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NOTE

From: General Secretariat of the Council
To: Council

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Subject: **Employment, Social Policy, Health and Consumer Affairs Council**
meeting on 17 June 2016
Draft Council conclusions on the next steps under a One Health approach
to combat antimicrobial resistance
- Adoption
(Public debate in accordance with Article 8(2) of the Council's Rules of
Procedure [proposed by the Presidency])

1. The text of the above draft Council conclusions has been discussed by the Working Party on Public Health and Veterinary (Attachés) followed by a written consultation concluded on 30 May 2016.
2. COREPER agreed to the text of draft conclusions, except for point 22.10 that the Presidency modified to take into account the proposal from the French delegation and after consulting all delegations.
3. The Council is invited to adopt the draft conclusions and forward them for publication in the Official Journal of the European Union.

Draft Council conclusions
on the next steps under a One Health approach to combat antimicrobial resistance

The Council of the European Union

1. **RECALLS** the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine¹ and the reports of December 2005, April 2010 from the Commission to the Council on its implementation² and the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections³ and the reports of November 2012 and June 2014 from the Commission to the Council on its implementation⁴.
2. **RECALLS** the Council conclusions of 10 June 2008 on antimicrobial resistance (AMR)⁵, the Council conclusions of 1 December 2009 on innovative incentives for effective antibiotics⁶, the Council conclusions of 22 June 2012 on the impact of antimicrobial resistance in the human health sector and in the veterinary sector – a 'One Health' perspective⁷ 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 resistance⁸.

1 OJ L 34, 5.2.2002, p.13

2 5427/06 [COM(2005)684 final] and 8493/10 [COM(2010)141 final]

3 OJ C 151, 3.7.2009, p.1

4 COM(2012)0658 and COM(2014)0371

5 9637/08

6 OJ C 302, 12.12.2009, p. 10

7 OJ C 2011, 18.7.2012, p. 2

8 OJ C 438, 6.12.2014, p. 7

3. **RECALLS** the European Parliament Resolution of 12 May 2011 on antibiotic resistance⁹, the European Parliament Resolution of 27 October 2011 on the public health threat of antimicrobial resistance¹⁰, the European Parliament Resolution of 11 December 2012 on the Microbial Challenges – Rising Threats from AMR¹¹ and the European Parliament Resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance¹².
4. **RECALLS** the 2001 Community Strategy against AMR¹³ and the European Commission Communication of 15 November 2011 on an action plan against the rising threats from Antimicrobial Resistance¹⁴ and the outcome of the evaluation of the 5 years action plan of the European Commission.
5. **WELCOMES** the Global Action Plan (GAP) on Antimicrobial Resistance¹⁵ 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 unanimously adopted in May 2015 by the 68th World Health Assembly, calling all Member States of the World Health Organization to put in place national action plans against AMR by mid-2017.
6. **WELCOMES** the Resolution on Antimicrobial Resistance adopted in June 2015 by the 39th Conference of the FAO and the Resolution combating Antimicrobial Resistance and promoting the prudent use of antimicrobial agents in animals in May 2015 at the World Assembly of Delegates of the OIE.
7. **WELCOMES** the Codex Alimentarius Commission¹⁶ initiative with regard to the need to review and update standards, codes and guidelines related to AMR.

⁹ P7_TA(2011)0238

¹⁰ P7_TA(2011)0473

¹¹ 2012/2041 (INI)

¹² 2014/2207(INI)

¹³ COM/2001/0333 final Volume I.

