

THE NEW EU ONE HEALTH ACTION PLAN AGAINST ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) presents a serious social and economic burden. It is estimated to be responsible for **25,000 deaths per year in the EU** alone and **700,000 deaths per year globally**. AMR also pushes up the cost of treatment and diminishes productivity due to illness: in the EU alone it is estimated that AMR costs **EUR 1.5 billion annually**. AMR also threatens the achievement of several of the United Nations' Sustainable Development Goals, particularly the targets for good health and well-being.

In the face of regional and global AMR challenges, **the EU stands at the forefront for addressing AMR**. However, no single action will, in isolation, provide an adequate solution. Resistant bacteria and infectious diseases do not respect borders. No individual Member State or the EU can tackle the problem on its own. The EU is nevertheless in a strong position to act given its commitment to a high level of human health protection.

The EU was quick to recognise the importance of tackling AMR, as the **2001 Community strategy** against AMR shows. This policy was reinforced with the **2011 Commission action plan**, notable for its One Health approach, addressing AMR in both humans and animals. **A new and comprehensive EU action plan on AMR** was requested by the Member States in the **Council conclusions** of 17 June 2016. It builds on the 2011 action plan, its **evaluation**,

One Health: is a term used to describe a principle which recognises that human and animal health are interconnected, that diseases are transmitted from humans to animals and vice versa and must therefore be tackled in both. It also encompasses the environment, another link between humans and animals and likewise a potential source of new resistant microorganisms.

the feedback received on a European Commission **roadmap** on AMR and an **open public consultation**.

This **new One Health action plan against AMR** will support the EU and its Member States in delivering **innovative**,

effective and sustainable responses to AMR; strategically reinforce the research agenda on AMR and enable the EU to actively promote global action and play a leading role in the fight against AMR. Its **overarching goal is to preserve the possibility of effective treatment of infections in humans and animals**. It provides a **framework for continued, more**

Antimicrobials: include antibiotics, antivirals, antifungals and antiparasitics. They are active substances of synthetic or natural origin which kill or inhibit the growth of microorganisms. Used in everyday medicine (e.g. urinary tract infections, surgery and care of premature babies), they are vital to preventing and treating infections in humans and animals.

Antimicrobial resistance (AMR): is the ability of microorganisms, such as bacteria, to become increasingly resistant to an antimicrobial to which they were previously susceptible. AMR is a consequence of natural selection and genetic mutation. Such mutation is then passed on conferring resistance. This natural selection process is exacerbated by human factors such as inappropriate use of antimicrobials in human and veterinary medicine, poor hygiene conditions and practices in healthcare settings or in the food chain facilitating the transmission of resistant microorganisms. Over time, this makes antimicrobials less effective and ultimately useless.

extensive action to reduce the emergence and spread of AMR and to increase the development and availability of **new effective antimicrobials** inside and outside the EU.

The **key objectives** of this new plan are built on three main pillars:

1. **Making the EU a best practice region**
2. **Boosting research, development and innovation**
3. **Shaping the global agenda**

The new plan contains **concrete actions with EU added value** that the Commission will develop and strengthen as appropriate in the coming years for a more integrated, comprehensive and effective approach to combating AMR. All these actions are important in themselves, but they are also interdependent and need to be implemented in parallel in order to achieve the best outcome.



1. MAKING THE EU A BEST PRACTICE REGION

Better evidence and awareness of the challenges of AMR

Strengthen One Health surveillance and reporting of AMR and antimicrobial use

- ◆ Review EU implementing legislation on **monitoring AMR in zoonotic and commensal bacteria in farm animals and food**;
- ◆ Review EU implementing legislation on **reporting communicable diseases** in humans;
- ◆ Identify and assess under the EU Animal Health Law **resistant bacteria that cause transmissible animal diseases** and, if necessary, develop harmonised rules for their surveillance;
- ◆ Improve AMR detection in the human health sector by providing EU support for **networking collaboration and reference laboratory activities**;
- ◆ Consider options for the **harmonised monitoring of AMR in the environment**.

Benefit from the best evidence-based analysis and data

- ◆ Provide **evidence-based data** on possible links between consumption of antimicrobial agents and the occurrence of antimicrobial resistance in humans and food-producing animals;
- ◆ Define a limited number of **key outcome indicators** for AMR and antimicrobial consumption;
- ◆ Support the development of a model aimed at helping Member States to assess the **economic burden that AMR imposes on people** and to estimate the **cost-effectiveness** of their national policies to reduce it.

Increase awareness and understanding

- ◆ Provide insights into reported public use of and knowledge about antimicrobials through **Eurobarometer surveys**;
- ◆ Support Member States' national awareness-raising efforts with specific communication tools targeting key audiences and contribute to the annual **European Antibiotic Awareness Days (EAAD)**.

