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# REPORT

on the Microbial Challenge – Rising threats from Antimicrobial Resistance  
(2012/2041(INI))

Committee on the Environment, Public Health and Food Safety

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## MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

### on the Microbial Challenge - Rising threats from Antimicrobial Resistance

(2012/2041(INI))

*The European Parliament,*

- having regard to 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” perspective’,
- having regard to the Commission communication of 15 November 2011 on an action plan against the rising threats from antimicrobial resistance (COM(2011)0748),
- having regard to the Commission recommendation of 27 October 2011 on the research Joint Programming Initiative ‘The Microbial Challenge – An Emerging Threat to Human Health’ (C(2011)7660),
- having regard to its resolution of 27 October 2011 on the public health threat of antimicrobial resistance,<sup>1</sup>
- having regard to its resolution of 12 May 2011 on antibiotic resistance,<sup>2</sup>
- having regard to the staff working paper of the Commission’s services of 18 November 2009 on antimicrobial resistance (SANCO/6876/2009r6),
- having regard to the Joint Technical Report by the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) of 17 September 2009 on ‘The bacterial challenge: time to react – A call to narrow the gap between multidrug-resistant bacteria in the EU and the development of new antibacterial agents’,<sup>3</sup>
- having regard to the second joint report of the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) of 14 March 2012 on antimicrobial resistance in zoonotic bacteria affecting humans, animals and food,<sup>4</sup>
- having regard to the 2876th Council Conclusions of 10 June 2008 concerning Antimicrobial resistance,
- having regard to the 2980th Council Conclusions of 1 December 2009 concerning innovative incentives for effective antibiotics,
- having regard to the Council recommendation of 9 June 2009 on patient safety, including

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<sup>1</sup> Texts adopted, P7\_TA(2011)0473.

<sup>2</sup> Texts adopted, P7\_TA(2011)0238.

<sup>3</sup> [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2009/11/WC500008770.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/11/WC500008770.pdf)

<sup>4</sup> <http://www.efsa.europa.eu/en/efsajournal/pub/2598.htm> EFSA Journal 2012;10(3):2598 [233 pp.].

the prevention and control of healthcare-associated infections,<sup>1</sup>

- having regard to the third revision of the World Health Organisation (WHO) list of critically important antimicrobials for human medicine (Report of the third meeting of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance in Oslo, Norway, on 14-17 June 2011, and to the World Organisation for Animal Health (OIE) List of Antimicrobial Agents of Veterinary Importance (OIE List, May 2007) and subsequent refinements to this list,
- having regard to the second report from the Commission to the Council of 9 April 2010 on the basis of Member States' reports on the implementation of the Council recommendation (2002/777/EC) on the prudent use of antimicrobial agents in human medicine<sup>2</sup>, and to the Commission staff working document accompanying that report<sup>3</sup>,
- having regard to 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 promoters<sup>4</sup>,
- having regard to the Council recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine<sup>5</sup> (2002/77/EC) and to the European Parliament resolution of 23 October 2001 on the proposal for that recommendation (COM(2001)0333),
- having regard to the Commission communication of 20 June 2001 on a Community strategy against antimicrobial resistance (COM(2001)0333),
- having regard to its resolution of 5 May 2010 on evaluation and assessment of the Animal Welfare Action Plan 2006-2010,<sup>6</sup>
- having regard to the recommendations for future collaboration between the US and EU of the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR),<sup>7</sup>
- having regard to the CODEX Alimentarius Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance,<sup>8</sup>
- having regard to the CODEX Code of practice to minimise and contain antimicrobial resistance (CAC/RCP 61-2005),
- having regard to the preparatory action "Antimicrobial resistance (AMR): Research on the causes of high and improper antibiotic usage" approved by Parliament in the framework of the EU Budget for the financial year 2012, which aims at studying the issue of

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<sup>1</sup> OJ C 151, 3.7.2009, p.1.

<sup>2</sup> [http://ec.europa.eu/health/antimicrobial\\_resistance/docs/amr\\_report2\\_en.pdf](http://ec.europa.eu/health/antimicrobial_resistance/docs/amr_report2_en.pdf)

<sup>3</sup> [http://ec.europa.eu/health/antimicrobial\\_resistance/docs/cswd\\_technicalannex\\_en.pdf](http://ec.europa.eu/health/antimicrobial_resistance/docs/cswd_technicalannex_en.pdf)

<sup>4</sup> OJ L 268, 18.10.2003, p. 29.

<sup>5</sup> OJ L 34, 5.2.2002, p.13

<sup>6</sup> Texts adopted, P7\_TA(2010)0130.

