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NOTE

From: General Secretariat of the Council
To: Council

Subject: **Employment, Social Policy, Health and Consumer Affairs Council session on 14 June 2019**
Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance
- Adoption

1. On 26 March 2019, the Presidency submitted a set of draft Council conclusions¹ to the Working Party on Public Health.
2. The Working Party examined the draft Council conclusions in two meetings and reached a tentative agreement following informal consultations on a text prepared by the Presidency.
3. On 24 May 2019, the Permanent Representatives Committee endorsed the draft conclusions tentatively agreed by the Working Party^{2 3} and decided to submit them to the Council (EPSCO) for adoption at its session on 14 June 2019.

¹ 7471/19

² 9274/19

³ The Presidency was mandated to finalise two references in point 7.

4. The Council is invited to:

- adopt the conclusions as set out in the Annex to this note, and
 - decide to have them published in the Official Journal of the European Union.
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**Draft Council conclusions on the next steps towards making the EU a best practice region
in combatting antimicrobial resistance**

THE COUNCIL OF THE EUROPEAN UNION

1. **RECALLS** that antimicrobial resistance (AMR) is a serious cross-border health threat that cannot be adequately addressed by one Member State alone and cannot be confined to a geographical region or a Member State and hence requires intensive cooperation and coordination between Member States, as stated in the Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health⁴.
2. **NOTES WITH GREAT CONCERN** that, according to official data, about 700 000 deaths^{5 6} may be caused globally each year by AMR, including 33 000^{7 8} deaths due to infections resistant to antibiotics in the European Union/EEA. Moreover, without policies to halt its spread, AMR is projected to cause millions of deaths worldwide.
3. **NOTES WITH GREAT CONCERN** that about 29% of deaths caused worldwide by infections resistant to antimicrobials are due to drug-resistant tuberculosis (DR-TB) and to multidrug-resistant TB (MDR-TB).⁹
4. **NOTES WITH GREAT CONCERN** that, according to the Organisation for Economic Co-operation and Development (OECD), if no effective action is put in place, and AMR rates follow the projected trends, up to EUR 1.1 billion are expected to be spent yearly between 2015 and 2050 due to AMR across EU and EEA countries¹⁰.

⁴ OJ L 293, 5.11.2013, p.1.

⁵ [Bulletin of the World Health Organization 2016;94:638-639](#)

⁶ [The review on Antimicrobial resistance chaired by Jim O'Neill: "Tackling drug-resistant infections globally", final report and recommendations, May 2016](#)

⁷ [The Lancet, Infectious diseases, Volume 19, Issue 1, January 2019](#)

⁸ [European Centre for Disease Prevention and Control, article on 6 November 2018](#)

⁹ [TB Alliance, "Drug resistance - a response to antimicrobial resistance including tackling TB"](#)

¹⁰ [OECD, Antimicrobial Resistance - "Tackling the Burden in the European Union", 2019](#)

5. **NOTES WITH GREAT CONCERN** that 75% of the burden of diseases from infections resistant to antibiotics in the EU is directly related to healthcare-associated infections (HAIs)¹¹.
6. **ACKNOWLEDGES** that, the use of antimicrobials is still too high in the Union as a whole and **NOTES** that there are differences in antimicrobial use between Member States.
7. **RECOGNISES** that AMR is a global public health concern, the impact of which goes beyond its severe consequences for human and animal health, as it also impacts on the environment and food production and consequently economic growth. Furthermore, AMR seriously affects the possibilities to achieve the Sustainable Development Goals.

It therefore **WELCOMES** the many international initiatives aimed at combatting AMR, including:

- the Global Action Plan (GAP) on Antimicrobial Resistance¹² developed by the World Health Organisation (WHO) with the contribution of the Food and Agricultural Organization (FAO) and the World Organization for Animal Health (OIE) and adopted unanimously in May 2015 by the 68th World Health Assembly;
- the UN political declaration of the High-Level meeting of its General Assembly on AMR of 21 September 2016¹³, aimed at combating the global threat posed by AMR and confirming the necessity of a "One Health" approach, as well as:
 - = the work of the UN Interagency Coordination Group on AMR (IACG), which has resulted in a set of recommendations set out in the report 'No time to wait: Securing the future from drug-resistant infections'¹⁴ to the UN Secretary-General;
 - = the report¹⁵ issued on 10 May 2019 by the UN Secretary-General on the implementation of the political declaration on AMR of 21 September 2016 and on recommendations emanating from the IACG;

