anticancer products
- New proposal to develop specific guidance for topically applied products

Thank you for your attention!