

# **Sales and use of antimicrobials**

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**Legal basis for collection of data**

**Mario Nagtzaam**

**Unit F2, DG Enterprise and Industry**

**Leena Räsänen, Unit E2, DG Health and Consumers**

**European Commission**

# The importance of monitoring the use of antimicrobials in veterinary medicine

In order to ensure public and animal health:

- Risk profiling
- Risk assessment
- Risk management
- Evaluation of trends and results of actions

# Context

- Council conclusions and recommendations 2001, 2008, 2009
- OIE, Codex and WHO guidelines
- EU-US taskforce
- Staff working paper of the services of the Commission on antimicrobial resistance
- Joint report on antimicrobial resistance focused on zoonotic infections
- EFSA, EMEA, ECDC reports and opinions

# Legal basis pharmaceutical legislation

- Article 27a of Directive 2001/82/EC and Article 13 of Regulation 726/2004 “Upon request by the competent authority/agency...the marketing authorisation holder shall provide the competent authority/agency with all data relating to the volume of sales of the veterinary medicinal product, and any data in his possession relating to the volume of prescriptions”

# Legal basis in food safety and zoonoses legislation “zoonotic AMR”

- Zoonoses Directive 2003/99/EC:
  - obligation for CAs to monitor AMR in zoonotic agents and collect and assess the data
  - Obligation to submit reports to the Commission at its request for specific additional information
- Food safety and hygiene legislation: a general obligation to provide and assess data related to food safety

# Data collection from harmonised monitoring

- Prevalence of resistant bacteria in food and animals.  
Since 2007: EU harmonisation
  - Decision 2007/407/EC on a harmonised monitoring of AMR in *Salmonella* in poultry and pigs
  - Decision 2007/516/EC on a *Campylobacter* survey in broilers in 2008
  - Decision 2008/55/EC on an MRSA prevalence survey in breeding pigs in 2008
  - EFSA recommendations on AMR indicators *E. coli* and *Enterococci*
  - Harmonised with monitoring in humans (EARSS)

# Political basis

- Request of the European Parliament: AMR in animal farming leading to possible problems in public health
- Slovenian Presidency Council conclusions of 10 June 2008 « calls upon the Member States ...to strengthen surveillance systems and improve data quality on AMR and use of antimicrobial agents from both human health and veterinary sector.. »
- International guidelines accepted by MS