

# Monitoring of Sales of Veterinary Antimicrobial Agents in Europe

## Considerations from Industry

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# Plan

- IFAH-Europe
- Reminder of previous meetings / papers
- Key principles
- How to collect data
- How to report data
- ATCvet code / DDD
- Case of feed additives
- Conclusion



## Updated market representation 2009

IFAH-Europe represents:

- 90% of the European market in veterinary medicinal products (VMP)
- 15% of this value is generic VMPs
- 15 international companies as corporate members
- 18 national associations, representing ~300 local companies
- VMP market is 3% of the human pharma market



# Key Elements for Consideration and Proposals ( Slide presented at Marianske Lazne 20th May 2009)

- All marketers to be involved!
- National approaches!  
may be the only way - versus central data generation
- Collection of context data!  
(*e.g. animal production numbers, disease prevalence*)
- Simple and pragmatic systems required
- Same or similar collection systems in all Member States
- Discussion on unsolved species differentiation
- Consultation with stakeholders on interpretation of data
- Joint effort industry / regulators essential



# Key principles

- As introduced in the HMA/EMA Meeting May 2009
  - Importance of contextual data
  - National, Harmonized collection of data
  - Industry can supply the most accurate data at a National level
  - Simple and robust system
  - Species split
  - Confidentiality rules
  - All marketers must be obliged to supply data – does the legal base exist for this?
  - IFAH-Europe supports pragmatic volume data collection

IFAH paper *Antibiotic Volumes and Context Septembre 2009*



# Why do we collect usage data ?

- **General framework of Risk Analysis**
  - Risk profile
  - **Risk assessment**
    - Hazard identification
    - Hazard characterization
  - Risk management
    - Measure the impact of risk management options
  - Risk communication
    - Transparency



# How to collect data ?

- Report from industry to national country authorities
  - Weight or presentations sold
  - By license number
  - All manufacturers
- Species split
  - Industry is open to harmonization with PSUR data



# How to report data ?

- Reporting of data by antimicrobial classes according to current third level of ATC vet code (e.g. Danmap)
- Oral / Parenteral / Intramammary / External
- Confidentiality of data at country / regional level
  - Some classes have too few compounds to be presented independently
- Importance of data formatting for potential risk assessment
  - Measuring exposure at animal level is essential





# ATCvet code / DDD

- Complexity
  - Numerous species, different weights
  - Compilation of data difficult
- Dosing / Posology not harmonized in Europe
  - Does not automatically reflect prescribed dose or used dose
- Few countries have adopted that approach yet
- Fitness for purpose ?



# Feed additives

- Ionophores explicitly out of WHO list
- Different legal status in Europe
- Not collected in every country as of today
- Not essential at this stage



# Conclusions

- Simple and robust
- All data to be collected
- Importance of contextual data
- Simple species split
- Need of Fitness for risk assessment



# Backup slides



# Proposed reporting

- Tetracyclins
  - Amphenicols
  - Penicillins
  - Cephalosporins
  - Trimethoprim / Sulfonamides
  - Macrolides / Lincosamides
  - Aminoglycosides
  - Polypeptids
  - Fluoroquinolones
  - Quinolones
  - Pleuromutilins
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- Proposal without prejudice to any national or regional confidentiality issue that may affect reporting
  - Classes used only in companion animals need to be taken into account again with due respect to confidentiality issues

