EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Key elements of the review of veterinary legislation

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Objectives of review

- Administrative simplification, including review of authorisation procedures

- Reduce the bureaucratic burden

- Achieve a genuine single European market in veterinary medicinal products (VMPs)

- Recognise the particular needs of the veterinary sector

→ **IMPROVED AVAILABILITY OF VETERINARY MEDICINES**

Administrative simplification

- High burden relative to small size of industry (13% of turnover vs 5-6% for human industry)
- Affects viability of veterinary companies which are smaller and sell to entirely private markets
- Benchmarking shows industry is moving industrial base out of EU to other regions with lower requirements
- Affects availability of products, particularly in smaller MS
- High number of resource intensive referrals
- Regulators and industry agree on need for simpler and more efficient authorisation system more suited to needs of veterinary medicines
- "As similar as possible, as different as necessary" compared to the human framework

Simplification of authorisation procedures

- Implement the concept of a single assessment in some form
- Concept accepted by all, finding a practical model proving more challenging
- Need for harmonisation of existing authorisations to reduce need for referrals
- Adapt data protection to the veterinary sector, including for generics (multiple species, entirely private market, no HTAs etc.)

Simplification of post-authorisation procedures

- Variations an obvious target for simplification

- Pharmacovigilance presented as a significant and growing burden by industry
  - ➢ Major simplification likely to be proposed
  - ➢ Increased deviation therefore likely in requirements between human and veterinary products

- Increased emphasis on monitoring of marketing authorisation holder for compliance (including for pharmacovigilance) by inspection rather than administrative procedures

Antimicrobial resistance

- Added as a specific topic due to increasing political profile and Commission Action Plan on Antimicrobial Resistance
- Range of tools will be provided to enable authorities to promote and enforce responsible use of veterinary antimicrobials and reduce potential risks to human health
  - How the tools will be applied will be determined by implementing measures in secondary legislation
  - Risk assessment and guidance will be produced by EMA/CVMP for decision on risk management measures by the European Commission

SMEs

- Support to SMEs remains a high priority for the Commission

- Administrative simplification and achievement of a genuine single market will be particularly beneficial for SMEs

- Support to products for Minor Use Minor Species (MUMS) was flagged by CVMP as an area for the European Commission to consider for additional support

What next?

- European Commission has held a series of open and targeted consultations as it develops the proposal
- Currently stated aim is to publish proposals by end of 2013
- Proposal will not be adopted in the current session of the European Parliament
- Earliest date for implementation likely to be 2017
- So…….we need to make the best use of existing framework and legislation for the next 3-4 years