<sup>7</sup> [http://ecdc.europa.eu/en/activities/diseaseprogrammes/TATFAR/Documents/210911\\_TATFAR\\_Report.pdf](http://ecdc.europa.eu/en/activities/diseaseprogrammes/TATFAR/Documents/210911_TATFAR_Report.pdf)

<sup>8</sup> CAC/GL 77- 2011

inappropriate use and sales of antimicrobial agents, with or without prescription, throughout the chain – from the doctor and the pharmacist to the patient – in terms of the behaviour of all actors involved,

- having regard to Rule 48 of its Rules of Procedure,
  - having regard to the report of the Committee on Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A7-0373/2012),
- A. whereas the development of drug resistance is a natural and unavoidable consequence of antimicrobial treatment; whereas this process can be accelerated by inordinate and indiscriminate use in human and veterinary medicine, which, combined with insufficient hygiene and infection control, can compromise the effective use of an already limited number of existing antimicrobials;
- B. whereas resistance to antibiotics for certain bacteria is as high as 25 % or more in several Member States;
- C. whereas much of the antimicrobial resistance problem stems from the misuse – in particular excessive use – of antibiotics;
- D. whereas many Member States do not have a solid legal and regulatory framework to mandate and support the rational use of medicines;
- E. whereas in the EU, Iceland and Norway alone antimicrobial resistant bacteria cause some 400 000 infections and 25 000 deaths annually, with at least EUR 1.5 billion spent on extra healthcare costs and productivity losses;
- F. whereas the rise of antimicrobial resistance (AMR) is a complex issue of cross-border nature driven by a variety of interconnected factors; whereas numerous intervention measures at various levels are necessary that require a strong collaboration between countries and sectors;
- G. whereas there is a growing gap between rising AMR and the development of new antimicrobials; whereas since the 1970s only three new systemically-administered antibiotics for multidrug-resistant Gram-positive bacteria<sup>1</sup> have been developed; whereas two-thirds of antimicrobial resistance-related deaths in the Union are due to Gram-negative bacteria, with no new agents planned to enter the market soon;
- H. whereas, given the lack of new antibacterial drug development, it is of paramount importance that the effective exploitation of existing antimicrobials is maintained for as long as possible via prudent use, preventive measures to contain infection, vaccinations, alternative treatments and controlled antimicrobial dosage;
- I. whereas, the only tuberculosis (TB) vaccine currently available (BCG), was developed over 90 years ago, and whereas it does not offer protection against the most common form

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<sup>1</sup> Refers to the retention or rejection of the violet colour of the stain used in Gram's method of staining micro-organisms; the staining property is a common method of classifying bacteria.

of TB – pulmonary TB;

- J. whereas, treatment of tuberculosis relies on antibiotics developed decades ago, many of which have serious toxic side effects;
  - K. whereas AMR affects both humans and animals and has dangerous implications for human and animal health; whereas there is a link between the use of antimicrobials in animals and the spread of resistance in humans which requires further research as well as a coordinated, multisectoral policy approach to AMR, based on the 'One Health' principle, targeting both practitioners and users in each sector;
  - L. whereas there is still a lack of sufficiently detailed and comparable data at European level for purposes of comprehensive cross-country monitoring and analysis linking antimicrobial use and resistance;
  - M. whereas, despite farmers' primary objective to keep their livestock healthy and productive through good agricultural practices (hygiene, proper feed, appropriate husbandry and good animal management), animals can still become ill, and appropriate therapy and veterinary medicines should be available for treatment of disease;
  - N. whereas no standard definition of 'preventive treatment' has been adopted to date and different interpretations of the term are giving rise to constant disagreement;
  - O. whereas there is a need to educate and raise awareness among those involved in antimicrobial use, including policy-makers, health professionals and the general public, in order to bring about necessary changes in the behaviour of prescribers, dispensers and citizens;
  - P. whereas antibiotics are still available without prescription in certain Member States, and whereas this practice aggravates the problem of antimicrobial resistance;
  - Q. whereas failure to respect basic rules of hygiene in human environments such as homes, and not only in hospitals, causes further spread of antimicrobial pathogens;
  - R. whereas diagnostics have a vital role to play in combating AMR by encouraging more targeted approaches to treatment;
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- 1. Considers that, while almost all Member States have developed national AMR strategies in accordance with the Council Recommendation on prudent use of antimicrobial agents in human medicine, progress with regard to meeting set objectives has been slow and uneven; calls for firm governmental commitment to full and timely implementation at national level;
  - 2. Welcomes the Commission's five-year strategic Action Plan on tackling AMR, but expresses concern that many of the action points reiterate measures prescribed over a decade earlier in Council Recommendation of 15 November 2001 on the prudent use of

antimicrobial agents in human medicine<sup>1</sup>;

3. Notes that, although the Commission's Action Plan goes in the right direction, it does not go far enough to contain the rising global threat from antimicrobial resistance; considers that the measures recommended in the Action Plan need to be implemented as soon as possible; calls, therefore, on the Commission for an integrated roadmap outlining relevant policy responses, including possible legislative action;
4. Underlines that the Action Plan should cover all animals under the EU animal welfare strategy, including, for instance, companion animals and animals used for sports, and should emphasise the logical connection between animal health and the use of antimicrobials, as well as the link between animal health and human health;

