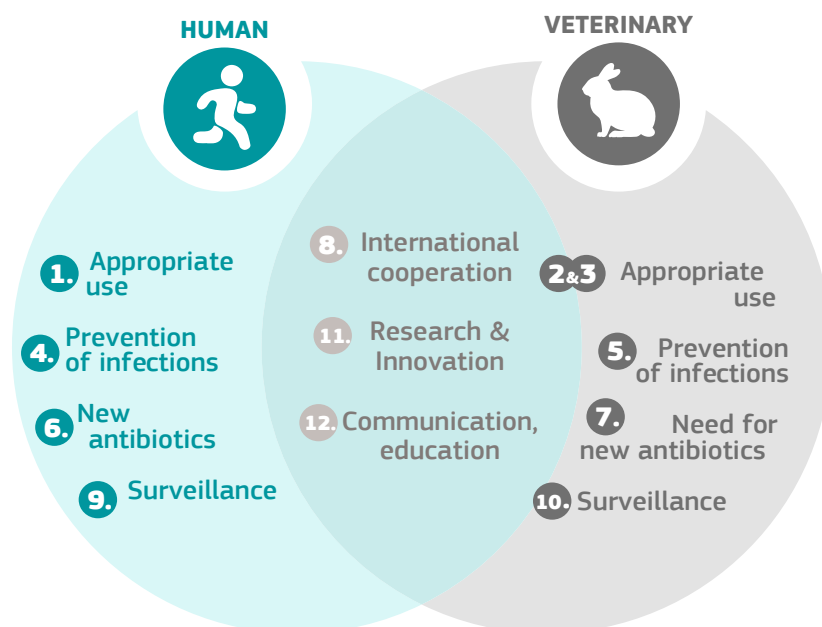


ANTIMICROBIAL RESISTANCE (AMR)

EVALUATION OF THE 2011-2016 ACTION PLAN

Each year, drug resistant infections result in at least 25 000 deaths in the EU and EUR 1.5 billion health care and productivity losses. Resistant infections are increasing worldwide - with estimates of the total number of deaths globally rising from 700 000 annually in 2015 to more than 10 million by 2050.

In response, the European Union in 2011 put in place an **Action Plan against the rising threats from Antimicrobial Resistance for the period 2011-2016**. This Action Plan took a **'One Health'** approach across multiple sectors, covering both human and veterinary aspects to protect both human and animal health. It contains 12 actions for implementation with EU Member States.



An **evaluation of the Action Plan** was carried out in September 2015. The evaluation concluded that the actions were **relevant** to address the problems identified in 2011 and are still relevant today.

The plan acted as a **symbol of political commitment, stimulated actions within Member States, strengthened international cooperation** and **provided a framework** to guide and coordinate activities on antimicrobial resistance at international level, including on research and development and monitoring and surveillance. Furthermore the evaluation concluded that the Commission's actions were appropriate in view of the EU and national competences.

KEY ACHIEVEMENTS

BEST PRACTICES

Human Health

- ▶ The evaluation of the **Council Recommendation on the prudent use of antimicrobials in humans** (2002) shows that 21 EU/EEA Member States now have a national action plan, up from 15 in 2008. All these plans covered topics such as the prudent use of antimicrobial agents and surveillance of AMR and antimicrobial use. Most plans address the issues of education and training of health professionals and information to the general public.
- ▶ The adoption of the **Council Recommendation on patient safety**, including the prevention and control of healthcare associated infections (2009) has triggered initiatives in 13 countries. Nowadays, 29 EU/EEA Member States have national guidelines for infection prevention and control and 11 Member States reported national requirements to communicate on the infection status of a patient in case of a cross-border transfer.
- ▶ The number of participating countries in the **European Antibiotic Awareness Day** grew from

