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NOTE From:	General Secretariat of the Council
To:	Council
Subject:	Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach
	(legal basis proposed by the Commission: Article 168(6)TFEU)
	- Adoption

- On 26 April 2023 the Commission submitted to the Council the proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance (AMR) in a One Health approach, based on Article 168(6) TFEU.
- 2. The proposal includes a series of actions to: strengthen national action plans against antimicrobial resistance; reinforce surveillance and monitoring of AMR and antimicrobial consumption (AMC); strengthen infection prevention and control as well as antimicrobial stewardship and prudent use of antimicrobials; recommend targets for AMC and AMR in human health; improve awareness, education and training; foster research and development, and incentives for innovation and access to antimicrobials and other AMR medical countermeasures; increase cooperation; and enhance global actions.

- 3. The Working Party on Public Health examined the proposal on 2, 11 and 22 May 2023.
- Following an informal written consultation concluded on 25 May 2023, the Working Party on Public Health agreed on the Presidency compromise text for the Recommendation<sup>1</sup>.
  A linguistic change was made to recital 11 and the final compromise text is set out in Annex to this note.
- 5. On 31 May 2023 the Permanent Representatives Committee (Part I) confirmed the agreement reached in the Working Party on Public Health and agreed to submit the corresponding text to the EPSCO Council of 13 June 2023 for adoption.
- The Council (EPSCO) is invited to adopt, at its session on 13 June 2023, the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, as set out in the Annex to this note.
- 7. After the Recommendation has been adopted, it will be published in the Official Journal of the European Union.

<sup>1 8902/2/23</sup> REV 2

## <u>ANNEX</u>

2023/0125 (NLE)

### 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 threats<sup>2</sup>. 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 antibiotics<sup>3</sup>. The health impact of AMR is comparable to that of influenza, tuberculosis and HIV/AIDS combined. Overall, the latest data<sup>4</sup> show significantly increasing trends in the number of infections and attributable deaths for almost all bacterium–antibiotic resistance combinations, especially in healthcare settings. It is estimated that around 70% of cases of infections with antibiotic-resistant bacteria were healthcare-associated infections. Furthermore, the health impact of fungicide-resistant fungi has become more apparent over the years.
- (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 countries<sup>5</sup>. 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, plant 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.

<sup>&</sup>lt;sup>2</sup> <u>https://health.ec.europa.eu/publications/hera-factsheet-health-union-identifying-top-3-priority-health-threats\_en.</u>

<sup>&</sup>lt;sup>3</sup> <u>https://www.ecdc.europa.eu/sites/default/files/documents/Health-burden-infections-antibiotic-resistant-bacteria.pdf.</u>

<sup>4</sup> https://www.ecdc.europa.eu/en/news-events/eaad-2022-launch.

<sup>5 &</sup>lt;u>https://www.oecd.org/health/health-systems/AMR-Tackling-the-Burden-in-the-EU-OECD-ECDC-Briefing-Note-2019.pdf</u>.

(4) The Commission's Communication of 29 June 2017 "A European One Health Action Plan against AMR" (the '2017 AMR Action Plan')<sup>6</sup> outlines over 70 actions covering human health, animal health and the environment, whose progress has been regularly monitored<sup>7</sup>. 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 for instance through this Recommendation. The Council conclusions of 14 June 2019 on the next steps towards making the EU a best practice region in combating antimicrobial resistance<sup>8</sup> and the Council conclusions of 7 December 2021 on strengthening the European Health Union<sup>9</sup> contribute to the work against AMR in that respect.

<sup>6 &</sup>lt;u>https://health.ec.europa.eu/system/files/2020-01/amr\_2017\_action-plan\_0.pdf.</u>

<sup>7</sup> https://health.ec.europa.eu/system/files/2022-04/amr\_2018-2022\_actionplan\_progressreport\_en.pdf.

<sup>8</sup> Council conclusions of 14 June 2019 on the next steps towards making the EU a best practice region in combating antimicrobial resistance.

<sup>&</sup>lt;sup>9</sup> <u>Council conclusions of 7 December 2021 on strengthening the European Health Union</u>.

- (5) The EU4Health Programme<sup>10</sup> 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 follow-up of this Council Recommendation across Member States. The Horizon Europe programme<sup>11</sup> will provide support to research and innovation actions and a partnership on One Health AMR<sup>12</sup>, while financing from the European Investment Bank<sup>13</sup> and assistance under the Technical Support Instrument<sup>14</sup> 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 resistance<sup>15</sup>, 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 AMR<sup>16</sup>. The Council Conclusions of 17 June 2016<sup>17</sup> 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.

<sup>10</sup> 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).

<sup>11</sup> 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).

