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DRAFT REPORT

on a European One Health Action Plan against Antimicrobial Resistance
(AMR)
(2017/2254(INI))

Committee on the Environment, Public Health and Food Safety

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MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on a European One Health Action Plan against Antimicrobial Resistance (AMR) (2017/2254(INI))

The European Parliament,

- having regard to Article 168 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to the Council conclusions of 17 June 2016 on the next steps under a One Health approach to combat antimicrobial resistance,
- having regard to the Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States,
- having regard to the Council conclusions of 6 June 2011 entitled ‘Childhood immunisation: successes and challenges of European childhood immunisation and the way forward’, adopted by the Health Ministers of the EU Member States,
- having regard to the Council conclusions of 6 December 2014 on vaccinations as an effective tool in public health,
- having regard to its resolution of 19 May 2015 entitled ‘Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance’¹,
- having regard to its resolution of 11 December 2012 entitled ‘The Microbial Challenge – Rising threats from Antimicrobial Resistance’²,
- having regard to Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC³,
- having regard to the Commission communication of 29 June 2017 on a European One Health Action Plan against Antimicrobial Resistance (COM(2017)0339),
- having regard to the World Health Organisation (WHO) Global Vaccine Action Plan (GVAP), endorsed by the 194 Member States of the World Health Assembly in May 2012,
- having regard to the WHO European Vaccine Action Plan (EVAP) 2015-2020,
- having regard to the UN Political Declaration of the high-level meeting of the General Assembly on antimicrobial resistance of 21 September 2016,
- having regard to the World Bank report of March 2017 entitled ‘Drug-Resistant

¹ OJ C 353, 27.9.2016, p. 12.

² OJ C 434, 23.12.2015, p. 49.

³ OJ L 293, 5.11.2013, p. 1.

Infections: A Threat to Our Economic Future’,

- having regard to the Organisation for Economic Co-operation and Development (OECD) report of September 2015 entitled ‘Antimicrobial Resistance in G7 Countries and Beyond: Economic Issues, Policies and Options for Action’,
 - having regard to Rule 52 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinions of the Committee on Industry, Research and Energy and the Committee on Agriculture and Rural Development (A8-0000/2018),
- A. whereas the excessive and inappropriate use of antibiotics and poor infection control practices have progressively rendered antimicrobial resistance (AMR) a massive threat to humankind;
- B. whereas the misuse of antibiotics is eroding their efficacy and leading to the spread of highly resistant bacteria that are especially resistant to last-line antibiotics; whereas according to data provided by the OECD, an estimated 700 000 deaths worldwide may be caused by AMR every year;
- C. whereas healthcare-associated infections (HAI) are often due to antibiotic-resistant bacteria; whereas the European Centre for Disease Prevention and Control (ECDC) estimates that approximately 4 million patients acquire a HAI each year in the EU and that approximately 37 000 deaths result directly from these infections;
- D. whereas if the current trend continues, AMR might cause more deaths than cancer by 2050¹;
- E. whereas the World Bank in its abovementioned report has warned that by 2050, drug-resistant infections could cause global economic damage on a par with the 2008 financial crisis;

Making the EU a best practice region

1. Believes that in order to take sufficient steps to tackle AMR, the One Health principle must play a central role, reflecting the fact that the health of people and animals are interconnected and that diseases are transmitted from people to animals and vice versa; stresses, therefore, that diseases have to be tackled in both people and animals, while also taking into consideration the environment, which can be another source of resistant microorganisms;
2. Stresses that the appropriate and prudent use of antimicrobials is essential to limiting the emergence of AMR in human healthcare, animal husbandry and aquaculture; stresses that there are considerable differences in the way Member States handle and address AMR; calls on the Commission to consider mandatory routine collection and submission of monitoring data at EU level and to establish indicators to measure progress in the fight against AMR;

