



**COUNCIL OF
THE EUROPEAN UNION**

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NOTE

from: General Secretariat of the Council
to: Permanent Representatives Committee (Part 1)/Council
Subject: The impact of antimicrobial resistance in the human health sector and in the veterinary sector – a “One Health” perspective"
- *Adoption of Council conclusions*
(Public debate in accordance with Article 8(2) of the Council's Rules of Procedure [proposed by the Presidency])

1. The Working Party on Public Health discussed and agreed on the draft Council conclusions as set out in the Annex. The Veterinary Attachées were invited to all relevant meetings and consulted during the entire process.
2. The COREPER is invited to confirm the Working Party’s agreement and submit the draft conclusions for adoption by the Council (EPSCO) at its meeting on 22 June 2012.
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 impact of antimicrobial resistance in the human health sector and in the
veterinary sector – a “One Health” perspective**

The Council of the European Union

1. **RECALLS** the Council conclusions of 10 June 2008 on antimicrobial resistance (AMR)¹.
2. **RECALLS** the Council conclusions of 23 November 2009 on innovative incentives for effective antibiotics².
3. **RECALLS** the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine³, including the reports of December 2005 and April 2010 from the Commission to the Council on its implementation⁴.
4. **RECALLS** the Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections⁵.
5. **ACKNOWLEDGES** the Scientific Opinion of October 2009 of the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on antimicrobial resistance focused on zoonotic infections⁶.
6. **ACKNOWLEDGES** the European Parliament Resolution of 5 May 2010 on evaluation and assessment of Animal Welfare Action Plan 2006-2010⁷.

¹ 9637/08

² OJ C 302, 12.12.2009, p. 10

³ OJ L 34, 5.2.2002, p.13

⁴ 5427/06 [COM(2005)684 final] and 8493/10 [COM(2010)141 final]

⁵ OJ C 151, 3.7.2009, p.1

⁶ EFSA Journal 2009; 7(11):1372,

http://ec.europa.eu/health/scientific_committees/emerging/opinions/scenihhr_o_026.pdf,
EMEA/CVMP/447259/2009

⁷ P7_TA(2010)0130,

7. **RECALLS** the European Parliament Resolutions of 12 May 2011 on antibiotic resistance⁸ and of 27 October 2011 on the public health threat of antimicrobial resistance⁹.
8. **WELCOMES** the European Commission Communication of 15 November 2011 on an action plan against the rising threats from Antimicrobial Resistance¹⁰.
9. **RECALLS** the Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition prohibiting the use of antibiotic growth promoters¹¹.
10. **STRESSES** that AMR is a growing European and global health problem in both humans and animals, leading to limited or poor options for treatment whilst diminishing the quality of life and to important economic consequences in terms of augmenting healthcare costs and productivity losses.
11. **RECOGNISES** that the development of AMR is accelerated by excessive and inappropriate use of antimicrobial agents which, together with poor hygiene or poor infection control practices, creates favourable conditions for the development, spread and persistence of resistant microorganisms in both humans and animals.
12. **RECOGNISES** that there are varying situations and different approaches in prescription, use and distribution of antimicrobials in the Member States, including types of antimicrobials used, in human medicine and in veterinary medicine.
13. **UNDERLINES** the need for an active holistic risk based approach based on a “One Health” perspective with the purpose of reducing the use of antimicrobials as much as possible and to maximise coordinated efforts between the human health sector and the veterinary sector in the fight against AMR.

⁸ P7_TA(2011)0238

⁹ P7_TA(2011)0473

¹⁰ 16939/11 [COM(2011)748]

