



# **Veterinary antimicrobials: state of play and future developments**

**2013 European Medicines Agency/IFAH-  
Europe Info Day  
7-8 March 2013**

**Mario Nagtzaam, SANCO D6**

## 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
- **EP Report on the Microbial Challenges – Rising Threats from AMR (2012/2041 (INI)) – adopted 11 December 2012**

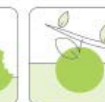
# Action plan against the rising threats from antimicrobial resistance

((COM (2011) 748) – 17 Nov 2011

Communication from the Commission to  
the European Parliament and the Council

Action plan against the rising threats from Antimicrobial  
Resistance

COM (2011) 748



# Action plan against the rising threats from antimicrobial resistance

Key areas:

- Appropriate use of antimicrobials
- Prevent microbial infections and their spread
- Develop new effective antimicrobials or alternatives for treatment
- Joining forces with international partners to contain the risks of spreading AMR from international trade and travel and via environment

# The 12 actions

Human

Veterinary

1. Appropriate use

4. Prevention of infections

6. New antibiotics

9. Surveillance

8. International cooperation

11. Research & Innovation

12. Communication, education

2 & 3. Appropriate use

5. Prevention of infections

7. Need for new antibiotics

10. Surveillance

## Action 2 & 3: Appropriate use 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 antimicrobials in veterinary medicines

- Strengthen the regulatory framework on veterinary medicines → Revision vet. medicines legislation  
**on-going DG SANCO activity**
  - 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

- Strengthen the regulatory framework on medicated feed  
Revision Medicated feed legislation  
on-going
  - avoid misuse of AMs
  - avoid carry-over of AMs into non-target animal feed
- Use existing legal tools to ensure prudent use (on-going):
  - updated priority list of CVMP
  - initiate referrals by Commission
- Require scientific advice agencies



## 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 → dead line 2014

## Request for advice

- Request to EMA (February 2013)
- Divided in four parts
- Three suggested dates for delivering: June 2013, June 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

## Action 5: New Animal Health Law

- A single, comprehensive, simplified and transparent legal framework for animal health  
On-going → final proposal by 2013
  - scope: transmissible diseases in animals
  - including zoonotic agents (direct contact)
  - more preventive driven approach (infection prevention)
  - providing legal framework for measures in relation to antimicrobial resistant pathogens (surveillance, eradication, control measures, etc.)

## Action 8: International cooperation

- O.I.E. → Chapter on Risk analysis assessment for antimicrobial resistance arising from the use of antimicrobial agents in animals  
Conference OIE March 2013
- WHO-EURO → bilateral contacts and participation in meetings
- TATFAR → TC USA-EU 11-12-2012, face to face meeting 2013 and follow up report by 2013
- Bilateral collaboration with other countries:
  - China → Human/veterinarian symposia March 2013
  - EU: DG SANCO (C3, G4), EFSA, EMA, ECDC
  - China: MoA, MoH
  - International: WHO, OIE

# Action 10: surveillance systems in veterinary medicine

## ■ Monitoring Consumption of antimicrobials → ESVAC (European Surveillance on Veterinary Antimicrobial Consumption)

Second ESVAC report published by EMA on 15-10-2012

- Sales data 2012
- Harmonized data from 19 EU/EEA countries
- 15 MS with national legal basis to report
- Sales data normalized against the animal population (focus: food-producing)

# Action 10: surveillance systems in veterinary medicine

- **Monitoring AMR in animals/food** → Review of the monitoring of AMR in zoonotic bacteria and indicators in all MS
  - request scientific advice EFSA
  - publication 3 reports including technical specifications on the harmonised monitoring and reporting of antimicrobial resistance



# Action 10: surveillance systems in veterinary medicine

- Legislative framework for harmonized Monitoring AMR in food/animals in EU → *draft Decision*

**On-going → Agenda point 2**

- Based scientific advice EFSA
- Salmonella, Campylobacter and indicator E. coli
- Certain animal populations/food
- Specific monitoring MRSA and ESBL/AmpC producing bacteria
- Allows comparison with resistance in humans

# 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.

# Something concerning antimicrobials and other veterinary medicines

# 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