¹¹ [The Lancet, Infectious diseases, Volume 19, Issue 1, January 2019](#)

¹² [WHO, Global Action Plan on Antimicrobial Resistance, A68/A/CONF./1 Rev.1 Agenda item 15.1, 25 May 2015](#)

¹³ [UN, General Assembly, Political Declaration of the high-level meeting of the General Assembly on antimicrobial resistance, 21 September 2016](#)

¹⁴ [IACG - "No time to wait: Securing the future from Drug-resistant infections" report, April 2019](#)

¹⁵ [Follow-up to the political declaration of the high-level meeting of the General Assembly on antimicrobial resistance - Report of the Secretary-General, 10 May 2019](#)

- the United Nations Environment Assembly (UNEA) resolution of December 2017¹⁶ on Environment and Health, which states that human, animal and plant health and the environment are interconnected and underlines the need to further understand the role of environmental pollution in the development of antimicrobial resistance;
 - the work of the Global AMR R&D Hub;
 - the Global Antibiotic Research and Development Partnership (GARDP)¹⁷;
 - the WHO AMR Resolution, adopted by the World Health Assembly on 24 May 2019¹⁸;
 - the International Centre for Antimicrobial Resistance Solutions (ICARS)¹⁹. The ICARS serves as an independent global knowledge hub focused on identifying and supporting the implementation of evidence-based solutions to AMR-related challenges in low- and middle-income countries;
8. **NOTES** that AMR has become an issue that is now discussed in many different international fora, including the G7²⁰ and the G20²¹.
9. **RECALLS** the 2015 Global action plan on AMR, in which the WHO called on all its Member States to put in place national action plans against AMR by 2017.
10. **TAKES NOTE** of the ongoing work of the OECD and **WELCOMES** its recent report indicating that investment in public health interventions could substantially reduce the burden on society caused by AMR²².

¹⁶ [UN Environment Assembly of the United Nations Environment Programme, Nairobi, 4–6 December 2017](#)

¹⁷ [the Global Antibiotic Research and Development Partnership](#)

¹⁸ [Draft text of the WHO AMR Resolution](#)

¹⁹ [the International Centre for Antimicrobial Resistance Solutions](#)

²⁰ [Declaration of the G7 Health Ministers, Berlin 8 - 9 October 2015](#)

²¹ [Berlin Declaration of the G20 Health Ministers "Together Today for a Healthy Tomorrow", 2017](#)

²² [OECD, a Policy brief: "Stemming the Superbug Tide", 2018](#)

11. **RECALLS** that Article 168 of the Treaty on the Functioning of the European Union (TFEU) provides for Union action to complement national policies and cover the fight against major health scourges, their transmission and their prevention, as well as health information, and education, and monitoring, and combating of serious cross-border threats to health. The Union is also required to encourage cooperation between the Member States and to foster cooperation with third countries and the competent international organisations in the sphere of public health.
12. **RECALLS** the Council conclusions of 17 June 2016 on the next steps under a One Health approach to combat antimicrobial resistance²³ and the specific references therein to the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine²⁴, the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections²⁵, and the Council conclusions of 1 December 2014 on patient safety and quality of care, including the prevention and control of healthcare-associated infections and antimicrobial resistance²⁶.
13. **WELCOMES** the publication by the Commission on 29 June 2017 of the Communication 'A European One Health Action Plan against Antimicrobial Resistance²⁷ and the actions listed therein to combat AMR and **SUPPORTS THE INTENTION** of making the EU a best-practice region in this respect.
14. **DRAWS ATTENTION** to the role of vaccination in the prevention of infection, the recently adopted Council Recommendation on strengthened cooperation against vaccine-preventable diseases and the fact that the Commission One Health Action Plan on antimicrobial resistance, highlights the need to support research on and development of new vaccines for pathogens associated with antimicrobial resistance²⁸.

²³ OJ C 269, 23.7.2016, p.26.

²⁴ OJ L 34, 5.2.2002, p. 13-16.

²⁵ OJ C 151, 3.7.2009, p.1.

²⁶ OJ C 438, 6.12.2014, p. 7.

