

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

The 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