ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

66th Meeting of ACAF on 2 February 2015

Presentation Paper :
Proposal for a new EU Regulation on medicated feed

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January 2015

Proposal for a new EU regulation on medicated feed

Manufacturing, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC

Lee Grist
Veterinary medicines legislation

Proposals became available on 10 September

Two Council Working Parties for each proposal
11 and 12 October and November

Next 27 and 28 January under Latvian Presidency

European Parliament Committees

Veterinary medicines:
Environment, Public Health and Food Safety

Medicated feeds:
Agriculture and Rural Development

VMD Recent Actions

- Workshop held at VMD in December
- Proposals reviewed with stakeholders
- Comments and concerns raised are now being collated

Addressing the public health risk of AMR

- Commitment in 2011 Action Plan on AMR
- Action 2: Strengthen the regulatory framework on veterinary medicines and on medicated feed:
  - Warnings and guidance on labels
  - Restrictions on the use of certain new or critically important antibiotics for humans in the vet sector
  - Amending the rules for advertising
  - Revisit authorisation requirements in order to sufficiently address the risk:benefit of antibiotics in veterinary medicines

Commission's objectives for medicated feed

- Harmonise the manufacture, marketing and use of medicated feed in the EU
- Make medicated feed available to farmers and pet owners at a competitive price
- Improve animal health by precise dosage of oral VMPs
- Remove barriers for innovative, "novel" medicated feed
- Over-come the zero-tolerance for unavoidable carry-over of VMPs
- Curb AMR-risk from residual and sub-therapeutic administration of antibiotics

Chapter I – Scope and definitions

- **Article 2 – Definitions**
  - *Medicated feed*
    - needs to explicitly state that only authorised products can be used
  - *Distributor*
    - not broad enough as only focusses on retail supply. Pet sector structure is different
  - *Intermediate product*
    - not clear whether this refers to final complementary feeds

Chapter II – Manufacture, storage, transport and placing on the market

- **Article 4 – HACCP**
  - Concerns from some MS that HACCP is inadequate and calls for GMP
- **Article 5 – Composition**
  - Zinc oxide: may need to adjust the amount of medicinal product to compensate for the presence of feed additive?

Chapter II (2)

- **Article 6 – Homogeneity**
  - Permitted tolerances in Annex 4 narrower than current requirements in Schedule 5 of the UK's Veterinary Medicines Regulations
  - Longer term arrangements in implementing act will give MS the opportunity to change the requirements

Chapter II (3)

- **Article 7 – Carry-over**
  - 1% for antibiotics:
    - Does not appear to take into account the activity of the antibiotic
    - More highly active substances will be difficult to detect
  - 3% for other substances
  - Delegated acts in future to establish specific carry-over limits will require EFSA's input
  - Will take time
  - Compare with the Undesirable Substances Directive

Chapter II (4)

- **Article 8 – Anticipated production**
  - On-farm mixers should not be permitted to produce without a prescription
  - Anticipated feed should not be produced in anticipation of cascade prescription
- **Article 10 – Packaging**
  - Commission has confirmed that sealed transport is acceptable, but seals should not be reused

Chapter III – Approval of establishments

- **Article 13 – Approval procedure and lists of approved establishments**
  - Reflects the current situation in the UK
- **Article 14 – Establishments approved in accordance with 90/167/EEC**
  - Requires FeBOs to submit a declaration that they still meet the requirements of 90/167

Chapter IV – Prescription and use

Article 15 – Prescription

- Stipulation on who keeps what record
- Records kept for 3 years
- Validity:
  - 6 months for non-food species
  - 3 weeks for food species (3 months in 90/167)
- Prescribed feed only to be used for animals **examined** by the person who issued the prescription and only for **diagnosed disease**

Chapter IV (2)

- **Article 16 – Use in food-producing animals**
  - Quantities supplied or mixed do not exceed:
    - the quantities stated in the prescription
    - one month's treatment
    - two week's treatment for feed containing antibiotics

Chapter IV (3)

- **Article 16 – Use in food-producing animals**

*"Medicated feed containing antimicrobial products shall **not be used to prevent diseases** in food-producing animals or to enhance their performance"*

  - What is meant by prevent?
    - Group of healthy animals showing no symptoms?
    - Prevention of a known and recurring condition?
    - Some animals in a group diagnosed with a disease and not being able to treat the healthy ones to stop the spread?

Chapter IV (4)

- **Article 17 – Collection systems of unused or expired products**
  - Would there be anything to collect?
  - Who would be responsible for collecting?

Chapter V – Procedural and final provisions

- **Article 18-23 – All procedural**
  - The entry into force date in Article 23 needs clarifying
  - Nothing else out of the ordinary relating to these articles

Next Steps

- UK Parliamentary scrutiny Impact Assessment
- Present the UK position to the European Council of Member States
- Negotiations estimated to be shorter than VMP proposal
- EP committee: lobby chair and MEPs

What we need

- Your comments/concerns regarding the proposal as soon as possible

- Is there anything you feel needs to be included?

Any Questions?