¹ https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf

3. Calls on the Commission and the Member States to align surveillance, monitoring and reporting of AMR patterns and pathogens;
4. Calls on the Commission to develop standardised surveys for collecting data on HAIs;
5. Urges the Commission to expand the role and funding of the ECDC in the fight against AMR;
6. Emphasises that infection prevention, biosecurity measures and control practices are critical in the control of all infectious microorganisms as they reduce the need for antimicrobials and consequently opportunities for microorganisms to develop and spread resistance;
7. Calls on the Commission and the Member States to develop public health messages to raise public awareness and in doing so promote a change in behaviour towards the use of antibiotics; underlines the importance of promoting ‘health literacy’, since it is crucial that patients understand healthcare information and are able to follow treatment instructions accurately;
8. Urges the Commission and Member States to create harmonised quality standards in EU-wide curricula and proper stewardship for health professionals in relation to prescribing, dosage, use and disposal of antimicrobials;
9. Is aware that health professionals often need to make quick decisions on therapeutic indication for antibiotic treatment; notes that rapid diagnostic tests can help to support these decisions;
10. Is aware that the cost of rapid diagnostic tools (RDT) may exceed the price of antibiotics; calls on the Commission to propose incentives for the industry to develop effective and efficient testing methods and calls on health insurance carriers to cover the extra cost arising from the use of RDT, given the long-term benefits of preventing the unnecessary use of antimicrobials;
11. Calls on the Commission and the Member States to restrict or stop the sale of antibiotics by those doctors or veterinarians who prescribe them;
12. Highlights the value of vaccines in combating AMR; recommends integration of targets for life-long vaccination as a key element of national action plans on AMR;
13. Highlights that the pollution of the environment by human and veterinary antibiotic residues is an emerging problem and encourages further research into the relative impact of this pollution on AMR;
14. Calls for environmental risk assessments as part of the marketing authorisation process for antimicrobials;

Boosting research, development and innovation with regard to AMR

15. Points out that with an investment of EUR 1.3 billion in AMR research, Europe is a leader in this domain, and that EU achievements include the launch of the New Drugs

for Bad Bugs (ND4BB) programme¹ and the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)²; notes with concern that no truly new antimicrobial classes have been introduced in recent years;

16. Welcomes recent research projects into bacteriophage therapy, such as the EU-funded Phagoburn project; notes that no bacteriophage therapies have been authorised at EU level so far; calls on the Commission to propose a legislative framework for bacteriophage therapy;
17. Encourages the European Medicines Agency (EMA) to review all available information on the benefits and risks of older antimicrobial agents and to consider whether any changes to their approved uses are required;
18. Calls on the Commission to increase funding for early research in epidemiology and immunology of AMR pathogens, in particular the pathways of transmission between animals and humans;
19. Calls on the Commission and the Member States to promote early and continuous dialogue with all stakeholders to elaborate incentives for research and development (R&D) in the field of AMR; acknowledges that there is no ‘one-size-fits-all’ approach;
20. Recalls that the Clinical Trials Regulation (EU No 536/2014) will help to encourage research into new antimicrobials in the EU; calls on the Commission and the EMA to implement the Clinical Trials Regulation without further delay;
21. Calls on the Commission and the Member States to support the implementation of new economic models, pilot projects and incentives to boost the development of new diagnostics, antibiotics, alternatives and vaccines;
22. Notes the hesitant approach of the industry to develop ‘last-line’ antibiotics against bacteria that are resistant to all other antibiotics owing to expected low profitability; calls for incentives for this research and definition of the regulatory pathway;
23. Calls on the Commission and Member States to develop new incentive models that delink payment from prescribing volume;

