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| From: | Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director |
| To: | Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union |
| No. Cion doc.: | COM(2023) 191 final |
| Subject: | Proposal for a COUNCIL RECOMMENDATION on stepping up EU actions to combat antimicrobial resistance in a One Health approach |

Delegations will find attached document COM(2023) 191 final.

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Brussels, 26.4.2023
COM(2023) 191 final

2023/0125 (NLE)

Proposal for a

COUNCIL RECOMMENDATION

on stepping up EU actions to combat antimicrobial resistance in a One Health approach

{SWD(2023) 190 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

In 2019, the World Health Organization (WHO) declared antimicrobial resistance (AMR) as one of the top 10 global public health threats facing humanity¹. In July 2022, the Commission, together with the Member States, identified AMR as one of the top three priority health threats in the EU².

AMR means the ability of a microorganism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually sufficient to inhibit or kill that micro-organism. It is a growing global health threat provoking grave societal and economic challenges³. A continued rise in resistance would result in an estimated 10 million deaths globally each year, in a reduction of 2% to 3.5% in global gross domestic product and would cost the world economy up to USD 100 trillion by 2050⁴. AMR is responsible for more than 35,000 deaths every year in the EU/EEA⁵.

Key advances in medicine were made possible thanks to antimicrobials. By reducing the ability to prevent and cure infectious diseases, AMR is increasingly threatening, among other things, the ability to perform surgery, the treatment of immunocompromised patients, organ transplantation and cancer therapy. AMR has a huge economic impact on healthcare systems⁶ as it leads to more complex treatments, higher hospital admission rates and extended stays. Food security and food safety are also threatened since AMR affects animal health and food production.

While AMR occurs naturally, the misuse and the overuse of antimicrobials in humans, animals and plants lead to its more frequent occurrence. Suboptimal hygiene practices and poor infection prevention and control in healthcare settings, where the number of infections may be very high and particularly problematic considering the vulnerable situation of patients, but also in veterinary medicine and in animal husbandry, have contributed to the issue. Additionally, increasing evidence demonstrates that the environment plays a role in the development and spread of AMR. Finally, the globalisation of markets and the growing movement across the world of people as well as of animals, plants and products derived thereof contributed to the spread of AMR.

¹ <https://www.who.int/news-room/spotlight/ten-threats-to-global-health-in-2019>.

² https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en.

³ [Global mortality associated with 33 bacterial pathogens in 2019: a systematic analysis for the Global Burden of Disease Study 2019 - The Lancet](#).

⁴ For the period 2014-2050 - [Antimicrobial Resistance: Tackling a crisis for the health and wealth of nations - The Review on Antimicrobial Resistance – December 2014](#).

⁵ <https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf>.

⁶ <https://www.oecd.org/health/health-systems/AMR-Tackling-the-Burden-in-the-EU-OECD-ECDC-Briefing-Note-2019.pdf>.

While existing antimicrobials must continue to be available, novel and effective antimicrobials must be developed and available to tackle the increasing resistance of microorganisms to existing products. Nevertheless, the pipeline of new antimicrobials remains dry. As of April 2021, after an analysis of the recently approved antibiotics, the WHO concluded that the latter are insufficient to tackle the AMR challenge⁷. Moreover, the COVID-19 pandemic and the Russian war of aggression against Ukraine have accentuated dependencies and vulnerabilities which challenge the availability and supply of existing antimicrobials in the EU⁸.

- **Policy context**

In 2001, the Union identified the importance of tackling AMR with the adoption of the 2001 Community strategy against AMR⁹. This policy was reinforced by the 2011-2016 Commission Action Plan¹⁰ designed to foster action among Member States. In June 2017, the Commission adopted the EU One Health Action Plan against AMR¹¹ ('the 2017 AMR Action Plan'), as requested by the EU Member States in the Council Conclusions of 17 June 2016¹². The 2017 AMR Action Plan built on the 2011-2016 Action Plan, its evaluation¹³, the feedback received on a Commission roadmap on AMR¹⁴, and an open public consultation¹⁵.

Since the adoption of the 2017 AMR Action Plan, some major initiatives have contributed to further strengthening the EU's response to AMR. These include *inter alia* the Strategic Approach to Pharmaceuticals in the Environment¹⁶, the Farm to Fork Strategy¹⁷ and the Zero Pollution Action Plan¹⁸, Regulation (EU) 2019/6 of the

7 <https://www.who.int/news/item/15-04-2021-global-shortage-of-innovative-antibiotics-fuels-emergence-and-spread-of-drug-resistance>.

8 https://eu-jamrai.eu/wp-content/uploads/2021/07/1.3.1_Policy_brief_Improving_access_to_essential_antibiotic.pdf.

9 [Communication from the Commission on a Community Strategy against antimicrobial resistance - COM/2001/0333final](#).

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

11 [Communication from the Commission to the Council and the European Parliament - A European One Health Action Plan against Antimicrobial Resistance \(AMR\) - COM\(2017\) 339 final](#).

12 [Council conclusions of 17 June 2016 on the next steps under a One Health approach to combat antimicrobial resistance](#).

13 https://health.ec.europa.eu/system/files/2020-01/amr_evaluation_2011-16_evaluation-action-plan_0.pdf.

14 https://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_176_action_plan_against_amr_en.pdf
15 https://health.ec.europa.eu/consultations/open-public-consultation-possible-activities-under-commission-communication-one-health-action-plan_en.

16 [Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee - European Union Strategic Approach to Pharmaceuticals in the Environment – COM \(2019\) 128 final](#).

17 [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system - COM/2020/381 final](#).

18 [Communication from the Commission to the European Parliament, the Council, the European Economic and Social committee and the Committee of the Regions Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' COM\(2021\) 400](#).

European Parliament and of the Council¹⁹ and Regulation (EU) 2019/4 of the European Parliament and of the Council²⁰, Commission Implementing Decision (EU) 2020/1729²¹ and the Pharmaceutical Strategy²².

In addition to these initiatives, a number of specific proposals were adopted, in particular the Commission proposal to revise the lists of pollutants in groundwater and surface water²³, the Commission proposal to revise the Urban Waste Water Treatment Directive²⁴ and the Commission proposal for a new Nature Restoration Regulation²⁵.

Further policy initiatives were triggered by the COVID-19 pandemic which brought a major shock to health systems of EU Member States and exposed weaknesses in our collective defenses against health threats. The Union launched the European Health Union²⁶ which provides opportunities for the fight against AMR. These measures include *inter alia* Regulation (EU) 2022/2371 of the European Parliament and of the Council²⁷, Regulation (EU) 2022/2370 of the European Parliament and of the Council²⁸ and Regulation (EU) 2022/123 of the European Parliament and of the Council²⁹, all of which entered into force in 2022. They also include the EU4Health programme³⁰, in particular its EUR50 million of direct grants to continue supporting Member States' actions on AMR (joint action to support Member States in their efforts to address infection prevention and control, prudent use of antimicrobials, surveillance, awareness raising and strengthening of national action plans) for the

¹⁹ [Regulation \(EU\) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC \(OJ L 4, 7.1.2019, p. 43\).](#)

²⁰ [Regulation \(EU\) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation \(EC\) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC \(OJ L 4, 7.1.2019, p. 1\).](#)

²¹ [Commission Implementing Decision \(EU\) 2020/1729 of 17 November 2020 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria and repealing Implementing Decision 2013/652/EU \(OJ L 387, 19.11.2020, p. 8\).](#)

²² [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Pharmaceutical Strategy for Europe - COM/2020/761 final.](#)

²³ https://environment.ec.europa.eu/publications/proposal-amending-water-directives_en.

²⁴ https://environment.ec.europa.eu/publications/proposal-revised-urban-wastewater-treatment-directive_en.