<sup>12 &</sup>lt;u>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.</u>

<sup>13 &</sup>lt;u>https://www.eib.org/en/index.htm</u>.

<sup>&</sup>lt;sup>14</sup> 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).

<sup>15</sup> https://digitallibrary.un.org/record/845917#record-files-collapse-header.

<sup>16 &</sup>lt;u>https://www.who.int/publications/i/item/9789241509763.</u>

<sup>17 &</sup>lt;u>Council conclusions of 17 June 2016 on the next steps under a One Health approach to combat antimicrobial</u> resistance.

- (7) In its overview report of 18 October 2022<sup>18,</sup> the Commission found that, while National Action Plans were in place in all Member States, with most based on a One 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, including following trends, 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) The availability of narrow spectrum antibiotics is essential in order to prevent the development and spread of antimicrobial resistance. Member States could therefore take special measures to address supply problems in the human and veterinary fields.

<sup>18 &</sup>lt;u>https://health.ec.europa.eu/publications/overview-report-member-states-one-health-national-action-plans-against-antimicrobial-resistance\_en</u>.

- (10) 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 species<sup>19</sup>. While the application and implementation of Regulation (EU) 2022/2371 of the European Parliament and of the Council<sup>20</sup> 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.
- (11) While there are still knowledge gaps on the development and spread of AMR through the exposure of pathogens to plant protection products and biocidal products, the risk of such resistance development should be taken into account as part of the safety evaluation and decision-making for plant protection products and biocidal products.
- (12) 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 groundwaters and surface waters, including coastal waters, 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.

<sup>&</sup>lt;sup>19</sup> in line with the requirements of Regulation (EU) 2019/6 on veterinary medicinal products.

<sup>20</sup> 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).

- (13) Residues of medicinal products are widely found in groundwaters and surface waters, including coastal waters 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.
- (14) While the Commission proposals of Autumn 2022 aim at strengthening the environmental monitoring of AMR in groundwaters and surface waters, including coastal waters, wastewater and agricultural soils<sup>21</sup>, the need to engage in an integrated AMR One Health approach for surveillance systems, including the environment, is recognised<sup>22</sup>. 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, at appropriate administrative levels, 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.

<sup>21</sup> 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).

<sup>22</sup> 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, <u>https://data.europa.eu/doi/10.2875/636347.</u>

(15) 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 AMR cases due to healthcare-associated infections<sup>23</sup>, there is a need for greater provision of high standards of infection prevention and control. This also includes high standards of patient safety. When taking national actions, the World Health Organisation work on infection prevention and control, hand hygiene and patient safety can be taken into account<sup>24</sup> <sup>25</sup> <sup>26</sup>.

<sup>23 &</sup>lt;u>https://www.ecdc.europa.eu/en/publications-data/health-burden-infections-antibiotic-resistant-bacteria-2016-2020</u>

<sup>24 &</sup>lt;u>WHO: Core components for infection prevention and control programmes</u> (https://www.who.int/teams/integrated-health-services/infection-prevention-control/core-components)

<sup>25</sup> WHO guidelines on Hand Hygiene in Health Care (https://www.who.int/publications/i/item/9789241597906)

<sup>&</sup>lt;sup>26</sup> <u>Global patient safety action plan 2021–2030: towards eliminating avoidable harm in health care. Geneva:</u> World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO

- (16) 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 medicine<sup>27</sup>, the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections<sup>28</sup>, and the 2017 guidelines for the prudent use of antimicrobials in human health<sup>29</sup>. It also complements the revision of the Union's pharmaceutical legislation which proposes to introduce, in the revised Directive on the Union code relating to medicinal products for human use<sup>30</sup>, specific regulatory measures to enhance the prudent use of antimicrobials.
- (17) 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.

<sup>27 &</sup>lt;u>Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine</u> (OJ L 34, 5.2.2002, p. 13).

<sup>28</sup> 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).

<sup>&</sup>lt;sup>29</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52017XC0701(01).

<sup>30</sup> 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.

- (18) 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, and the refining of existing data are necessary, it is recommended to introduce prudent manure management practices.
- (19) 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 progress<sup>31</sup>. Discussions on AMR targets have taken place internationally, for example in the context of the Transatlantic Task Force on Antimicrobial Resistance<sup>32</sup>, the UN Sustainable Development Goals<sup>33</sup> and the G7<sup>34</sup>.

<sup>31 &</sup>lt;u>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.</u>

<sup>32 &</sup>lt;u>https://www.cdc.gov/drugresistance/tatfar/index.html</u>.