### **Prudent use of antimicrobials in human and veterinary medicine**

5. Underlines that the key objective of any AMR strategy is to maintain the efficiency of existing antimicrobials by using them responsibly at the correct therapeutic level only when strictly necessary and prescribed over a specific time at the appropriate dosage, and reducing the use of antimicrobials in general and especially of Critically-Important Antimicrobials (CIAs)<sup>2</sup> in human and veterinary medicine, thereby also taking into account the OIE List ; underlines the absolute need for an active holistic approach, based on a 'One Health' perspective, in order to achieve better and more efficient coordination between the human health sector and the veterinary sector; calls for enhanced surveillance of the use of antimicrobials in babies and young children, as well as in clinical treatment, where there is a need to control and measure antimicrobial use;
6. Points out that the use of antimicrobials in sub-therapeutic levels is prohibited in the EU;
7. Stresses that more efforts are needed to control the use of antimicrobials in human and veterinary medicine; strongly disapproves of the regular prophylactic use of antimicrobials in animal husbandry; endorses the Council conclusions of 22 June 2012 which call on the Member States to limit the prophylactic use of antimicrobials to cases with defined clinical needs and to limit the 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; stresses that livestock farming and aquaculture should focus on disease prevention through good hygiene, housing and animal husbandry, as well as through strict bio-security measures, rather than through the prophylactic use of antimicrobials; believes that controls on food imports from non-Member States should be enhanced, in particular in light of the risk that such imports contain irregular traces of antimicrobials;
8. Points out that AMR in animals differs between species and between different forms of animal husbandry;

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<sup>1</sup> OJ L 34, 5.2.2002, p. 13-16 .

<sup>2</sup> Report of the 3rd meeting of the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance, 14-17 June 2011, Oslo, Norway.

9. Calls on the European Food Safety Authority (EFSA) to give special attention to the task of monitoring and analysing the situation as regards AMR in livestock across the EU;
10. Calls for prudent and responsible use of antimicrobials in animals, and for more information to veterinarians and farmers that helps them minimise the development of antimicrobial resistance; calls for the exchange of best practices for combating the development of antimicrobial resistance, such as guidelines on the prudent use of antimicrobials;
11. Calls on the Member States to use electronic recording systems to ensure that usage patterns on individual farms are appropriate, thus ensuring responsible and minimal use;
12. Stresses the need to review provisions pertaining to farm animal welfare measures to improve animal health, with the aim of reducing the use of veterinary pharmaceuticals; calls on the Commission to re-evaluate current provisions on maximum animal density in livestock farming, as herd sizes today often present obstacles to the treatment of individual or smaller groups of animals, providing incentives for the prophylactic use of antimicrobials; believes that focusing on livestock strains that are resistant to disease could help ensure that fewer veterinary pharmaceuticals will be needed for rearing purposes but considers that this should not replace sound farm management and animal husbandry;
13. Agrees with the Commission that the regulatory framework for veterinary medicines and medicated feed needs to be strengthened, and demands that consistency be maintained in the formulation and maintenance of EU rules;
14. Calls for the introduction of reliable approaches to rearing animals for effecting a significant decrease in AMR; notes that particular attention should be paid to the rearing of young animals, as they often come from different breeders and are therefore exposed to risks of infection when brought together;
15. Calls on the Commission to come up with a legislative proposal for the veterinary sector to limit the use of third- and fourth-generation CIAs for humans; stresses that any such proposal must be founded on evidence-based European guidelines on the prudent use of antimicrobials in veterinary medicine;
16. Considers that the pending revision of Directive 2001/82/EC offers an important opportunity to take effective measures to reduce AMR through strengthening the provisions for veterinary medicines, such as:
  - limiting the right to prescribe antimicrobials to professionally qualified veterinarians only;
  - separating the right to prescribe from the right to sell antimicrobials, thereby eradicating economic incentives to prescribe;
17. Calls on the Commission to follow up on its AMR Action Plan with concrete initiatives to implement the 12 actions and to publish its progress report on implementation of the AMR Action Plan by the end of 2013, stressing that the report should include an overview



of the reductions in the use of veterinary antimicrobials achieved in each Member State;

18. Stresses that there are substantial differences amongst Member States in how antibiotics are used and distributed; calls on the Commission to assess and monitor the Member States' implementation of relevant EU legislation on antimicrobials, in particular with regard to the prescription-only use of antibiotics in the human health and veterinary sectors, and the ban on antimicrobials as growth promoters in animal feed;
19. Calls on the Commission to examine the condition 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;
20. Calls on the Commission and the Member States to encourage efforts to ensure that hospital epidemiologist are employed at all hospitals;
21. Calls on the Commission to monitor the use of nanosilver in consumer products as it may increase the resistance of micro-organisms to silver, including nanosilver and silver-based compounds, which in turn can limit the usefulness of nanosilver in medical devices and other medical applications;
22. Underlines that in order to allow a reduction in the use of antimicrobials, the accuracy of diagnoses needs to be improved and, therefore, the use of diagnostics must be increased;
23. Calls on the Commission and the Member States to encourage efforts, maintained on a routine basis, to study hospital outbreaks and the possible role that the spread of drug-resistant clones plays in these outbreaks;

