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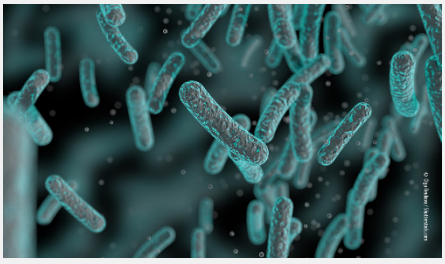

EU action to fight antimicrobial resistance

February 2019

Antimicrobial resistance (AMR) has been identified by the World Health Organization (WHO) as a serious global health threat. Already, an estimated 33 000 patients die each year in the EU from infections caused by drug resistant bacteria and this results in estimated economic losses of around €1.5 billion annually due to extra health care costs and productivity losses. The World Bank has warned that, by 2050, drug-resistant infections could cause as much global economic damage as the 2008 financial crisis.

The European Court of Auditors is conducting an audit on the Commission's and relevant agencies' management of key activities and resources to support Member States as well as EU research aimed at fighting AMR. In particular, we are focusing on the support provided by Commission and the European Centre for Disease Prevention (ECDC) to Member States on strengthening their One Health Action Plans, on the EU framework for monitoring antimicrobial resistance and consumption in the veterinary sector, and on the Commission's and agencies' coordination, targeting and evaluation mechanisms within the framework of EU support for AMR research.

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CONTENTS

WHAT IS ANTIMICROBIAL RESISTANCE?

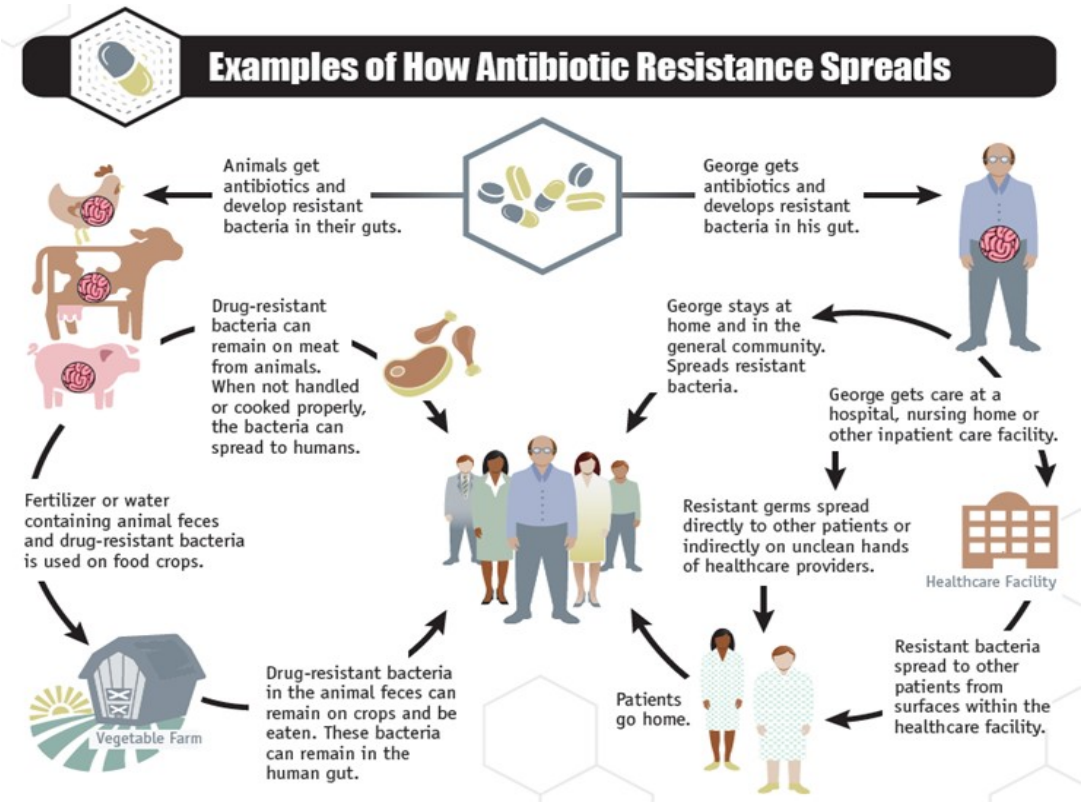
What is AMR?

Antimicrobial resistance (AMR) happens when microbes (bacteria, viruses, parasites, and fungi) develop resistance against medicines previously able to fight them, such as antibiotics, antivirals, antifungals and antiprotozoals. It has been identified by the World Health Organization (WHO) as a serious global health threat. Already, an estimated 33 000 patients die each year in the EU from infections caused by drug-resistant bacteria. The annual economic cost of such infections, due to extra health care costs and productivity losses, is estimated at around €1.5 billion.