Shaping the global agenda

24. Recalls that owing to the complexity of the problem, its cross-border dimension, the severe consequences for human and animal health and the high economic burden, AMR requires urgent and coordinated global and intersectoral action;
25. Welcomes the WHO Global Action Plan (GAP) on AMR, which was adopted unanimously in May 2015 by the 68th World Health Assembly;
26. Notes that AMR is of serious concern in many poverty-related and neglected diseases (PRNDs), including HIV/AIDS, malaria and tuberculosis (TB); highlights that about 29 % of deaths caused by AMR are due to drug-resistant TB, and calls on the

¹ <http://www.imi.europa.eu/content/nd4bb>

² <http://www.jpiamr.eu>

Commission and the Member States to increase their support to research for health tools to address PRNDs affected by AMR;

27. Calls on the Commission to advocate EU standards and measures for tackling AMR in trade agreements;
28. Calls on the Commission and the Member States to strengthen measures to combat illegal practices related to the trade and use of antimicrobials;
29. Calls on the Commission to work towards continued high-level political attention and commitment to AMR action, including in UN forums, the G7 and the G20;

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30. Instructs its President to forward this resolution to the Council, the Commission, the European Centre for Disease Prevention and Control, the European Medicines Agency, the European Chemicals Agency, the European Food Safety Authority, the European Environment Agency and the World Health Organisation.

EXPLANATORY STATEMENT

A definition: ‘antimicrobial resistance’ is the resistance to drugs of infections which are triggered not only by bacteria but also by other microbes such as parasites, viruses and fungi.

Antibiotics have become one of the cornerstones of modern medicine since the introduction of penicillin in particular in the 1940s. They form the basis of treating bacterial infections in humans and animals. However, it is becoming increasingly difficult to treat bacterial infections successfully because of resistance. If determined action is not taken soon, we risk the return of a ‘pre-antibiotics/penicillin’ age. The consequences might be that lung infections, for example, would again be fatal, the risk factor for routine operations would increase and treatments such as chemotherapy, which suppress the immune system, would become too dangerous for patients. Expensive, prolonged treatments would be needed, leading to an enormous financial burden on the health system.

Our approach to antimicrobial resistance must focus on a holistic concept based on the ‘One Health’ initiative. This would ensure better coordination in public health and veterinary services.

Although AMR is a phenomenon which occurs naturally over time, its development is accelerated by the following factors:

- unprofessional application (misuse and over-use) of antibiotics, both in human medicine (e.g. to treat viral infections, against which they are not effective) and in animal treatment (prophylaxis and growth)
- transfer of resistant bacteria from animals to humans through direct contact or via the food chain and release of antimicrobial substances into the environment
- improper disposal of unused medicines into the groundwater
- inadequate development of new antibiotics

Medical diagnoses should also be supported by so-called rapid tests, which quickly show whether the cause of an infection is viral or bacterial and whether antibiotics should be used at all. These tests are, however, currently not fully developed and are often more expensive than many antibiotics. They are therefore a burden on health insurance schemes – even though resistance to antibiotics is far more costly for the health system in the long term.

But prevention is, of course, better than treatment with antibiotics. There are effective vaccines which protect against a range of microbial pathogens. People who have been vaccinated cease to be carriers, so that not only are they protected but so are those around them.

We must ensure that antibiotics are used properly by means of education and information. There is an urgent need to develop training facilities for medical professionals focusing on the careful use of antibiotics. In addition, the public must be better informed about the viral origin of many infectious diseases and the prudent use of antibiotics.

There is a similar need for business models which create incentives for R&D but which also

ensure that any such exercise is cost-effective.

We welcome the fact that the EU has so far spent over a billion euros on research into AMR. The Horizon 2020 research programme finances such projects as ATx201 for new antibiotics. More investment will be needed in the future if AMR is to be tackled properly, as 25 000 people die every year in the EU from infections caused by multi-drug-resistant microbes. The global figure is around 700 000 per year (Review on antimicrobial resistance. Tackling drug-resistant infections globally) [Internet]. London: Wellcome Trust; 2014..

<http://www.who.int/bulletin/volumes/93/2/15-152710.pdf>).