²⁵ https://environment.ec.europa.eu/topics/nature-and-biodiversity/nature-restoration-law_en

²⁶ [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats - COM\(2020\) 724 final](#)

²⁷ [Regulation \(EU\) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU \(OJ L 314, 6.12.2022, p. 26\).](#)

²⁸ [Regulation \(EU\) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation \(EC\) No 851/2004 establishing a European Centre for Disease prevention and Control \(OJ L 314, 6.12.2022, p. 1\).](#)

²⁹ [Regulation \(EU\) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices \(OJ L 20, 31.1.2022, p. 1-37\).](#)

³⁰ [Regulation \(EU\) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health \('EU4Health Programme'\) for the period 2021-2027, and repealing Regulation \(EU\) No 282/2014 \(OJ L 107, 26.3.2021, p. 1\).](#)

period 2023-2026³¹ and the creation of the Commission's Health Emergency Preparedness and Response Authority (HERA)³². These new rules create a reinforced legal and financial framework to improve EU health security and capacity in the areas of prevention, preparedness, surveillance, risk assessment, early warning and response, including on AMR. AMR is also placed at the heart of the EU's Global Health Strategy³³ launched on 30 November 2022. Finally, AMR is a key action track of the the Quadripartite's (the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Organization for Animal Health (WOAH) and the World Health Organization (WHO)) One Health Joint Plan of Action (2022-2026)³⁴.

- **Challenges regarding AMR**

AMR is a One Health, cross-border and cross-cutting issue. This means that it affects humans, animals and plants, as well as the environment, impacting healthcare and food production systems³⁵. This means also that it should be tackled in all these sectors, involving a wide range of stakeholders, and at all levels, including at global level.

At the same time, the Union and Member States have different levels of competence across the One Health approach. Additionally, AMR affects Member States differently, some countries facing more challenges than others in tackling AMR and applying the One Health approach.

Since the adoption of the 2017 AMR Action Plan, progress has been made in research, development and innovation having the potential to influence the fight against AMR. Many tools to prevent, detect or treat infections caused by resistant pathogens are in the R&D process, including point-of-care tests that quickly determine the identity and the antibiotic sensitivity of the infecting organism before deciding to use an antibiotic or not. Developing and maintaining these tests will require a constant surveillance of antimicrobial resistant bacteria at global level using genomic technologies. Science is continuing to advance further in generating new knowledge and tools and in developing new products (e.g. antimicrobials, diagnostics and vaccines). For instance, ongoing research focuses on the development of new approaches for clinical management and prevention of resistant bacterial infections in high prevalence settings and on the establishment and functioning of a pan-European clinical research network to increase efficiency for testing and developing new diagnostics, preventive and/or therapeutic strategies for infectious diseases³⁶. The AMR Accelerator under the Innovative Medicines

³¹ https://ec.europa.eu/assets/sante/health/funding/wp2022_en.pdf.

³² [Commission Decision of 16 September 2021 establishing a Health Emergency Preparedness and Response Authority - C\(2021\) 6712 final.](#)

³³ [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU - Global Health Strategy Better Health for All in a Changing World - COM\(2022\) 675 final.](#)

³⁴ <https://www.who.int/publications/i/item/9789240059139>.

³⁵ A full definition of One Health is provided by OHHLEP under <https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health>.

³⁶ <https://www.ecraid.eu/projects/ecraid-base/about-ecraid-base>.

Initiative³⁷ addresses many of the scientific challenges of AMR and supports the development of new ways to prevent and treat AMR.

Behavioural and societal changes are also shaping a new context for AMR. The 2022 Special Eurobarometer on AMR³⁸ shows that, although some progress has been achieved since the last Eurobarometer report in 2018³⁹, reducing the misuse of antimicrobials remains a challenge. Optimising antimicrobial consumption (AMC) and improving public awareness about antimicrobials and AMR are crucial to the achievement of a high level of human health protection across the Union.

There is also increasing evidence that the release of antimicrobials into the environment is driving the emergence of more resistant strains.

- **Moving towards a coherent and effective framework**

Given the complexity of AMR, it is crucial to address it through a One Health approach in a coherent framework. Cooperation and coordination at Union level on AMR policies make possible a more coherent, effective and efficient way of making progress in the Union as well as contributing to global efforts.

While much progress has been achieved in the veterinary sector, notably through Regulations (EU) 2019/6 and (EU) 2019/4 and the target on the reduction of antimicrobial sales set out in the Farm to Fork Strategy and in the Zero Pollution Action Plan, it is now crucial to further address human health, where Member States' efforts remain pivotal, and increase action in the environmental domain. It is also necessary to set recommended targets for AMR and AMC in relation to human health in order to achieve common goals within a specified time frame and to monitor progress. In addition, development of and accessibility to antimicrobials and other medical countermeasures relevant to combat AMR in humans should be promoted and innovative financial options should be implemented to support the development and access to effective antimicrobials. Finally, the activities implemented under the 2017 AMR Action Plan need to be extended and complemented to maximise synergies and achieve a stronger response to AMR across the Union and beyond.

With its suggested actions, the objectives of this proposal for a Council Recommendation are to:

- strengthen One Health national action plans on AMR;
- reinforce surveillance and monitoring of AMR and AMC;
- strengthen infection prevention and control;
- strengthen antimicrobial stewardship and prudent use of antimicrobials;
- recommend targets for AMR and antimicrobial consumption in human health;

³⁷ <https://amr-accelerator.eu>.

³⁸ <https://europa.eu/eurobarometer/surveys/detail/2632>.

³⁹ https://health.ec.europa.eu/latest-updates/eurobarometer-antimicrobial-resistance-2018-11-15_en.

- improve awareness, education and training;
- foster research & development, and incentives for innovation and access to antimicrobials and other AMR medical countermeasures;
- increase cooperation; and
- enhance global actions.

The Commission proposal for a Council Recommendation on AMR comes together with the AMR-related measures proposed under the revision of the Union’s pharmaceutical legislation⁴⁰ (i.e. to incentivise the development of innovative novel antimicrobials, to ensure their prudent use and to strengthen the environmental risk assessment as part of the marketing authorisation). Together, they will complement and extend the actions carried out under the 2017 AMR Action Plan and equip the Union with the tools it needs to combat this silent pandemic.

- **Consistency with existing policy provisions in the policy area**

The objectives of this proposal are consistent with existing measures in the policy area, and in particular with the 2017 AMR Action Plan, which aims to: (i) make the Union a best practice region in the fight against AMR; (ii) boost research, development and innovation; and (iii) shape the global agenda. It is also consistent with the following:

- the Strategic Approach to Pharmaceuticals in the Environment which includes several actions to tackle AMR;
- Regulation (EU) 2019/6 and Regulation (EU) 2019/4 which provide for a wide range of measures to fight AMR;
- Commission Implementing Decision (EU) 2020/1729;
- the Pharmaceutical Strategy for Europe that recognised several AMR challenges including the lack of investment in antimicrobials and the inappropriate use of antibiotics, which are now being addressed through the pharmaceutical legislative proposals;
- the EU4Health Programme (2021-2027) and the Horizon Europe programme (2021-2027) under which several actions against AMR are funded; and
- the Global Health Strategy which, under one of its guiding principles, calls to apply a comprehensive One Health approach and intensify the fight against AMR.

⁴⁰ Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC [and amending Directives] and Directive 2009/35/EC and Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006.

- **Consistency with other Union policies**

The objectives pursued by this proposal are consistent with other Union policies, in particular the common agricultural policy⁴¹ which lists AMR among its key objectives⁴², the Farm to Fork Strategy and the Zero Pollution Action Plan which aim at reducing by 50% the overall Union sales of antimicrobials for farmed animals and in aquaculture by 2030. The Horizon 2020 programme⁴³ mobilised over EUR 690 million to support research and innovation on AMR as part of a broader research portfolio on infectious diseases. Support to AMR research and innovation is now continuing under the Horizon Europe programme.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The Treaty on the Functioning of the European Union, and in particular Article 168(6), provides that the Council, on a proposal from the Commission, may adopt recommendations for the purposes set out in that article. This includes the possibility to adopt a recommendation on stepping up Union actions to combat antimicrobial resistance in a One Health approach, which complements national policies and contributes to fighting AMR, which is a major health issue in the Union.