Challenges

There are two major problems linked to the growth of AMR. The first problem is an excessive or imprudent use of antibiotics in the human and animal health sectors (**Figure 1** provides an explanation).

Figure 1 – How AMR spreads



Source: https://www.cdc.gov/drugresistance/about.html

Antimicrobial resistance develops naturally over time anyway, usually through genetic changes[1], but it accelerates when antimicrobials are not used prudently. The other major problem is a lack of development: no new classes of antibiotics have been discovered for decades and there are very few promising leads for new products. Moreover, this is an area of clear market failure: the pharmaceutical industry has limited commercial incentive to invest in the discovery and development of new antibiotics. External incentives may therefore be needed to boost research and development. A further challenge in this area is developing and using better diagnostics for animals and humans. This is to ensure that antibiotics are used only where needed, and that infections are targeted by the most appropriate antibiotics rather than broad-spectrum or last-line antibiotics.

Fighting AMR, then, essentially involves ensuring more prudent and efficient use of existing antimicrobials (including through increasing awareness, better training, surveillance and monitoring, enhanced diagnostics) in humans, plants and animals, and discovering and making available new antimicrobials (through research and development).

Potential impact

AMR threatens to lead to a situation where bacterial diseases and infections cannot be treated effectively and are often fatal. Infections caused by organisms that have developed resistance may require lengthier and costlier treatments, some with serious side effects, and carry a higher risk of death for patients. The World Bank has warned that, by 2050, drug-resistant infections could cause as much global economic damage as the 2008 financial crisis.

STATE OF PLAY

AMR in humans

In some countries, 25 % or more of certain infections are highly resistant to antimicrobials. In a study published in 2018[2], ECDC staff estimated that in 2015, more than 63 % of antibiotic-resistant infections were associated with healthcare. Infections also occur within the community (e.g. outside healthcare facilities, for example through contaminated food).

There is large variation in antibiotic consumption among EU Member States. Between 2013 and 2017, Finland, Germany, Italy, Luxembourg, the Netherlands, Sweden and the UK showed a decreasing trend in antibiotics consumption in human health. In 2017[3], consumption ranged from 11 (the Netherlands) to 34 DDD[4] per 1 000 inhabitants per day (Spain).

AMR in animals

While some caution applies, there is a high degree of consensus in Europe that AMR in livestock and the inappropriate veterinary use of antimicrobials pose health risks to humans. Sales of animal antibiotics have generally been falling since 2011 – dramatically so in some countries – but with notable exceptions. Data collected by the EMA indicates that there is great scope to reduce the sale and use of antibiotics in veterinary medicine across Europe.

EU POLICY AND LEGAL FRAMEWORK

Relevant EU policies and strategies

AMR action plans

The first notable EU policy document on AMR dates from 2001, with the Council Recommendation on the prudent use of antimicrobial agents in human medicine. This was followed by a series of further conclusions and recommendations

The Commission launched a first AMR action plan in 2011[5], covering both human and veterinary medicine.

One Health

The main international policy document on AMR is the WHO's Global Action Plan[6], adopted in 2015. The plan is underpinned by a "One Health" approach, meaning a holistic approach based on coordination between various players, such as human and veterinary medicine, the agriculture, finance and environmental sectors, and well-informed consumers. Under the WHO plan, countries had to develop and implement One Health Action Plans (covering human, animal and environmental health) by mid-2017.

The Commission adopted a One Health action plan for the EU[7] in 2017, in line with the WHO's Global Action Plan. In it, the Commission sets out 76 actions and its ambition to make the EU a best-practice region, boost research innovation on AMR and shape the global agenda. The Commission's action plan is supported by a number of actions co-funded under the EU Health Programme, to help Member States strengthen their own individual One Health approach.

EU support to combat AMR

One of the Commission's flagship initiatives in research and development is the New Drugs for Bad Bugs Programme, launched in 2012. The programme is funded from the seventh Framework Programme and managed by the Joint Undertaking Innovative

Medicines Initiative (JU IMI). Its aim is to allow academia and industry to share information and forge a public-private partnership for the discovery, development and marketing of new antibiotics. Such a public-private partnership was deemed necessary in the area of AMR research because of the market failure (see above). Also, academia and the public sector alone would not have been capable of developing and marketing new drugs without help from the pharmaceutical industry. The Commission also funds dedicated coordination and individual research actions under the seventh Framework Programme/Horizon 2020.

The EU Health Programme funds the Joint Action on AMR (JAMRAI – 2017 to 2020), the aim of which is to build cooperation between EU Member States on developing and implementing national AMR action plans. The Commission also makes available direct grants to the WHO Regional Office for Europe (WHO EURO) and the OECD for AMR actions and studies. For example, it currently funds a WHO-led AMR project (2018-2021), which aims to support EU Member States in improving their approach to combating AMR.

