Joint HMA/EMEA Meeting On Promoting Prudent and Responsible Use Of Antimicrobials In Veterinary Medicine, 19 – 20 May 2009, Marienbad, Czech Republic

Coordination of collection of data on sales of antimicrobials

Jordi Torren
Safety of Veterinary Medicines,

European Medicines Agency (EMEA)

- Origin and purpose
- EMEA activities
- Step 1: Overall national usage
- Stage 2: Data per animal species
- Last phase
- Presentation of the data

Origin and purpose

- March 09 the Commission requests the EMEA to take the lead in collecting data on the use of antimicrobials in animals

- Purpose of monitoring ➜ document variations in antibacterial drug consumption
  - ◆ to allow risk profiling,
  - ◆ for setting risk management priorities
  - ◆ to assess the impact of recommendations

EMEA activities

- Identify the existing data/surveillance systems in the Member States ✓ (in collaboration with HMA)

- Developing a harmonised approach;
  - ◆ for the collection and reporting of data
  - ◆ estimations of usage in at least major groups of species (poultry, pigs, veal, other ruminants, pets and fish).

- Defining the minimum requirements for the collection of data.

- Clarifying legal basis for requiring data

EMEA activities

- Meeting in autumn 09 with responsible Member State bodies
- Options analysis of the means required
- Analysis of existing data for 2009 by November 2010
- First phase of coordinated data collection during 2010

Step 1: Overall national usage

- To be reported by e.g. pharmaceutical industry, wholesalers and feed mills,
- Antibacterial drugs belonging to the following groups/ATCvet codes:
  - Intestinal antibiotics (QA07AA)
  - Antbiotics for gynecological use (QG01AA)
  - Systemic use (QJ01)
  - Intramammary use (QJ51)
  - *Coccidiostats as feed additives?*
- Population data to be included e.g. pigs slaughtered.
- Time frame: 2010 onwards.

Step 1: Overall national usage

- Required data/fields in worksheet:
  - National ID number for the VMP/Commercial name of the VMP (label)
  - Route of administration (e.g. oral) (or formulation)
  - Number of administration units per package
  - Strength, i.e. quantity of active substance per administration unit (e.g. 50 mg/ml), measuring unit (e.g. mg; mg/ml)),
  - Active drug substance(s) or the complete ATCvet code
  - Number of packages sold per year
  - Animal species
- Time frame: 2010 onwards.

Stage 2: Data per animal species

- Further discussions required
- Data should include use in all food animals (including farmed aquatic species) and the major companion animals
- Per age groups (e.g., weaning pigs, slaughter swine), per type of animal production (e.g., dairy cattle, beef cattle) and usage at herd or farm level
- To be reported by veterinarians, pharmacies and feed mills (when relevant)
- 2012 forward?

Last phase

- To collect the data from Member States and manage the data base;
  - Focus on what can be easily obtained and comparable from different Member States
- To draft a summary annual report with the data from Member States
- To analyse the data

Presentation of the data

Discussion required.

- ATCvet code proposed

- Aggregated national sales data do not provide information specific to the various animal species ➡ estimates on usage of antibacterial drugs in selected animal species may be calculated based on sales statistics

- DDDanimal ➡not developed yet. Currently under discussion a new proposal to interested parties to be circulated soon

Thanks

- For your patience
- To Kari Grave, and colleagues from the EMEA secretariat; C. Muñoz, K. Grein and D. Mackay