Request for advice on the impact on public health and animal health of the use of antibiotics in animals

Animal Health Advisory Committee
22 March 2013

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Political commitments as to addressing AMR in the EU

- Resolutions EP: 12 May 2011 on antibiotic resistance and 27 October 2011 on the public health threat of antimicrobial resistance

- Council conclusions on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a "One Health" perspective – 22 June 2012

- Council Recommendation of 9 June 2009 on the prevention and control of health-care associated infections

Action plan against the rising threats from antimicrobial resistance
(COM (2011) 748) – 17 Nov 2011
The 12 actions

Human

1. Appropriate use
4. Prevention of infections
6. New antibiotics
9. Surveillance

Veterinary

2 & 3. Appropriate use
5. Prevention of infections
7. Need for new antibiotics
10. Surveillance
11. Research & Innovation
12. Communication, education

DG SANCO
Road map and progress report

- Publication integrated **road map** of the 5 years action plan, including the specific activities, operational objectives and the concrete deadlines.
- Publication by the end of 2013 of a **progress report** on the implementation of the 5 years action plan.
Action 2 & 3: Appropriate use of antimicrobials in veterinary medicines

Guidance document on recommendations for prudent use of antimicrobials

on-going DG SANCO activity in cooperation with Member States

- including examples from national actions as inspiration for other MS
- additionally to legal provisions
Action 2 & 3: Appropriate use of antimicrobials in veterinary medicines

- Strengthen the regulatory framework on veterinary medicines → Revision veterinary medicines legislation

- Incentives for new veterinary antimicrobials
- Cascade
- New and better legal tools for management of AMR
- Advertising
- Decoupling sales and prescription
- Monitoring sales
Action 2 & 3: Appropriate use antimicrobials in veterinary medicines

Use existing legal tools to ensure prudent use (on-going):

- updated priority list of CVMP
- initiate referrals by Commission
Actions 7: need of new veterinary antibiotics

- Promote efforts to analyse the need for new antibiotics into veterinary medicine

- Request for scientific advice from agencies to clarify in particular whether the development of new veterinarian antimicrobials would reduce/affect AMR

Request to EMA has been launched
Request for advice

- Request to EMA (February 2013)
- Divided in four parts
- Suggested dates for delivering: June 2013, June 2014, December 2014 and December 2014
- Implementing actions 2, 3 § 7 of Action Plan AMR
Terms of reference - advice

- 'Old' antibiotics
  - link between animal husbandry use and resistance in animals
  - possible impact of restricting the use as veterinary medicine on human health
- Ranking antibiotics according to their relative importance for human health
Terms of reference - advice

- New classes of veterinary antibiotics
  - impact of authorising new classes of veterinary antibiotics on human health
  - whether there is a need for restrictions

- Critically important antibiotics for humans
  - possibilities for risk mitigation options
Pharmaceuticals and Environment: *Human and veterinary medicinal products!*

**Council:** priority substances in the field of water policy

**Commission Report**
- Global analysis of the situation
- Legislative or non legislative actions (*pharma or other relevant EU legislation*)

**Process**
- Preparatory study by contractor ongoing
- Stakeholders were and will be consulted
- Report scheduled for end 2013
Thank you