²⁷ [COM \(2017\) 339 final of 29.6.2017](#)

²⁸ OJ C 466, 28.12.2018, p.1.

15. **RECALLS** the European Parliament Resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance²⁹.
16. **WELCOMES** the Communication from the Commission on 11 March 2019 to the European Parliament, the Council and the European Economic and Social Committee on the European Union Strategic Approach to Pharmaceuticals in the Environment³⁰.
17. **DRAWS ATTENTION** to the fact that the EU has established legal restrictions to avoid misuse of antimicrobials in animals. Since 2006, the use of antibiotics as feed additives for growth promotion has been banned³¹. The recently adopted Regulation (EU) 2019/6 on veterinary medicinal products³² and Regulation (EU) 2019/4 on medicated feed³³ also prevent the use of antimicrobial veterinary medicinal products for promoting growth or to increase yield³⁴, the preventive use of veterinary antimicrobial medicinal products via medicated feed³⁵ and the preventive use of veterinary antibiotics in groups of animals³⁶. The Regulation on veterinary medicinal products also provides for restrictions on the metaphylactic use of antimicrobial medicinal products and contains provisions that allow for the possibility to reserve, based on specific criteria, certain critical antimicrobials for human use only, in order to better preserve their efficacy³⁷, as well as obligations on Member States to collect data on the sales and use of antimicrobials in animals.
18. **WELCOMES** the enhanced cooperation between the Member States and the Commission through the EU AMR One Health Network³⁸ established in 2017 and **NOTES** the importance of its regular meetings as part of the implementation of the EU Action Plan on AMR.

²⁹ [European Parliament resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance \(AMR\) \(2017/2254\(INI\)\)](#)

³⁰ [COM \(2019\) 128 final of 11 March 2019](#)

³¹ Article 11 of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 36)

³² OJ L 4, 7.1.2019, p. 43-167.

³³ OJ L 4, 7.1.2019, p. 1-23.

³⁴ Article 107 of Regulation (EU) 2019/6 on veterinary medicinal products (OJ L 4, 7.1.2019, p. 104)

³⁵ Article 17 of Regulation (EU) 2019/4 on the manufacture, placing on the market and use of medicated feed (OJ L 4, 7.1.2019, p. 12)

³⁶ Article 107 of Regulation (EU) 2019/6 (OJ L 4, 7.1.2019, p. 104)

³⁷ Articles 37 and 107 of Regulation (EU) 2019/6 (OJ L 4, 7.1.2019, p. 72 and 104)

³⁸ [European Commission - EU Action on Antimicrobial Resistance](#)

19. **ACKNOWLEDGES** the findings in the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) reports on AMR³⁹, jointly published by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA), and **DRAWS ATTENTION** to the fact that a legal basis for those activities has been introduced in Regulation (EC) No 726/2004⁴⁰ by the recently adopted Regulation (EU) 2019/541.
20. **STRESSES** that more cooperation between Member States and with the Commission and the pharmaceutical industry is crucial to tackle insufficient availability of antimicrobials, whether caused by lack of initial supply, by withdrawals from the market of antimicrobials or by other supply problems, that may lead to shortages in antimicrobials supply and inadequate replacement therapy.
21. **NOTES WITH GREAT CONCERN** the market failure in antibiotic development and **UNDERLINES** the need for urgent action to stimulate the development of new antimicrobials, alternative therapies and rapid and modern diagnostics, including methods for antimicrobial susceptibility testing. EU and global coordination and cooperation on research programmes and incentives are needed, and the Council **RECOGNISES**, inter alia, the proposals and activities of the Antimicrobial Resistance Review team⁴², the 'Breaking Through the Wall' report⁴³ and the Joint Programming Initiative on Antimicrobial Resistance⁴⁴.
22. **STRESSES** that the success of the global fight against AMR relies heavily on the commitment and willingness of governments to take action to ensure the implementation of the initiatives under the One Health approach in accordance with National Action Plans (NAPs), thereby involving all relevant sectors, and that the fight against AMR could be given a strengthened impetus from cooperation of EU Institutions and Member States in international fora and through regional and bilateral collaboration.

³⁹ [EMA - Analysis of antimicrobial consumption and resistance \('JIACRA' reports of 2011 and 2013\)](#)

⁴⁰ OJ L 136, 30.04.2004, p.1.