<sup>33 &</sup>lt;u>https://sdgs.un.org/goals.</u>

<sup>34 &</sup>lt;u>https://www.g7germany.de/resource/blob/974430/2042058/5651daa321517b089cdccfaffd1e37a1/2022-05-20-g7-health-ministers-communique-data.pdf.</u>

(20) 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 Strategy<sup>35</sup> and in the Zero Pollution Action Plan<sup>36</sup> and the reduced use of antimicrobials in farmed animals should be monitored through the common agricultural policy support measures<sup>37</sup>, there is currently no AMR related target in the human health sector at EU 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.

<sup>&</sup>lt;sup>35</sup> 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.

<sup>36</sup> 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.

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 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).

- (21) 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 2019<sup>38</sup>, 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.
- (22) The 2022 Special Eurobarometer on AMR<sup>39</sup> 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.
- (23) Education, awareness and training of professionals working in human health, veterinary, environmental 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.

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

<sup>&</sup>lt;sup>39</sup> <u>https://europa.eu/eurobarometer/surveys/detail/2632.</u>

- (24) 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 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.
- (25) 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-should address the antimicrobial market failure and promote the development and accessibility of medical countermeasures relevant to combatting AMR, including new and old antimicrobials, diagnostics and vaccines against resistant pathogens.
- (26) 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 JAMRAI<sup>40</sup>, which delivered on 31 March 2021 a "strategy for implementing multi-country incentives in Europe to stimulate antimicrobial innovation and access"<sup>41</sup>.

<sup>40 &</sup>lt;u>https://eu-jamrai.eu/.</u>

<sup>41 &</sup>lt;u>https://eu-jamrai.eu/wp-content/uploads/2021/03/EUjamrai\_D9.2\_Strategy-for-a-multi-country-incentive-in-Europe\_INSERM-FHI.pdf.</u>

- (27) The Commission commissioned a study entitled "bringing AMR Medical Counter Measures on the market"<sup>42</sup> 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.
- (28) The EU4Health work programme 2023<sup>43</sup> offers a sizeable investment in combating AMR, in particular through the specific action "Support innovation and access to antimicrobials"<sup>44</sup>. 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.
- (29) 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.
- (30) 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.

<sup>&</sup>lt;sup>42</sup> 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, <u>https://data.europa.eu/doi/10.2925/442912</u>.

<sup>43 &</sup>lt;u>https://health.ec.europa.eu/publications/2023-eu4health-work-programme\_en.</u>

<sup>44 &</sup>lt;u>https://health.ec.europa.eu/system/files/2022-11/wp2023\_annex\_en.pdf</u>.

- (31) 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 Network<sup>45</sup>.
- (32) A high level of cooperation between Union Agencies (European Food Safety Authority (EFSA)<sup>46</sup>, European Centre for Disease Prevention and Control (ECDC)<sup>47</sup> and European Medicines Agency (EMA)<sup>48</sup> should be reinforced and extended to include the European Environmental Agency (EEA)<sup>49</sup> and the European Chemical Agency (ECHA)<sup>50</sup>, to ensure a coherent, One Health, evidence-based response to AMR.

<sup>45 &</sup>lt;u>https://health.ec.europa.eu/antimicrobial-resistance/events\_en?f%5B0%5D=topic\_topic%3A173.</u>

<sup>46 &</sup>lt;u>https://www.efsa.europa.eu/eu</u>.

<sup>47 &</sup>lt;u>https://www.ecdc.europa.eu/en.</u>

<sup>48 &</sup>lt;u>https://www.ema.europa.eu/en.</u>

<sup>49 &</sup>lt;u>https://www.eea.europa.eu/about-us.</u>

<sup>50 &</sup>lt;u>https://echa.europa.eu/.</u>

- (33) Combatting AMR in the context of the One Health approach is a priority in the EU Global Health Strategy<sup>51</sup>, 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 response<sup>52</sup>. 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)<sup>53</sup>, the United Nations Environment Programme (UNEP)<sup>54</sup>, the World Organization for Animal Health (WOAH)<sup>55</sup> and the World Health Organization (WHO)<sup>56</sup>). This recommendation is without prejudice to the need to establish Union positions in accordance with the procedures laid down in the Treaties, in particular through Council decisions pursuant to Article 218 TFEU.
- (34) The follow-up given to 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.

- 53 <u>https://www.fao.org/home/en.</u>
- 54 <u>https://www.unep.org/.</u>
- 55 <u>https://www.woah.org/en/home/.</u>
- 56 <u>https://www.who.int/.</u>

<sup>51 &</sup>lt;u>https://health.ec.europa.eu/system/files/2023-02/international\_ghs-report-2022\_en.pdf.</u>

<sup>&</sup>lt;sup>52</sup> <u>https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord.</u>

## HAS ADOPTED THE FOLLOWING RECOMMENDATION:

# A. <u>National Action Plans against AMR</u>

### HEREBY ENCOURAGES MEMBER STATES TO:

 Have in place by [1 year after adoption of the Council Recommendation], and regularly update and implement National Action Plans against AMR ("National Action Plans"), based on the One Health approach and taking into account 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.

