European Parliament

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Committee on Industry, Research and Energy

2017/2254(INI)

22.2.2018

OPINION

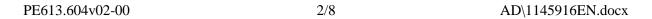
of the Committee on Industry, Research and Energy

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

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

Rapporteur: Lieve Wierinck

AD\1145916EN.docx PE613.604v02-00



SUGGESTIONS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following suggestions into its motion for a resolution:

- A. whereas it is estimated that AMR could result in up to 10 million deaths per year by 2050, and whereas more than 9 million of the estimated deaths would occur outside the EU, notably in Asia and Africa;
- B. whereas it is estimated that the cost of taking global action on AMR is up to USD 40 billion over a 10-year period;
- C. whereas antimicrobial resistance (AMR)-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in public and private research & innovation (R&I) so that better tools, products and devices, new treatments and alternative approaches can be developed following a One Health approach;
- D. whereas under the Fifth to Seventh Framework Programmes (FP5-FP7), more than EUR 1 billion has been invested in AMR research, and under Horizon 2020 (H2020), a cumulative budget of over EUR 650 million has already been mobilised so far; whereas the Commission has committed to invest more than EUR 200 million in AMR for the last three years of Horizon 2020;
- E. whereas different funding instruments under H2020 will deliver research results on AMR, in particular:
 - the Innovative Medicines Initiative (IMI), with a focus on all aspects of antibiotic development including research into AMR mechanisms, drug discovery, drug development, and economics and stewardship, with seven ongoing projects under the umbrella of the ND4BB programme with a total budget of more than EUR 600 million of Commission funding and in-kind contributions from companies;
 - the European and Developing Countries Clinical Trials Partnership (EDCTP), with a focus on the development of new and improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria, with 32 ongoing projects worth more than EUR 79 million;
 - the Joint Programming Initiative on AMR (JPIAMR) with its focus on consolidation of otherwise fragmented national research activities and with ongoing projects worth EUR 55 million:
 - the European Research Council (ERC), with its 'investigator-driven' or 'bottom-up' research projects;
 - the InnovFin Infectious Diseases Financial Facility (IDFF) for close-to-market projects, with seven loans totalling EUR 125 million granted so far;
 - the SME Instrument and Fast Track to Innovation (FTI) which support SMEs in developing novel solutions and tools to prevent, diagnose and treat infectious diseases and improve infection control, with 36 AMR-related projects and a budget of EUR 33 million;
- F. whereas effective action against AMR is reliant on reducing the excessive and incorrect usage of antibiotics in humans, animals and the environment, making it a key work

- priority in this area;
- G. whereas effective action against antimicrobial resistance must be part of a broader international initiative engaging as many international institutions, agencies and experts as possible, as well as the private sector;
- H. whereas effective action is primarily reliant on better knowledge and rational use of existing antimicrobial medicines; whereas vaccination is one effective way of preventing infections that would need treatment with antibacterials, thereby reducing the development of resistance;
- I. whereas more than 20 new classes of antibiotics were developed until the 1960s, but only one new class of antibiotics has been developed since despite the spread and progress of new resistant bacteria; whereas, moreover, there is clear evidence of resistance to new agents within existing classes of antibiotics;
- J. whereas the 'Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance' ask the Commission and the Member States to align strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostics within a One Health Network on AMR;
- K. whereas the political declaration endorsed by Heads of State at the United Nations General Assembly in New York in September 2016 and the Global Action plan in May 2015 signalled the world's commitment to taking a broad, coordinated approach to address the root causes of antimicrobial resistance across multiple sectors;
- L. whereas more than 100 companies signed the Davos declaration in January 2016, which calls for collective action to create a sustainable and predictable market for antibiotics, vaccines and diagnostics that enhances conservation of new and existing treatments;
- M. whereas there are positive spillover effects of new antimicrobials on public health and science:
- N. whereas there are successful examples of programmes that have improved global access to drugs in HIV, TB and malaria;
- O. whereas nosocomial infections pose a major threat to preserving and guaranteeing basic healthcare throughout the world;
- 1. Emphasises the need to increase the funding for R&I with a cross-sectoral and interdisciplinary approach in epidemiology and immunology for AMR pathogens and healthcare-associated infections (HAI), in new antimicrobial drug resistance mechanisms, in developing new rapid diagnostics and preventive measures, including vaccines, and in drug delivery technologies and techniques; stresses the need for antimicrobial stewardship in order to improve evidence-based prescription; calls for further scientific evidence and cautious exploration of the possibilities for using off-label medicines and alternative or additional treatments in AMR, such as phage therapy;

¹ OJ C 269, 23.7.2016, p. 26.

