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

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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"

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
  - 3rd and 4th 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
    - 3rd and 4th 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
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’