The National Action Plans on combatting AMR should, taking into account an evidencebased and cost-effective approach, in particular:

- a. feature as a priority of national health systems and promote the prudent use of antimicrobials.
- b. include intersectoral coordination, implementation and monitoring plans and mechanisms to ensure their effective governance;
- c. include specific measures to achieve overarching measurable goals, and implementation arrangement and indicators to assess progress towards achieving these goals, including the recommended targets set out in the section E of this Recommendation;
- d. refer to the relevant elements of the National Common Agricultural Policy Strategic Plans to combat AMR;
- e. include evidence-based measures to prevent, monitor and reduce the spread of AMR in the environment; and

- 2. Allocate, with support from the Commission where relevant, appropriate human and financial resources for the effective implementation of the National Action Plans.
- Evaluate, regularly, and at least every three-years, the outcomes of the National Action Plans and take actions to address the findings of these evaluations and other relevant inputs, while taking into account new findings and emerging trends.
- 4. Ensure that National Action Plans and the regular evaluation of their outcomes are made publicly available within six months after completion of the evaluation.

### B. <u>Surveillance and monitoring of AMR and antimicrobial consumption (AMC)</u>

## HEREBY ENCOURAGES MEMBER STATES TO:

- 5. Close existing surveillance and monitoring gaps and ensure completeness of data, including real-time data and timely access to data where appropriate by 2030, on both 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, in coordination with ECDC, 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;

- requiring, taking into account any methodology established at EU level, that infections caused by critical (high negative health impact) multidrug-resistant organisms resistant to last line treatments, *e.g.* carbapenem-resistant *Acinetobacter baumannii*, carbapenem-resistant Enterobacteriaceae (*e.g. Klebsiella pneumoniae*, *Escherichia coli*) and *Candida auris*, are notifiable diseases under national legislation. Member States can decide if other resistant organisms are notifiable, according to the national situation and need;
- 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 AMC, in humans at the appropriate levels to allow the monitoring of antimicrobial prescribing and to provide timely feedback on prescription trends and patterns involving, among others, prescribers, pharmacists and other parties collecting such data, and where possible and appropriate using EU level digital infrastructure.

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), taking into account the Commission feasibility study on integrated systems, the work of the Quadripartite QTS-AIS expert group on Integrated Surveillance<sup>57</sup> as well as other initiatives already launched, such as the WHO Tricyle protocol for an integrated global surveillance on ESBL-producing E. coli across the human, animal and environmental sectors. Such integrated and continuous intersectorial monitoring should be designed to efficiently and rapidly detect emerging resistant infections and outbreaks but equally as regards soil and water bodies to determine the presence of AMR genes and antimicrobials, the trends and their toxicity. The results of this surveillance should inform effective strategies to tackle AMR across sectors and at appropriate administrative levels.

<sup>57 &</sup>lt;u>The Quadripartite Organizations established the Technical Group on Integrated Surveillance on Antimicrobial</u> <u>use and resistance (who.int)</u>

### HEREBY WELCOMES THE COMMISSION'S INTENTION TO:

6. 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) 2016/429<sup>58</sup> with a view to categorising them for any regulatory surveillance, control or other management measures.

# C. <u>Infection prevention and control</u>

## HEREBY ENCOURAGES THE MEMBER STATES TO:

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

<sup>58</sup> 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).

- b. upgrading existing health care facilities including 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 by clinical laboratories and patient records;
- d. ensuring continuous training regarding knowledge on infection prevention and control for all personnel in the community, hospitals and long-term care facilities, with the help of pedagogical and behavioural insights;
- fully developing and implementing national immunisation programmes and taking measures to effectively prevent vaccine preventable diseases on the basis of Council Recommendation of 7 December 2018 on Strengthened Cooperation against Vaccine Preventable Diseases<sup>59</sup>.
- f. Ensure adequate coordination between infection prevention and control and antimicrobial stewardship programmes.
- 8. 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;

<sup>&</sup>lt;sup>59</sup> <u>Council Recommendation 2018/C 466/01 of 7 December 2018 on Strengthened Cooperation against Vaccine</u> <u>Preventable Diseases (OJ C 466, 28.12.2018, p. 1).</u>

- making use of the support available in the context of the common agricultural policy to take preventive actions against infectious diseases<sup>60</sup> that go beyond EU minimum legal requirements;
- making use of the European Maritime, Fisheries and Aquaculture Fund (2021-2027)<sup>61</sup> for projects included in the national programmes, and in accordance with the eligibility rules defined by the Member States concerned;
- e. taking forward 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"<sup>62</sup>;
- f. encouraging breeding techniques<sup>63</sup> 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 also including feed additives to improve the physiological status of animals;
- i. ensuring continuous training regarding knowledge on infection prevention and control and biosecurity of all personnel in relevant settings, with the help of pedagogical and behavioural insights;

<sup>&</sup>lt;sup>60</sup> 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).

