EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH

Request for an opinion: Managing Antimicrobial Resistance across the Health System

Background - Rationale

EU action on antimicrobial resistance (AMR) has been on the policy agenda for many years. A wide range of measures has been put in place to fight AMR and promote a more prudent and responsible use of antimicrobials in humans and in animals. It is important to note that AMR is a cross sectoral issue and needs to be addressed at all levels and across all of the One Health dimensions, acknowledging the interlinkages between humans, animals, plants and the environment.

Commissioner Kyriakides was mandated by the Commission President to focus on the full implementation of the European One Health Action Plan against Antimicrobial Resistance¹ and to work with our international partners to advocate for a global agreement on the use of and access to antimicrobials.² The Commission actively engages with international partners like the AMR Tripartite Alliance (WHO, FAO and OIE) as well as UNEP, G7, G20 in order to address the AMR threat. In particular, it advocates for the revision of the 2015 AMR Global Action Plan and supports inclusion of AMR in the global agreement on pandemic preparedness and response on which the World Health Assembly agreed on the 1 December 2021 to launch negotiations.

In June 2017, the European Commission adopted the EU One Health Action Plan against AMR³. Under the plan, the Commission adopted the EU Guidelines on the prudent use of antimicrobials in human health⁴. The guidelines aim to reduce inappropriate use and promote prudent use of antimicrobials in people. They target all actors who are responsible for or play a role in antimicrobial use. This complements the EU Guidelines on the prudent use of antimicrobials in animal health⁵. The European Medicine Agency (EMA), the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) are all engaged in tackling AMR⁶.

Since the implementation of the 2017 AMR EU Action Plan, new policy initiatives have been launched that reinforce action on AMR, for example:

¹ https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

² https://ec.europa.eu/commission/commissioners/sites/default/files/commissioner_mission_letters/mission-letterstella-kyriakides_en.pdf

³ https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-antimicrobial-resistance/

⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC0701(01)

⁵https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf

^{6 &}lt;a href="https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/antimicrobial-resistance">https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/antimicrobial-resistance
https://www.efsa.europa.eu/en/topics/topic/antimicrobial-resistance
https://www.edc.europa.eu/en/topics/topic/antimicrobial-resistance
https://www.edc.europa.eu/en/topics/topic/antimicrobial-resistance

- The new EU Regulation on veterinary medicines and medicated feed, which will apply as of 28 January 2022. It provides for a wide range of concrete measures to fight AMR and promote prudent and responsible use of antimicrobials in animals.
- In May 2020, the European Commission adopted the Farm to Fork Strategy⁷, a tool to help shape the EU's path towards sustainable food systems. It includes an objective to reduce by 50% of the overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030.
- In November 2020, the Commission proposed legislative changes to the existing EU health security framework as part of the European Health Union⁸ package, including strengthening of the mandates of ECDC and EMA and the creation of the European Health Emergency Preparedness and Response Authority (HERA), which will also cover work on AMR.
- Also as part of the European health Union, the Commission adopted the Pharmaceutical Strategy for Europe⁹, under which the Commission will explore new types of incentives for innovative antimicrobials and consider in the review of the pharmaceutical legislation to introduce measures to restrict and optimise the use of antimicrobial medicines. Moreover, the strategy will also cover actions on improving healthcare professionals' and European citizens' awareness on antimicrobial resistance.
- In November 2020, the new Commission Implementing Decision (EU) 2020/1729 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria¹⁰ was published. This Decision is based on the latest scientific opinions and addresses known implementation issues while scientifically responding and ensuring continuity in assessing future trends in AMR.
- In March 2019, European Union Strategic Approach to Pharmaceuticals in the Environment COM (2019) 128 final was adopted which covers also the antimicrobial resistance in the environment.

Almost all EU countries have put in place One Health national action plans and strategies on AMR¹¹ and twice a year, the European Commission issues a progress report¹² on the implementation of the 2017 European One Health Action Plan against AMR¹³.