¹¹ OJ L 268, 18.10.2003, pp. 29-43

14. **STRESSES** that microbiological diagnosis together with standardised susceptibility testing create the basis for a correct choice of antimicrobial treatment and de-escalation of the initial empirical treatment, thus allowing antimicrobials to be used in the most appropriate way with the objective to limiting the use of antibiotics in general and especially of CIAs.
15. **ACKNOWLEDGES** the definitions of CIAs for humans and animals by the World Health Organisation (WHO) and the World Organisation for Animal Health (OIE), respectively, as the basis for European efforts.
16. **STRESSES** the need to target the use of CIAs to specific cases in which the use is considered appropriate.
17. **STRESSES** the need to be restrictive in both the human and veterinary use of CIAs and newly developed antimicrobials, eventually with the aim in the future to reserve CIAs as much as possible for human use.
18. **STRESSES** the need for all Member States to require that, as a minimum, oral, inhaled and parenteral antimicrobial agents are only available through prescription or in clearly defined circumstances, under the supervision of a regulated health care professional.
19. **RECOGNISES** that some practises in human and in animal healthcare including the possible incentives deriving from the prescription and subsequent sale of antimicrobial agents may lead to inappropriate use and overuse of antimicrobial agents.
20. **STRESSES** the importance of effective surveillance systems in both the human health sector and the veterinary sector based on existing monitoring systems under the auspices of EFSA, the ECDC European Surveillance of Antimicrobial Consumption Network (ESAC-net), the ECDC European Antimicrobial Resistance Surveillance Network (EARS-net), and the EMA European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) to allow collection of comparable and timely data on AMR and on the use of antimicrobial agents.

21. **RECOGNISES** the importance of EU support through existing EU financial instruments such as the Health Programme and the EU Framework Programme for Research and Innovation including the Innovative Medicine Initiative (IMI) to improve research and development on AMR and strengthen prevention and control against AMR and the need to continue these activities and implementing the results.
22. **STRESSES** the importance of enhancing the coordination of Member States research activities on countering AMR in the EU¹².
23. **STRESSES** the need to actively raise awareness in the general public, and in the human health sector and veterinary sector about the risks of AMR due to excessive and inappropriate use of antimicrobial agents and the consequences of AMR for the individual and society in general and, **RECOGNISES** the importance of the European Antibiotic Awareness Day as a platform for national awareness campaigns.
24. **STRESSES** the importance of continuous training and education of human health and veterinary professionals in the diagnosis, treatment and prevention of infectious diseases and in the appropriate use of antimicrobials and where relevant, continuous training and education in prevention of infectious diseases and in the appropriate use of antimicrobials shall also involve livestock keepers.
25. **RECOGNISES** that health care acquired infections are an important factor in the spread of antimicrobial resistance and in an increased use of antibiotics.
26. **STRESSES** the importance of effective preventive and hygiene measures, especially hand hygiene and biosecurity measures to prevent and control infections and their spread in both the human health sector and in the veterinary sector.
27. **HIGHLIGHTS** the importance of international cooperation on AMR, including the work carried out by the World Health Organization (WHO), the World Organisation for Animal Health (OIE), Codex Alimentarius and the Transatlantic Task Force on Antimicrobial Resistance (TATFAR).
28. **WELCOMES** the Conference on AMR in Copenhagen on 14-15 March 2012, which provided valuable contributions to the further work to counter AMR through actions against overuse of antimicrobials in humans and animals with a particular focus on critically important antimicrobials and strengthened surveillance.

¹² 16314/11 [C(2011)7660] COMMISSION RECOMMENDATION of 27.10.2011 on the research joint programming initiative "The Microbial Challenge – An Emerging Threat to Human Health

29. CALLS UPON THE MEMBER STATES TO

- 1) develop and implement national strategies or action plans for countering AMR which include the following elements:
 - a. development and implementation of national guidelines on the treatment of humans and animals with antimicrobial agents ensuring a more prudent use and thus a reduced risk of AMR;
 - b. Clinical sampling and the use of diagnostic on- site tests and susceptibility testing in order to secure that antimicrobial treatments are based on microbiological diagnosis and susceptibility and ensure sufficient microbiological capacity specifically adapted to both human and veterinary use;
 - c. development and implementation of communication guidelines and programmes for education and training of professionals on the appropriate use of antimicrobial agents and methods to reduce the transmission of pathogens, including infection control and hygiene measures in both the human health sector and the veterinary sector;
 - d. enforcement of national legislation preventing all illegal sales of antimicrobials including illegal sales over the Internet, in both the human health sector and the veterinary sector;
 - e. limit the use of Critically Important Aintibiotics to cases where microbiological diagnosis and susceptibility testing has determined that no other type of antimicrobials will be effective. In acute cases in the treatment of infections in humans and animals, CIAs can be used initially when necessary, but must be re-evaluated and if possible de-escalated depending on test results;