<sup>61</sup> https://oceans-and-fisheries.ec.europa.eu/funding/emfaf\_en.

<sup>&</sup>lt;sup>62</sup> 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.

<sup>&</sup>lt;sup>63</sup> DNA engineering techniques limited to the use of species that have undergone a risk assessment with favourable outcome.

- j. 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.
- 9. Make use of 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.

# HEREBY WELCOMES THE COMMISSION'S INTENTION TO TAKE THE FOLLOWING ACTION, IN CLOSE COOPERATION WITH THE MEMBER STATES:

10. Develop, in coordination with ECDC, EU infection prevention and control guidelines in human health, taking into account a cost-effective approach, notably for hospitals and long-term care facilities by [3 years after adoption of the Council Recommendation]. When developing these guidelines, international guidelines should be taken into account and close collaboration with European and national professional societies should be ensured.

### D. <u>Antimicrobial stewardship and prudent use of antimicrobials</u>

### HEREBY ENCOURAGES THE MEMBER STATES TO:

- 11. Ensure that measures are put in place in human health to support the prudent use of antimicrobial agents, in health care settings, including primary health care settings and long-term care facilities, and community care in particular by:
  - a. making use of, and adapting to national circumstances where needed, EU guidelines for the treatment of common infections and for perioperative prophylaxis in order to respect best practices and optimise prudent use of antimicrobials;
  - b. designing measures for health professionals, including pharmacists to ensure their adherence to prudent use guidelines;

- c. encouraging and supporting the uptake of diagnostic tests, in particular in primary care, to optimise antimicrobial treatment, and;
- d. ensuring the appropriate competences and organisation of personnel.
- 12. 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, veterinary medicine providers, veterinary premises and manufacturing facilities of antimicrobials.

# HEREBY WELCOMES THE COMMISSION'S INTENTION TO TAKE THE FOLLOWING ACTION, IN CLOSE COOPERATION WITH THE MEMBER STATES:

13. 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 book<sup>64</sup> should be taken into account and a close collaboration with European and national professional societies should be ensured. In addition, recognising that resistance patterns in organisms can vary in different regions, the specific clinical requirements should be determined by individual Member states.

<sup>64 &</sup>lt;u>https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2022.02.</u>

# HEREBY WELCOMES THE COMMISSION'S INTENTION AND ENCOURAGES THE MEMBER STATES TO TAKE THE FOLLOWING ACTIONS:

14. 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 research and evidence, as part of the safety evaluation and decision-making on these products and reviewing decisions as appropriate if new evidence emerges. Where necessary, appropriate conditions or restrictions of use should be implemented for the products concerned.

#### E. <u>Recommended targets for antimicrobial consumption and antimicrobial resistance</u>

### HEREBY INVITES THE MEMBER STATES TO:

- 15. Take appropriate national measures aimed at ensuring 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 and in home-care settings, is reduced by 20% in the Union compared with the baseline year 2019.
- 16. Take appropriate national measures aimed at ensuring 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 WHO<sup>65</sup>.
- 17. Take appropriate national measures aimed at ensuring 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.

<sup>65 &</sup>lt;u>https://www.who.int/publications/i/item/2021-aware-classification.</u>

- 18. Take appropriate national measures aimed at ensuring 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.
- Take appropriate national measures aimed at ensuring 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.

20. Set up indicators and share best practices on their use, 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.

# HEREBY WELCOMES THE COMMISSION'S INTENTION AND ENCOURAGES THE MEMBER STATES TO TAKE THE FOLLOWING ACTIONS:

 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. <u>Awareness, education and training</u>

### HEREBY ENCOURAGES THE MEMBER STATES TO:

- 22. Ensure, in cooperation with higher and professional education institutions as well as stakeholders, and with the help of pedagogical and behavioural insights, that national continuous education programmes and curricula, in *inter alia* medicine, nursing, midwifery, pharmacy, dentistry, veterinary medicine, agriculture and agronomics, environmental and ecological 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.
- 23. 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, and share best practices.
- 24. 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.
- 25. 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.

### HEREBY WELCOMES THE COMMISSION'S INTENTION TO:

- 26. Support and complement Member States' awareness-raising activities on AMR and prudent use of antimicrobials with pan-European communication actions taking into account a cost-effective approach and on the basis of Member States' needs.
- 27. 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 initiative<sup>66</sup>.

<sup>66 &</sup>lt;u>https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/legislation-official-controls/better-training-safer-food\_en</u>.