¹⁴ 16939/11 [COM(2011)748]

¹⁵ http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_ACONF1Rev1-en.pdf?ua=1

¹⁶ CAC 39-CL2015/21

8. **WELCOMES** other international and regional initiatives such as the declaration by the G7 on Antimicrobial Resistance¹⁷ and the decision to put antimicrobial resistance on the agenda of the G20.
9. **RECALLS** that regarding human health, the Union's action is defined by Article 168 of the Treaty on the Functioning of the European Union.
10. **RECALLS** that antimicrobial resistance is a 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 health¹⁸.
11. **RECALLS** that in the veterinary sector a number of legislative and non-legislative measures have already been taken and are taken at EU level to coordinate and ensure a common EU approach reducing the risk of AMR. These measures include especially those set out in the Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹⁹, prohibiting the use of antibiotics as growth promoters, Commission Implementing Decision 2013/652/EU on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria²⁰, Commission Decisions following referral procedures under Directive 2001/82/EC, resulting in modifications of marketing authorisations for products containing critically important antimicrobials in order to reflect specific measures against development of AMR and in the Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)²¹.
12. **WELCOMES** the ongoing work of the Organisation for Economic Co-operation and Development (OECD) and the World Bank on the economic impact of AMR.

¹⁷ https://www.g7germany.de/Content/EN/Artikel/2015/06_en/g7-gipfel-dokumente_en.html

¹⁸ OJ L 293, 5.11.2013, p.1-15

¹⁹ OJ L268, 18.10.2003, p. 29

²⁰ OJ L 303, 14.11.2013, p. 26

²¹ OJ C 299, 11.9.2015, p. 7

13. **EXPRESSES ITS CONCERN** regarding the data provided by OECD, according to which, it is estimated that about 700 000 deaths may be caused globally each year by AMR. Compared to a world with no AMR, the economic impact associated with current rates of AMR may reach about 0.03% of GDP in 2020 in OECD countries, 0.07% in 2030 and 0.16% in 2050. This would result in cumulative losses of about USD 2.9 trillion by 2050²².
14. **ACKNOWLEDGES** the Scientific Opinions and reports on antimicrobial resistance published by the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA).
15. **RECOGNISES** that due to the complexity of the problem, its cross-border dimension and the high economic burden, the impact of antimicrobial resistance goes beyond its severe consequences for human and animal health and has become a global public health concern that affects the whole of society and requires urgent and coordinated intersectoral action, where necessary based on the precautionary principle²³.
16. **UNDERLINES** that in order to stimulate the development of new antimicrobials, alternative therapies and (rapid) diagnostics, EU and global coordination and cooperation on research programmes and incentives are needed and **RECOGNISES** the work done by the Innovative Medicines Initiative (IMI) project DRIVE-AB (Driving reinvestment in research and development and responsible antibiotic use), the proposals of the Antimicrobial Resistance Review team²⁴ and the Joint Programming Initiative on Antimicrobial Resistance²⁵ among others.

²² <http://www.oecd.org/els/health-systems/Antimicrobial-Resistance-in-G7-Countries-and-Beyond.pdf> ;

NB: in the quoted report the amount "trillion" means 10¹²

²³ Communication from the Commission on the precautionary principle (COM(2000) 1 final of 2 February 2000).

²⁴ Lead by J. O'Neill (<http://amr-review.org/>)

²⁵ <http://www.jpiamr.eu/>

17. **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. **HIGHLIGHTS** that to make progress in the fight against AMR, the new EU Action Plan should contain measurable (clearly defined quantitative or qualitative) goals, benchmarks and effective measures to achieve these goals.
19. **HIGHLIGHTS** that the success of the fight against antimicrobial resistance 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 on the will of the EU Member States to cooperate within the EU and at an international level.
20. **WELCOMES** the EU Ministerial One Health Conference on AMR²⁶ held in Amsterdam on 9 and 10 February 2016, at which the political will to tackle the AMR problem, by means of a One Health approach was expressed, including among others, enhanced cooperation between the Member States through a EU One Health Network on AMR. The EU One Health Network will not be a new governance structure, but it will work through joint meetings of existing groups or bodies in the human health, food and veterinary field, such as the AMR working group and the Health Security Committee. The EU One Health Network will be used on a regular basis, to discuss AMR related issues from a one health perspective, i.a. the exchange of information between Member States about the progress made on the implementation of the National Action Plans against AMR and the development and implementation of the EU Action Plan.

