



EU Action Plan to combat the rising threats from Antimicrobial Resistance: State of play

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Communication from the Commission to the European Parliament and the Council

Action plan against the rising threats from Antimicrobial Resistance

COM (2011) 748

















AMR a public health priority!

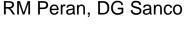
COM (2011) 748 - 17 Nov 2011

- 5 year action plan
- Holistic approach
- 7 key areas
- 12 concrete actions



The 7 areas in 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





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:

Appriopriate use of antimicrobials in veterinary medicine



a) Strengthen the regulatory framework on veterinary medicines and medicated feed

Revision legislation on veterinary medicinal products

On 10 September 2014 the Commission adopted a proposal on veterinary medicines

The proposal gives new regulatory tools to the Commission and Member States to reduce the risks to human and animal health of the use of antimicrobials in animals



Addressing antimicrobial resistance

- Promoting prudent use:
 - restriction off-label use
 - supply and advertising
- Comprehensive evaluation of new marketing autorisation applications
- Ensuring that risk-benefit balance remains favourable of authorised antimicrobials
- Providing legal tool for preserving critical antimicrobials for the treatment of human infections
- Establishing an effective and harmonised monitoring system of veterinary antimicrobials



b) Strengthen the regulatory framework on medicated feed → Revision medicated feed legislation On 10 September 2014 the Commission adopted a proposal on medicated feed

- avoid carry-over of AMs into non-target animal feed
- Medicated feed containing AM: use no allowed to prevent diseases

c) Use existing legal tools to ensure prudent use:

• Initiate evaluation of antimicrobials on the market (referrals): colistin and updated priority list of EMA

d) Guidance document on prudent use vet. antimicrobials:

Complementing other actions: legal tools, research



Action 5:

Prevention of microbial infections and their spread (animal health)



EU Regulation on Animal Health

- Scope: Prevention and control of transmissible diseases (microbial ones, certain zoonotic)
- Preventive driven approach: improvement animal health and biosecurity measures, good farming practices
- With clear responsibility for all players for animal health
- Prioritising EU intervention
 - Different disease preventive and control measures may apply (surveillance, eradication, other control measures)
 - -Legal basis monitoring AMR in animal pathogens (technical advice EFSA needed)

"Prevention is better than cure"



Action 7:

Need for new antimicrobials vet. medicine



Mandate from the Commission to EMA:

- Advice on 'old' antibiotics or new antibiotics belonging to 'old' classes of antibiotics that have been re-introduced or have a new use to treat multi-resistant bacteria in humans, in particular colistin and tigecycline. EMA should consider in particular:
- a) Possible links between the use of those substances in animals (where relevant) and resistance in bacteria of animal origin;
- b) The impact of use of those substances or other related antibiotics in animals on human health and whether restricting or not their use as veterinary medicines would have an impact on the development of reciptance in bacteria causing infections in



EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director General

Brussels, SANCO/MN/sl/ddg1.d.6(2012)8317

Dear Professor G. Rasi,

Subject: Request for advice on the impact on public health and animal health of the

use of antibiotics in animals

ranked according to their relative particular considering whether these affections in humans in the EU. The g work of the WHO on critical es, disadvantages and feasibility of econd line or last resort antibiotics.

the treatment of resistant bacteria in new classes of veterinary antibiotics, use in animals of certain new classes lly those that are important in human stressed that the advice could discuss nent of resistance in animals) or a velopment of resistance in humans).

natives], including an assessment of in classes of antibiotics or antibiotic

DG Sanco substances that are of critical important in human medicine and are currently authorised as veterinary medicinal products.



