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NOTE

From: General Secretariat of the Council
To: Working Party on Public Health

Subject: Draft Council conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance

Delegations will find enclosed a first set of draft Council conclusions prepared by the Presidency and intended for discussion at the meeting of the Working Party on 2 April 2019.

**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 sufficiently addressed by one Member State alone and cannot be confined to a geographical region or a Member State and hence needs 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 health¹.
2. **NOTES WITH GREAT CONCERN** that, according to official data, about 700 000 deaths^{2 3} may be caused globally each year by AMR, 33 000^{4 5} of these in the European Union/EEA. If the current trend continues, AMR could cause more deaths than cancer by 2050.
3. **NOTES WITH CONCERN** that 75% of the burden of diseases from resistant infections in the EU is due to healthcare-associated infections (HAI) acquired in hospitals⁶.

¹ OJ L 293, 5.11.2013, p.1

² <https://www.who.int/bulletin/volumes/94/9/16-020916/en/>

³ data from 2016 - https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

⁴ <https://ecdc.europa.eu/en/news-events/33000-people-die-every-year-due-infections-antibiotic-resistant-bacteria>

⁵ data from 2015 (ECDC, see above)

⁶ [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(18\)30605-4/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(18)30605-4/fulltext)

4. **RECOGNISES** that AMR is a global public health concern, the impact of which goes beyond its severe consequences for human and animal health and therefore **WELCOMES** the many international initiatives aiming at combatting AMR, *inter alia*:
- the UN political declaration of the High-Level meeting of its General Assembly on AMR of 21 September 2016⁷, aimed at combating the global threat posed by AMR and confirming the necessity of a "One Health" approach;
 - the Global Action Plan (GAP) on Antimicrobial Resistance⁸ 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;
- and
- the work of the UN Interagency coordination Group on AMR (IACG) that has drawn up a set of draft recommendations⁹.
5. **NOTES** that AMR by now has become an issue discussed in many other *fora* in an international context, such as the G7 Health Ministers¹⁰ and the G20¹¹.
6. **RECALLS** the call by the WHO on all its Member States to put in place national action plans against AMR by 2017.
7. **TAKES NOTE** of the ongoing work of the Organisation for Economic Co-operation and Development (OECD) and **WELCOMES** its recent report indicating that investment in public health interventions could substantially reduce the burden on society caused by AMR¹².

⁷ <https://digitallibrary.un.org/record/842813?ln=en>

⁸ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_ACONF1Rev1-en.pdf?ua=1

⁹ https://www.who.int/antimicrobial-resistance/interagency-coordination-group/Draft_IACG_recommendations_for_public_discussion_290119.pdf

¹⁰ https://www.g7germany.de/Content/EN/Artikel/2015/06_en/g7-gipfel-dokumente_en.html

¹¹ https://www.consilium.europa.eu/media/23955/g20-hamburg-leaders_-communiqu%C3%A9.pdf

¹² <http://www.oecd.org/els/health-systems/Stemming-the-Superbug-Tide-Policy-Brief-2018.pdf>

8. **RECALLS** that Article 168 of the Treaty on the Functioning of the European Union (TFEU), provides that Union action shall complement national policies and shall cover the fight against major health scourges, their transmission and their prevention, health information, education, monitoring, and combating serious cross-border threats to health. The Union shall furthermore encourage cooperation between the Member States and shall foster cooperation with third countries and the competent international organisations in the sphere of public health.
9. **RECALLS** the Council conclusions of 17 June 2016 on the next steps under a One Health approach to combat antimicrobial resistance¹³ and the references therein to, notably, the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections¹⁴, 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 resistance¹⁵.
10. **WELCOMES** the publication by the Commission on 29 June 2017 of "A European One Health Action Plan against Antimicrobial Resistance"¹⁶ and the actions listed therein to combat AMR and **SUPPORTS THE INTENTION** of making the EU a best practice region in this respect.
11. **RECALLS** the European Parliament Resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance¹⁷.