# G. <u>Research & development and incentives for innovation and access to antimicrobials and</u> <u>other AMR medical countermeasures</u>

# HEREBY WELCOMES THE COMMISSION'S INTENTION AND ENCOURAGES MEMBER STATES TO TAKE THE FOLLOWING ACTIONS:

- 28. Support research and technological innovation with push incentives 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 on One Health AMR to allow coordination, alignment and funding of crosssectorial research and innovation.
- 29. Promote in a coordinated manner with national and multicountry initiatives, 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:

- a. continue to 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 in alignment with national initiatives;
- 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, in liaison with Member States, by supporting and coordinating-Member States' initiatives on the manufacturing, procurement and stockpiling and by addressing hurdles at EU level;

- d. improve demand forecast, assessing and addressing antibiotics supply chain vulnerabilities, and implement targeted antibiotics stockpiling actions as appropriate, to avoid shortages.
- 30. Contribute to the design and governance of a Union multi-country pull incentive scheme in order to improve innovation, the development of new antimicrobials and access to existing and new antimicrobials where Member States can participate on a voluntary basis. Such scheme could e.g. take the form of revenue guarantee, market entry rewards combined with revenue guarantee, lump-sum market entry rewards or milestone payments and may be financed at EU level, national level or co-financed, as appropriate.
- 31. Pool resources, take collaborative actions, financially contribute to the implementation of the pull incentive scheme, and commit to participate in the network<sup>67</sup> referred to under the EU4Health work programme 2023.
- 32. Regularly review the scheme and its impact on the development and accessibility of antimicrobials.
- 33. Incentivise the development and placing on the market of effective and evidence-based alternatives to the use of antimicrobials and of vaccines for animal health.

### H. <u>Cooperation</u>

### HEREBY ENCOURAGES THE MEMBER STATES TO:

 Report data on AMR and on antimicrobial consumption to the Global Antimicrobial Resistance and Use Surveillance System (GLASS)<sup>68</sup>.

<sup>&</sup>lt;sup>67</sup> CP-p-23-16 Support innovation and access to antimicrobials.

<sup>68 &</sup>lt;u>https://www.who.int/initiatives/glass.</u>

- 35. 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;
  - exchange best practices, notably on measures to ensure adherence of healthcare professionals to prudent use guidelines, and on proven effective measures to raise awareness;
  - 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 relevant exchange of experience.
- 36. Enhance the cooperation on AMR between professionals working in human health, veterinary, environment and agronomy sectors and with stakeholders, in order to improve the One Health approach on AMR.

## HEREBY WELCOMES THE COMMISSION'S INTENTION TO:

- 37. 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.
- 38. Develop a monitoring framework to assess the progress and results achieved in implementing the 2017 AMR Action Plan and this Recommendation.

# I. <u>Global</u>

# HEREBY WELCOMES THE COMMISSION'S INTENTION AND ENCOURAGES THE MEMBER STATES TO TAKE THE FOLLOWING ACTIONS:

- 39. Advocate for the development, and the implementation by third countries, of standards by the International Standard Setting Bodies, in particular:
  - a. for more ambitious WOAH 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 Convention<sup>69</sup>;
  - c. for the implementation of the Codex Alimentarius standards<sup>70</sup>, Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance<sup>71</sup>, the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance<sup>72</sup> and the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance<sup>73</sup>.

<sup>69 &</sup>lt;u>https://www.ippc.int/en/.</u>

<sup>70 &</sup>lt;u>Foodborne antimicrobial resistance (fao.org)</u>

<sup>71 &</sup>lt;u>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.</u>

<sup>72 &</sup>lt;u>https://www.fao.org/fao-who-codexalimentarius/sh-proxy/ar/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards</u> %252FCXG%2B94-2021%252FCXG 94e.pdf.

<sup>73 &</sup>lt;u>https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B77-2011%252FCXG\_077e.pdf</u>

- Work towards preventing AMR through the One Health approach by strengthening capacities in cooperation with the Quadripartite as described in Action track 5 of the One Health Joint Plan of Action (2022-2026) (OH JPA) developed by the Quadripartite<sup>74</sup>.
- Work towards the inclusion of concrete and relevant provisions on AMR following a One Health approach in the context of negotiation on a potential WHO international agreement on pandemic prevention, preparedness and response, in accordance with Council Decision (EU) 2022/451<sup>75</sup>.
- 42. Support the WHO initiatives to prepare guidance on how good manufacturing practices should be applied 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 matter<sup>76</sup>.
- 43. Advocate for AMR to feature as a high political priority in G7 and G20 settings, leading to ambitious commitments at global level, including to fairly share, among the G20 or G7 countries, the financial burden arising from push and pull incentives for antimicrobials.
- 44. Advocate for the planned United Nations High Level conference on AMR in 2024 to raise global commitments to address AMR.
- 45. Support and engage actively in the Quadripartite's "AMR Multi-Stakeholder Partnership Platform"<sup>77</sup>, to help establish a shared global vision and build more consensus on AMR.