Action 8:

International cooperation



■ WHO HQ: Global Action Plan (GAP) on Antimicrobial Resistance

WHA (24th May 2014): Resolution AMR (WHA67.25)

Public Consultation Outline GAP (1st Sept. 2014)

Draft GAP published October 2014:

- Informal MS Consultation (16th Oct. 2014; WHO-HQ, Geneva)
- STAG-group (17th Oct. 2014)

Supporting conferences/meetings:

Netherlands: Min. Conference AMR (25-26th June)

Norway: Surveillance use (13-14th November)

Sweden: Surveillance resistance(2-3 December)

Brazil: R&I (January-February 2014)



FAO

- 24th COAG:
 - The Global Agenda for Sustainable Livestock FAO's Strategy for Improving Food Safety Globally
- WHO-Europe → Bilateral contacts and joint actions/meetings, participation member countries workshop/training
- O.I.E. → Gral. Session May 2014 (Chapter 6.10) Ad hoc group AMR (monitoring use AM) Chapter 6.5 Risk Analysis for AMR arising from the use of antimicrobial agents in aquatic animals



OECD (Organisation for Economic Co-operation and Development)

Health Division/Health Committee

Program 2015-16

Study on the economic and health impact of AMR

Agricultural Division/Committe for Agriculture

Working party on Agricultural policies and market 18-20 Nov. 2014 (Paris)

Agenda Item 6.

Global antimicrobial use in the livestock sector

TAD/CA/APM/WP(2014)34

Conference AMR (2015)



Bilateral collaboration:

- TATFAR (EU-US) →
 - * Progress report published 13th May 2014
 - * New additional recommendation 18: Establish a joint working group to identify key knowledge gaps in understanding the transmission to man of AMR arising of use of AM in animals and on the development of effective intervention measures to prevent transmission, incl. development of alternatives to AM.
 - * US Strategy AMR published 18th September 2014
- China → study in the public health sector (China-EU policy)



Action 10:

Surveillance systems (veterinary medicine)



a) Monitoring Consumption of AM \rightarrow ESVAC

European Surveillance Veterinary Antimicrobial Consumption

Conclusions 4th ESVAC report (15/10/2014)

(Data for 2012: 26 EU/EEA countries)

15% DECREASE IN SALES OF VET. MEDICINES 2010-2012

(18/20 countries)

Collection data by species →
 start pilot project pigs: testing phase
 5 farms/9 MS

Units of measurement → 2015
 Guidelines on how to assign technical units of measurement (DDD)





b) Monitoring AMR in animals/food

Decision on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria (2013/652/EU) → into force 2014

- Based scientific advice EFSA
- Certain animal populations/food
- Zoonotic bacteria and indicators: better harmonization and comparability
 - Member States
 - Allows comparison with resistance in humans
- Monitoring ESBL/AmpC/carbapenemase-producing bacteria
 → EURL protocol (2015)
 Validation + Expert meeting for endorsement
 Training by EURL (all NRL + 3rd countries)



Data of the surveillance/monitoring systems in human and veterinary medicine



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

DECEMBER 2014





Action 12:

Communication, education, training



- **BTSF** 2015-16 → AMR training
- **EURL-AR**Training National Ref. Labs (EU and selected 3rd countries)
- European Antibiotic Awareness Day 2014 Self medication Stockholm, 17 November 2014, ECDC Participation of Copa Cocega /FVE
- Road map http://ec.europa.eu/dgs/health-consumer/docs/road-map-amr-en.pdf



Progress delivered in Europe based on the Action plan

- Effective actions based on consolidated surveillance systems have strengthened the appropriate use of antimicrobials
- The prudent use of antimicrobials is being actively encouraged and pursued
- The sales of both human and veterinary antimicrobials are regulated and require responsible health expertise
- Research on antimicrobial resistance is boosted and transnational research is better coordinated
- Public-private partnerships are investing in the development of new antimicrobials
- AMR in the international agenda: WHO, OIE, OECD, GHSA
 RM Peran, DG Sanco



Thank you for your attention!



http://ec.europa.eu/health/antimicrobial resistance/policy/index en.htm

http://ec.europa.eu/food/biosafety/antimicrobial resistance/index en.htm