### **Prevention**

24. With a view to limiting inappropriate use and uncontrolled access to antimicrobial agents, including through increasing illegal internet sales, welcomes Member States' initiatives to review the legal status of all oral, inhaled and parenteral antimicrobials (including antimalarial, antiviral and antifungal drugs) that remain available to patients without a prescription; stresses that antimicrobials should not be freely available without a prescription as this encourages self-treatment, often based on inaccurate assumptions; calls on the Member States to raise awareness against over-the-counter and illegal sales of antimicrobials in both the human health and the veterinary sector;
25. Notes the important role of vaccines in limiting the development of AMR by reducing the amounts of antimicrobial agents required to treat infections in both humans and animals, but believes that, with respect to the veterinary sector, this should not replace sound farm management and animal husbandry; calls on the Commission to examine what further preventive measures could be taken so as to reduce the spread of infections and diseases in livestock farming;
26. Proposes that measures be taken to promote sustainable livestock systems, based on good management practices, that maximise the efficient use of resources and reduce farmers' dependency on costly and unsustainable inputs that pose a high risk to the environment and to public health;

27. Calls on the Commission and the Member States, in cooperation with the competent EU Agencies, to devise and promote prudent use guidelines aimed at reducing non-essential and inappropriate exposure to antimicrobials as part of a holistic approach to human and veterinary medicine, livestock farming, agriculture, aquaculture and horticulture;
28. Calls on the Commission to classify, in the forthcoming review of the European veterinary pharmaceuticals legislation, medicated feeding stuffs as 'pharmaceuticals' and not as 'feeding stuffs', in order to ensure that, in future, the sensitive area of medicated foodstuffs is monitored under pharmaceuticals legislation and that official inspections are carried out accordingly, while ensuring that medicated foodstuffs fall into the 'prescription only' category;
29. Underlines that infection prevention and control is a vital cornerstone in the fight against AMR; calls on the Member States to improve infection control, and to raise and promote good standards of hygiene – especially hand hygiene, particularly in sensitive environments, such as healthcare institutions – in order to prevent the spread of infections and reduce the need for antibiotics; calls on the Commission and the Member States to increase the exchange of best practices for preventing and reducing healthcare-associated infections (HAIs) and to broaden research into the epidemiology of HAIs due to MRSA, *C. difficile* and other emerging multidrug-resistant organisms;

#### **Development of new antimicrobials or alternatives for treatment**

30. Calls on the Commission and the Member States to encourage efforts to develop new and innovative public-private partnership (PPP) business models that delink investment in R&D for new antibiotics and diagnostic tools from sales transactions, in order to promote greater access and affordability and limit the unnecessary use of antimicrobials;
31. Calls for more and better-coordinated research on new antimicrobials, on other alternatives (vaccination, biosecurity, breeding for resistance) and on evidence-based strategies to avoid and control infectious diseases in animals;
32. Calls on the Commission and the Member States to accelerate R&D activities in order to provide new tools to fight tuberculosis and drug-resistant tuberculosis;
33. Calls on the Commission to invest in R&D aimed at alternatives for antimicrobial use in livestock production and to support innovation in agriculture practices, in line with the goals of the future European Innovation Partnership on Agricultural Productivity and Sustainability;
34. Highlights the need to be restrictive with the use of CIAs and newly developed antimicrobial agents and technologies for use in human and veterinary medicine; stresses the importance of appropriately targeting the use of CIAs to specific cases;
35. Calls on the Commission and the Member States to examine new regulatory approaches, including transferable intellectual property rights and patent term extensions, with a view to encouraging private-sector investment in antimicrobial development;
36. Notes the importance of access to rapid, reliable and affordable diagnostic tools in the

development of new treatment strategies;

37. Calls on the Commission and the Member States to examine new regulatory approaches oriented towards subsidising research for the development of new antimicrobials which can have a fiscally beneficial result for both the public and the private sector;
38. Calls on the Commission and Member States to strengthen incentives for public and private sector cooperation to reinvigorate antimicrobial R&D; believes that sharing knowledge and pooling resources through innovative public-private partnerships (PPPs) will be critical to ensuring the clinical efficacy and availability of existing antimicrobials;
39. Calls on the Commission to ensure that, as part of the EU 2020 strategy, farmers across all EU Member States can have access to smart, effective and alternative tools to cure their animals, including for minor uses and minor species (MUMS), which currently face a substantial lack of veterinary medicines;
40. Calls on the Commission to ensure the development and availability of more on-farm tools for early, rapid diagnosis and control of diseases, as well as for a broad and effective diagnostic system at Member State level which can ensure the timely delivery of results in case bacteriological examinations are performed;

#### **Monitoring and reporting**

41. Calls on the Commission and Member States to seek greater cooperation and coordination on early detection, alert and coordinated response procedures regarding pathogenic antimicrobial resistant bacteria in humans, animals, fish and foodstuffs in order to continuously monitor the extent and growth of AMR; urges the Member States in this context, to set up national databanks, conforming to uniform standards, in which dealers, veterinary surgeons and farmers are required to document the administration and use of antibiotics;
42. Stresses that sound information on the use of antimicrobials in some Member States is still lacking; emphasises the importance of establishing an effective European network of national surveillance systems in the human health and veterinary sectors, based on uniform standards for all Member States, in order to compile clear, comparable, transparent and timely reference data on antimicrobial drug usage; believes this should be based on the existing monitoring networks operated by EFSA, the ECDC European Surveillance of Antimicrobial Consumption Network (ESAC-net), the ECDC European Antimicrobial Resistance Surveillance Network (EARS-net), the ECDC Food- and Waterborne Disease Network (FWD-Net), and the EMA European Surveillance of Veterinary Antimicrobial Consumption (ESVAC);
43. Is of the view that data gathered on the use of antibiotics should be made accessible only to the experts, authorities and decision-makers concerned.
44. Recalls that, in its resolution of 12 May 2011 on antibiotic resistance, it stressed the need to get a full picture of when, where, how and on which animals antimicrobials are used; believes that such data should be collected, analysed and made public by the Commission without delay, and that the data collected should be harmonised and made comparable in

order to allow proper analysis and effective, co-ordinated, species-specific action, tailored to different types of animal husbandry, in order to combat AMR on both EU and Member State level;

