FEEVA Medicines Aim

Joe Collins FEEVA President

- To protect equine health and welfare across Europe
  - Wide range of safe, efficacious medicinal agents
  - Clinical freedom exercised in the patient's interest
  - Harmonised licensing rules
  - Managed efficient route of supply
  - Policing of illicit use
- To protect food chain and user safety
  - Responsible professions (vets, pharm., tox., medic)
  - Treat as 'companion animals'!
  - Policing of supply and use
  - Residue testing

Medicines Background

- Commission Regulation 1950/2006 established a list of substances **essential** for the treatment of equidae
- **Positives** list not a **negatives** list
- The cascade applies, i.e. **exceptional use, protect the welfare of the animal,** under the **direct responsibility** of the veterinarian.
- Non-annex medicines (EC 2377/90)
- ‘Essential’

Essential Medicines

- Sedatives 9
- Cardio-respiratory medicines 12
- Analgesics and anaesthetics 8
- Muscular function 4
- GI Tract 4
- Antimicrobial agents 10
- Anticonvulsants 2
- Ophthalmic 13
- Misc. 9

… proposal for a regulation of the **European Parliament** and of the **Council** laying down Community procedures for the establishment of **residue limits of pharmacologically active substances** in **foodstuffs of animal origin**.

Committee on the Environment, Public Health and Food Safety

Rapporteur: Avril Doyle MEP

General policy objective

- … to continue to limit consumer exposure to pharmacologically active substances … used in veterinary medicinal products for food producing animals ...
- Improve availability of veterinary medicinal products for food producing animals
- …to ensure animal health and welfare and avoid illegal use of substances…

General amendments

Priority should be given to the detection of the use of prohibited substances ...

… recommendations should take into account any relevant scientific findings of the European Food Safety Authority ...

Medicines Directive 2001/82/EC as amended by Regulation EC 470/2009

T*he Commission shall establish a list of substances:*

- *which are essential for the treatment of equidae,* ***or***
- ***which bring added clinical benefit compared to other treatment options available for equidae***
- *and for which the withdrawal period shall be not less than six months according to the control mechanisms laid down in Commission Decisions 93/623/EEC and 2000/68/EC.*

Consultation

- Joint FVE / FEEVA
- Feb 2009 – Commission
- July 2009 – EMEA
- September 2009 – Commission
- Aims:
  - Propose substances for addition
  - Clarify Essentials vs. National licensing rules
  - Promote ‘legal medicines usage’

Terms of Reference - Additions

- Cascade provisions still apply – YES
- Annex IV medicines - NO
- Purely economic considerations – NO
- Chronic medication required – NO
- Multiples in same class – YES
- Different modes of action – YES
- Different routes of action – YES
- Different pharmacokinetic profile – YES
- Safety studies - ???????

FVE / FEEVA proposal

- 20 substances
- Additional corticosteroid (triamcinolone)
- Opiate – codeine
- 1 antibacterial – clarithromycin
- Radiopharmaceutical (T99)
- Halothane
- Phenylbutazone
- Also German submission

CVMP proposal

- 21 additions; 1 loss
- Extra antimicrobial – Polymyxin B
- ‘Chronic’ therapies – Cyproheptadine
- Not halothane – ‘existing user-safety concerns’
- Not phenylbutazone – ‘outstanding information on the teratogenic and carcinogenic potential’

Current position

- Clarify terms of reference for CVMP
- Clarify terms of reference for Commission
- Clarify discrepancies between Essentials List and National Medicines licensing rules
- Ease mobility of medicines
  - To match vets, horses, knowledge
- Emphasize role of the professions in safeguarding animal and human health