


European Commission



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

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Coordination Action Plan against AMR
Workshop EURL-AMR
Lyngby, 23-24 April 2015


European Commission


Directorate-General for Health & Consumers

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

AMR a public health priority!

COM (2011) 748 – 17 Nov 2011

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




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Political commitments in the EU

- Council Recommendation of 9 June 2009 on the prevention and control of health-care associated infections
- 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 (DK)
- EP Report on the Microbial Challenges – Rising Threats from AMR (2012/2041 (INI)) – 11 December 2012
- Council Conclusions on Patient Safety, Healthcare associated infections and AMR – 1 December 2014


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The 12 actions

Human	Veterinary
1. Appropriate use	2 & 3. Appropriate use
4. Prevention of infections	5. Prevention of infections
6. New antibiotics	7. Need for new antibiotics
9. Surveillance	10. Surveillance
8. International cooperation	
11. Research & Innovation	
12. Communication, education	

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Action 2 & 3: Prudent use of antimicrobials in veterinary medicine

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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

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Revision EU-law on veterinary medicines and medicated feed

- Promoting prudent use:
 - restriction off-label use
 - limiting supply and advertising
- Comprehensive evaluation of new marketing authorisation applications and re-evaluating authorised antimicrobials
- Providing legal tool for preserving critical antimicrobials only for the treatment of human infections
- Establishing harmonised monitoring of use of veterinary antimicrobials
- Medicated feed containing AM: not allowed to prevent disease

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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 not 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

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Action 5:

Prevention of microbial infections and their spread (animal health)

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EU Regulation on Animal Health: "Prevention is better than cure"

Commission Proposal adopted 6 May 2013 → ordinary legislative procedure.

- **European Parliament** adopted a resolution on its first reading position on 15 April 2014, confirmed it after elections in September 2014
- **Council** agreed its position in December 2014
- **Trilogues** started in February 2015

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Action 7:

Need for new antimicrobials vet. medicine

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- Analyse the need for new antibiotics into veterinary medicine and its repercussion on AMR
 - Request for scientific advice: Will the use of new types of veterinary antimicrobials reduce the development of resistance in animals and humans?
 - **Published: December 2014**

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Mandate from the Commission to EMA:

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Director General

Rosevelt,
SANCO/MN-044q1.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

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1. Advise on the antibiotics or new antibiotics belonging to the 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 in veterinary medicines would have an impact on the development of resistance in bacteria causing infections in humans.

ranked according to their relative particular considering whether these decisions in humans in the EU. The work of the WHO on critical use, disadvantages and feasibility of reuse use or just reuse antibiotics.

the treatment of resistant bacteria in any classes of veterinary antibiotics, for in animals of certain use classes by those that are important in human health that the advice could decrease use of resistance in animals) or a judgment of resistance in humans).

advice) including an assessment of substances that are of critical importance in classes of antibiotics or antibiotic substances in veterinary medicinal products.

Action 8:

International cooperation

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Multilateral:

WHO, OIE, FAO, Codex
OECD



Bilateral:

U.S.A (TATFAR)
China (MoH and MoA)



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World Health Organization
Food and Agriculture Organization of the United Nations

Antimicrobial resistance
Develop global action plan on antimicrobial resistance
Report by the Secretariat

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Action 10:

Surveillance systems (veterinary medicine)

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a) Monitoring Consumption of AM → 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

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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

- Co-financing
- FVO inspections implementation Decision 2013/652/EU as from September 2015



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
30 JANUARY 2014

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Action 12:

Communication, education, training

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- **BTSF**
2015-16 → AMR training
- **EURL-AR**
Training National Ref. Labs (EU and selected 3rd countries)
- **Progress report** on the implementation of the 5 years action plan (11 March 2015)
- **Road map** (updated 17-03-2015)
- **Ex-post evaluation** (initiating procedure)

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Progress delivered in Europe based on the Action plan

- Consolidated **surveillance** systems: consumption /resistance
- 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, (prescription only!)
- **Research** on AMR: boosted and better coordinated
- Public-private partnerships are investing in the **development of new antimicrobials**
- **AMR in the international agenda:** WHO, OIE, OECD, GHSA

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Thank you for your attention!



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

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