Better coordination and implementation of EU rules to tackle AMR

Improve the coordination of Member States' One Health responses to AMR

- ◆ Make available regular information on AMR in the context of the **AMR One Health network**, which gives an overview of the AMR epidemiological situation at Member State and EU level;
- ◆ Support the **implementation** of national One Health action plans;
- ◆ Launch a **joint action** to tackle AMR and healthcare-

associated infections to support collaborative activities and policy development by Member States;

- ◆ Make increased use of the **EU Health Security Committee** and the **Commission Working Group on AMR** in the veterinary and food areas to strengthen coordination and share information;
- ◆ Seek to **co-fund and collaborate with the World Health Organisation (WHO)** on activities to help EU Member States develop and implement national One Health action plans against AMR.

Better implementation of EU rules

- ◆ Assess the effectiveness of the implementation of EU legislation on, inter alia, monitoring AMR in food-producing animals and food by **regular audits in Member States**;
- ◆ Develop **training programmes** for Member State competent authorities under the Better Training for Safer Food (BTSF) initiative and for health professionals.
- ◆ Advise Member States on the **Structural Reform Support Service (SRSS)** funding for designing and implementing policies against AMR.

Better prevention and control of AMR

Strengthen infection prevention and control measures

- ◆ Support **good practices in infection prevention and control** in hospital environments;
- ◆ Support activities for **infection prevention and control in vulnerable groups**, in particular to tackle resistant tuberculosis strains;
- ◆ Promote **uptake of vaccination in humans** to prevent infections and subsequent use of antimicrobials;
- ◆ Continue to **promote animal husbandry systems, and feeding regimes which support good animal health and welfare** to reduce antimicrobial consumption.

Promote the prudent use of antimicrobials

- ◆ Work towards **EU implementing and delegated acts** under the forthcoming veterinary medicinal products and medicated feed Regulations, including **rules on reserving antimicrobials for human use**, drawing up a list of antimicrobials that cannot be used off-label, and methods for data gathering and reporting on the sales and use of antimicrobials;
- ◆ Develop **EU guidelines for the prudent use of antimicrobials in human medicine**;
- ◆ Assist Member States implement EU guidelines for the **prudent use of antimicrobials in veterinary medicine**;
- ◆ Encourage the EMA to **review all available information on the benefits and risks of older antibacterial agents**.

Better addressing the role of the environment

- ◆ Adopt an **EU strategic approach to pharmaceuticals in the environment**;
- ◆ **Maximise the use of data** from existing monitoring to improve knowledge, including by using the Information Platform for Chemical Monitoring (IPChem);
- ◆ Reinforce the role of the **Scientific Committee on Health and Environmental Risks (SCHER)** in providing the expertise on environment-related AMR issues.

A stronger partnership against AMR and better availability of antimicrobials

- ◆ Engage with and support **collaboration among key stakeholders** in the human health, animal health,

food, water and environmental sectors to encourage the **responsible use** of antimicrobials and appropriate handling of waste material;

- ◆ Work with stakeholders to ensure the **availability of human and veterinary antimicrobials** and **continued access to established products**; provide incentives to increase the **uptake of diagnostics, antimicrobial alternatives and vaccines**;
- ◆ **Reduce the scope for falsified medicines** by assisting Member States and stakeholders in the implementation of the safety features (unique identifier);
- ◆ Discuss the availability of **veterinary antimicrobials** in the Veterinary Pharmaceutical Committee.



2. BOOSTING RESEARCH, DEVELOPMENT AND INNOVATION ON AMR

Improve knowledge on detection, effective infection control and surveillance

- ◆ Support research into the development and assessment of interventions that prevent the development and spread of AMR;
- ◆ Support research into understanding the **epidemiology of AMR**, in particular the pathways of transmission between animals and humans, and their impact;
- ◆ Support research into the development of **new tools for early (real-time) detection** of resistant pathogens in humans and animals;
- ◆ Support research into **new eHealth solutions** to improve prescription practices, self-management of health, care solutions, and improving awareness of AMR.

Develop new therapeutics and alternatives

- ◆ Support research into the **development of new antimicrobials and alternative products** for humans and animals as well as the **repurposing of old antimicrobials** or the development of new combination therapies;
- ◆ Support SMEs in their R&D efforts towards **innovative and/or alternative therapeutic approaches** for the treatment or prevention of bacterial infections;
- ◆ Facilitate **sharing of antimicrobial research data among relevant stakeholders**;
- ◆ Support the establishment of a **European-wide sustainable clinical research network**;
- ◆ Support research and innovation to **promote the use of digital technologies** supporting the development of new therapeutics and alternatives.