²⁶ <http://english.eu2016.nl/events/2016/02/10/ministerial-conference-on-amr>

21. CALLS UPON THE MEMBER STATES TO:

1. have in place before mid-2017 a national action plan against Antimicrobial Resistance, based on the One Health approach and in line with the objectives of the WHO Global Action Plan. The national action plan, adapted to the national situation, should:
 - a) ensure that measures and actions in the different domains take into account the public health concerns of AMR;
 - b) be developed and implemented in cooperation between all relevant ministries and the relevant stakeholders in the public and private sector;
 - c) include measurable goals to reduce infections in humans and animals, the use of antimicrobials in the human and veterinary sector and antimicrobial resistance in all domains. These goals could be qualitative and/or quantitative and should be addressed through effective measures adapted to the Member States' national situations;
 - d) include measures to reduce the risk of AMR and strengthen the prudent use of antimicrobials in veterinary medicine, according to EU²⁷ and national guidelines, including actions to avoid the routine preventive use of veterinary antimicrobials and actions to restrict the use in animals of antimicrobials that are of critical importance to human health (e.g. use on the basis of antimicrobial susceptibility testing);
 - e) include measures to reduce the risk of AMR and strengthen the prudent use of antimicrobials in human medicine including actions to improve prescribing practices and prudent use of antimicrobials that are of critical importance to human health (e.g. use on the basis of antimicrobial susceptibility testing);

²⁷ Commission Guidelines for the prudent use of antimicrobials in veterinary medicine (2015/C 299/04)
http://ec.europa.eu/health/antimicrobial_resistance/docs/2015_prudent_use_guidelines_en.pdf

- f) include the mechanism for implementation of national action plans and monitoring of their progress, including the way to further strengthen surveillance and to improve the quality and comparability of the data reported to ECDC, EFSA and EMA on the use of antimicrobials and on resistance in humans, animals, the food chain and possibly the environment;
 - g) include the way enforcement of legislation relevant to AMR is organised and ensured in the Member State;
 - h) include education programmes, where appropriate, and targeted campaigns to raise awareness among consumers, animal keepers and relevant professionals;
2. within the EU One Health Network, present their national action plans and share best practices, discuss policy options, ways to better coordinate responses and keep each other updated on the progress made on the implementation of the action plans;
 3. support dialogue with the pharmaceutical industry in order to keep existing effective antimicrobials used in human and veterinary medicine on the market, and explore alternative solutions to ensure availability of these antimicrobials on the market;
 4. join or strengthen their commitment to the existing Joint Programming Initiative on AMR²⁸;
 5. promote and facilitate the implementation of measures to prevent infections in animals such as the use of vaccines and biosecurity measures in order to reduce infection pressure and therefore the need to use antibiotics;
 6. promote the use of diagnostic tools including rapid tests and their uptake in the human and veterinary sector as means to improve the prescription of antimicrobials.

²⁸ <http://www.jpiamr.eu/>

22. CALLS UPON THE MEMBER STATES AND THE COMMISSION TO:

1. develop together, while respecting Member States competencies, a new and comprehensive EU Action Plan on Antimicrobial Resistance based on the One Health approach, taking into account the evaluation of the current Action Plan, the discussion at the EU Ministerial One Health Conference on AMR of 10 February 2016 and the WHO Global Action Plan. The new EU Action Plan should include the following measures and measurable²⁹ goals:
 - a) measures to prevent infections and to ensure prudent use of antimicrobials in human and veterinary medicine;
 - b) measures to combat illegal practices related to the trade and use of antimicrobials, in human and veterinary medicine;
 - c) align surveillance on AMR in humans, food, animals and environment at EU level;
 - d) decrease, over the period of the new EU Action Plan, antimicrobial resistance in humans, animals and in the environment in the EU;
 - e) decrease, over the period of the new EU Action Plan, the differences between Member States, in use of antimicrobials in both human and animal health, whereas Member States with a relatively low use should also try to further pursue prudent use of antimicrobials;
 - f) decrease, over the period of the new EU Action Plan, healthcare associated infections in the EU;
 - g) develop indicators to assess the progress made on addressing AMR and on the implementation of the EU Action Plan.

²⁹ See paragraph 18.