45. Calls on the Commission to include in its progress report on the implementation of the AMR action plan an overview of the reductions achieved by each Member State in the use of veterinary antimicrobials;
46. Calls on the Commission to oblige the Member States to monitor the use of antibiotics in animal husbandry more efficiently, and in an integrated way, through the use of databases; points out that registering the use of antibiotics on farms is obligatory;
47. Calls on the Member States to ensure separate monitoring and control of resistance among livestock, domestic animals, racing animals, etc., and to do so without causing additional financial or administrative burdens for farmers, breeders or veterinarians;
48. Calls on the Member States to promote closer inter-sectoral collaboration between relevant authorities and sectors, in order to encourage a more integrated veterinary-human health approach, and to monitor the implementation of national AMR strategies;
49. Emphasises the need to support sustainable food production systems which, in contrast to 'factory farming', are potentially less exposed to AMR;
50. Calls on the Commission and the Member States to ensure that future measuring and reporting on the use of antimicrobials in both the human and veterinary sectors will be broadened out, showing not only the total amount of antimicrobials used but also the types of antimicrobials, the treatment times, etc.;

### **Communication, education and training**

51. Notes that the encouragement of appropriate antimicrobial use depends on a change of attitude, practice and education among patients, farmers, pharmacists, medical doctors, veterinarians and other practitioners in the spheres of human and veterinary medicine; considers that more effective and continuous educational and training measures, as well as comprehensive information in schools, starting generally at an early age, should be taken at both national and European levels to raise awareness of the consequences of the improper consumption of antimicrobials;
52. Notes that one of the most common uses for antibiotics is as treatment against the common cold, and that much would be gained if the public could be made aware of the fact that the common cold is a viral infection whereas antibiotics only provide protection against bacterial infections;
53. Welcomes the annual European Antibiotic Awareness Day (18 November) instituted to promote the responsible use of antimicrobials; considers, however, that its visibility and potential could be more effectively maximised through strengthened political support at national and European levels, a broader approach which covers also animals, and coordinated, innovative and high-impact campaigns based on the experience derived from successful European and international initiatives; calls on the Commission to provide

year-round information on the correct dosages of prescribed antibiotics;

54. Calls on the Commission – in recognition of the fact that sharing information among citizens, and not just among health and veterinarian professionals, is key to better awareness and hence prevention – to compile a best practice list with regard to the implementation of effective communication campaigns and professional training courses aimed at raising AMR awareness, such as the work of the multi-stakeholder European Platform for the Responsible Use of Medicines in Animals(EPRUMA), with a view to supporting the effective implementation of such awareness campaigns;
55. Takes the view that effective information and awareness campaigns must be developed with a view to heightening awareness of the dangers of the unintentional spread of antimicrobial pathogens in hospitals and in the home, and awareness of the means of avoiding this;
56. Calls on the Commission to examine, in the study on the improvement of the package leaflet and the drug fact box, the idea of providing patients with better information about the antibiotic in question, for example by ensuring that it contains a warning such as: "Please take this antibiotic medicine only if it is prescribed by a doctor to you and take it as prescribed. Improper use of antibiotics can create resistance which harms yourself and other people.";

### **International cooperation**

57. Highlights that burgeoning international travel and, more significantly, global food and feed trade could increase the crossborder spread of AMR; believes that concerted and timely international action that avoids overlap and builds critical mass is the only way forward in minimising the threat to public health that AMR poses globally;
58. Acknowledges the importance of adopted international initiatives by WHO, OIE, FAO and other relevant global organisations; stresses, however, the importance of global adherence to adopted international standards and guidelines; calls on the Commission, in its evaluation of the implementation of the current AMR Action Plan, to report on Member States' progress on key international AMR commitments;
59. Welcomes the establishment of the Transatlantic Task Force on Antimicrobial Resistance (TATFAR) and the set of recommendations, adopted in September 2011, for future EU-US cooperation; stresses, in particular, the importance of specific actions for:
  - comparable data collection and data sharing for human and veterinary antimicrobials;
  - the development of common blueprints based on best practice for the management of healthcare-associated infections;
  - enhanced cooperation between the US Food and Drug Administration and EMA on coordinated approaches facilitating antibacterial drug development and regulation, specifically with regard to the clinical trials stage;
60. Calls on the Commission to build on the work of the TATFAR and to promote similar

multilateral and bilateral commitments for the prevention and control of AMR with other global partners;

61. Urges the Commission and the Member States to encourage and promote global risk management initiatives, such as the WHO list of CIAs for human medicine and the OIE List of Antimicrobials of Veterinary Importance;
62. Supports an international approach to the control of counterfeit antimicrobials in line with the WHO guidelines;

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63. Instructs its President to forward this resolution to the Council, the Commission and the Member States.