- **Subsidiarity**

AMR is a cross-cutting and cross-border issue, affecting human, animal and plant health, and the environment. It requires a strong and coordinated response. Actions to address AMR at Union level have a clear added value since no single action and no single Member State can, on its own, provide an adequate solution.

This proposal for a Council recommendation sets out areas where Member States can act in a coherent and coordinated manner, while respecting their responsibilities for the definition of their health policy and for the organisation and delivery of health services and medical care in accordance with Article 168(7) TFEU.

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⁴¹ https://agriculture.ec.europa.eu/common-agricultural-policy/cap-overview/cap-glance_en.

⁴² https://agriculture.ec.europa.eu/common-agricultural-policy/cap-overview/new-cap-2023-27/key-policy-objectives-new-cap_en; and Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulations (EU) No 1305/2013 and (EU) No 1307/2013 (OJ L 435, 6.12.2021, p. 1).

⁴³ [Regulation \(EU\) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation \(2014-2020\) and repealing Decision No 1982/2006/EC \(OJ L 347, 20.12.2013, p. 104\).](#)

Proportionality

This proposal is suitable for achieving the intended objectives and does not go beyond what is necessary and proportionate.

- **Choice of the instrument**

A Council recommendation is an appropriate instrument that has been frequently used for Union actions in the field of public health. As a legal instrument, it signals the political will of Member States to achieve the measures presented and to cooperate in this area, while fully respecting the competences of Member States in the field of public health.

3. RESULTS OF *EX POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- ***Ex post* evaluations/fitness checks of existing legislation**

The 2017 AMR Action Plan provides a framework for continued and extensive action to reduce the emergence and spread of AMR. An evaluation of the 2017 AMR Action Plan is not yet feasible as its implementation is still ongoing. Nevertheless, the staff working document accompanying this proposal for a Council recommendation is supported by a future proofing analysis study assessing the outcomes of the 2017 AMR Action Plan to date and identifying priorities to inform improvements for the future.

- **Stakeholder consultations**

Input was gathered through a call for evidence on “Antimicrobial resistance – recommendation for greater action”⁴⁴, which ran from 24 February 2022 to 24 March 2022, with 161 unique feedbacks and 28 relevant documents.

Stakeholders’ views were also gathered through targeted consultations with Member States and experts in the field of AMR conducted in the context of the various studies and reports feeding into this proposal.

- **Collection and use of expertise**

Input for the proposal was gathered from the following studies and reports:

- study on a future proofing analysis of the EU AMR Action Plan (i) to identify current and future challenges and opportunities for the fight against AMR and identify areas for EU action and (ii) to perform a preliminary outcome assessment of some of the activities of the 2017 AMR Action Plan⁴⁵;

⁴⁴ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13322-Antimicrobial-resistance-recommendation-for-greater-action_en.

⁴⁵ European Commission, Directorate-General for Health and Food Safety, Study on a future-proofing analysis of the 2017 AMR action plan: final report, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2875/636347>.

- two studies to support the Commission services⁴⁶ (i) on AMR feasibility on stockpiling⁴⁷ and (ii) on bringing AMR medical countermeasures to the market⁴⁸;
- opinion on “Managing antimicrobial resistance across the health system” from the independent expert panel on effective ways of investing in health⁴⁹;
- overview report on Member States’ One Health National Action Plans against AMR⁵⁰;
- results of the 2022 Eurobarometer on AMR; and
- report of the subgroup⁵¹ under the EU AMR One Health Network⁵².

- **Impact assessment**

An impact assessment was not carried out due to the complementary approach of the recommended activities to Member State initiatives, the non-binding and voluntary nature of the proposed activities, and the leeway for Member States to adapt their approaches to national needs. The development of the proposal was informed by studies, consultations of Member States and a call for evidence.

- **Regulatory fitness and simplification**

Not applicable

- **Fundamental rights**

This proposal for a Council Recommendation respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, notably the right, under Article 35, of a high level of human health protection being ensured in the definition and implementation of all Union’s policies and activities.

⁴⁶ Studies commissioned by European Health Emergency Preparedness and Response Authority (HERA)
⁴⁷ https://health.ec.europa.eu/latest-updates/hera-commissioned-feasibility-study-stockpiling-antimicrobials-against-amr-published-2023-02-02_en.

⁴⁸ European Commission, European Health and Digital Executive Agency, *Study on bringing AMR medical countermeasures to the market : final report*, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2925/442912>.

⁴⁹ https://health.ec.europa.eu/publications/managing-antimicrobial-resistance-across-health-system-0_en

⁵⁰ https://health.ec.europa.eu/publications/overview-report-member-states-one-health-national-action-plans-against-antimicrobial-resistance_en.

⁵¹ This subgroup was tasked to provide technical expertise and opinions from the Member States, “to the Commission on needed concrete objectives and activities to strengthen EU and Member States action against antimicrobial resistance (AMR), in particular in the area of public health, animal health, plant health and the environment, taking into account the latest policy developments and the need to decrease antimicrobial resistance”.

⁵² https://health.ec.europa.eu/latest-updates/final-report-subgroup-established-under-eu-amr-one-health-network-formulate-suggestions-amr-actions-2022-09-05_en.

4. BUDGETARY IMPLICATIONS

None

5. OTHER ELEMENTS

• **Implementation plans and monitoring, evaluation and reporting arrangements**

The Commission will report in [4 years after adoption] on progress in implementing this Recommendation. To that effect, a monitoring framework will be developed.

Proposal for a

COUNCIL RECOMMENDATION

on stepping up EU actions to combat antimicrobial resistance in a One Health approach

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(6) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) In July 2022, the Commission, together with the Member States, identified antimicrobial resistance (AMR) as one of the top three priority health threats¹. It is estimated that more than 35,000 people die each year in the EU/EEA as a direct consequence of an infection due to bacteria resistant to antibiotics². The health impact of AMR is comparable to that of influenza, tuberculosis and HIV/AIDS combined. Overall, the latest data³ show significantly increasing trends in the number of infections and attributable deaths for almost all bacterium–antibiotic resistance combinations, especially in healthcare settings. Around 70% of cases of infections with antibiotic-resistant bacteria were healthcare-associated infections.
- (2) AMR has serious human health and economic consequences for healthcare systems. By reducing the ability to prevent and treat infectious diseases, AMR threatens *inter alia* the ability to perform surgery, the treatment of immunocompromised patients, organ transplantation and cancer therapy. It results in high costs to the healthcare systems of EU/EEA countries⁴. AMR is also a threat to food safety and food security as it has an impact on animal health and production systems.
- (3) AMR is a One Health issue, meaning that it encompasses human health, animal health and the environment, and is a multi-faceted cross-border threat to health that cannot be tackled by one sector independently or by individual countries alone. Tackling AMR requires a high level of collaboration across sectors and between countries, including at global level.

¹ https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats_en.

² <https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf>.

³ <https://www.ecdc.europa.eu/en/news-events/eaad-2022-launch>.

⁴ <https://www.oecd.org/health/health-systems/AMR-Tackling-the-Burden-in-the-EU-OECD-ECDC-Briefing-Note-2019.pdf>.