<sup>74</sup> One health joint plan of action (2022–2026): working together for the health of humans, animals, plants and the environment (who.int)

<sup>75</sup> Council Decision (EU) 2022/451 of 3 March 2022 authorising the opening of negotiations on behalf of the European Union for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005), OJ L 92, 21.3.2022, p. 1.

<sup>76 &</sup>lt;u>https://apps.who.int/gb/ebwha/pdf\_files/EB144/B144\_19-en.pdf.</u>

<sup>&</sup>lt;sup>77</sup> <u>https://www.fao.org/antimicrobial-resistance/quadripartite/the-platform/en/.</u>

- 46. 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 approach<sup>78</sup>, which notably aims to contribute to tackle AMR;
  - 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)<sup>79</sup>;
  - c. contributing to the efforts in tackling infectious diseases and AMR in low and middle-income countries such as through the European and Developing Countries Clinical Trial Partnership (Global Health EDCTP3 Joint Undertaking)<sup>80</sup> and where appropriate through non-governmental initiatives, such as the International Centre for Antimicrobial Resistance Solutions (ICARS)<sup>81</sup>, the Global Antibiotic Research and Development Partnership (GARDP)<sup>82</sup> and ReAct<sup>83</sup>.

<sup>78 &</sup>lt;u>https://europa.eu/capacity4dev/tei-jp-tracker/tei/sustainable%C2%A0health-security-africa.</u>

<sup>79 &</sup>lt;u>https://mptf.undp.org/fund/amr00.</u>

<sup>80 &</sup>lt;u>https://research-and-innovation.ec.europa.eu/research-area/health/edctp\_en.</u>

<sup>81 &</sup>lt;u>https://icars-global.org/</u>

<sup>82 &</sup>lt;u>https://gardp.org/</u>

<sup>83 &</sup>lt;u>https://www.reactgroup.org/</u>

## J. <u>Reporting</u>

## HEREBY WELCOMES-THE COMMISSION'S INTENTION TO:

47. Report to the Council four years after adoption on the follow-up given to this Recommendation.

Done at Brussels,

For the Council The President

## <u>ANNEX</u>

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Member States contributions to reach EU recommended targets set out in point E of this Recommendation<sup>84</sup>.

 National recommended targets on total consumption of antibiotics in the community and hospital sectors combined, including in long-term care facilities (DDD per 1000 inhabitants per day)

Member State	Total consumption of antibiotics in the community and, hospital sectors combined, including long-term care facilities (DDD per 1000 inhabitants per day) in 2019 <sup>85</sup>	Recommended target reduction by 2030
NL	9.5	3%
АТ	11.6	3%
EE	11.8	3%
SE	11.8	3%
DE	12.686	9%
SI	13.0	9%
LV	13.9	9%
HU	14.4	9%

<sup>&</sup>lt;sup>84</sup> Some Member States have made progress in tackling AMR or antimicrobial consumption since the baseline year of 2019.

<sup>&</sup>lt;sup>85</sup> Data from European Surveillance of Antimicrobial Consumption Network (ESAC-Net). Population data are from Eurostat.

<sup>&</sup>lt;sup>86</sup> Germany did not report consumption data for the hospital sector to ESAC-Net. Total consumption was estimated based on the EU average proportion of hospital sector consumption as part of total consumption.

FI	14.7	9%
DK	15.3	9%
LT	16.1	9%
CZ	16.9	9%
HR	18.8	9%
РТ	19.3	9%
SK	19.3	9%
BG	20.7	18%
MT	20.7	18%
LU	21.1	18%
BE	21.4	18%
IT	21.7	18%
IE	22.8	27%
PL	23.6	27%
ES	24.9	27%
FR	25.1	27%
RO	25.8	27%
СҮ	30.1	27%
EL	34.1	27%

 National recommended targets on the percentage of consumption of Access group antibiotics out of consumption of all antibiotics (Access, Watch, Reserve, Unclassified) listed in the AWaRe classification of WHO<sup>87</sup>)

Member State	Percentage of consumption of Access group antibiotics out of consumption of all antibiotics (Access, Watch, Reserve, Unclassified) listed in the AWaRe classification in 2019 <sup>88</sup>	Recommended target by 2030
DK	79.1	At least 65%
FI	73.2	
FR	72.0	
NL	71.2	
SE	71.0	
IE	70.3	
LV	68.6	
BE	67.9	
LT	67.5	
ES	63.0	
HR	62.7	
SI	62.1	
РТ	61.4	

<sup>87 &</sup>lt;u>https://www.who.int/publications/i/item/2021-aware-classification</u>

<sup>88</sup> Data from European Surveillance of Antimicrobial Consumption Network (ESAC-Net). Population data are from Eurostat.