- 2 Stresses the urgent need for in-depth research into the impact of the presence of antimicrobial substances in food crops and animal feed on the development of AMR, and into the microbial community in soil;
- 3. Recognises the shortcomings and limited returns of the usual economic models used by the industry to develop new antibiotics; calls for the development of various push and pull incentives to create new medicines and medical devices, and to find and implement new treatments; believes that incentives for industry are meaningful when they are sustainable over the long term, are needs-driven, stimulate investment across the entire product development and life cycle, target key public health priorities, support appropriate medicinal use and are guided by the principles of affordability, effectiveness and efficiency; calls on the Commission to urgently present its analysis and review of the current R&I incentive models in this area; notes that the incentivisation of industry could be improved by the Transferable Market Exclusivities model and calls for an impact assessment of the model by the Commission; welcomes initiatives that explore alternative business models to promote and incentivise R&I;
- 4. Expresses the urgent need to foster partnerships within the EU and beyond in order to enhance the exchange of best practices, including in reducing the excessive and incorrect usage of antibiotics, and to improve knowledge on AMR; highlights the role of the Commission in monitoring and co-ordinating national plans and strategies to fight AMR;
- 5. Urges the Commission to develop an 'AMR mission' in the future FP9 with a cross-sectoral and interdisciplinary approach;
- 6. Recognises the differences between Member States' practices and use of antimicrobial medicines; stresses that approximately one third of prescriptions are issued in primary care; highlights, therefore, the need for an EU data collection system to support the correct use of all antibiotics, to enhance cooperation and the sharing of best practices between Member States, to develop evidence-based guidance for the use of antimicrobial medicines and their prescription by veterinarians and primary care doctors especially, to combat over-usage, and to foster research into AMR;
- 7. Underlines the lack of data on AMR, its impact on health and its socioeconomic burden; stresses the need to improve data collection on a systemic level throughout the EU, including environmental and prescription-related data, and to monitor and act rapidly on AMR-related trends, patterns and developments; points out the added value of eHealth and the development of personalised care, digitalisation and big data, which offer opportunities to develop standards, pool and cumulate data on AMR, and foster a holistic approach in the fight against AMR; calls for the strengthening of AMR surveillance in developing countries;
- 8. Underlines the systemic nature of AMR; supports the Commission's renewed commitment to promoting EU actions and leadership in fighting AMR, including internationally; highlights the need for global monitoring on antimicrobial usage in line with the Global Action Plan agreed by the World Health Assembly in 2015; stresses also the need for enhanced collaboration, for example within the G7, G20 and BRICS, including in R&I, and the role of science diplomacy, in fostering synergies and optimising resource allocation; calls for a similar collaborative effort to address issues

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of access to antibiotics as was made in the field of HIV, TB and malaria;

- 9. Believes in the need for different models of collaboration that are driven by the public sector and involve industry; underlines the importance of balanced Public Private Partnerships and closer collaboration between the public sector, industry, SMEs and public researchers through, for example, the creation of dedicated structures within universities and scientific centres to foster innovation and to overcome the scientific challenges of creating new antibiotics, vaccines and diagnostics to fight AMR; encourages the further pursuit of public-private collaboration similar to that under IMI programmes, the ERA-NET, EARS-Net, ESAC-Net, CAESAR, JIACRA, PIRASAO, AMC, PRND and EDCTP;
- 10. Stresses the importance of improving awareness and understanding of AMR through effective sanitation, preventive measures, and education and training, including EU public awareness campaigns and targeted training for health professionals, pharmacists, veterinaries and livestock breeders.

INFORMATION ON ADOPTION IN COMMITTEE ASKED FOR OPINION

Date adopted	21.2.2018
Result of final vote	+: 52 -: 1 0: 4
Members present for the final vote	Zigmantas Balčytis, Bendt Bendtsen, Xabier Benito Ziluaga, José Blanco López, Jonathan Bullock, Cristian-Silviu Buşoi, Jerzy Buzek, Angelo Ciocca, Edward Czesak, Jakop Dalunde, Christian Ehler, Fredrick Federley, Ashley Fox, Adam Gierek, Theresa Griffin, Rebecca Harms, Hans-Olaf Henkel, Eva Kaili, Kaja Kallas, Barbara Kappel, Krišjānis Kariņš, Jeppe Kofod, Peter Kouroumbashev, Zdzisław Krasnodębski, Miapetra Kumpula-Natri, Christelle Lechevalier, Paloma López Bermejo, Edouard Martin, Nadine Morano, Dan Nica, Angelika Niebler, Morten Helveg Petersen, Miroslav Poche, Paul Rübig, Massimiliano Salini, Algirdas Saudargas, Sven Schulze, Neoklis Sylikiotis, Dario Tamburrano, Evžen Tošenovský, Vladimir Urutchev, Kathleen Van Brempt, Henna Virkkunen, Martina Werner, Lieve Wierinck, Hermann Winkler, Anna Záborská, Flavio Zanonato
Substitutes present for the final vote	Cornelia Ernst, Gerben-Jan Gerbrandy, Françoise Grossetête, Werner Langen, Luděk Niedermayer, Dominique Riquet, Davor Škrlec
Substitutes under Rule 200(2) present for the final vote	Jan Keller

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

52	+
ALDE	Fredrick Federley, Gerben-Jan Gerbrandy, Kaja Kallas, Morten Helveg Petersen, Dominique Riquet, Lieve Wierinck
ECR	Edward Czesak, Ashley Fox, Hans-Olaf Henkel, Zdzisław Krasnodębski, Evžen Tošenovský
EFDD	Dario Tamburrano
ENF	Angelo Ciocca, Barbara Kappel, Christelle Lechevalier
PPE	Bendt Bendtsen, Cristian-Silviu Buşoi, Jerzy Buzek, Christian Ehler, Françoise Grossetête, Krišjānis Kariņš, Werner Langen, Nadine Morano, Angelika Niebler, Luděk Niedermayer, Paul Rübig, Massimiliano Salini, Algirdas Saudargas, Sven Schulze, Vladimir Urutchev, Henna Virkkunen, Hermann Winkler, Anna Záborská
S&D	Zigmantas Balčytis, José Blanco López, Adam Gierek, Theresa Griffin, Eva Kaili, Jan Keller, Jeppe Kofod, Peter Kouroumbashev, Miapetra Kumpula-Natri, Edouard Martin, Dan Nica, Miroslav Poche, Kathleen Van Brempt, Martina Werner, Flavio Zanonato, Carlos Zorrinho
VERTS/ALE	Jakop Dalunde, Rebecca Harms, Davor Škrlec

1	-
EFDD	Jonathan Bullock

4	0
GUE/NGL	Xabier Benito Ziluaga, Cornelia Ernst, Paloma López Bermejo, Neoklis Sylikiotis

Key to symbols: + : in favour - : against 0 : abstention