There is a wealth of research and studies available on AMR, commissioned by the European Commission and other international organisations.¹⁴ For example, the OECD has been providing an important contribution to the understanding on the economic side of the burden of AMR and

⁷ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0381

 $[\]frac{8}{\text{https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en}$

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761

¹⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L .2020.387.01.0008.01.ENG

¹¹ https://www.ecdc.europa.eu/en/publications-data/directory-guidance-prevention-and-control/antimicrobial-resistance-strategies

¹² https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2018-2022_actionplan_progressreport_en.pdf

¹³ https://ec.europa.eu/health/sites/default/files/antimicrobial resistance/docs/amr 2017 action-plan.pdf

¹⁴ https://ec.europa.eu/health/antimicrobial-resistance/research-projects-studies en

the cost to health systems¹⁵. According to ECDC, 75% of the health burden of AMR in the EU/EEA is due to health care associated infections, while nearly 40% of the health burden of AMR is caused by infections with bacteria resistant to last-line antibiotics such as carbapenems and colistin.¹⁶ The Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance of June 2019 recognised the need for more action across several areas.¹⁷

Against this background, there are still challenges in effective implementation of AMR policies across health systems. This can be due to the complexity of AMR: comprising several pathogens, requiring concerted efforts across acute healthcare and primary care settings, and across stakeholders: doctors, microbiologists, hospital managers, policy-makers, patients, etc. This systemic approach for the health system as a whole: looking at institutional, behavioural and structural challenges and opportunities, does not seem to have been covered in existing studies so far.

AMR is a good example of a One Health matter in which human health is connected to that of animals and to the environment. As a result, health systems both contribute to the presence of AMR in the environment and are impacted by it. However, knowledge gaps still exist in understanding the environmental aspects of AMR and its relevance to health systems. The 2017 EU AMR Action Plan has various projects addressing this issue (the progress report¹⁸: One Health EJP, EFFORT, JPIAMR, 3rd ERA-NET Co-fund). In addition, EFSA recently adopted an opinion on "Role played by the environment in the emergence and spread of antimicrobial resistance (AMR) through the food chain" following a self-mandate.

The **target audience** of this opinion are EU institutions, national governments and health authorities, as well as other stakeholders relevant to tackling AMR. The scope is EU rather than global action. Also taking into account the limited competence in health, the opinion should differentiate between action that can be taken at EU and at Member State levels.

The findings and recommendations of the Expert Panel opinion will feed into a new proposal for a Council Recommendation on AMR to be issued later in 2022.

Questions for the Expert Panel

The Expert Panel is requested to provide a concise policy-oriented opinion with analysis and recommendations on the following points:

¹⁵ https://www.oecd.org/health/stemming-the-superbug-tide-9789264307599-en.htm

¹⁶ https://www.ecdc.europa.eu/en/news-events/33000-people-die-every-year-due-infections-antibiotic-resistant-bacteria

¹⁷ https://data.consilium.europa.eu/doc/document/ST-9765-2019-INIT/en/pdf

¹⁸ https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/amr_2018-2022 actionplan progressreport en.pdf

¹⁹ https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6651

- 1. Taking into account the One Health dimension of antimicrobial resistance (AMR), including the role of the environment and of veterinary medicine in the emergence and spread of AMR, what are necessary systemic²⁰ elements, conditions and interventions of effective management of antimicrobial resistance (AMR) across, but also beyond, the health systems that could translate into effective policy interventions and National Action Plans (national and EU targets, core requirements for antimicrobial stewardship and infection prevention and control standards, etc.)?
- 2. How concretely could new technologies (e.g. digital apps, in vitro diagnostics) help tackle AMR in health systems?
- 3. Taking also into account the existing studies (e.g. OECD, ECDC) on the burden of diseases, where are the areas for most urgent investment across health systems for maximum benefit to tackle AMR?
- 4. What concrete strategies can be recommended to Member States to implement existing and planned policies to tackle AMR?

Timing:

- Start of the work: January 2022

- Finalisation in July 2022

²⁰ This should include the whole health system – from doctor's prescriptions, to information for patients, infection prevention and control measures as well as other preventive measures, the structures and resources of health care systems, antimicrobial stewardship measures, and legislation that prevents sales of antibiotics 'over the counter' without a prescription.