¹³ OJ C 269, 23.7.2016, p.26

¹⁴ OJ C 151, 3.7.2009, p.1

¹⁵ OJ C 438, 6.12.2014, p. 7

¹⁶ [COM \(2017\) 339 final](#)

¹⁷ [EP \(2018\) 0354](#)

12. **DRAWS THE 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 is banned¹⁸. The recent adoption of Regulation (EU) 2019/6 on veterinary medicinal products¹⁹ and Regulation (EU) 2019/4 on medicated feed²⁰ prevent also the use of antimicrobial veterinary medicinal products for promoting growth or to increase yield²¹, the preventive use of veterinary antimicrobial products via medicated feed²² and the preventive use of veterinary antibiotics in groups of animals²³. The Regulation on veterinary medicinal products also contain provisions that allow for the possibility to reserve certain antimicrobials for human use only, in order to better preserve their efficiency²⁴.
13. **WELCOMES** the enhanced cooperation between the Member States and the Commission through the EU AMR One Health Network²⁵ established in 2017 and **NOTES** the importance of its regular meetings as part of the implementation of the EU Action Plan on AMR.
14. **ACKNOWLEDGES** the findings in the JIACRA reports on AMR²⁶ 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 THE ATTENTION** to the fact that a legal basis for those activities has recently been introduced into Regulation (EC) No 726/2004²⁷.
15. **STRESSES** that more cooperation between Member States and with the Commission and pharmaceutical industry is crucial regarding the reduced availability including possible withdrawals from the market of antimicrobials that may lead to shortages in antimicrobials and inadequate replacement therapy.

¹⁸ Article 11 of Regulation (EC) No 1831/2003

¹⁹ OJ L 4, 7.1.2019, p. 43

²⁰ OJ L 4, 7.1.2019, p. 1

²¹ Article 107 of Regulation (EU) 2019/6 (see above)

²² Article 17 of Regulation (EU) 2019/4 (see above)

²³ Article 107 of Regulation (EU) 2019/6 (see above)

²⁴ Articles 37 and 107 of Regulation (EU) 2019/6 (see above)

²⁵ <https://ec.europa.eu/health/amr/>

²⁶ <https://www.ema.europa.eu/en/veterinary-regulatory/overview/antimicrobial-resistance/analysis-antimicrobial-consumption-resistance-jiacra-reports>

²⁷ OJ L 136, 30.04.2004, p.1

16. **UNDERLINES** that in order to stimulate the development of new antimicrobials, alternative therapies and (rapid and modern) diagnostics, EU and global coordination and cooperation on research programmes and incentives are needed and **RECOGNISES** the proposals of the Antimicrobial Resistance Review team²⁸ and the Joint Programming Initiative on Antimicrobial Resistance²⁹ among others.
17. **HIGHLIGHTS** that the success of the global fight against AMR relies heavily on the commitment and willingness of governments to take actions to ensure the implementation of the initiatives under the One Health approach involving all relevant sectors and could be given a strengthened impetus from cooperation of EU Institutions and Member States in international *fora*.
18. **STRESSES** the importance of the Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (JAMRAI) and **WELCOMES** its work on policies for prevention of HAI and their implementation.
19. **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, focusing on three key objectives:
- (1) improve the quality of infection prevention and control measures and optimise antimicrobial use across the human, animal and environmental health sectors;
 - (2) strengthen the implementation of "One Health" national action plans;
 - (3) encourage solidarity between countries by working together to combat AMR.

