EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

One Health
Antimicrobial resistance, Human nutrition

AMR One Health Network meeting of 29 February 2024

MINUTES

Session with Member States and stakeholders

1. Welcome and opening remarks by the European Commission, DG SANTE, Directorate A 'One Health'

The **Commission** welcomed the AMR One Health Network and thanked the attendees and speakers for joining both in-person and online. Acknowledging the severity of AMR-related figures in terms of deaths and economic consequences, the Commission emphasized the continued priority of combating AMR in the EU and globally. The Commission noted that 2024 will be an important year for global achievements in the fight against AMR, including the UN General Assembly (UNGA) high-level meeting in September, and the ongoing negotiations for a Pandemic Agreement. The Commission outlined the meeting's aim to facilitate continued discussions on how to tackle AMR through a 'One Health' approach, particularly focusing on implementing the Council Recommendation on AMR. The agenda of the meeting as well as the presentations on international developments, AMR in the environment, latest scientific developments, and the role of finance in the fight against AMR were introduced.

2. Implementation of the Council Recommendation on AMR: State of play of Commission's actions – Commission services / Q&A

The **Commission** presented the state of play of several Commission's actions to implement the Council Recommendation on AMR. Specifically, the progress on two studies were outlined: the study on the design of a monitoring framework and the feasibility study on integrated surveillance systems. The study on the design of a monitoring framework was launched in December 2023 and aims to set up indicators to assess the progress and results achieved in implementing the 2017 AMR Action Plan and the Council Recommendation on AMR. The AMR One Health Network will be consulted on the proposed indicators through a targeted written consultation. In addition, it was announced that a feasibility study will be launched after the summer to support Member States in their efforts to develop integrated systems for the surveillance of AMR and antimicrobial consumption. Regarding developments in human health, key articles and elements relevant to AMR in Regulation (EU) 2022/2371 on serious cross-border threats to health were presented. Finally, AMR actions by the European Health Emergency Preparedness and Response Authority (HERA) were presented. Information about funding initiatives for priority signalling and strengthening of surveillance capacities was provided, as well as about push funding for AMR

medical counter measures and the improvement of continuity of supply. The state of play of the HERA pilot project aimed at designing and implementing an EU pull incentive scheme through procurement mechanisms was also presented.

During the discussion, the members of the network exchanged about the goal of the integrated surveillance study and its relation with the work package on integrated surveillance in the EU JAMRAI-2 initiative, the voluntary mechanism in the pull incentive pilot led by HERA, and the definition of "AMR vaccines" as medical counter measures.

3. International developments / Q&A

Presentation on the process leading up to the UNGA 2024 High-level meeting on AMR

The **EU Delegation to the United Nations in New York** (NY-DEL) informed the members of the network about the process leading up to the forthcoming political declaration on AMR and the UNGA High-level meeting in September 2024. NY-DEL explained that negotiations are underway for the modality's resolution, which will lay down the process, format, and organization of the high-level meeting on AMR, with possible adoption in March. Subsequent steps include an interactive multi-stakeholder hearing in April/ May 2024 to engage civil society and other stakeholders, followed by negotiations on the zero-draft of the Political Declaration commencing in May 2024. NY-DEL emphasized the importance of focusing discussions on a specific set of priorities to facilitate agreement on a concise Political Declaration that is both actionable and accountable.

Presentation on the state of play of the Quadripartite AMR Multi-Stakeholder Partnership Platform and the Action Groups

On behalf of the Quadripartite, **FAO** presented the aim and governance structure of the AMR Multi-Partnership Platform, focussing on the established Action Groups and their expected outcomes for the global, regional, and sector-specific communities. FAO explained how the Platform can contribute to the UNGA High-level meeting on AMR in 2024. In particular, the Platform is hosting an Action Group that is developing policy recommendations for the UNGA High-level meeting. These key recommendations will be launched during a virtual event in April, followed by a statement sent by the Platform to the co-facilitators and UN Member States. Additionally, the Platform aims to achieve wide dissemination of the key recommendations through advocacy initiatives and active participation in the UN multi-stakeholder hearings.

4. AMR in the environment / Q&A

Presentation on the pilot study on environmental sustainability in antibiotic production (Germany)

A representative from **AOK Baden-Württemberg** presented the key findings of a pilot study on tackling AMR at antibiotic active pharmaceutical ingredients (API) production sites. The study has shown that production sites within the EU and in third countries can be hot spots for environmental pollution with antibiotics and may contribute to AMR. To safeguard public health and amid the One Health policy, there is an urgent need for actions to reduce pharmaceutical emissions from API production facilities in Europe and in third countries. Proposed solutions

include strengthened environmental criteria within the EU marketing authorisation framework, legally binding emission limits for production sites, and mandatory and uniform audit requirements.

During the discussion, members of the network exchanged on best practices to diminish AMR in the environment, a possible voluntary approach to auditing requirements at API production sites and audits for wastewater in hospitals and farms.