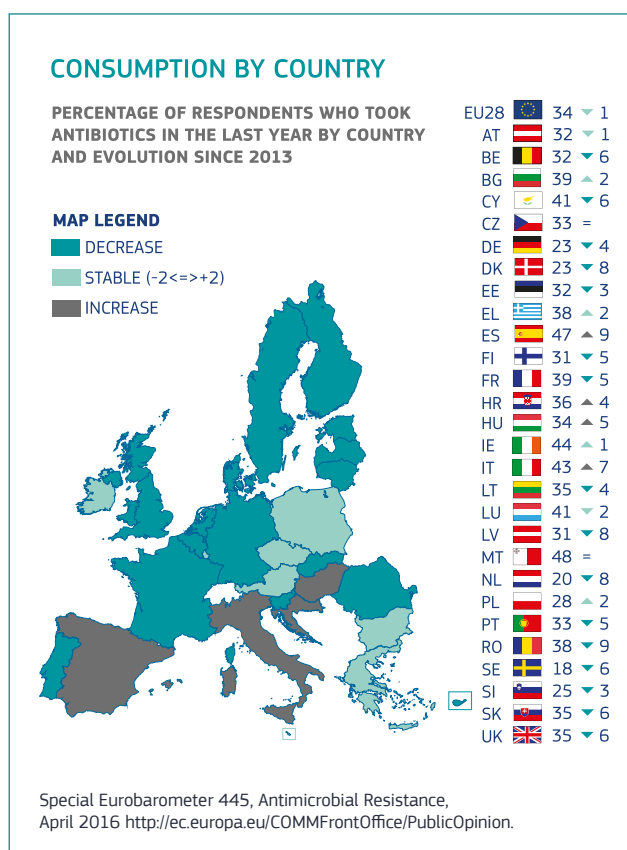
32 in 2008 to 43 in 2013. This European Day has provided a platform for national campaigns and encouraged similar campaigns to develop in other countries. In total 22 countries reported in 2013 that there had been a change in their country that could be attributed to the momentum created by the European Antibiotic Awareness Day.

Animal Health

- ▶ The Commission proposed in September 2014 a new **regulatory framework on veterinary medicines and medicated feed**. This framework addresses AMR-related issues that include ensuring appropriate warnings and guidance on the labels of veterinary antimicrobials, restrictions on the regular or the off-label use in the veterinary sector of certain new or critically important antimicrobials for humans, the rules for the advertisement of veterinary antimicrobials and a review of the authorisation requirements in order to sufficiently address the risks and benefits of antimicrobial medicines. Furthermore, it provides a number of other relevant provisions such as the legal basis for collection of data on use of sales of antimicrobials. This legal framework, as well as the **Guidelines for the prudent use of antimicrobials in veterinary medicine** (September 2015) are expected to promote appropriate use of veterinary antimicrobials in the coming years.

- ▶ The **Animal Health Regulation** adopted in March 2016, which focuses on better prevention and control of listed animal diseases, will allow for EU interventions on animal pathogens that show resistance to treatments, among them AMR. It introduces various measures for the prevention and control of transmissible animal diseases in general and provides a legal basis for the harmonised monitoring of animal pathogens in particular. Therefore, this regulation is expected to contribute to the efforts tackling AMR, once applicable from April 2021.

- ▶ The **Decision on monitoring and reporting of AMR** (2013) has extended the coverage and scope (for instance species and substances) of data collected in bacteria in food producing animals and certain food. As a result, we have more specific veterinary data which is much easier to compare.