- (4) The Commission’s Communication of 29 June 2017 “A European One Health Action Plan against AMR” (the '2017 AMR Action Plan')⁵ outlines over 70 actions covering human health, animal health and the environment, whose progress has been regularly monitored⁶. However, further action is needed, in particular in the areas of human health and the environment, which requires the Commission and Member States to give more attention to these areas through this Recommendation.
- (5) The EU4Health Programme⁷ offers a sizeable investment in combating AMR, in particular through direct grants to Member State authorities for the implementation of AMR measures, amongst others supporting Member States in the implementation of One Health AMR National Action Plans, infection prevention and control of both community-acquired and healthcare-associated infections and antimicrobial stewardship strategies. This should serve to support the implementation of this Council Recommendation across Member States. The Horizon Europe programme⁸ will provide support to research and innovation actions and a partnership on One Health AMR⁹, while financing from the European Investment Bank¹⁰ and assistance under the Technical Support Instrument¹¹ could provide additional support to the implementation of this Council Recommendation.
- (6) One Health AMR National Action Plans are essential for a coordinated AMR response across sectors. In the 2016 political declaration of the high-level meeting of the General Assembly on antimicrobial resistance¹², Member States committed to work at national, regional and global levels to develop, in line with the World Health Assembly resolution 68.7, multisectoral action plans, in line with a One Health approach and the Global Action Plan on AMR¹³. The Council Conclusions of 17 June 2016¹⁴ called on Member States to have in place before mid-2017 a national action plan against AMR, based on the One Health approach and in line with the objectives of the WHO Global Action Plan on AMR.
- (7) In its overview report of 18 October 2022¹⁵, the Commission found that, while National Action Plans were in place in all Member States, with most based on a One

⁵ https://health.ec.europa.eu/system/files/2020-01/amr_2017_action-plan_0.pdf.

⁶ https://health.ec.europa.eu/system/files/2022-04/amr_2018-2022_actionplan_progressreport_en.pdf.

⁷ [Regulation \(EU\) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health \(‘EU4Health Programme’\) for the period 2021-2027, and repealing Regulation \(EU\) No 282/2014 \(OJ L 107, 26.3.2021, p. 1\).](https://eur-lex.europa.eu/eli/reg/2021/522/oj)

⁸ [Regulation \(EU\) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations \(EU\) No 1290/2013 and \(EU\) No 1291/2013 \(OJ L 170, 12.5.2021, p. 1\).](https://eur-lex.europa.eu/eli/reg/2021/695/oj)

⁹ https://cordis.europa.eu/programme/id/HORIZON_HORIZON-HLTH-2024-DISEASE-09-01;
https://research-and-innovation.ec.europa.eu/system/files/2022-02/ec_rtd_he-partnerships-onehealth-amr.pdf.

¹⁰ <https://www.eib.org/en/index.htm>.

¹¹ [Regulation \(EU\) 2021/240 of the European Parliament and of the Council of 10 February 2021 establishing a Technical Support Instrument \(OJ L 57, 18.2.2021, p. 1\).](https://eur-lex.europa.eu/eli/reg/2021/240/oj)

¹² <https://digitalibrary.un.org/record/845917#record-files-collapse-header>.

¹³ <https://www.who.int/publications/i/item/9789241509763>.

¹⁴ [Council conclusions of 17 June 2016 on the next steps under a One Health approach to combat antimicrobial resistance.](https://eur-lex.europa.eu/eli/concl/2016/17/oj)

¹⁵ https://health.ec.europa.eu/publications/overview-report-member-states-one-health-national-action-plans-against-antimicrobial-resistance_en.

Health approach at least to some extent, these action plans varied considerably in content and detail. It also concluded that many Member States should work more following a One Health approach, particularly regarding measures concerning the environment, which are often missing or not well developed. Finally, core components, such as the operational, monitoring and evaluation parts, were generally not well developed in the National Action Plan themselves, nor available in related documents. Furthermore, budgeting information was mostly absent from the National Action Plans. These issues raise concerns about the sustainable implementation of the National Action Plans and the arrangements in place in Member States to ensure that their strategic objectives are achieved effectively. Member States should therefore ensure they have National Action Plan based on the One Health approach, underpinned by appropriate structure, monitoring and resources.

- (8) Robust surveillance and monitoring on AMR and antimicrobial consumption (AMC) at all levels in human health, but also in the veterinary, plant and environmental sectors, are crucial to assess the spread of AMR, support the prudent use of antimicrobials and inform infection prevention and control responses.
- (9) Member States have to collect relevant and comparable data on the volume of sales of veterinary antimicrobial medicinal products and on the use of antimicrobial medicinal products per animal species¹⁶. While the application and implementation of Regulation (EU) 2022/2371 of the European Parliament and of the Council¹⁷ makes it possible to improve collection of comparable and compatible data and information on AMR and AMC, further action by Member States is necessary to close existing surveillance and monitoring gaps and to ensure completeness of data both on AMR and AMC at all levels, including by recommending data to be reported and by developing integrated systems for the surveillance of AMR and AMC that encompasses human health, animal health, plant health, food, wastewater and the environment.
- (10) More evidence is needed on the development and spread of AMR through the exposure of pathogens to plant protection products and biocidal products. The possibility for such resistance development should be taken into account as part of the safety evaluation and decision-making for plant protection products and biocidal products.
- (11) While the environmental dimension of AMR has been comparatively less in focus than AMR in human or animal health, growing evidence shows that the natural environment may be a major reservoir and driver of AMR. In line with the One Health approach, environmental monitoring of AMR in freshwater, wastewater and agricultural soils is essential to further understand the role played by the presence in the environment of antimicrobial residues in the emergence and spread of AMR, the levels of environmental contamination and the risks posed to human health. Monitoring is also essential to complement clinical data by providing sampling material from a large population.

¹⁶ in line with the requirements of Regulation (EU) 2019/6 on veterinary medicinal products.

¹⁷ [Regulation \(EU\) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU \(OJ L314, 6.12.2022, p. 26\).](#)

- (12) Residues of medicinal products are widely found in freshwater (surface water and groundwater) and soils, and several publications show that antibiotic residues can contribute to AMR. A potential entry point of AMR genes and organisms into the environment is wastewater treatment plants.
- (13) While the Commission proposals of Autumn 2022 aim at strengthening the environmental monitoring of AMR in freshwater, wastewater and agricultural soils¹⁸, the need to engage in an integrated AMR One Health approach for surveillance systems, including the environment, is recognised¹⁹. An integrated surveillance of findings on drug-resistant microorganisms in humans, animals, plants, food, wastewater and the environment is necessary in order to rapidly detect and prevent outbreaks and to tackle AMR across sectors. Closer cooperation across these sectors may also lead to financial savings. This process involves sharing data and information across sectors for a more effective and coordinated response to combating AMR. The data provided by these surveillance systems can enhance the understanding of the complex epidemiology of AMR to guide policy recommendations and develop initiatives to respond to AMR risks before they become large-scale emergencies.
- (14) Robust infection prevention and control, in particular in acute care settings such as hospitals and in long-term care facilities, contribute to fighting AMR. The COVID-19 pandemic brought heightened awareness of infection prevention and control, including hygiene measures, to promote a reduction in the transmission of microbes, including resistant ones. However, with over 70% of the AMR burden due to healthcare-associated infections, there is a need for greater provision of high standards of infection prevention and control. This also includes high standards of patient safety.
- (15) While it is well-recognised that the inappropriate use of antimicrobials, both in humans and in animals, is a main driver behind increased levels of AMR, there are consistent reports on shortcomings in ensuring high levels of antimicrobial stewardship across Member States. Prudent use of antimicrobials and high standards of infection prevention and control at the levels of the community, hospitals and long-term care facilities are essential aspects in reducing the emergence and development of AMR. This Recommendation complements Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine²⁰, the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections²¹, and the 2017 guidelines for the prudent use of antimicrobials in human health²². It also complements the revision of

¹⁸ [Commission proposal of 26 October 2022 for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy. COM \(2022\) 540 final and Commission proposal of 26 October 2022 for a Directive concerning urban wastewater treatment \(recast\) COM\(2022\) 541 final\).](#)

¹⁹ European Commission, Directorate-General for Health and Food Safety, Study on a future-proofing analysis of the 2017 AMR action plan: final report, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2875/636347>.

²⁰ [Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine \(OJ L 34, 5.2.2002, p. 13\).](#)

²¹ [Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections \(OJ C 151, 3.7.2009, p. 1\).](#)

²² [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC0701\(01\).](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC0701(01))

the Union's pharmaceutical legislation which proposes to introduce, in the revised Directive on the Union code relating to medicinal products for human use²³, specific regulatory measures to enhance the prudent use of antimicrobials.