Develop new preventive vaccines

- ◆ Continue to support **research into the development of new effective preventive vaccines** for humans and animals;
- ◆ Support increasing the knowledge base concerning the **barriers that influence the wider use of vaccination** in medical and veterinary practice.

Develop novel diagnostics

- ◆ Support research into the development of **new diagnostic tools in particular on-site tests** in humans and animals;
- ◆ Support the use of **IT solutions in developing tools for diagnosing** human and animal infections;
- ◆ **Encourage the uptake of diagnostics** in medical and veterinary practice.

Develop new economic models and incentives

- ◆ Increase the evidence base for **understanding the societal costs and benefits of different strategies for fighting AMR**;
- ◆ Support research into the **development of new economic models**, exploring and analysing incentives to boost the development of new therapeutics, alternatives, vaccines and diagnostics;
- ◆ **Analyse EU regulatory tools and incentives** – in particular orphan and paediatric legislation – **to use them for novel antimicrobials and innovative alternative medicinal products** that currently do not generate sufficient returns on investment;
- ◆ Encourage Member States to explore results and recommendations of EU research projects on new economic business models;
- ◆ Develop new or improved methodological HTA

approaches and foster methodological consensus-building.

Close knowledge gaps on AMR in the environment and on how to prevent transmission

- ◆ Support research into knowledge gaps on the release of resistant microorganisms and antimicrobials into the environment and their spread;
- ◆ Explore risk assessment methodologies to evaluate the risks to human and animal health from the presence of antimicrobials in the environment;
- ◆ Support the development of new tools for monitoring antimicrobials and microorganisms resistant against antimicrobials in the environment;
- ◆ Support the development of technologies that enable efficient and rapid degradation of antimicrobials in wastewater and the environment and reduce the spread of AMR.



3. SHAPING THE GLOBAL AGENDA

A stronger EU global presence

- ◆ Continue to actively contribute towards the normative work of WHO, the World Animal Health Organisation (OIE), the Food and Agriculture Organization (FAO) and the Codex Alimentarius on the development of ambitious international frameworks and standards/ norms/ guidelines/ methodologies related to AMR;
- ◆ Reinforce technical cooperation with the WHO and its members in key areas of the WHO Global Action Plan on AMR;
- ◆ Boost support for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and the Veterinary International Conference on the Harmonisation (VICH) on relevant international guidelines/ standards /norms related to AMR;
- ◆ Work towards continued high-level political attention and commitment to AMR action, including in the United Nations forums, the G7 and the G20;
- ◆ Look for synergies with the UN Strategic Approach to International Chemicals Management's work on the emerging policy issue of pharmaceuticals in the environment;
- ◆ Analyse the feasibility of setting up a global AMR clinical studies network in collaboration with G7 members;
- ◆ Continue and strengthen collaboration within the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), which includes the EU, the USA, Canada and Norway;
- ◆ Promote international regulatory convergence between the EMA and other regulatory agencies such as the US Food and Drug Administration (FDA) and the Japan Pharmaceuticals and Medical Devices Agency (PMDA) on development plans for new promising antimicrobials.

Stronger bilateral partnerships for stronger cooperation

- ◆ Advocate EU standards and measures for tackling AMR in trade agreements and incorporate them into cooperative arrangements in trade agreements;
- ◆ Engage with major global players and strategic

countries (e.g. Brazil, China, India), contributing towards achieving objectives of the WHO Global Action Plan on AMR;

- ◆ Support EU candidate countries, potential candidate countries and neighbouring countries to which the ENP applies in the alignment with, and capacity building for the implementation of EU legislation related to AMR and EU standards;
- ◆ Invite the European Parliament, Member States and stakeholders to share views on actions to be taken to ensure that efforts to combat AMR made by EU producers, including farmers, do not place them at a competitive disadvantage.

Cooperating with developing countries

- ◆ Continue to contribute to reducing AMR in least developed countries through infectious disease programmes;
- ◆ Assist in the development of AMR strategies in the areas of food safety and animal health through regional training workshops on AMR;
- ◆ Support partner countries' policy initiatives on AMR, where appropriate, through international cooperation and development instruments;
- ◆ Support the development of resilient health systems in partner countries.

Developing a global research agenda

- ◆ Improve global coordination of research activities;
- ◆ Support the establishment of a virtual research institute under the Joint Programming Initiative on AMR (JPIAMR);
- ◆ Continue collaborative research with Sub-Saharan African in the context of the European and Developing Countries Clinical Trial Partnership (EDCTP) in particular in relation to tuberculosis, HIV/AIDS, malaria and neglected infectious diseases;
- ◆ Foster international research collaboration on AMR in the animal health sector in the STAR-IDAZ International Research Consortium.