EC actions against the rising threats from Antimicrobial Resistance

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According to data from 2011, **25 000 patients die annually** as a result of infections caused by resistant bacteria in the EU. The costs incurred by drug resistant infections amount to an estimated **€1.5 billion** annually, due to increases in healthcare expenditure costs and productivity losses.
AMR a public health priority

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 is a major European and global societal problem

Decision-makers

- European Commission
- European Parliament
- Council of the European Union

Guidelines, technical reports, scientific advice, recommendations

Scientific advice

- Committees
  - CHMP
  - CVMP
  - ESVAC

- Networks
  - EARS-Net
  - ESAC-Net
  - SCENIHR

Guidelines, reports

International organisations

- World Health Organization
- Codex Alimentarius
- Food and Agriculture Organization of the United Nations
- World Organisation for Animal Health
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!

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

8. International cooperation
11. Research & Innovation
12. Communication, education
A. Appropriate use of antimicrobials

Action nº1: Strengthen the promotion of the appropriate use of antimicrobials in human medicine in all Member States

- Support the implementation of Council Recommendation 2002/77/EC
  - ARNA project (launched in 2012): key factors that drive sales and non-prudent use of antibiotics in human medicine
  - Consultation with MSs on implementation
  - ARPEC project: identify specific antibiotics used in primary care/hospitals for common infections and AMR patterns

- Stimulate appropriate use on AM in human medicines
  - Workshop "Best use of medicines legislation to bring new antibiotics to patients and combat resistance problems"

- Research on improving appropriate use of AM
  - Funded under the 7th Framework programme: GRACE and APRES

Milestones / Deadlines

- Results 2016
- End 2015
- Completed
- Completed
- Completed

Glossary

ARNA: "Antimicrobial resistance and causes of non-prudent use of antibiotics in human medicine"
ARPEC: "Antimicrobial Resistance and Prescribing in European Children"
GRACE: "Genomics to combat Resistance against antibiotics in Community acquired low respiratory tract infections in Europe"
APRES: " The Appropriateness of Prescribing antibiotics in primary health care in Europe with respect to antibiotic resistance"
A. Appropriate use of antimicrobials

Action nº2: Strengthen the regulatory framework on veterinary medicines and on medicated feed

- Revision of the Veterinary Medicines Legislation
  - Scientific risk-benefit analysis for granting of **marketing authorisations for veterinary antimicrobials**, the prudent **use of antimicrobials**, a legal tool to **preserve** certain antimicrobials for human use and a requirement to gather information on the **use of veterinary antimicrobials**

- Revision of the Medicated Feed Legislation
  - Provides a **prohibition on the preventive use** of antimicrobials included in medicated feed;
  - measures to increase the quality of medicated feed (**more precise dosage**) to avoid sub-therapeutic exposure and establishes **thresholds for residual levels** of antimicrobials in ordinary compound feed

- Verify implementation of prudent use measures
  - FVO questionnaire to MSs
A. Appropriate use of antimicrobials

Action nº3: Introduce recommendations for prudent use in veterinary medicine (1/2)

- Use existing legal tools
  - Publication of Commission decisions (SPC), Reflection Papers and associated recommendations (EMA)
  - Initiate referrals on veterinary medicines products
  - Completed
  - Completed

- Scientific recommendations on use in veterinary sector of last resort antimicrobials for humans
  - Advice on last resort antimicrobials
  - Colistin
  - Completed
A. Appropriate use of antimicrobials

Action nº3: Introduce recommendations for prudent use in veterinary medicine (2/2)

- Reduce overall use of AM in veterinary medicine

**Milestones / Deadlines**

- **Completed**
B. Prevent microbial infections & spread

Action nº4: Strengthen infection prevention and control in healthcare settings

- Support the implementation of Council Recommendation 2009/C 151/01
  - EC reports on *implementation* of the Council recommendation
  - Support priority areas such as Health Associated Infections (HAI) through the Health Programme
  - HAI are included in the New Decision on serious cross border health threats
  - Foster with ECDC the development of guidance on infection prevention and control, strengthening of HAI surveillance (HAI-Net) and development of training curricula for HCP

Milestones / Deadlines

- 2012 & 2014
- Call in 2014
- Several guidance reports published
B. Prevent microbial infections & spread

Action nº5: Adoption of a proposal for an EU Animal Health Law

- Animal Health legal framework based on "Prevention is better than cure"
  - Animal Health Law proposal for a regulation lays down responsibilities on:
    - operators to ensure the required level of animal health and biosecurity;
    - veterinary professionals to adopt effective measures to prevent the spread of pathogens and to raise awareness;
    - competent authorities to protect animal health, human health and the environment;
  - Proposal provides for an assessment, prioritisation and categorisation of diseases or disease agents
  - Proposal clarifies obligations to ensure appropriate monitoring, surveillance and early detection of pathogens