## EXPLANATORY STATEMENT

Since the discovery of penicillin, in the 1930s, antimicrobials have revolutionised medical and veterinary practice, leading to significant reductions in the mortality rate from a wide range of serious and often fatal bacterial infections while paving the way for innovative invasive surgeries to enter widespread use. The extraordinary medicinal progress of the antibiotic era, however, risks being undermined by the growing threat of antimicrobial resistance (AMR).

AMR is the ability of a microbial organism to flourish and survive in the presence of an antimicrobial at a usually sufficient dosage to inhibit or kill microorganisms of the same species. As a result, antimicrobial organisms may develop a profound resistance to certain antimicrobial agents to which they are ordinarily sensitive<sup>1</sup>.

After eighty years of widespread use, the evolution and adaptation of disease-causing microbes has resulted in many antimicrobials losing their effectiveness. This nascent crisis is a consequence of two fundamental and related issues: the inappropriate use of antimicrobials in human and veterinary medicine, and a forty-year innovation gap in the development of novel antimicrobials due to low returns on R&D investments.

The issue of AMR has been further exacerbated by the emergence of multi-drug resistance in some bacterial organisms, which can counteract the effectiveness of a variety of unrelated antimicrobials and compromise treatment choices for both humans and animals, prolong recovery, or lead to treatment failure.

While many are familiar with very difficult- to-treat MRSA (Methicillin-resistant *Staphylococcus aureus*) bacterium, which is commonly spread by patients moving between hospitals, the list of multi-drug resistant infections is long and includes among others, urinary tract infections, pneumonia, and tuberculosis. According to the World Health Organization (WHO), there are at least 440,000 individual cases of multi-drug resistant tuberculosis across the globe, resulting in more than 150, 000 deaths annually<sup>2</sup>.

Unsurprisingly, European healthcare systems are already shouldering increased expenditures resulting from antimicrobial resistant infections. Not only are the costs of the drugs needed to treat these cases often high, but also treatment plans are longer and more complex. According to the WHO and the European Centre for Disease Control (ECDC), in 2007 drug-resistant infections resulted in more than 2.5 million additional days of hospitalisation in the EU, Norway, and Iceland<sup>3</sup>, and 25,000 extra fatalities in the same region<sup>4</sup>. Without concerted efforts to address the growing problem of antimicrobial resistance, these figures are expected to increase significantly in the coming years.

Moreover, modern-day medical practices are accelerating the emergence of drug-resistant organisms, namely through the improper use of antimicrobials; including excessive and

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<sup>1</sup> [http://www.vmd.defra.gov.uk/pdf/leaflet\\_antimicrobials.pdf](http://www.vmd.defra.gov.uk/pdf/leaflet_antimicrobials.pdf)

<sup>2</sup> <http://www.who.int/mediacentre/factsheets/fs194/en/>

<sup>3</sup> [http://whqlibdoc.who.int/publications/2012/9789241503181\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241503181_eng.pdf)

<sup>4</sup> [http://www.ecdc.europa.eu/en/aboutus/organisation/Director%20Speeches/20120314\\_AMR\\_presentation\\_Copenhagen\\_EUpresidency.pdf](http://www.ecdc.europa.eu/en/aboutus/organisation/Director%20Speeches/20120314_AMR_presentation_Copenhagen_EUpresidency.pdf)

irresponsible dosages, intake of poor-quality antibiotics, and failure to complete a full treatment cycle as prescribed by a qualified physician. This wasteful consumption of antimicrobial agents is compounded by the link between their use in animal husbandry and the spread of resistance in humans.

All bacteria possess an innate flexibility that enables them to evolve genes that render them resistant to any antimicrobial, and by eradicating susceptible bacteria, antimicrobials provide selective pressures that favour overgrowth of bacteria carrying a resistance gene. The prolonged use of antimicrobial agents therefore serves to encourage the wide-spread dissemination of resistant strains.

The problem is amplified by a notable decline in the development of new antimicrobials. While the list of drug-resistant microbes continues to increase, there are relatively few - and for some evolving drug-resistant organisms no - new antimicrobials being developed. As a result, the trend of infections becoming increasingly difficult to treat is set to become more severe without coordinated prevention and control measures to counter antimicrobial resistance.

The implications are highly alarming; antimicrobials that cost tens of millions of euros in R&D, and take close to a decade to reach the market, tend to have an ever-decreasing life span in which they are effective. As resistance spreads, an antimicrobial's lifespan diminishes, and as fewer new antimicrobials become available, the gulf between infection and control grows ever wider. According to the WHO, AMR threatens a return to 'the pre-antibiotic era'.<sup>1</sup>

The borderless nature of infectious diseases makes the rise of drug-resistant microbes a global problem, and it must be dealt with as such. It remains crucial, however, that the EU takes concerted action to address this issue. Over the past decade, European Council conclusions and European Parliament resolutions have all repeatedly called for the prudent use of existing antimicrobials, and to foster initiatives aimed at the development of new ones. It is the rapporteur's belief that these conclusions and resolutions must finally, and urgently, be acted upon, both by Member States and by the EU as a whole.