⁴¹ OJ L 4, 7.1.2019, p.24.

⁴² [The review on Antimicrobial resistance chaired by Jim O'Neill: "Tackling drug-resistant infections globally", final report and recommendations, May 2016](#)

⁴³ [Federal Ministry of Health, BCG the Boston Consulting Group "Breaking through the Wall" - A Call for Concerted Action on Antibiotics Research and Development](#)

⁴⁴ [Joint Programming Initiative on Antimicrobial Resistance - Global Coordination of Antimicrobial Resistance Research](#)

23. **STRESSES** the importance of the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI)⁴⁵ and **WELCOMES** its work, including that on policies for prevention of HAI and antimicrobial stewardship and their implementation.
24. **RECALLS** the conference on the 'Next steps towards making the EU a best practice region in combatting antimicrobial resistance through a One Health approach', held in Bucharest on 1 March 2019 and organised by the Romanian Presidency, which focused on three key objectives:
- (1) to improve the quality of infection prevention and control measures and optimise antimicrobial use across the human, animal and environmental health sectors;
 - (2) to strengthen the implementation of 'One Health' NAPs;
 - (3) to encourage solidarity between countries by working together to combat AMR.

CALLS UPON Member States to:

25. Ensure that all Member States have in place multi-sectoral NAPs and coordination and monitoring mechanisms in fulfilment of their commitments under the Global Action Plan on AMR and in line with the One Health approach;
26. Allocate sufficient human and financial resources for the development and implementation of actions on AMR, Infection Prevention and Control (IPC) and antimicrobial stewardship at policy and clinical level;
27. Reinforce the implementation of legislation and current policies and existing commitments regarding AMR at EU and international level, based on the One Health approach;
28. Strengthen IPC measures, both in the human and the animal health sectors, in particular in healthcare settings, by investing in hygiene practices and prevention actions, including vaccinations, biosecurity and ensuring of access to standard and rapid diagnostic methods to be used to confirm the type of infection prior to the use of antibiotics, thereby helping to reduce the inappropriate use of antibiotics and the associated risk of developing AMR;

⁴⁵ [EU-JAMRAI: "Europe fostering synergies to reduce the burden of AMR: what is EU doing to support Member States?", 1 March 2019](#)

29. Strengthen and coordinate their response, using an inter-sectoral approach, to counteract the cross-border spread of resistant infections, in particular through the Health Security Committee established under Decision (EU) 1082/2013;
30. Enforce existing legislation on the use and sales of antimicrobials, in particular to restrict over-the-counter sales and, where appropriate, consider further regulation;
31. Prioritise training of the health workforce across relevant sectors on AMR, IPC and antimicrobial stewardship, including actions set out in the EU guidelines for the prudent use of antimicrobials, and knowledge of the One Health approach;
32. Develop information activities on infection prevention and control and antimicrobial stewardship in human and animal healthcare settings, for health workers, patients and their relatives, veterinarians, farmers, and the general public, including children;
33. Establish national measurable targets, inter alia, on reduction of overall use of antimicrobials and monitor progress towards reducing the spread of AMR, taking into account to the appropriate extent the indicators developed by EFSA, EMA and ECDC;

CALLS UPON Member States and the Commission to:

34. Continue to develop long-term policies to tackle the AMR threat;
35. Strengthen cooperation and solidarity on combating AMR by engaging as appropriate, bilaterally, in twinning projects, and multilaterally on sharing of best practices and expertise and to provide support to each other for the implementation of the NAPs as well as of IPC and antimicrobial stewardship programmes across the human health, food, animal health, environmental, research and other relevant sectors;
36. Support the full implementation of available guidelines, taking into account specific national circumstances, and where appropriate, develop additional guidance in the areas of AMR, IPC and antimicrobial stewardship, inter alia as regards improved use of diagnostics and vaccines, as well as surveillance (inter alia by ECDC) to assist actions at national and local level;