- (16) AMR leads to increased morbidity and mortality of animals. It endangers animal health and welfare and, therefore animal productivity, having a major socio-economic impact in the agricultural sector. The safety of the food chain is affected by animal health and welfare, particularly those farmed for food production. Ensuring a high level of animal health and welfare leads to improved resilience in animals, making them less vulnerable to diseases, which helps decrease antimicrobial use.
- (17) The application of sewage sludge and manure as fertilisers on agricultural soil may lead to the development of AMR through the spread of antimicrobial resistant bacteria and antimicrobial resistance genes in the environment, further contaminating the food chain. While more data are necessary, introducing prudent manure management practices is necessary.
- (18) The setting of concrete measurable targets is an effective way to achieve goals related to the prevention and reduction of AMR within a specified timeframe and to monitor progress²⁴. Discussions on AMR targets have taken place internationally, for example in the context of the Transatlantic Task Force on Antimicrobial Resistance²⁵, the UN Sustainable Development Goals²⁶ and the G7²⁷. More recently, in November 2022, the third Global High-level Ministerial Conference on Antimicrobial Resistance recognised the value of setting targets to galvanise strong national and global political action and consolidation of efforts and commitment²⁸.
- (19) While a target for a 50% reduction of overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030 has been included in the Farm to Fork Strategy²⁹ and in the Zero Pollution Action Plan³⁰ and the reduced use of antimicrobials in farmed animals should be monitored through the common agricultural policy support measures³¹, there is currently no AMR related target in the human health sector at EU

²³ Proposal for a Directive of the European parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC [and amending Directives] and Directive 2009/35/EC.

²⁴ [ECDC, EFSA and EMA Joint Scientific Opinion on a list of outcome indicators as regards surveillance of antimicrobial resistance and antimicrobial consumption in humans and food-producing animals.](https://www.ecdc.europa.eu/en/our-work/antimicrobial-resistance/antimicrobial-resistance-surveillance/antimicrobial-resistance-surveillance-in-humans-and-food-producing-animals)

²⁵ [https://www.cdc.gov/drugresistance/tatfar/index.html.](https://www.cdc.gov/drugresistance/tatfar/index.html)

²⁶ [https://sdgs.un.org/goals.](https://sdgs.un.org/goals)

²⁷ [https://www.g7germany.de/resource/blob/974430/2042058/5651daa321517b089cdccfaffd1e37a1/2022-05-20-g7-health-ministers-communicate-data.pdf.](https://www.g7germany.de/resource/blob/974430/2042058/5651daa321517b089cdccfaffd1e37a1/2022-05-20-g7-health-ministers-communicate-data.pdf)

²⁸ [https://fm.gov.om/global-conference-on-antimicrobial-resistance-issues-muscat-manifesto/.](https://fm.gov.om/global-conference-on-antimicrobial-resistance-issues-muscat-manifesto/)

²⁹ [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system - COM/2020/381 final.](https://ec.europa.eu/commission/presscorner/detail/en/ip_2020_381)

³⁰ [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' COM\(2021\) 400.](https://ec.europa.eu/commission/presscorner/detail/en/ip_2020_381)

³¹ On the basis of result indicator R.43 (share of livestock units concerned by supported actions to limit the use of antimicrobials) of the CAP Strategic Plan Regulation (Regulation (EU) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural

level. The Commission, with the European Centre for Disease Prevention and Control (ECDC), has designed concrete targets both at Union and Member States level that would reduce the unnecessary use of antimicrobials. The recommended targets at Member States level take due consideration of each national situation and different existing levels of antimicrobial consumption and spread of key resistant pathogens. They reflect the level of efforts to be provided by each Member State to reach the EU common targets while not compromising patient health and safety. They also allow for targeted support where necessary and for monitoring the progress made in the coming years.

- (20) Setting up recommended targets at EU level on AMC and AMR is a useful tool to achieve and monitor progress in both the underlying factors influencing AMR, notably antimicrobial consumption, and the spread of AMR, in particular regarding pathogens that pose the highest burden and threat to public health in the EU. The recommended targets are based on existing data reported under EU surveillance in 2019³², chosen as a baseline year, given that the situation in 2020 and 2021 is deemed exceptional, and therefore inappropriate to serve as a basis, due to the COVID-19 pandemic and the unusual restrictive measures in place. The recommended targets should contribute to achieving common goals and can be complemented by national targets that cover other AMR-related aspects, such as infection prevention and control, antimicrobial stewardship, prescription practices and training.
- (21) The 2022 Special Eurobarometer on AMR³³ reveals that knowledge about antibiotics is still lacking in the EU with only half of those questioned being aware that antibiotics are ineffective against viruses, and that there are still great differences in Union citizens' awareness across Member States. In addition, almost one in ten Union citizens are taking antibiotics without prescription. Those results demonstrate the need to increase and improve communication and awareness-raising activities on AMR and prudent use of antimicrobials at all levels as means to promote knowledge and behavioural change.
- (22) Education, awareness and training of professionals working in human health, veterinary and agronomy sectors on AMR, on infection prevention and control and on the One Health approach play an important role in the fight against AMR, due in particular to their roles as advocates for prudent antimicrobial use and educators of patients and farmers. Continuous education programmes and curricula should include mandatory cross-sectoral training and competence courses on AMR, on infection prevention and control, on environmental risk, on biosecurity and on antimicrobial stewardship, as appropriate.
- (23) According to the World Health Organisation (WHO), 11 new antibiotics have been approved (by either the Commission or the US Food and Drug Administration or both) since July 2017. With some exceptions, the newly approved antibiotics have limited clinical benefit over existing treatments, as over 80% are from existing classes where resistance mechanisms are well established and rapid emergence of resistance is

[Fund for Rural Development \(EAFRD\) and repealing Regulations \(EU\) No 1305/2013 and \(EU\) No 1307/2013 \(OJ L 435, 6.12.2021, p. 1\).](#)

³² Based on existing data available from the European Antimicrobial Resistance Surveillance Network (EARS-Net).

³³ <https://europa.eu/eurobarometer/surveys/detail/2632>.

foreseen. Currently in the pipeline there are 43 antibiotics and combinations with a new therapeutic entity. Only a few of them meet at least one of the WHO innovation criteria (i.e. absence of known cross-resistance, new binding site, mode of action and/or class). Overall, the clinical pipeline and recently approved antibiotics are insufficient to tackle the challenge of increasing emergence and spread of AMR. The failure to develop and make available effective new antibiotics is further fuelling the impact of AMR; there is, therefore, an urgent need to develop and implement new incentives.

- (24) The Commission aims at improving preparedness and response to serious cross-border threats in the area of medical countermeasures, notably by promoting advanced research and development of medical countermeasures and related technologies and by addressing market challenges. In that context, the Commission, in a complementary manner to the regulatory framework applicable to medicinal products for human use, should address the antimicrobial market failure and promote the development and accessibility of medical countermeasures relevant to combat AMR, including new and old antimicrobials, diagnostics and vaccines against resistant pathogens.
- (25) Since the 2017 AMR Action Plan, several proposals for new economic models for bringing new antimicrobials to the market have been proposed, including in the conclusions of the JAMRAI³⁴, which delivered on 31 March 2021 a “strategy for implementing multi-country incentives in Europe to stimulate antimicrobial innovation and access”³⁵.
- (26) The Commission commissioned a study entitled “bringing AMR Medical Counter Measures on the market”³⁶ simulating four types of pull mechanisms of different financial size for ensuring access to antimicrobials: revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards and milestone payments, and providing options for their implementation at EU level.
- (27) The EU4Health work programme 2023³⁷ offers a sizeable investment in combating AMR, in particular through the specific action “Support innovation and access to antimicrobials”³⁸. This will enable the creation a network supporting the Commission and the Member States for the preparation and implementation of procurement(s) of medical countermeasures and reserve capacities for the production or access to targeted AMR medical countermeasures.
- (28) Actions on research and innovation supported by the Horizon 2020 and the Horizon Europe programmes are key for the development, evaluation and implementation of measures against AMR. Continued support and collaboration remain crucial to strengthen the impact of research and innovation for the detection, prevention and treatment of infections caused by resistant pathogens and should be ensured.

