

Microbial challenge - rising threats from antimicrobial resistance

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PURPOSE: to establish an action plan against the rising threats from Antimicrobial Resistance (AMR).

BACKGROUND: since the introduction of penicillin in the 1940s antimicrobial medicines, such as antibiotics, have become essential for the treatment of many microbial infections in humans and animals. In addition to the treatment of infectious diseases (e.g. pneumonia, tuberculosis, malaria, HIV/AIDS) and hospital-acquired infections (e.g. methicilin resistant *Staphylococcus aureus* (MRSA), antimicrobials are vital for reducing the risk of complications in relation to complex medical interventions, such as hip replacements, organ transplants, cancer chemotherapy and the care of premature babies. In addition, antimicrobials are used in veterinary medicine and for non-therapeutic purposes (e.g. disinfectants, preservatives, and food and feed additives).

Seventy years later, these applications are now seriously **jeopardized by the emergence and spread of microbes that are resistant** to affordable and effective firstchoice, or "first-line" medicines, rendering the drugs concerned ineffective for the treatment of the infection. This resistance is a natural biological phenomenon but is amplified by a variety of factors. The inappropriate use of therapeutic antimicrobials in human and veterinary medicine, the use of antimicrobials for non-therapeutic purposes as well as the pollution of the environment by antimicrobials is accelerating the emergence and spread of resistant microorganisms. The consequences are severe.

The Commission recall that a subset of drug-resistant bacteria is responsible for about 25 000 human deaths annually. In addition to avoidable death, this also translates into extra healthcare costs and productivity losses of at least EUR 1.5 billion.

For their part, the Council and the European Parliament have already examined this issue and on **12May 2011** the **European Parliament** adopted a [non-legislative resolution](#) on antibiotic resistance in which it stresses that AMR has become a huge issue in recent years. To cope with this growing problem and the consequent treatment failures, the EP calls on the Commission to establish an EU-wide plan to combat AMR.

This Communication responds to this request.

CONTENT: in this regard, the Commission has taken a number of important actions:

- in the field of human medicine, the 2001 Community Strategy against AMR called for EU actions against AMR in the fields of surveillance, research, prevention and international cooperation. This led to the adoption of EU wide recommendations and guidelines against AMR;
- in animal husbandry, the ban on the use of antimicrobials for growth promotion was introduced in 2006. The Commission has developed legislation on the control of Salmonella at all relevant stages of production, processing and distribution in order to reduce the exposure of humans to potentially resistant Salmonella;
- in the field of veterinary medicine, the emphasis has been in monitoring zoonotic AMR (i.e. resistance transmissible between animals and humans) and on the use of antimicrobials in animals;
- the authorisation requirements of human and veterinary medicines and other products, such as food enzymes, probiotics and decontamination agents, with possible effects on development of AMR have also been the focus areas;
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AMR is the subject of research funded under the Seventh Framework Programme (FP7) and the Innovative Medicines Initiative (IMI). AMR is also the subject of a proposed Joint Programming Initiative (JPI), which aim to coordinate research activities among EU Member States;

- scientific opinions on AMR by EU Risk Assessment bodies i.e. the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) have formed the basis for policy planning, for example, development of new antimicrobials and monitoring AMR and antimicrobial usage.

Based on such holistic approach, the new actions put forward in this Action Plan aim at:

1. mitigating the risk of developing AMR in humans from the **use** of antimicrobials both in humans and animals by effectively ensuring across the EU their appropriate use, and promoting **microbiological diagnosis** as the means to determine, to the extent possible, the need for antimicrobials;
2. putting in place effective ways to **prevent microbial infections** and their spread;
3. developing effective antimicrobials or alternatives for treatment of human and animal infections;
4. joining forces with **international partners** to contain the risks of spreading AMR from international trade and travel and via the environment;
5. reinforcing **research** to develop the scientific basis and innovative means to combat AMR.

The Commission proposes to put in place a 5-year Action Plan to fight against AMR based on 12 key actions:

- **Action n° 1:** Strengthen the promotion of the appropriate use of antimicrobials in all Member States.
- **Action n° 2:** Strengthen the regulatory framework on veterinary medicines and on medicated feed.
- **Action n° 3:** Introduce recommendations for prudent use in veterinary medicine, including follow-up reports.
- **Action n° 4:** Strengthen infection prevention and control in healthcare settings.
- **Action n° 5:** Introduce of a legal tool to enhance prevention and control of infections in animals in the new Animal Health Law.
- **Action n° 6:** Promote, in a staged approach, unprecedented collaborative research and development efforts to bring new antimicrobials to patients.
- **Action n° 7:** Promote efforts to analyse the need for new antibiotics into veterinary medicine.
- **Action n° 8:** Develop and/or strengthen multilateral and bilateral commitments for the prevention and control of AMR in all sectors.
- **Action n° 9:** Strengthen surveillance systems on AMR and antimicrobial consumption in human medicine.
- **Action n° 10:** Strengthen surveillance systems on AMR and antimicrobial consumption in animal medicine.
- **Action n° 11:** Reinforce and co-ordinate research efforts.
- **Action n° 12:** Survey and comparative effectiveness research.

Several Member States have been pro-active in carrying out actions related to those considered at EU level. These actions at national level and the experience gained from it should be the basis of the practical development and implementation of this Action Plan.