It is important to stress that AMR cannot be resolved by one simple solution. Rather, a multifaceted approach is required:

### **Prudent use of antimicrobials in human and veterinary medicine**

First and foremost, it is imperative to ensure the prudent use of antimicrobials. This includes the prescription-only use of antibiotics by a physician and refraining from using antibiotics unnecessarily, such as for the treatment of common human viral-infections; similar prudent use must be applied throughout the veterinary sector. To this end, both the Commission and Member States whole must work together to develop compatible strategic action plans to promote prudent use.

### **Prevention**

It is essential that better measures be taken to prevent both the emergence and the spread of drug-resistance. This includes improved monitoring and reporting of drug-resistance

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<sup>1</sup> <http://www.who.int/mediacentre/factsheets/fs194/en/>



organisms, as well as more effective infection control measures, including the use of vaccinations.

### **Development of new antimicrobials or alternatives for treatment**

While it is essential to limit the emergence of resistant drugs, it is also necessary to foster the development of new antimicrobial agents. One way forward can be through public-private partnerships; however, it is also important to examine new regulatory approaches that can stimulate industry research and the development of novel antimicrobials while at the same time ensuring patient safety.

### **Monitoring and reporting**

Effective action requires accurate and timely data from all Member States. It is therefore important to have Europe-wide surveillance in both the human health and the veterinary sectors. One problem requiring particular attention is the need for clear, comparable, transparent and timely reference data on antimicrobial drug usage across all Member States.

### **Communication, education and training**

The exchange of best practices, together with better communication, education, and training among practitioners in both the veterinary and human health sectors is needed to combat the rise in antimicrobial resistance. In addition, improved communication of information on this issue to the public is essential to ensure prudent use by patients.

### **International cooperation**

Given the borderless nature of the spread of infectious it is imperative that the issue be dealt with on the international level. The work undertaken by the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) presents an excellent model for international cooperation on AMR, and similar multilateral and bilateral commitments should be encouraged.

15.10.2012

## **OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT**

for the Committee on the Environment, Public Health and Food Safety

on the Microbial Challenge – Rising threats from Antimicrobial Resistance  
(2012/2041(INI))

Rapporteur: Martin Häusling

## SUGGESTIONS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions in its motion for a resolution:

1. Notes that, although the Commission's action plan goes in the right direction, it does not go far enough to contain the rising global threat from antimicrobial resistance; considers that the measures recommended in the action plan need to be implemented as soon as possible; calls, therefore, on the Commission for an integrated roadmap outlining relevant policy responses, including possible legislative action;
2. Underlines that the action plan should cover all animals under the EU animal welfare strategy, including, for instance, companion animals and animals used for sports, and should emphasise the logical connection between animal health and the use of antimicrobials, as well as the link between animal health and human health;
3. Agrees that a holistic approach is needed that is based on prudent and responsible use of antimicrobials, and on continuous improvements to biosecurity and animal husbandry systems that promote good animal health, allow animals to express species-specific behaviour, minimise disease occurrence and limit disease transmission, thus reducing the need for antimicrobials to be prescribed;
4. Calls for the introduction of reliable approaches to effecting a significant decrease in resistance when rearing animals; notes that particular attention should be paid to the rearing of young animals, as they often come from different breeders and are therefore exposed to a risk of infection when brought together;
5. Calls for more and better-coordinated research on new antimicrobials, on other alternatives (vaccination, biosecurity, breeding for resistance) and on evidence-based strategies to avoid and control infectious diseases in animals;
6. Suggests that research, innovation, better communication and better education and professional training with regard to the use of antimicrobials be promoted;
7. Proposes to promote sustainable livestock systems based on good management practices maximising the efficient use of resources and reducing farmers' dependency on costly and unsustainable inputs that pose a high risk to the environment and to public health;
8. Agrees with the Commission that the regulatory framework for veterinary medicines and medicated feed needs strengthening, and demands consistency in the EU rules and their enforcement;
9. Points out that the use of antimicrobials in sub-therapeutic levels is prohibited in the EU;
10. Calls on the Commission to ensure implementation of the ban, adopted in 2006, on the use of antimicrobials as growth promoters in the Member States;