³⁴ <https://eu-jamrai.eu/>.

³⁵ https://eu-jamrai.eu/wp-content/uploads/2021/03/EUjamrai_D9.2_Strategy-for-a-multi-country-incentive-in-Europe_INSERT-FHI.pdf.

³⁶ European Commission, European Health and Digital Executive Agency, *Study on bringing AMR medical countermeasures to the market : final report*, Publications Office of the European Union, 2023, <https://data.europa.eu/doi/10.2925/442912>.

³⁷ https://health.ec.europa.eu/publications/2023-eu4health-work-programme_en.

³⁸ https://health.ec.europa.eu/system/files/2022-11/wp2023_annex_en.pdf.

- (29) Vaccines are cost-effective powerful tools to prevent communicable diseases in both humans and animals, and therefore have the potential to curb the spread of AMR infections and reduce the use of antimicrobials. It is therefore necessary to promote the use of vaccination as well as the development of, the availability of and the access to vaccines.
- (30) Member States cross-sectoral cooperation and stakeholders' involvement are crucial to ensure the full and effective implementation of One Health AMR policies and actions and it is proposed to enhance this cooperation, particularly through the EU AMR One Health Network³⁹.
- (31) A high level of cooperation between Union Agencies (European Food Safety Authority (EFSA)⁴⁰, European Centre for Disease Prevention and Control (ECDC)⁴¹ and European Medicines Agency (EMA)⁴² should be reinforced and extended to include the European Environmental Agency (EEA)⁴³ and the European Chemical Agency (ECHA)⁴⁴, to ensure a coherent, One Health, evidence-based response to AMR.
- (32) Combatting AMR in the context of the One Health approach is a priority in the EU Global Health Strategy⁴⁵, including through the inclusion of concrete provisions on AMR in the context of the negotiation of a potential WHO international agreement on pandemic prevention, preparedness and response⁴⁶. While global attention to AMR is growing, fostering international cooperation, is needed to ensure a coordinated response from the global community and adequate support mainstreamed towards priorities established at global and regional levels for funding, research and policy efforts. In that respect enhanced cooperation should take place, in particular in the context of the United Nations, G7, G20 and with the quadripartite organisations (the Food and Agriculture Organization of the United Nations (FAO)⁴⁷, the United Nations Environment Programme (UNEP)⁴⁸, the World Organization for Animal Health (WOAH)⁴⁹ and the World Health Organization (WHO)⁵⁰).
- (33) The implementation of the 2017 AMR Action Plan and of this Recommendation should be monitored regularly to measure progress towards achieving their objectives and identify gaps in the efforts to tackle AMR.

HAS ADOPTED THIS RECOMMENDATION:

A. National Action Plans against AMR

³⁹ https://health.ec.europa.eu/antimicrobial-resistance/events_en?f%5B0%5D=topic_topic%3A173.

⁴⁰ <https://www.efsa.europa.eu/eu>.

⁴¹ <https://www.ecdc.europa.eu/en>.

⁴² <https://www.ema.europa.eu/en>.

⁴³ <https://www.eea.europa.eu/about-us>.

⁴⁴ <https://echa.europa.eu/>.

⁴⁵ https://health.ec.europa.eu/system/files/2023-02/international_ghs-report-2022_en.pdf.

⁴⁶ <https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord>.

⁴⁷ <https://www.fao.org/home/en>.

⁴⁸ <https://www.unep.org/>.

⁴⁹ <https://www.woah.org/en/home/>.

⁵⁰ <https://www.who.int/>.

Member States are invited to:

1. Have in place by [1 year after adoption of the Council Recommendation], regularly update and implement National Action Plans against AMR (“National Action Plans”), based on the One Health approach and in line with the objectives of the World Health Organization Global Action Plan and the 2016 Declaration of the United Nations high-level meeting of the General Assembly on AMR.

Member States should in particular:

- a. ensure that in the National Action Plans combating AMR and promoting the prudent use of antimicrobials feature as a priority of their national health systems.
 - b. ensure that the National Action Plans include intersectoral coordination, implementation and monitoring plans and mechanisms to ensure their effective governance;
 - c. ensure that the National Action Plans include specific measures to achieve overarching measurable goals, implementation modalities and indicators to assess progress towards achieving these goals, including the recommended targets set out in the section E of this Recommendation;
 - d. Ensure that the National Action Plans refer to the relevant elements of the National Common Agricultural Policy Strategic Plans to combat AMR;
 - e. ensure that the National Action Plans include evidence-based measures to prevent, monitor and reduce the spread of AMR in the environment; and
 - f. allocate appropriate human and financial resources for the effective implementation of the National Action Plans.
2. Evaluate, every 2 years, the outcomes of the National Action Plans and take actions to address the outcomes of these evaluations and other relevant inputs, while taking into account new findings and emerging trends.
 3. Ensure that National Action Plans and the regular evaluation of their outcomes are made publicly available within 6 months after completion of the evaluation.

B. *Surveillance and monitoring of AMR and antimicrobial consumption (AMC)*

Member States are invited to:

4. Close existing surveillance and monitoring gaps and ensure completeness of data, by 2030, both on AMR and AMC at all levels (e.g. community, hospitals and long-term care facilities) to support the prudent use of antimicrobials in human health, by:
 - a. ensuring that surveillance of AMR in bacteria from humans encompasses not only bloodstream and cerebrospinal fluid isolates (invasive isolates) but also all other isolates from clinical microbiology laboratories, and that the

corresponding data are regularly reported to the ECDC to rapidly detect and better gauge the scale and spread of antimicrobial resistant pathogens within and across Member States;

- b. requiring that infections by critical multidrug-resistant organisms, e.g. carbapenem-resistant *Acinetobacter baumannii*, carbapenem-resistant Enterobacteriaceae (e.g. *Klebsiella pneumoniae*, *Escherichia coli*) and *Candida auris*, are notifiable diseases under national legislation;
- c. expanding surveillance of AMR in humans to pathogens with emerging or established AMR, due to their exposure to substances in the environment, in particular those used in plant protection products or biocidal products;
- d. collecting data on prescription of antimicrobials in humans at the appropriate levels, *inter alia* through using electronic prescriptions, to allow the monitoring of antimicrobial prescribing and to provide feedback on prescription trends and patterns involving, among others, prescribers, pharmacists and other parties collecting such data;
- e. developing integrated systems for the surveillance of AMR and AMC encompassing human health, animal health, plant health, food, wastewater and the environment (in particular water and soil). Such integrated and continuous monitoring must be designed to efficiently and rapidly detect outbreaks but equally as regards soil and water bodies to determine the presence of AMR genes, the trends and their toxicity. The results of this surveillance must inform effective strategies to tackle AMR across sectors.

The Council welcomes the Commission's intention to:

5. Continue to assess on the basis of opinions of the European Food Safety Authority (EFSA) animal diseases caused by bacteria resistant to antimicrobials, to ascertain if it is needed to list any of those diseases in Regulation (EU) 2016/429⁵¹ with a view to categorising them for any regulatory surveillance, control or other management measures.