2. strengthen coordination and cooperation between Member States, between Member States and the Commission, and between human, food, veterinary, environmental, research and other relevant sectors and actively participate in the joint discussions of the EU One Health Network as defined in paragraph 20;
3. within the One Health Network, discuss the development, progress and implementation of the EU Action Plan;
4. strive for ambitious legislative measures that address the public health risk of AMR, in the areas where there is competence to do it, for example in the area of veterinary medicinal products and medicated feed;
5. develop European Union guidelines on prudent use of antimicrobials in human medicine to support national guidelines and recommendations;
6. set up a voluntary country-to-country peer review system in which representatives from one or several Member States evaluate each other's national action plan, reflect about policy options and provide recommendations to support Member States to improve measures taken. This country-to-country peer review system is complementary to other existing assessment tools or audit activities (e.g. ECDC, Directorate on Health and Food Audits and Analysis³⁰ or WHO);
7. ensure that the EU has a common approach in the global discussions on AMR, especially on the implementation of the GAP of the WHO, the FAO and the OIE Resolutions on AMR and on the implementation and updating the intergovernmental standards related to AMR published by Codex Alimentarius and the OIE;

³⁰ The Directorate on Health and Food Audits and Analysis of the European Commission's Directorate-General for Health and Food Safety, formerly the "Food and Veterinary Office".

8. in the framework of the One Health Network on AMR align strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostics, set priorities based on societal needs in the field of public health, animal health and the environment, taking into account the gaps analysis in this domain;
9. actively engage in initiatives and proposals to implement a new business model to bring new antibiotics to the market, including models in which investment costs or revenues are de-linked from sales volumes;
10. encourage all relevant partners, including national regulatory authorities to launch a reflection, within the existing appropriate fora (e.g. the One Health Network), regarding the regulatory framework with regards to antibiotics in order to stimulate research and development and to facilitate marketing authorization procedure for new antimicrobials;
11. encourage the use of alternative treatment and prevention options including vaccines and the development and use of affordable diagnostics tests in human and veterinary medicine;
12. support in close cooperation between the Member States and the Commission, the proposals to put AMR on the agenda of the United Nations General Assembly in September 2016, as mandated by the WHO GAP and the FAO Resolutions on AMR, in order to raise awareness of the issue at the highest political level, involving all Heads of State and all relevant UN organisations and aim for ambitious outcomes.

23. CALLS UPON THE COMMISSION TO:

1. facilitate and support Member States in the development, assessment and implementation of national action plans against AMR, including support to strengthen monitoring and surveillance systems and consider financial support within existing frameworks;
2. facilitate and support the regular meetings of the EU One Health Network on AMR as defined in paragraph 20;

3. report to the Council at least once a year on the activities of the One Health Network including the developments in the area of the implementation of the EU Action Plan against AMR;
4. establish a harmonised approach to prevent introduction and spread of emerging antimicrobial resistance in animal husbandry and the food chain with potential impact in public health (e.g. carbapenem resistance);
5. develop as a matter of priority specific acts under the Regulation on transmissible animal diseases ('Animal Health Law')³¹ including infection prevention measures, good management practices in animal husbandry and harmonised surveillance systems of relevant animal pathogens;
6. actively promote and defend in multilateral and bilateral dialogues and agreements between the EU and its counterparts the EU standards and EU policies on AMR, especially:
 - a) the importance of infection prevention, prudent use of antimicrobials and strengthening the awareness of the risks of AMR in human and veterinary medicine;
 - b) the ban on the use of antibiotics as growth promoters in livestock farming;
 - c) the avoidance of the routine preventive use of antimicrobials in veterinary practice;
 - d) the restrictions on the use in veterinary practice of antimicrobials that are not authorised or which use has been restricted in the EU due to the fact that they are critically important for the prevention and treatment of life-threatening infections in humans;

³¹ Regulation (EU) No 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 84, 31.3.2016, p. 1).

- e) the EU requirements for the import of live animals and products thereof;
 - f) the concept of the precautionary principle³².
7. promote economic impact studies in the human and animal sector to assess the cost of AMR.
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³² See also paragraph 15.