- f. limit prophylactic use of antimicrobials to cases with defined clinical needs;
- g. limit prescription and use of antimicrobials for herd treatment of animals to cases where a veterinarian has assessed that there is a clear clinical and where appropriate epidemiological justification to treat all animals;
- h. encourage incentives for the animal production and marketing systems that serves the continuous improvement of animal health, including the prevention of diseases, enhancement of hygiene measures and as a result reduce the need for antimicrobials;
- i. ensure effective surveillance systems, including both the human health sector and the veterinary sector with the aim of collecting timely data that are comparable between sectors and Member States on AMR and on the use of antimicrobial agents;
- j. transmission to surveillance systems of data on the prescription and/or sales of all antimicrobial agents for use in humans;
- k. collect data on sale and use of antimicrobials in animals;
- l. set up an intersectoral coordination mechanism at national level involving relevant authorities and-sectors to monitor the implementation of the national strategies or action plans on antimicrobial use and resistance.

30. CALLS UPON THE MEMBER STATES AND THE COMMISSION TO

1. ensure continued advancement and strengthening of intersectoral cooperation, nationally and internationally, including on the advancement of prudent use of antimicrobial agents. Where appropriate identify options and models to strengthen incentives to conduct research and development of new effective antimicrobials or alternatives and their controlled use;
2. continue the efforts to raise public awareness about the risks of AMR due to excessive use of antimicrobial agents, including through continued support for the European Antibiotics Awareness Day;
3. develop a classification of antimicrobials including a specific list that are essential to treat infections caused by multiresistant organisms for which other antimicrobials have become ineffective and to promote and carry out education and guidance of health and veterinary professionals alike on limiting the use of these antimicrobials for humans and especially for animals;
4. invite WHO and OIE to collaborate on the update of the respective lists of CIAs for the human and veterinary sector;
5. cooperate on the early detection of pathogenic antimicrobial resistant bacteria in humans, in animals and in food in order to continuously monitor the development of AMR;
6. use the existing early warning systems for the swift detection of new mechanisms of resistance;

7. Examine the conditions for prescription and sale of antimicrobials in order to ascertain whether practices in human and animal healthcare may lead to over-prescription, overuse or misuse of antimicrobials;
8. work actively to promote international initiatives to limit the use of antimicrobials which would include international requirements on-prescription for antimicrobials, international requirements on surveillance and reporting of antimicrobial use and resistance and a global ban on antimicrobial growth promoters in animals;
9. work actively to promote adoption of rules at international level, including through WHO resolutions and OIE and Codex Alimentarius standards, for surveillance and reporting of antimicrobial use and resistance;
10. reinforce and coordinate research and innovation efforts to combat AMR and to maintain the efficacy and availability of existing antimicrobials, including through public-private collaboration.

31. CALLS UPON THE COMMISSION TO

1. follow up on its Communication of 15 November 2011 through concrete initiatives to implement the 12 actions indicated in the Communication, and to present a timeline for the implementation of the initiatives and for the reporting on the implementation to the Council;
2. expand the existing food and veterinary working group on AMR to fully involve the human health sector to support the implementation of a comprehensive approach against AMR at EU and national level taking into account the “One Health” perspective of the initiatives;
3. expedite the review of Directives 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community¹³, and 2001/82/EC on the Community code relating to veterinary medicinal products¹⁴, taking AMR better into account, including considering that prescription of antibiotic veterinary medical products may only be carried out by a veterinarian;

¹³ OJ L 92, 7.4.1990, pp. 42-48

¹⁴ OJ L 136, 30.4.2004, pp. 58-84

4. collaborate closely with the ECDC, EFSA and EMA in strengthening the assessment and evaluation of the occurrence of AMR in humans, in animals and in food in the EU;
5. ensure effective mechanisms to process data from the Member States' surveillance systems on AMR in humans, animals and food and on the use of antimicrobial agents in humans and animals in order to ensure timely and comparable data in the EU;
6. initiate baseline surveys on AMR in both humans animals and food at appropriate intervals;
7. collaborate with other countries and international organisations to scale up visibility and raise global awareness of the issue of AMR and develop and strengthen multilateral and bilateral commitments for the prevention and control of AMR in all sectors;
8. follow up on the Council conclusions in connection with the evaluation of its Communication of 15 November 2011 by including national follow-up reports on the implementation and actions taken at national level.