Milestones / Deadlines
- Agreement on June 2015
C. Develop new effective AM or alternatives for treatment

Action n°6: Promote unprecedented collaborative research (1/2)

- Reactivate R&D by Industry for new antibiotics and related issues – Innovative Medicines Initiative
  - IMI is a PPP between the EC and EFPIA already in its 11th call for proposals
  - Launch of large "New Drugs 4 Bad Bugs" project with a budget of over €600 million
- EC and EIB launched a financing facility to target Infectious Diseases (risk-adapted loans)
C. Develop new effective AM or alternatives for treatment

Action nº6: Promote unprecedented collaborative research (2/2)

- Increase efficiency of marketing authorisation process
  - EMA updated guidance to companies developing antibiotics which addresses how they should carry out studies to test these medicines' benefits and risks
  - EMA addendum on how to study medicines for the most common indications and existing options for clinical development of antibacterial agents, in particular for multi-drug resistant pathogens

Milestones / Deadlines

- End 2015
- Completed
C. Develop new effective AM or alternatives for treatment

**Action nº7: Promote efforts to analyse need for new antibiotics into veterinary medicine**

- Facilitate the **use of alternatives** that reduce need for treatment with AM
  - Proposal on veterinary medicinal products provides incentives for the development of new types of veterinary antimicrobials
- EC request to EFSA and EMA to evaluate **impact of measures** on the reduction of Need for Antimicrobials in Food-producing Animals

**Milestones / Deadlines**
- Proposal
  - Sept 2014
- End
  - 2016
D. Join forces with international partners

Action nº8: Develop and / or strengthen multilateral and bilateral commitments for the prevention and control of AMR

- Maintain and deepen EU/US cooperation
  - Implement 18 recommendations from TATFAR
  - Bi-annual TATFAR conference meetings
- World Health Organisation
- OIE & FAO
- Bilateral cooperation

- May 2014
- 2012
E. Monitoring and surveillance

**Action nº9: Strengthen surveillance systems on AMR and antimicrobial consumption in human medicine**

- **Sustainability of the ESAC-Net**
  - Transfer to ECDC of the ESAC-Net
  - Publication of ESAC reports, EARS-Net reports and Europe-wide point prevalence surveys in HAI
  - Implementation of the newly adopted measures on new case definitions for antimicrobial resistance and healthcare-associated infections

**Milestones / Deadlines**

- **2012**
  - Monitoring by end 2015
E. Monitoring and surveillance

**Action nº10: Strengthen surveillance systems on AMR and antimicrobial consumption in animal medicine**

- Harmonised surveillance systems
  - **ESVAC** project collects and analyses national sales from MSs
  - Harmonisation of surveillance and monitoring of AMR in the food chain
    - Decision 2013/652/EU on harmonised monitoring and reporting on antimicrobial resistance in the food chain in the EU
    - Decision 2013/653/EU on financial aid towards a coordinated control plan for AMR monitoring

- Surveillance and monitoring in the Animal Health Law proposal

- EFSA, EMA and ECDC combined information
  - First Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) Report

**Milestones / Deadlines**

- 2013
- Completed
- Completed
F. Additional Research and Innovation

Action nº11: Reinforce and co-ordinate research efforts.

Innovation.

- Reinforce AMR research in a coordinated fashion
  - Projects respond to the following calls:
    - Antimicrobial transfer throughout the food chain
    - Antimicrobial resistance in farming and animal production
    - Development of diagnostic tools for infectious diseases
    - Mobilise Small and medium enterprise (SME) to develop new antimicrobials and vaccines
    - Research to the use of antimicrobials via personalised approaches
    - Developing novel nanotechnology enabled therapies for bacterial infectious diseases
    - Support the Joint Programming Initiative (JPI) on Antimicrobial Resistance (AMR)
    - Contribute to a global mapping of drug resistance
    - Foster Innovation-Focus group on reduction of antimicrobials in pig production
G. Communication, education and training

Action nº12: Survey and comparative effectiveness research

- Assess and improve impact of EU awareness and communication activities
  - European Antibiotic Awareness Day (EEAD) evaluation report
  - Completed
- Monitor evolution of behaviour on AMR
  - Eurobarometer survey presented at the EEAD 2013
  - Completed
- Conference on antimicrobial resistance 2013
  - Completed
- Inform about progress and evaluate impact
  - AMR progress report
  - Completed
  - Ex-post evaluation (roadmap)
  - Mid 2016
Concluding remarks

- AMR remain a top priority for European Commission to lead at EU and global level
- Ongoing evaluation of the EC Action Plan – basis to decide on the follow-up
Thank you for your attention