Presentation on an update on AMR-related issues in several environmental policy contexts

The **Commission** provided an update on AMR-related issues in several reviews of environmental legislation, including the Strategic Approach to Pharmaceuticals in the Environment, the Water Framework Directive (WFD), the Industrial Emissions Directive, the Urban Waste Water Treatment Directive, and the Sewage Sludge Directive. Information on soil monitoring was also provided and AMR monitoring activities linked to the Water Framework Directive were presented, including projects by the European Environment Agency (EEA) and the method developed by the Joint Research Centre to monitor the presence in water of genes encoding for AMR.

The members of the network discussed about sampling methods for AMR in the environment and the methodology that should be used to identify the relevant antimicrobial genes.

Presentation on environmental risk assessment in the revision of the EU pharmaceutical legislation

The **Commission** presented how the EU pharmaceutical legislation aims to strengthen the environmental risk assessment (ERA) requirements for pharmaceuticals in the environment. The approach to strengthening the ERA requirements for medicinal products includes, amongst others, the inclusion of a stand-alone ground of refusal if the ERA does not sufficiently substantiate and address risks to the environment and public health, the mandatory compliance with EMA's scientific Guideline on the ERA of Medicinal Products for Human Use, as well as the obligation to conduct post-authorisation ERA studies at the time or after marketing authorisation.

Presentation on the JAMRAI-2 environmental aspects

The **Commission** presented the environmental aspects of the work of the new Joint Action on AMR (EU JAMRAI-2). Stewardship actions include training and mentorship to key professionals on the impact of prescriptions and antimicrobial stewardship on environmental contamination, as well as work with target groups to perform a gap analysis to reduce environmental AMR emission. Environmental elements are also addressed in surveillance actions, including the mapping of existing AMR environmental surveillance and the setting up an EARS-Env network with harmonised goals, indicators, sampling sites, and methods, and developing protocols for implementation in National Action Plans.

Presentation on the risk of AMR in the environment

Health Care Without Harm Europe (HCWH) presented the ecological impacts of antibiotics in the environment, including on soil fertility and water ecosystems. HCWH highlighted three main contributors to antibiotic discharge in the environment: pharmaceutical manufacturing, healthcare

delivery and food production. The main actions to reduce antibiotic discharge into the environment include improving transparency in the supply chain (green procurement) for pharmaceutical manufacturing, establishing strong protocols for the management of waste and wastewater in hospital settings, and focusing on animal welfare to reduce the need for antibiotics in food production. HCWH also considered that the EU could lead by example and become a key actor in the UNGA High-level meeting on AMR to reduce antimicrobial use in farmed animals globally.

5. **Latest JIACRA (Joint Inter-Agency Antimicrobial Consumption and Resistance Analysis) report / Q&A**

EMA presented the fourth joint inter-agency report on integrated analysis of antimicrobial agent consumption and occurrence of AMR in bacteria from humans and food-producing animals in the EU/EEA. The 4th JIACRA report is the outcome of a collaboration between EMA, EFSA and ECDC and was published on 21 February 2024. It presents results of analysis to assess the relationship between AMC and AMR in food-producing animals and humans. The results of the analysis show that AMR has decreased in countries that have reduced the use of antibiotics in both humans and animals, indicating that the concerning trends in AMR can be reversed. The agencies issue several key recommendations in their report, including continued coordinated action to achieve an overall reduction in the use of antimicrobials (20% in people, 50% in animals), increased focus on infection prevention and control, responsible and prudent use of antimicrobials, complementary data collection for future analysis of links between AMC and AMR and the need for targeted studies to understand the transmission of AMR.

During the discussion, participants raised questions regarding the extent to which pet animals and environmental factors would be considered in the analysis, and the impact of under-reporting from some Member States on the results.

6. **European Investment Bank contribution to the fight against AMR / Q&A**

The **European Investment Bank** (EIB) presented its activities to contribute to the fight against AMR through a holistic and sustainable investment strategy approach. EIB is a contributor to the AMR Action Fund which is an initiative from leading biopharmaceutical companies that have pledged to invest nearly USD 1 billion, with the aim to bring 2-4 new antibiotics to market by 2030. EIB highlighted that healthcare systems should meet the fundamental principle of social solidarity, allowing the whole population to have equal access to a reasonable range of drugs and standard of health care irrespective of their ability to pay for health care. Finally, EIB presented two case studies of successful investments across EU countries: animal health R&D investments in France and the development of a novel protein-based vaccine against Group B Streptococcus in Denmark.

The discussion focused on the special loans developed by EIB for the life-science space, as well as the funding opportunities for academia and small and medium-sized enterprises.

Conclusion

The Commission thanked the participants and speakers for the positive interactions. The Commission announced that the next meeting of the One Health Network is planned for 8 October 2024 and will take place virtually.