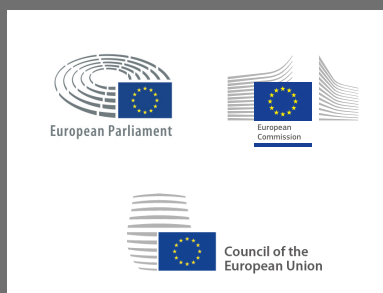
RESEARCH AND DEVELOPMENT

- ▶ A **Joint Programming Initiative (JPI)** was launched in 2011 to coordinate national research activities related to AMR. It now includes 22 countries. It developed a strategic research agenda that provides a framework for future investment and research priorities regarding AMR. This agenda is mentioned in the WHO global action plan as the basis for a global AMR research agenda.
- ▶ A public-private collaboration programme for research on new antibiotics was launched under the **Innovative Medicines Initiative: «New Drugs for Bad Bugs»**. It boosts the development of antibiotics along the value chain from basic science to new business models. Seven projects with a total budget of about EUR 650 million have been initiated so far.
- ▶ In June 2015, a new **financing instrument for infectious diseases, «InnovFin ID»** was launched by the Commission and the European Investment Bank to facilitate the development of novel interventions for infectious diseases. It has an initial budget of EUR 200 million. Since the launch of this new financial facility, loans were granted to a Swedish small/medium-sized enterprise, a French biopharmaceutical company and a Finnish molecular diagnostics company. Additional proposals that have been submitted are under evaluation.
- ▶ In February 2015 an innovative inducement **prize** of EUR 1 million on the **‘Better use of antibiotics’** was launched as one of the first prizes under Horizon 2020. This prize will be awarded for a rapid test to identify, at the point of care, patients with upper respiratory tract infections that can be treated safely without antibiotics.

INTERNATIONAL ACTIVITIES

- ▶ The **European Union Reference Laboratory for AMR (EURL-AMR)** is actively collaborating with the **WHO** supporting activities of the Global Foodborne Infections Network and the Advisory Group on Integrated Surveillance of Antimicrobial Resistance which has the aim to develop global standards for monitoring of antimicrobial resistance. Furthermore, the EURL-AMR supports capacity building for AMR monitoring in the food chain in member countries of the WHO/Europe region.
- ▶ **The Commission continued contributing to OIE activities** such as the new global database on the use of antimicrobial agents in animals.
- ▶ Under **the EU/African, Caribbean and Pacific Group of States/WHO Renewed Partnership project**, the Commission provides some EUR 10 million to support the strengthening of pharmaceutical systems and improving access to quality essential medicines. As part of work on ‘Improved medicines selection, prescribing, dispensing and use and strengthening capacity of health care providers’, a number of countries have prioritized actions to combat antimicrobial resistance.
- ▶ **The Transatlantic Taskforce on Antimicrobial Resistance (TATFAR)** was created as a collaboration between the U.S. and the EU in 2011. The objective was improving cooperation in three key areas: 1) appropriate therapeutic use of antimicrobial drugs in medical and veterinary communities, 2) prevention of healthcare- and community-associated drug-resistant infections, and 3) strategies for improving the pipeline of new antimicrobial drugs. The TATFAR has been extended to include Canada and Norway and the collaboration has led to increased information exchange, understanding of best approaches and practices and development of peer relationships in the fight against AMR.

EU DECISION-MAKERS



SCIENTIFIC ADVICE



INTERNATIONAL ORGANISATIONS



LESSONS FOR THE FUTURE

The available evidence and the assessments made show that **the 2011-2016 Action Plan addressed the problems identified in 2011. However, the AMR problem is persisting and continued action is needed to tackle AMR.** If no action is undertaken, AMR might by 2050 result in 10 million deaths globally each year. This is a convincing basis to continue efforts on combatting AMR, while respecting the respective competencies of the EU and of its Member States.

The evaluation of the 2011-2016 Action Plan shows that:

Support Member States' AMR efforts



- ▶ There are still considerable disparities between Member States in antimicrobial consumption in humans and animals and in spread of AMR. There is still a lack of knowledge of citizens. In addition, further understanding is needed of the effectiveness of AMR policies to make them more effective. Therefore, there is a clear need to **support and assist Member States** in developing and implementing national action plans, to foster collaboration across sectors, to improve knowledge of citizens and to strengthen monitoring and surveillance systems. **The Union should be a global best practice region on AMR.**

Push for Research and Innovation



- ▶ The research expenditures have been in line with the Action Plan. However, it should be recognised that to increase R&D efficiency a **continued coordination and collaboration on research and innovation** is needed to boost the development of new antimicrobials, rapid diagnostics tests, vaccines and alternative treatments, as well as new business models to sustain investment and increase the knowledge on the transmission of AMR for a better understanding of the mechanisms causing resistance.

EU action at international level



- ▶ The activities of the Commission, the EU Member States, other countries and other international organisations are complementary and reinforcing each other without overlapping each other. Given the cross-border nature of AMR, a **strong EU voice at international level** remains necessary, to raise awareness, to encourage countries to consider their own measures against AMR and to take global measures such as WHO implementing policies and the development and implementation of OIE standards.