37. Develop voluntary common guidelines on infection prevention and control and antimicrobial stewardship in healthcare settings, including for staffing levels and education, based on best practices;
38. Increase capacity in all Member States to respond to the threats from AMR and thus reduce the current differences in outcomes, as regards the control and prevention of AMR and HAIs;
39. Assess reasons for variations between and within Member States, regarding the proportion of broad spectrum antibiotic use in human and animal medicine, with a view to better understanding and controlling AMR;
40. Develop and effectively implement, at EU and national level, coordinated communication strategies for the purposes of both prevention of outbreaks of antimicrobial-resistant infections and use in the event of such outbreaks;
41. Boost efforts on awareness-raising through the mass media and social media, aimed at society in general, about the importance of AMR as a health threat and the need to prevent infections and use antimicrobials prudently;
42. Strengthen and widen the scope of surveillance of AMR and HAI rates and consumption of antimicrobials, both in the human and the animal health sectors, update treatment guidelines, achieve prudent use of antibiotics, monitor the emergence of AMR and develop effective IPC measures for the prevention of AMR. One Health surveillance programmes should be considered in order to allow for the integrated analysis of data on AMR in the human health, animal health, food and environmental sectors;
43. Identify and support appropriate mechanisms to guarantee availability throughout the Union, of existing effective antimicrobials, in particular first line narrow spectrum antimicrobials, both for human and veterinary use, taking into account inter alia the specificities of small markets;

44. Boost research, development and innovation related to AMR, and support EU and global coordination and cooperation including activities through the Joint Programming Initiative on Antimicrobial Resistance⁴⁶ and the Global AMR R&D Hub⁴⁷;
45. Support initiatives such as the GARDP, which was launched by the WHO and the Drugs for Neglected Diseases initiative (DNDi)⁴⁸ in May 2016. The GARDP addresses global public health needs by developing and delivering new or improved antibiotic treatments. Each of its programmes incorporates sustainable access and stewardship strategies to ensure treatments are affordable and available to all those who need them;
46. Implement and expand research agendas in line with the One Health approach, with the aim to develop new antimicrobials, vaccines, alternatives to antimicrobials, improved rapid diagnostics and renewed and better use of old antibiotics, guided by the principles of accessibility, efficiency and affordability;
47. Identify and support research on and implementation of appropriate economic models for the development of new antimicrobials that incorporate global antibiotic stewardship for prudent use, efficiency and affordability.
48. Improve information and research on effective policies to support human behaviour change in order to combat AMR;
49. Support research on improved economic models, management, governance, incentives and other measures and techniques related to AMR to ensure effective policy implementation;
50. Systematically coordinate Member States' positions and work towards a common 'EU voice', as a best-practice region in international fora, that declares the urgent need to address antimicrobial resistance and consistently pushes for an accelerated global response in multilateral and bilateral relations;

⁴⁶ [Joint Programming Initiative on Antimicrobial Resistance - Global Coordination of Antimicrobial Resistance Research](#)

⁴⁷ [Federal Ministry of Education and Research - Collaborations in Global Health](#)

⁴⁸ [Drugs for Neglected Diseases initiative](#)

51. Continue to actively promote and defend EU standards and EU legislation and policies on AMR in multilateral and bilateral negotiations and in international fora;
52. Provide enhanced information and facilitate use of the ESIF funds for national, regional and local investment in action related to AMR, antimicrobial stewardship and IPC, thus reducing gaps in capacity and implementation of comprehensive One Health strategies between and within Member States;
53. Explore possibilities, including, as appropriate, regulation, to prevent non-prudent use of antimicrobials obtained through cross-border purchases for personal use, cross-border prescriptions and sales via the Internet;
54. Monitor antimicrobial residues from use and production and resistant microorganisms in soil, ground and surface water in accordance with EU and national legislation in force and consider further legislative measures, as appropriate, to address their presence in the environment;
55. Increase the evidence base on development and spread of AMR, particularly in the environment.

CALLS UPON the Commission to:

56. Make use of the EU AMR 'One Health Network' to enhance cooperation with and between Member States on AMR, IPC and antimicrobial stewardship;
57. Continue to support Member States in the implementation of multi-sectoral NAPs and national strategies on AMR and increase the dedicated funding;
58. Support data collection by Member States on the sales and use of antimicrobials for animals so as to ensure the effective implementation of data collection and processing in line with Regulation (EU) 2019/6 on veterinary medicinal products, and consider the allocation of dedicated financial resources;
59. Support Member States with identifying the barriers to the development and implementation of NAPs on AMR, and of IPC and antimicrobial stewardship measures, at both the policy and clinical levels, so as to contribute to identifying effective measures to overcome such barriers.