Legal framework

The EU legal framework for combating AMR consists of a number of Regulations and decisions covering the human health and veterinary sectors. The Commission also issues guidelines.

General/human health

- At an overarching level, Article 168 of the Treaty on the Functioning of the European Union provides that "*a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities*";

- Decision (EU) 1082/2013 of the European Parliament and the Council on serious cross-border threats to health; this defines AMR as a cross-border threat to health requiring intensive cooperation and coordination between Member States;

- EU Guidelines on the prudent use of antimicrobials in human health, published in 2017;

Specific to the veterinary sector

- Regulation (EU) No 1831/2003 on additives for use in animal nutrition; this prohibits, among other things, the authorisation of antibiotics as growth promoters in animal nutrition;

- Commission Implementing Decision 2013/652/EU on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria; this is currently under review, with new legislation expected in the coming years;

- Regulation (EU) No 2019/6 on veterinary medicinal products and Regulation 2019/4 on medicated feed, which will take effect over the next five years.

ROLES AND RESPONSIBILITIES

European Commission and agencies

The European Commission's Directorate General for Health and Food Safety (DG SANTE) is responsible overall for the policy areas of human and animal health and health security. It is also responsible for implementing the EU's One Health action plan, coordinating and facilitating key platforms such as the Health Security Committee and One Health Network, and conducts Food and Health Audits and fact-finding visits in the animal health/veterinary sector, as well as joint One Health visits with the ECDC.

The Directorate-General for Research and Innovation (DG RTD) manages the Horizon 2020 Programme and health-related research projects aimed at tackling the global problem of AMR.

The European Centre for Disease Prevention and Control (ECDC) operates an AMR and healthcare-associated infections (HAI) programme with an annual budget of approximately €1.5 million. The ECDC's main role is to manage monitoring and reporting systems for AMR and HAI and provide support to the Member States.

The European Food Safety Authority (EFSA) monitors and analyses the situation as regards antimicrobial resistance in food and food-producing animals, and publishes specific summary reports each year together with ECDC on the occurrence of AMR in zoonotic and indicator bacteria from humans, food-producing animals and food in the EU.

The European Medicines Agency (EMA) authorises new medicines for use in the EU. It works closely with the EFSA and the ECDC to analyse whether AMR might be linked to the consumption of antimicrobials by humans and animals. The EMA monitors sales volumes of antibiotics for animal health via the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project.

The Consumer, Health, Agriculture and Food Executive Agency (CHAFEA) manages EU funding under the Health Programmes.

The Joint Undertaking Innovative Medicines Initiative (JU IMI) manages the New Drugs for Bad Bugs Programme, as well as other AMR-related actions it funds from its budget.

Member States

Member States are entirely responsible for their own national public health policies. This includes responsibility for their One Health action plans.

MAIN ISSUES IDENTIFIED WHEN PREPARING THE AUDIT

In the course of our audit on EU action to fight antimicrobial resistance, we will look at a number of areas related to the issues that have been identified. In particular, we will examine whether:

- the Commission and the ECDC manage key activities and resources well;
- the Commission and EU agencies make an effective contribution towards reducing antimicrobial resistance and promoting the prudent use of antimicrobials in animals within the EU;
- the Commission and EU agencies have appropriate mechanisms to coordinate and evaluate EU support for AMR research.

Since these issues are identified before the audit work commences, they should not be regarded as audit observations, conclusions or recommendations.

ABOUT ECA SPECIAL REPORTS AND AUDIT PREVIEWS

The ECA's special reports set out the results of its audits of EU policies and programmes or management topics related to specific budgetary areas.

Audit previews provide information in relation to an ongoing audit task. They are based on preparatory work undertaken before the start of the audit and are intended as a source of information for those interested in the policy and/or programme being audited.

If you wish to contact the team in charge of this audit, please do so through the following e-mail address: **ECA-AMR-audit@eca.europa.eu.**

[1] World Health Organisation, Antimicrobial resistance, webpage publication (http://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance), 15 February 2018.

[2] Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis, A. Cassini et al., 5 November 2018.

[3] Surveillance report – Annual epidemiological report for 2017 – Antimicrobial Consumption, ECDC, Stockholm November 2018.

[4] Antibiotic consumption in the EU/EEA is expressed as the number of defined daily doses (DDD) per 1 000 inhabitants per day.

[5] Communication from the Commission to the European Parliament and the Council, Action plan against the rising threats from Antimicrobial Resistance, COM(2011) 748 final.

[6] World Health Organization, Global action plan on antimicrobial resistance, 2015, ISBN: 9789241509763.

[7] European Commission, A European One Health Action Plan against Antimicrobial Resistance (AMR), 2017.