EU policy to combat AMR: prudent use of antimicrobials

Dr. Koen Van Dyck
Head of Unit
SANCO G4: Food, Alert system and Training
DG Health and Consumers
European Commission
Outline

- Background
- EU policy against AMR: the 5 year action plan
- The specific actions on the food/veterinary field
  - Action 2&3: Appropriate use antimicrobials
  - Action 5: New Animal Health Law
  - Action 7: Need of new veterinary antibiotics?
  - Action 10: Surveillance systems in veterinary medicine
Some actions taken so far

- Ban on the use of AM for growth promotion (2006)
- Monitoring AMR and use of antimicrobials (EU agencies: EFSA, EMA, ECDC)
- International activities (TATFAR, Codex, OIE)
- Research

Scientific opinions, data on monitoring

*Not enough, further action needed!*
AMR - Public Health priority

Some data about AMR in Europe:

- 25,000 human deaths annually
- Cost EUR 1.5 billion (lost productivity, extra health care, etc)
- 4 million patients/year acquiring a healthcare associated infection

New strategy needed

Development of a new strategy to combat AMR based on:

- EC Staff working paper developed in 2009
- Public consultation
- Scientific advice of the EU Agencies (EMA, EFSA, ECDC)
Action plan against the rising threats from antimicrobial resistance

• 5 year action plan
• 7 key areas
• 12 concrete actions

Communication from the Commission to the European Parliament and the Council
Action plan against the rising threats from Antimicrobial Resistance

DG SANCO
The overall aims of the 5-year action plan

- To combat the rising threats from AMR → reinforcing the actual measures and setting a new set of rigorous measures:
  - To reduce and prevent spread of AMR
  - To preserve the ability to combat microbial infections
- Holistic / global approach (human+veterinary/food) → in line with “One Health” principle
- Ex-post evaluation
The 7 areas where action is needed

- **Appropriate use** of antimicrobials (humans and animals)
- **Prevention** microbial infections and their spread
- Development **new effective antimicrobials** or **alternatives** for treatment
- Improvement monitoring and **surveillance** (human and animal medicine)
- Cooperation with **international** partners to contain the risks of AMR
- Promotion **research** and innovation
- Improvement **communication**, education and training
Action 2 & 3: Appropriate use of antimicrobials in veterinary medicine (1/4)

- Reduction of overall use of antimicrobials → “Cornerstone” of the new policy
  - use only if necessary
  - better targeted treatments
  - according to best practices

- Increasing concern on use of antimicrobials in vet. sector: 3rd and 4th generation cephalosporins
  - WHO → critically important antibiotics for humans
  - EFSA opinion → stop/restriction use as a highly effective control option to control AMR
  - EMA reflection paper → better alternatives
Action 2 & 3: Appropriate use antimicrobials in veterinary medicine (2/4)

Legislative tools:

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

  - To provide incentives for the development and marketing of new medicines
  - To improve the operation of the cascade (restriction off-label use)
  - consider restrictions of certain new or CIAs (to contribute towards the management of antimicrobial resistance)
Action 2 & 3: Appropriate use of antimicrobials in veterinary medicines (3/4)

- **Revision Medicated feed legislation** → Strengthen the regulatory framework on medicated feed
  - avoid misuse of AMs
  - avoid carry-over of AMs into non-target animal feed
- Use **existing legal tools** to ensure prudent use:
  - Initiate referrals
- Require **scientific advice** agencies (EMA, EFSA, ECDC)
Action 2 & 3: Appropriate use antimicrobials in veterinary medicines (4/4)

Additionally to legal provisions

- Guidance document on recommendations and practical guidance for prudent use of antimicrobials in veterinary medicine
  - including examples
  - only part of an overall strategy on AMR (need to be supplemented by other actions EC action plan: authorisation policy on antimicrobials, research activities, etc.)
Action 5: New Animal Health Law

Scope:

- A single, comprehensive, simplified and transparent legal framework for animal health → Prevention of microbial infections and their spread

Prevention disease → Reduction infections → Reduction need for AM

“Prevention is better than cure”

- Improvement of animal health and bio security measures
- Promotion of Good Farming Practices
- Legal framework for AMR pathogens
Actions 7: Need of new veterinary antibiotics?

- Promote efforts to analyse the need for new antibiotics into veterinary medicine and its repercussion on AMR.

- Request for scientific advice from agencies (EMA) to clarify in particular whether the development of new veterinarian antimicrobials (or new uses) would reduce/affect AMR.
Action 10: Surveillance systems in veterinary medicine (1/5)

- Surveillance and monitoring should provide data about:
  - resistant bacteria (animal, food, environment, human)
  - use or consumption of antimicrobials

- Harmonised (= comparable) data is the key to:
  - Greater understanding of epidemiology, origin, transmission, spread AMR
  - Risk assessment
  - Risk management decisions
  - Evaluation of the measures taken
Action 10: Surveillance systems in veterinary medicine (2/5)

- Monitoring Consumption of AM → ESVAC (European Surveillance on Veterinary Antimicrobial Consumption)

EU Agency → EMA
Second ESVAC report published on 15-10-2012
Action 10: Surveillance systems in veterinary medicine (3/5)

- Monitoring AMR in animals/food
  - Monitoring at EU-level in place since 2003
  - Review of the monitoring of AMR in zoonotic bacteria and indicators in all MS → better harmonization human/vet, MS

- Publication 3 EFSA reports including technical specifications on the harmonised monitoring and reporting of antimicrobial resistance
- Publication other scientific opinions on risk assessment AMR
Action 10: Surveillance systems in veterinary medicine (4/5)

- Legislative framework for harmonized Monitoring AMR in food/animals in EU → on going (into force 2014)
  - *Salmonella*, *Campylobacter* and indicator *E. coli* (and enterococci)
  - Certain animal populations/food
  - Specific monitoring MRSA and ESBL/AmpC/carbapenemase producing bacteria
  - Allows comparison with resistance in humans
Action 10: Surveillance systems in veterinary medicine (5/5)

- data of the surveillance/monitoring system
- At request European Commission
- Joint report 3 agencies (ECDC/EFSA/EMA) on the analysis of the relationship between consumption of antimicrobial agents and the occurrence of AMR
Future

- Progress report by end 2013
- AMR Road map available on EU Commission website
Thank you for your attention!

http://ec.europa.eu/food/food/biosafety/antimicrobial_resistance/index_en.htm

Acknowledgement: Rosa Peran, Kris De Smet

DG SANCO