



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# One Health –coordinating prudent use of antimicrobials in human and veterinary medicine

---

Presented by: David Mackay  
Head of Veterinary Medicines Division

An agency of the European Union





# Outline

- Defining the 'One Health' approach and its implementation at the European Medicines Agency (EMA)
- Promoting responsible use of antimicrobials in veterinary medicine
- Ensuring alignment between human and veterinary sectors to minimise risks arising from use of antibiotics



## A definition of 'One Health'

- "the collaborative effort of multiple disciplines — working locally, nationally, and globally — to attain optimal health for people, animals and the environment"

The American Veterinary Medical Association. One Health Initiative Task Force. "One Health: A New Professional Imperative". July 15, 2008. [https://www.avma.org/KB/Resources/Reports/Documents/onehealth\\_final.pdf](https://www.avma.org/KB/Resources/Reports/Documents/onehealth_final.pdf). Accessed September 1, 2011.



# EMA approach to antimicrobial resistance

- **Any** use of antimicrobial agents has the potential to select for resistant organisms
- EMA is responsible for overseeing both human and veterinary medicines, including antimicrobials, and so is well placed to adopt the One Health approach
- Prudent and responsible use is the key to effectively minimising risks from AMR
- EMA
  - takes direct action within its areas of competence
  - fosters cooperation with other stakeholders where responsibility is shared



# EMA approach to antimicrobial resistance

- Whilst adopting a One Health approach EMA recognises the specificities of each sector
- Different priorities drive the activities undertaken by EMA
  - The overarching paradigm for benefit risk assessment differs between man and animals, particularly for food producing species
  - For human medicines
    - promote the availability of antimicrobials to treat multidrug resistant organisms
  - For veterinary medicine
    - ensure the continued availability of veterinary antimicrobials whilst limiting the risk to man from the use of antimicrobials in animals

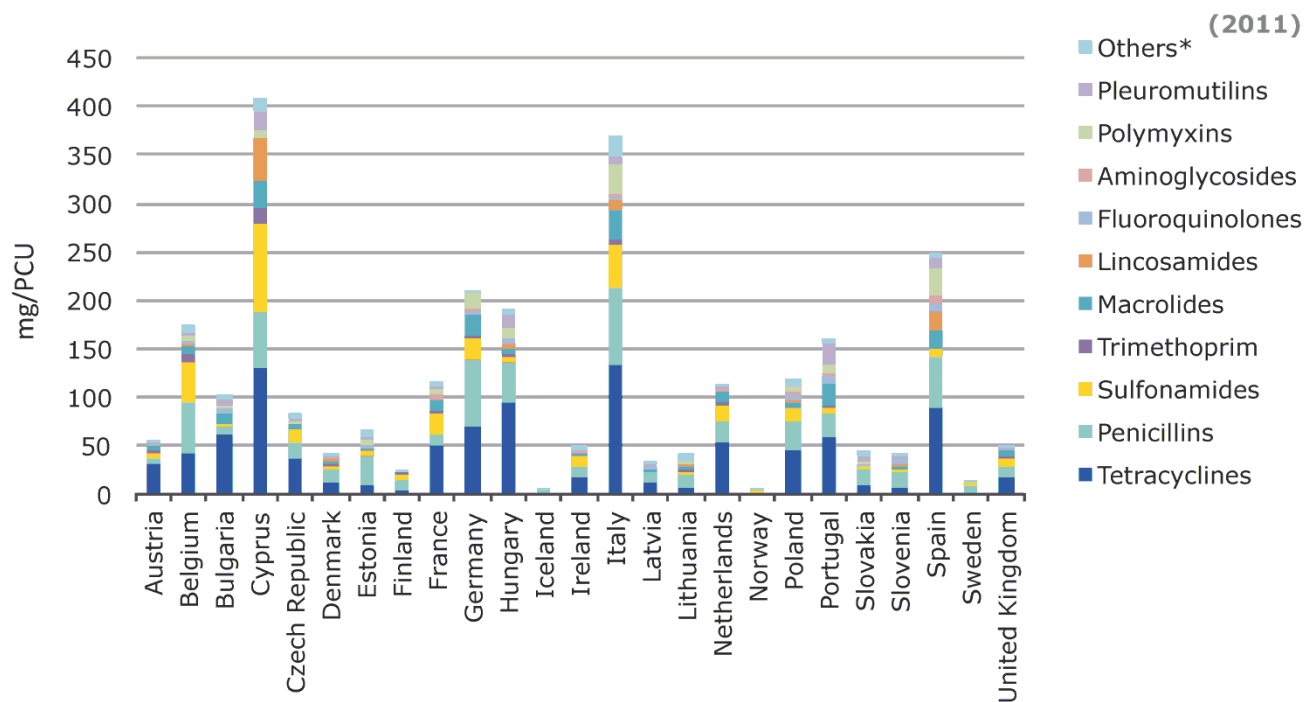


# EMA activities in relation to antimicrobials

- Guidance on requirements for authorisation and use in guidelines, reflection papers and scientific advice
- Authorisation of antimicrobials and subsequent maintenance and monitoring
- Amendments and updating of the approved conditions of use, as contained in 'Summary of Product Characteristics' through referral procedures
- Opinions and advice to the European Commission on any aspect of authorisation and use
- Monitoring of use of veterinary antimicrobials by the European Surveillance of Veterinary Antimicrobials (ESVAC) project



Sales for food-producing species, including horses, in mg/PCU (Population Correction Unit), of the various veterinary antimicrobial classes by country for 25 countries in 2011





## Veterinary use of antimicrobials

- Similar classes of antimicrobials used in man and animals
- Attention has been focused on antimicrobials classified by WHO as Critically Important Antimicrobials for use in man
- CVMP has produced reflection papers on use in food producing animals of
  - Fluoroquinolones
  - 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins
  - Macrolides, lincosamides and streptogramins
  - Pleuromutilins (draft)
- “Healthy animals make safe food”





# Veterinary use of antimicrobials

- Outcomes
  - Recommendations on authorisation and use
  - Referrals of classes of antimicrobials classified at CIAs
    - Fluoroquinolones
    - 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins
  - Referrals on individual antimicrobials by Member States
  - Publication of ESVAC report has made use of antimicrobials transparent and stimulated measures to reduce inappropriate use in some Member States



# Advice to the European Commission

- Four questions asked with respect to the risks to man from the use of antimicrobials in veterinary medicine
    - Use of the antibiotics colistin and tigecycline which are used for MDR infections in man
    - Usefulness of classifying antimicrobials with respect to their use in man
    - Authorisation of new antimicrobials for veterinary use
    - Need for additional or alternative controls on use of currently authorised antimicrobials
  - AntiMicrobial Expert Group established with expertise from human and veterinary sectors
    - *Views of stakeholders will be sought*
    - *Answers will need to explore the extent to which use of antimicrobials in veterinary medicine has the potential to impact on human health*
  - Answer will assist the European Commission in deciding on appropriate risk management measures to apply
- 9 One Health –coordinating prudent use of antimicrobials in human and veterinary medicine



## Conclusions

- AMR is a high priority area for the EMA
- EMA adopts a 'One Health' approach but recognises the specific nature of the human and veterinary sectors
- Rapid progress made in the area of monitoring use of veterinary antimicrobials within the EU
- Action ongoing to promote prudent and responsible use of CIAs in veterinary medicine
- Preparation of advice to the European Commission as part of their 'Action Plan on Antimicrobial Resistance'