11. Is of the view that the main objective of farmers should be to implement suitable rearing methods, in order to keep their cattle healthy and productive, and to safeguard their wellbeing; stresses, however, that the proper use of antibiotics in animal husbandry is necessary in order to ensure animal wellbeing;
12. Points out that antimicrobial resistance in animals differs between species and between different forms of animal husbandry;
13. Emphasises that the ultimate objective is to maintain antimicrobials as an effective tool to combat disease, both in animals and in humans, while strictly keeping the use of antimicrobials to the minimum necessary; proposes, therefore, that the use for livestock of antimicrobials classified by the WHO as critically important for human treatment be limited and gradually phased out;
14. Notes the importance of vaccines in limiting disease and in reducing antimicrobial use within the context of good husbandry practices; believes that vaccines should not be a substitute for good husbandry or appropriate biosecurity measures, and that veterinary surgeons should only administer antibiotics where there is good reason to do so;
15. Calls on the European Food Safety Authority (EFSA) to give special attention to monitoring and analysing the situation as regards antimicrobial resistance in livestock across the EU;
16. Calls for a prudent and responsible use of antimicrobials in animals, and for more information to veterinarians and farmers helping them to minimise the development of antimicrobial resistance; calls for the exchange of best practices, that can serve as important tools to combat the development of antimicrobial resistance, such as the adoption of guidelines on the prudent use of antimicrobials;
17. Calls for continued efforts to ensure that antimicrobials are only used in both veterinary and human medicine where such use can be justified;
18. Stresses that sound information on the use of antimicrobials in some Member States is lacking, and that transparent, coherent and consistent data are needed;
19. Calls on the Member States to use electronic recording systems to ensure that usage patterns on individual farms are appropriate, thus ensuring responsible and minimal use;
20. Recalls that, in its resolution of 12 May 2011 on antibiotic resistance, it stressed the need to get a full picture of when, where, how and on which animals antimicrobials are used, and believes that such data should be collected, analysed and made public by the Commission without delay, and that the data collected should be harmonised and made comparable in order to allow proper analysis and effective, co-ordinated, species-specific action, tailored to different types of animal husbandry, in order to combat antimicrobial resistance on both EU and Member State level;
21. Calls on the Commission to include in its progress report on the implementation of the antimicrobial resistance action plan an overview of the reductions achieved by each Member State in the use of veterinary antimicrobials;

22. Calls on the Commission to oblige the Member States to monitor the use of antibiotics in animal husbandry more efficiently and in an integrated way through the use of databases; points out that registering the use of antibiotics on farms is obligatory;
23. Calls on the Commission to take all actions needed to ensure a broad and effective diagnostic system at Member State level, and thereby ensure the timely delivery of results when bacteriological examinations are performed;
24. Calls on the Member States to ensure separate monitoring and control of resistance among livestock, domestic animals, racing animals, etc., and to do so without causing additional financial or administrative burdens for farmers, breeders or veterinarians;
25. Is of the view that data gathered on the use of antibiotics should be made accessible only to the experts, authorities and decision-makers concerned.

## RESULT OF FINAL VOTE IN COMMITTEE

<b>Date adopted</b>	11.10.2012
<b>Result of final vote</b>	+: 35 -: 1 0: 1
<b>Members present for the final vote</b>	John Stuart Agnew, Eric Andrieu, José Bové, Luis Manuel Capoulas Santos, Vasilica Viorica Dăncilă, Michel Dantin, Paolo De Castro, Albert Deß, Diane Dodds, Herbert Dorfmann, Robert Dušek, Mariya Gabriel, Iratxe García Pérez, Julie Girling, Béla Glattfelder, Martin Häusling, Esther Herranz García, Peter Jahr, Elisabeth Jeggle, Jarosław Kalinowski, Elisabeth Köstinger, Agnès Le Brun, George Lyon, Gabriel Mato Adrover, Mairead McGuinness, James Nicholson, Rareş-Lucian Niculescu, Wojciech Michał Olejniczak, Georgios Papastamkos, Marit Paulsen, Britta Reimers, Alfreds Rubiks, Czesław Adam Siekierski, Sergio Paolo Francesco Silvestris, Alyn Smith, Janusz Wojciechowski
<b>Substitute(s) present for the final vote</b>	Alejandro Cercas, Ismail Ertug, Petri Sarvamaa

## RESULT OF FINAL VOTE IN COMMITTEE

<b>Date adopted</b>	6.11.2012
<b>Result of final vote</b>	+: 62 -: 0 0: 0
<b>Members present for the final vote</b>	Martina Anderson, Elena Oana Antonescu, Kriton Arsenis, Sophie Auconie, Pilar Ayuso, Paolo Bartolozzi, Sergio Berlato, Lajos Bokros, Nessa Childers, Yves Cochet, Tadeusz Cymański, Chris Davies, Anne Delvaux, Edite Estrela, Jill Evans, Karl-Heinz Florenz, Elisabetta Gardini, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Satu Hassi, Jolanta Emilia Hibner, Karin Kadenbach, Christa Klaß, Eija-Riitta Korhola, Holger Kraemer, Jo Leinen, Peter Liese, Zofija Mazej Kukovič, Linda McAvan, Radvilė Morkūnaitė-Mikulėnienė, Miroslav Ouzký, Vladko Todorov Panayotov, Antonyia Parvanova, Andres Perello Rodriguez, Mario Pirillo, Pavel Poc, Anna Rosbach, Oreste Rossi, Dagmar Roth-Behrendt, Kārlis Šadurskis, Carl Schlyter, Horst Schnellhardt, Richard Seeber, Bogusław Sonik, Salvatore Tatarella, Thomas Ulmer, Anja Weisgerber, Åsa Westlund, Sabine Wils, Marina Yannakoudakis
<b>Substitute(s) present for the final vote</b>	Frieda Brepoels, Nikos Chrysogelos, Christofer Fjellner, Julie Girling, Jutta Haug, Riikka Manner, Britta Reimers, Alda Sousa, Marita Ulvskog, Kathleen Van Brempt, Andrea Zanoni