EE	61.3	At least 65%
PL	60.4	
CZ	60.2	
LU	59.5	
AT	58.1	
RO	52.8	
HU	50.5	
MT	49.9	
IT	48.9	
СҮ	48.9	
EL	46.8	
BG	45.1	
SK	42.4	
DE	No data <sup>89</sup>	

<sup>&</sup>lt;sup>89</sup> Germany did not report consumption data for the hospital sector to ESAC-Net. This percentage can therefore not be calculated.

3. National recommended targets on incidence of methicillin-resistant *Staphylococcus aureus* (MRSA) bloodstream infections (number per 100,000 population)

Member State	Incidence of methicillin-resistant <i>Staphylococcus</i> <i>aureus</i> (MRSA) bloodstream infections (number of bloodstream infections <sup>90</sup> per 100,000 population) in 2019	Recommended target reduction by 2030
NL	0.4	3%
DK	0.8	3%
EE	0.8	3%
FI	1.1	3%
SE	1.3	3%
BG	1.5	3%
LV	1.9	6%
LU	2.1	6%
AT	2.2	6%
LT	2.2	6%
SI	2.4	6%
BE	2.6	6%
HR	2.7	6%
IE	3.1	6%
CZ	3.1	6%

<sup>90</sup> Based on existing data on invasive isolates available from the European Antimicrobial Resistance Surveillance Network (EARS-Net), in which invasive isolates are mostly (>99%) from bloodstream infections with a very small percentage (<1%) of isolates from meningitides. Population data are from Eurostat.</p>

DE	3.6	10%
MT	3.8	10%
HU	4.2	10%
ES	4.2	10%
PL	4.3	10%
EL	4.6	10%
SK	5.0	10%
FR	5.6	18%
СҮ	6.9	18%
РТ	11.4	18%
IT	13.6	18%
RO	13.7	18%

4. National recommended targets on incidence of third-generation cephalosporin-resistant *Escherichia coli* bloodstream infections (number per 100,000 population)

Member States	Incidence of third- generation cephalosporin- resistant <i>Escherichia</i> <i>coli</i> bloodstream infections <sup>91</sup> (number per 100,000 population) in 2019	Recommended target reduction by 2030
EL	2.6	0%
BG	4.3	0%
NL	4.5	0%
LV	5.0	0%
HR	5.3	0%
LT	5.6	0%
HU	5.7	0%
СҮ	6.2	5%
RO	6.3	5%
SK	6.4	5%
CZ	6.6	5%
DK	6.6	5%
AT	7.1	10%
PL	7.4	10%
SI	7.7	10%
ES	7.8	10%

<sup>91</sup> Based on existing data on invasive isolates available from the European Antimicrobial Resistance Surveillance Network (EARS-Net), in which invasive isolates are mostly (>99%) from bloodstream infections with a very small percentage (<1%) of isolates from meningitides. Population data are from Eurostat.</p>

EE	7.9	10%
FI	8.0	10%
IE	8.3	10%
FR	8.6	10%
SE	9.6	10%
LU	10.1	12%
РТ	10.3	12%
DE	12.0	12%
МТ	12.4	12%
BE	13.2	12%
IT	23.2	12%

5. National recommended targets on incidence of carbapenem-resistant *Klebsiella pneumoniae* bloodstream infections (number per 100,000 population)

Member State	Incidence of carbapenem-resistant <i>Klebsiella</i> <i>pneumoniae</i> bloodstream infections <sup>92</sup> (number per 100,000 population) in 2019	Recommended target reduction by 2030
EE	0.00	0%
LV	0.00	0%
NL	0.02	0%
SE	0.03	0%
SI	0.05	2%
FI	0.06	2%
DK	0.07	2%
CZ	0.09	2%
HU	0.09	2%
IE	0.11	2%
LU	0.16	2%
DE	0.20	2%
AT	0.20	2%
FR	0.22	2%
BE	0.27	2%
SK	0.52	4%

<sup>&</sup>lt;sup>92</sup> Based on existing data on invasive isolates available from the European Antimicrobial Resistance Surveillance Network (EARS-Net), in which invasive isolates are mostly (>99%) from bloodstream infections with a very small percentage (<1%) of isolates from meningitides. Population data are from Eurostat.</p>

LT	0.54	4%
ES	0.76	4%
HR	1.20	4%
PL	1.38	4%
МТ	2.13	4%
BG	2.29	4%
СҮ	2.61	5%
РТ	2.93	5%
RO	7.12	5%
IT	8.51	5%
EL	13.05	5%