²⁸ Lead by J. O'Neill (<http://amr-review.org/>)

²⁹ <http://www.jpamr.eu/>

CALLS UPON Member States to:

20. Ensure that all Member States have in place multi-sectoral national action plans in fulfilment of their commitments under the Global Action Plan on AMR, following a One Health approach;
21. 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;
22. Strengthen their cooperation and solidarity to combat AMR by engaging bilaterally, in twinning projects, and multilaterally in collaboration to facilitate sharing of best practices and expertise and to support each other in the implementation of their AMR National Action Plans (NAPs) as well as of IPC and antimicrobial stewardship programmes;
23. Reinforce the implementation of current policies and existing commitments regarding AMR at EU and international level, based on the One Health approach;
24. Strengthen IPC measures, in particular in healthcare settings, by investing in hygiene practices and prevention actions, including vaccinations, and ensuring access to standard and rapid diagnostic methods for HAIs to be used to confirm the type of infection prior to the use of antibiotics, and thus to contribute to reducing the inappropriate use of antibiotics and the associated risk of developing AMR;
25. 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;
26. Explore possibilities for regulating the use and sales of human antimicrobials, in particular over-the-counter sales.

CALLS UPON Member States and the Commission to:

27. Continue to develop long-term policies to tackle the AMR threat;
28. Strengthen coordination and cooperation between Member States, as well as between Member States and the Commission, across the human health, food, veterinary, environmental, research and other relevant sectors;
29. 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 to assist actions at national and local level;
30. Develop voluntary minimum common standards on infection prevention and control in healthcare setting, based on best practices;
31. Establish EU and national measurable targets on progress towards reducing the spread of AMR, based on the indicators developed by EFSA, EMA and ECDC;
32. Increase capacity amongst 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;
33. Assess reasons for variations regarding the proportion of broad spectrum antibiotic use in hospitals and other healthcare settings, especially in surgical antibiotic prophylaxis, with a view to better understanding and controlling HAI;
34. Prioritise adequate training of the health workforce across sectors on AMR, IPC and antimicrobial stewardship *inter alia* through improved undergraduate education, which highlights the risks of AMR related to inappropriate prescription, dosage, use and disposal, and includes actions set out in the EU guidelines for the prudent use of antimicrobials;

35. Develop and effectively implement, at EU and national level, coordinated communication strategies aimed at both the prevention of outbreaks of antimicrobial-resistant infections and at being used in case of such outbreaks;
36. Boost efforts at awareness-raising through the mass media and social media to reach out and sensitise the general public on the importance of AMR as a health threat and on the subsequent need to use antimicrobials prudently;
37. 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, to 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 integrate the data on AMR in the human health, veterinary, food and environmental sectors;
38. Facilitate further work aiming at improving availability throughout the Union, of existing effective antimicrobials and ensuring their appropriate use;
39. Expand the research agenda in line with a One Health approach, with the aim to identify alternatives to antimicrobials, to develop new antimicrobials, vaccines, monoclonal antibodies and bacteriophages, and improved rapid diagnostics, guided by the principles of accessibility, efficiency and affordability;
40. Improve information and research on effective policies to support human behaviour change in order to combat AMR;
41. Support research on improved economic models, management, governance, incentives, sanctions and other techniques in relation to AMR to ensure effective policy implementation;
42. Coordinate Member States positions and work towards a common 'EU voice' in international fora on the urgent need to address antimicrobial resistance to push for accelerated global response in multilateral and bilateral relations;

43. Continue to actively promote and defend EU standards and EU legislation and policies on AMR in multilateral and bilateral negotiations and in international fora;
44. Provide enhanced information and facilitate use of the ESIF funds for national, regional and local investment in action related to AMR and IPC, thus reducing gaps in capacity and implementation of comprehensive one Health strategies between and within Member States.

CALLS UPON the Commission to:

45. Make use of the EU AMR “One Health Network” to enhance cooperation with and between Member States on AMR, IPC and antimicrobial stewardship;
46. Continue to support the implementation of NAPs and national strategies on AMR in Member States and make dedicated funding available;
47. Support Member States in identifying the barriers to the development and implementation of NAPs on AMR, of IPC and antimicrobial stewardship measures, at policy and clinical level in order to contribute to identifying effective measures to overcome such barriers;
48. Explore possibilities, including, as appropriate, by means of regulation at EU level, to prevent non-prudent use of antimicrobials obtained through cross-border prescription and sales via the Internet;
49. Monitor antibiotic residues in ground and surface water and consider legislative measures, as appropriate, to address the problem of environment pollution as a cause of AMR.