C. Infection prevention and control

Member States are invited to:

6. Ensure that infection prevention and control measures in human health are implemented and continuously monitored to contribute to limiting the spread of antimicrobial resistant pathogens, in particular by:

⁵¹ [Regulation \(EU\) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health \('Animal Health Law'\) \(OJ L 084 31.3.2016, p. 1\).](#)

- a. strengthening infection prevention and control in healthcare settings and long-term care facilities through:
 - ensuring core competencies for infection prevention and control/hospital hygiene professionals;
 - ensuring adequate resources for infection prevention and control programmes;
 - quality control;
 - surveillance;
 - developing appropriate guidelines; and
 - awareness raising and training activities.
 - b. upgrading existing hospital infrastructures to ensure a high level of infection prevention and control;
 - c. ensuring strong links to patient safety and prevention of healthcare associated infections, including sepsis, notably by improving training of healthcare personnel and ensuring high quality microbiological support and patient records;
 - d. ensuring continuous training regarding knowledge on infection prevention and control of all personnel in community, hospitals and long-term care facilities;
 - e. fully developing and implementing national immunisation programmes and taking measures to progressively eliminate vaccine preventable diseases on the basis of Council Recommendation of 7 December 2018 on Strengthened Cooperation against Vaccine Preventable Diseases⁵².
7. Take measures to improve the health and welfare of food-producing animals in order to decrease the occurrence and spread of infectious diseases in farming and subsequently reduce the need for antimicrobial use, in particular by:
- a. encouraging veterinarians and other relevant actors to advise farmers on preventive and control measures against infectious diseases;
 - b. encouraging the uptake of biosecurity and infection prevention and control measures in farms;
 - c. making use of the support available in the context of the common agricultural policy to implement preventive actions against infectious diseases⁵³ that go beyond EU minimum legal requirements;

⁵² [Council Recommendation 2018/C 466/01 of 7 December 2018 on Strengthened Cooperation against Vaccine Preventable Diseases \(OJ C 466, 28.12.2018, p. 1\).](#)

⁵³ [Regulation \(EU\) 2021/2115 of the European Parliament and of the Council of 2 December 2021 establishing rules on support for strategic plans to be drawn up by Member States under the common agricultural policy \(CAP Strategic Plans\) and financed by the European Agricultural Guarantee Fund](#)

- d. making use of the European Maritime, Fisheries and Aquaculture Fund (2021-2027)⁵⁴ for projects included in the national programmes, and in accordance with the eligibility rules defined by the Member States concerned;
 - e. implementing the Member State actions outlined in the Annex of the “Strategic guidelines for a more sustainable and competitive EU aquaculture for the period 2021 to 2030”⁵⁵;
 - f. encouraging breeding techniques⁵⁶ in aquaculture for the development of disease resistant strains, as a contributor to reduced antimicrobial use;
 - g. promoting the use of vaccination, including in aquaculture, and alternatives to help prevent certain diseases and avoid the unnecessary use of antimicrobials;
 - h. promoting the development and use of innovative feed additives;
 - i. developing targeted measures by sector once data on the use of antimicrobials by species of food-producing animals become available under Article 57 of Regulation (EU) 2019/6.
8. Implement good, evidence-based, manure management practices and good sewage sludge management practices addressing their application in agriculture to reduce environmental exposure to substances with antimicrobial properties and to AMR determinants.

The Council welcomes the Commission’s intention, in cooperation with Member States, to:

- 9. Develop EU infection prevention and control guidelines in human health, notably for hospitals and long-term care facilities by [3 years after adoption of the Council Recommendation].

D. Antimicrobial stewardship and prudent use of antimicrobials

Member States are invited to:

- 10. Ensure that measures are implemented in human health to support the prudent use of antimicrobial agents, in particular by:
 - a. implementing, and adapting to national circumstances where needed, any EU guidelines for the treatment of common infections and for perioperative

[\(EAGF\) and by the European Agricultural Fund for Rural Development \(EAFRD\) and repealing Regulations \(EU\) No 1305/2013 and \(EU\) No 1307/2013 \(OJ L 435, 6.12.2021, p. 1\).](#)

⁵⁴ https://oceans-and-fisheries.ec.europa.eu/funding/emfaf_en.

⁵⁵ [Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Strategic guidelines for a more sustainable and competitive EU aquaculture for the period 2021 to 2030 COM\(2021\) 236 final.](#)

⁵⁶ DNA engineering techniques limited to the use of species that have undergone a risk assessment with favourable outcome.

- prophylaxis in order to respect best practices and optimise prudent use of antimicrobials;
- b. designing measures for health professionals to ensure their adherence to prudent use guidelines; and
 - c. encouraging and supporting the uptake of diagnostic tests, in particular in primary care, to optimise antimicrobial treatment.
11. Have in place programmes for the collection and safe disposal of unused, expired and leftover antimicrobials from the community, hospitals and long-term care facilities, farms and veterinary medicine providers.

The Council welcomes the Commission's intention, in cooperation with Member States to:

12. Work towards the development of EU guidelines for the treatment of major common infections in humans and for perioperative prophylaxis in humans, which would include information on the use of adequate diagnostic tests, the need for antibiotics, the choice of the appropriate antibiotic (if needed), the dose and dose intervals, and the duration of treatment/prophylaxis, taking into account best available practice, the availability of antibiotics and the need to ensure their most optimal and prudent use. When developing these guidelines, the WHO AWaRe antibiotic book⁵⁷ should be taken into account and a close collaboration with European and national professional societies should be ensured.

The Council welcomes the Commission's intention and Member States are invited to:

13. Consider the risk of development of resistance to human and veterinary antimicrobials from the use of plant protection products or biocidal products, based on scientific evidence, as part of the safety evaluation and decision-making on these products; and, if necessary, implement appropriate conditions or restrictions of use for the concerned products.

E. Recommended targets for antimicrobial consumption and antimicrobial resistance

Member States are invited to:

14. Take appropriate national measures to ensure that, by 2030, the total consumption of antibiotics in humans (in Defined Daily Dose (DDD) per 1 000 inhabitants per day), in the community and hospital sectors combined, including in long-term care facilities, is reduced by 20% in the Union compared with the baseline year 2019.
15. Take appropriate national measures to ensure that, by 2030, at least 65% of the total consumption of antibiotics in humans belongs to the Access group of antibiotics as defined in the AWaRe classification of the WHO⁵⁸.

⁵⁷ <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2022.02>.

⁵⁸ <https://www.who.int/publications/i/item/2021-aware-classification>.

16. Take appropriate national measures to ensure that, by 2030, the total incidence of bloodstream infections with methicillin-resistant *Staphylococcus aureus* (MRSA) (number per 100,000 population) is reduced by 15% in the EU, compared to the baseline year 2019.
17. Take appropriate national measures to ensure that, by 2030, the total incidence of bloodstream infections with third generation cephalosporins-resistant *Escherichia coli* (number per 100,000 population) is reduced by 10% in the EU, compared to the baseline year 2019.
18. Take appropriate national measures to ensure that, by 2030, the total incidence of bloodstream infections with carbapenem-resistant *Klebsiella pneumoniae* (number per 100,000 population) is reduced by 5% in the EU, compared to the baseline year 2019.

Member States' recommended individual contributions to reach these Union targets are presented in the Annex to this Recommendation.

19. Set up indicators that would support the attainment of the recommended targets as well as targets on other AMR-related aspects such as infection prevention control, antimicrobial stewardship, prescription practices and training.

The Council welcomes the Commission's intention and Member States are invited to

20. Put in place appropriate measures to contribute to the achievement of the Farm to Fork Strategy and Zero Pollution Action Plan target of 50% reduction of the overall EU sales of antimicrobials used for farmed animals and in aquaculture by 2030.

F. Awareness, education and training

Member States are invited to:

21. Ensure, in cooperation with higher and professional education institutions as well as stakeholders, that national continuous education programmes and curricula, in *inter alia* medicine, nursing, pharmacy, dentistry, veterinary medicine, farming schools and agronomics sciences include mandatory cross-sectoral training and competence on AMR, on infection prevention and control, on environmental risks, on biosecurity and on antimicrobial stewardship, including prudent use of antimicrobials, as appropriate.
22. Raise awareness among the public and health professionals working in human health and veterinary sectors on the existence of programmes for the collection and safe disposal of unused, expired and leftover antimicrobials and the importance of those programmes in the prevention of AMR.
23. Increase and improve communication and awareness-raising on AMR and prudent use of antimicrobials to promote knowledge and behavioural change by:
 - a. providing professionals working in human health, veterinary and agronomy sectors with regularly updated information about AMR at national and local

- levels as well as information materials on AMR and the importance of effective infection prevention and control, environmental risks, biosecurity and antimicrobial stewardships, including prudent use of antimicrobials;
- b. developing public awareness-raising activities and large-scale communication campaigns on AMR, notably its prevention through hygiene, in particular hand hygiene, and prudent use of antimicrobials at national level;
 - c. developing targeted communication campaigns to raise awareness in specific population groups, using appropriate means and channels of communication for these specific groups.
24. Inform and coordinate on the above-mentioned awareness-raising activities and communication campaigns between them, with the Commission, with relevant Union Agencies, and with other relevant bodies, in order to maximise their impact.

