The Current Situation with Legislation on Farm Antibiotic Use

Peter Stevenson
Compassion in World Farming
The Veterinary Medicinal Products Directive 2001/82/EC

• sets out controls on manufacture, authorisation, marketing, distribution of veterinary medicines
• also applies to pre-mixes for medicated feedingstuffs
Summary of Product Characteristics

An application for marketing authorisation must include a Summary of Product Characteristics that contains clinical particulars including:

- target species
- indications for use
- contra-indications
- special warnings for each target species
- special precautions for use
Labelling & package leaflet

• Competent authority must approve the packaging & package leaflet

• Package leaflet must state:
  – species for which intended
  – the therapeutic indications
  – contra-indications
Mutual recognition procedure

• A Member State (MS) must recognise a veterinary medicine authorised in another MS except on grounds of a potential serious risk to human or animal health or to the environment
Community authorisation procedures

• Medicinal products developed by means of certain biotechnological processes must be authorised at Community level (not at MS level)

• Other medicinal products may be authorised at Community level (instead of MS level)

• European Medicines Agency must approve the Summary of Product Characteristics & package leaflet
Use of antibiotic growth promoters phased out by EU law between 1997 & 2006
What limitations are there on regular prophylactic use?

- European Parliament, 2012: stresses that no standard definition of ‘preventive treatment’ has been adopted to date and different interpretations of the term are giving rise to constant disagreement
- Summary of Product Characteristics (SPC) is tool for controlling use of antimicrobials
- SPC describes the conditions under which antimicrobial products may be used
Committee for Veterinary Medicinal Products (CVMP) guidelines, 2011

- A number of antibiotics for food producing species, authorised through the centralised procedure, have indications containing the expression “For treatment and prevention of …”.
- How does CVMP interpret “treatment and prevention”? “‘For treatment and prevention of …’ should only be read in combination and does not include routine preventive use in animals where the bacterial disease has not been established in the group/flocks at the time of treatment”
- “‘treatment’ refers to the treatment of an individual animal, or a group of animals showing clinical signs of an infectious disease.”
- “‘prevention’, refers to the administration of the product at the same time to other in-contact animals, to prevent them from developing clinical signs, and to prevent further spread of the disease …
- “...The presence of the disease in the group/flock must be established before the product is used”.

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Further clarification in CVMP strategy on antimicrobials 2011-2015

- Preventive treatment of an entire group/flock when infection has started in some animals should be restricted to highly contagious and severe diseases
- Oral products for group or flock medication is of special concern since in intensive animal production there might be comprehensive use of antimicrobials
3rd & 4th Generation Cephalosporins

Commission Implementing Decision of 31.01.2012 concerning the marketing authorisations for veterinary medicinal products which contain the active substances “Cefquinome and Ceftiofur”
Commission Implementing Decision of 31.01.2012: Changes to the product information for 3rd & 4th generation cephalosporins

- **SPC - Section 4.3 Contraindications:** Add “Do not use in poultry (including eggs) due to risk of spread of antimicrobial resistance to humans”

- **SPC - Section 4.5 Special precautions for use:** Add “[product name] should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly (refers to very acute cases when treatment must be initiated without bacteriological diagnosis) to first line treatment”

- **SPC - Section 4.5 Special precautions for use:** Add “[product name] is intended for treatment of individual animals. Do not use for disease prevention or as a part of herd health programmes. Treatment of groups of animals should be strictly restricted to ongoing disease outbreaks”
Forthcoming revision of EU legislation

• European Commission due to publish proposed revision of legislation on veterinary medicines & medicated feed later this year
• Represents major opportunity to strengthen this legislation to end regular prophylactic use of antimicrobials & severely restrict use of Critically Important Antimicrobials in farming
• Calls on MS to limit the use of Critically Important Antibiotics to cases where microbiological diagnosis & susceptibility testing have determined that no other type of antimicrobials will be effective
• In acute cases in the treatment of infections in humans and animals, CIAs can be used initially when necessary, but must be re-evaluated & if possible de-escalated depending on test results
• Limit prophylactic use of antimicrobials to cases with defined clinical needs
• Limit use of antimicrobials for herd treatment to cases where vet has assessed that there is a clear clinical & where appropriate epidemiological justification to treat all animals
Position of European Parliament: Resolution, 11 December 2012:

• strongly disapproves of the regular prophylactic use of antimicrobials in animal husbandry
• endorses Council Conclusions on limiting prophylactic use of antimicrobials
• calls on Commission to propose limit in veterinary sector on use of 3rd & 4th generation CIAs
Proposals by Alliance to Save Our Antibiotics:
routine prophylactic use

• A legally binding timetable to phase out routine prophylactic use of antibiotics:

• welcome the CVMP’s 2011 clarification that, for products authorised through the centralised procedure, prophylactic use is not permitted unless the presence of the disease has been established

• should be extended to all antibiotic products including those authorised through the decentralised & mutual recognition procedures

• should be given legal force by inclusion in revised veterinary-medicines and medicated-feed legislation
Proposals by Alliance to Save Our Antibiotics: Critically Important Antimicrobials

• ban on the use of modern cephalosporins in poultry welcome & must be fully implemented (Commission Decision, 2012)
• ban should also be introduced on their use in pigs & for dry-cow therapy in cattle
• their off-label use should no longer be permitted
• ban on the use of fluoroquinolones in poultry
Proposals by Alliance to Save Our Antibiotics: how best to prevent disease

- new legislation aimed at improving animal health & welfare and ensuring animals are kept in less-intensive conditions with, wherever possible, access to the outdoors
- European Parliament, 2012: livestock farming should focus on disease prevention through good hygiene, housing and animal husbandry rather than through prophylactic use of antimicrobials