The Council welcomes the Commission's intention to:

- 25. Support and complement Member States' awareness-raising activities on AMR and prudent use of antimicrobials with pan-European communication actions when relevant.
 - 26. Support Member States in the continuous training and life-long learning of the professionals working in human health, veterinary and agronomy sectors about the threat of AMR and its prevention following the One Health approach through training opportunities such as the Better Training for Safer Food initiative⁵⁹.
- G. *Research & development and incentives for innovation & access to antimicrobials and other AMR medical countermeasures***

The Council welcomes the Commission's intention to and Member States are invited to:

- 27. Support research and technological innovation for the detection, prevention and treatment of infections in humans caused by antimicrobial resistant pathogens, including the establishment of and significant investment in a European partnership to allow coordination, alignment and funding of cross-sectorial research and innovation on "One Health AMR".
- 28. Promote the development of and accessibility to antimicrobials and other medical countermeasures relevant to combat AMR in humans, notably diagnostic tests and vaccines targeting antimicrobial resistant pathogens.

To that end, the Council welcomes the Commission's intention to:

⁵⁹ https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/legislation-official-controls/better-training-safer-food_en.

- a. support Member States in identifying priority antimicrobial resistant pathogens at Union and Member State level, in mapping existing, upcoming and missing AMR medical countermeasures, and in defining target product profiles;
 - b. support research and development of AMR medical countermeasures, notably by coordinating funding of translational research and late-stage development of AMR medical countermeasures, including clinical trials for antimicrobials;
 - c. improve the continuity of supply of antimicrobials and other AMR medical countermeasures in the EU, notably by supporting and coordinating Member States' initiatives on the manufacturing, procurement and stockpiling;
 - d. improve demand forecast, assessing and addressing antibiotics supply chain vulnerabilities, and implement targeted antibiotics stockpiling actions to avoid shortages.
29. Contribute to the design and governance of a Union multi-country pull incentive scheme in order to improve innovation, development and access to antimicrobials. Such scheme could take the form of revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards or milestone payments. It should be implemented in a complementary manner to the regulatory framework applicable to medicinal products for human use.
30. Pool resources, take collaborative actions, financially contribute to the implementation of the pull incentive scheme, and commit to participate in the network⁶⁰ referred to under the EU4Health work programme 2023.
31. Regularly review the scheme and its impact on the development and accessibility of antimicrobials.
32. Incentivise the development and placing on the market of alternatives to antimicrobials and vaccines for animal health.

H. Cooperation

Member States are invited to:

33. Report data on AMR and on antimicrobial consumption to the Global Antimicrobial Resistance and Use Surveillance System (GLASS)⁶¹.
34. Take opportunities of the regular meetings of the EU AMR One Health Network and other relevant committees and working groups discussing AMR to:
- a. enhance their cooperation between them , as well as with the Commission, with the relevant Union Agencies, and with AMR stakeholders, professionals and experts;

⁶⁰ CP-p-23-16 Support innovation and access to antimicrobials.

⁶¹ <https://www.who.int/initiatives/glass>.

- b. exchange best practices, notably on measures to ensure adherence of healthcare professionals to prudent use guidelines;
 - c. share National Action Plans on AMR and related implementation reports and evaluations with each other, with the Commission and with relevant Union Agencies, and enable the peer-review of those documents.
35. Enhance the cooperation on AMR between professionals working in human health, veterinary and agronomy sectors and with stakeholders, in order to improve the One Health approach on AMR.

The Council welcomes the Commission's intention to:

36. Enhance the cooperation on AMR between EFSA, EMA, ECDC, EEA and ECHA and reinforce the One Health approach on AMR through an interagency AMR working group. The working group will:
- a. provide an effective platform holding regular meetings to ensure exchange of information on AMR and discuss upcoming requests and mandates; and
 - b. work toward an integration of surveillance data across sectors.
37. Develop a monitoring framework to assess the progress and results achieved in implementing the 2017 AMR Action Plan and this Recommendation.

I. Global

The Council welcomes the Commission's intention and Member States are invited to:

38. Advocate for the development, and the implementation by third countries, of standards by the International Standard Setting Bodies, in particular:
- a. for more ambitious WOH standards and guidelines on the responsible and prudent use of antimicrobials agents in veterinary medicine, which should reflect the need to phase out antimicrobial use to promote growth or increase yield in animals on a global scale;
 - b. for the development of guidance on the prudent use of antimicrobial agents for phytosanitary purposes by the International Plant Protection Convention⁶²;
 - c. for the implementation of the revised Codex Alimentarius *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance*⁶³ and the

⁶² <https://www.ippc.int/en/>

⁶³ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXC%2B61-2005%252FCXC_061e.pdf

*Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance*⁶⁴.

39. Work towards the inclusion of concrete provisions on AMR following a One Health approach in the context of negotiation on a potential WHO international agreement on pandemic prevention, preparedness and response⁶⁵.
40. Support the WHO initiatives to prepare guidance on how good manufacturing practices should be implemented to waste and wastewater management in the context of the production of antimicrobials, following the WHO's Executive Board decision of 30 November 2018 on that matter⁶⁶.
41. Advocate for AMR to feature as a high political priority in G7 and G20 settings, leading to ambitious commitments at global level, including to establish and advocate for the adoption of guiding principles in order to fairly share, among the G20 or G7 countries, the financial burden arising from pull incentives for antimicrobials.
42. Advocate for the planned United Nations High Level conference on AMR in 2024 to raise global commitments to address AMR, including *inter alia* on targets on antimicrobials use building on the Muscat Ministerial manifesto on AMR.
43. Support and engage actively in the Quadripartite's "AMR Multi-Stakeholder Partnership Platform"⁶⁷, to help establish a shared global vision and build more consensus on AMR.
44. Provide development capacity and support AMR actions in low-and-middle income countries, in particular through:
 - a. engaging in the Team Europe Initiative with Africa on sustainable Health security using a One health approach⁶⁸, which notably aims to contribute to tackle AMR;
 - b. supporting the implementation of AMR One Health National Action Plans in low and middle-income countries, in particular through the UN AMR Multi-Partner Trust Fund (MPTF)⁶⁹;
 - c. contributing to the efforts in tackling infectious diseases and AMR in low and middle-income countries such as through the European and Developing

⁶⁴ https://www.fao.org/fao-who-codexalimentarius/sh-proxy/ar/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B94-2021%252FCXG_94e.pdf

⁶⁵ <https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord>.

⁶⁶ https://apps.who.int/gb/ebwha/pdf_files/EB144/B144_19-en.pdf.

⁶⁷ <https://www.fao.org/antimicrobial-resistance/quadripartite/the-platform/en/>.

⁶⁸ <https://europa.eu/capacity4dev/tei-jp-tracker/tei/sustainable%C2%A0health-security-africa>.

⁶⁹ <https://mptf.undp.org/fund/amr00>.

Countries Clinical Trial Partnership (Global Health EDCTP3 Joint Undertaking)⁷⁰.

J. Reporting

The Council welcomes the Commission's intention to:

45. Report to the Council 4 years after adoption on progress in implementing this Recommendation.

Done at Brussels,

*For the Council
The President*

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https://research-and-innovation.ec.europa.eu/research-area/health/edctp_en.