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A European One Health Action Plan against Antimicrobial Resistance

European Parliament resolution of 13 September 2018 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 2017 World Health Organisation (WHO) guidelines on use of medically important antimicrobials in food-producing animals,

– having regard to the report of the Federation of Veterinarians of Europe of 29 February 2016, providing replies to questions from the European Medicines Agency (EMA) and the European Food Safety Authority (EFSA) on antimicrobial use in food-producing animals[1],

– 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’[2],

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1 Federation of Veterinarians of Europe, ‘Antimicrobial use in food-producing animals: Replies to EFSA/EMA questions on the use of antimicrobials in food-producing animals in EU and possible measures to reduce antimicrobial use’, 2016.

2 OJ C 353, 27.9.2016, p. 12.

– having regard to its resolution of 11 December 2012 entitled ‘The Microbial Challenge – Rising threats from Antimicrobial Resistance’[1],

– 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/EC[2],

– 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 its resolution of 26 November 2015 on a new animal welfare strategy for 2016-2020[3],

– having regard to the 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 general interest paper entitled ‘The Role of the European Food Safety Authority (EFSA) in the Fight against Antimicrobial Resistance (AMR)’, published in the journal Food Protection Trends in 2018,

– having regard to the Commission Roadmap for a strategic approach to pharmaceuticals in the environment and the current draft of the strategic approach[4],

– 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 Infections: A Threat to Our Economic Future’,

– having regard to the proposal for a regulation of the European Parliament and of the Council on veterinary medicinal products (COM(2014)0558),

– 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 the EMA/EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA opinion),

– having regard to the Seventieth World Health Assembly resolution of 29 May 2017 on improving the prevention, diagnosis and clinical management of sepsis,

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1 OJ C 434, 23.12.2015, p. 49.
2 OJ L 293, 5.11.2013, p. 1.
3 OJ C 366, 27.10.2017, p. 149.
4 https://ec.europa.eu/info/consultations/public-consultation-pharmaceuticals-environment_en#add-info

– having regard to the European Centre for Disease Prevention and Control (ECDC)-EFSA-EMA first joint report (JIACRA I), published in 2015, and second joint report (JIACRA II), published in 2017, on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals,

– having regard to its resolution of 2 March 2017 on EU options for improving access to medicines[1],

– having regard to the ECDC's 2016 report on the surveillance of antimicrobial resistance in Europe,

– having regard to the European Union summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food in 2016, produced by the ECDC and EFSA[2],

– 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 (A8-0257/2018),

A. whereas the excessive and incorrect use of antibiotics, particularly in livestock farming (antibiotics used for prophylaxis and as growth activators), and poor infection control practices in both human and veterinary medicine have progressively rendered antimicrobial resistance (AMR) a massive threat to human and animal health;

B. whereas it is estimated that at least 20 % of healthcare-associated infections (HAIs) can be prevented through sustained and multifaceted infection prevention and control programmes[3];

C. whereas prudent antibiotic use and infection prevention and control in all healthcare sectors, including animal health, are cornerstones for the effective prevention of the development and transmission of antibiotic-resistant bacteria;

D. whereas 50 % of antibiotic prescriptions written for humans are ineffective and 25 % of consumption in humans is not well administrated; whereas 30 % of hospitalised patients use antibiotics and whereas multidrug-resistant bacteria pose a particular threat in hospitals and nursing homes and among patients whose care requires devices such as ventilators and blood catheters;

E. whereas antibiotics continue to be used in animal husbandry for disease prevention and to compensate for poor hygiene rather than being prescribed in cases of need, which contributes to the emergence of antimicrobial-resistant bacteria in animals which can then be transmitted to humans;

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1 Texts adopted, P8_TA(2017)0061.

2 http://www.efsa.europa.eu/en/press/news/180227

3 https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/healthcare-associated-infections-antimicrobial-use-PPS.pdf

F. whereas the existence of a correlation between resistance to antibiotics detected in food-producing animals (e.g. broiler chickens) and the fact that a large proportion of bacterial infections in humans come from the handling, preparation and consumption of the meat of these animals has also been confirmed by the EU agencies[1];

G. whereas the misuse of antibiotics is eroding their efficacy and leading to the spread of highly resistant microbes 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; whereas 25 000 of these deaths occur in the EU and the rest outside the EU, meaning that cooperation in development policy and coordination and monitoring of AMR at international level are crucial;

H. whereas AMR could cause up to 10 million deaths per year in 2050 if no action is taken; whereas 9 million of these estimated deaths would occur outside the EU in developing countries, particularly in Asia and Africa; whereas infections and resistant bacteria spread easily and there is therefore an urgent need for global action;

I. whereas vaccinations and rapid diagnostic tools (RDTs) have the potential to limit antibiotic abuse; whereas RDTs enable healthcare professionals to quickly diagnose a bacterial or viral infection and therefore to reduce the misuse of antibiotics and the risk of resistance developing[2];

J. whereas the continued spread of highly resistant bacteria could make it impossible to provide good healthcare in the future when it comes to invasive operations or well established treatments for some groups of patients requiring radiotherapy, chemotherapy and transplants;

K. whereas bacteria are constantly evolving, the research and development (R&D) and regulatory environments are complex, certain specific infections are rare, and expected returns on new antimicrobials remain limited;

L. whereas HAIs are due to a lack of prevention measures which result in antibiotic-resistant bacteria and poor hygiene practices, particularly in hospitals; whereas the ECDC estimates that approximately 4 million patients acquire a HAI every year in the EU and that approximately 37 000 deaths a year result directly from these infections; whereas the number of deaths could be even higher than this; whereas the previous figure of 25 000 deaths in the Union per year has proven to be a serious underestimate;

M. whereas the lack of access to effective antibiotics in developing countries still causes more deaths than AMR; whereas actions to address AMR that focus too heavily on restricting access to antibiotics may exacerbate the already serious crisis of the lack of access to medicines, which today causes more than one million deaths per year in children under five; whereas actions to address AMR must aim to ensure sustainable access to medicines for all, meaning access for those in need but excess for none;

N. whereas several Member States are experiencing rapidly rising levels of multi-resistant fungi leading to a sharp increase in the length of hospitalisations and increased mortality

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1 EFSA, ECDC, 'The European Union Summary report on antimicrobial resistance in zoonotic and indicator bacteria from human, animal and food in 2014', 2016.

2 World Health Organisation, 'Global guidelines on the prevention of surgical site infection', 2016. Available at: http://www.who.int/gpsc/ssi-guidelines/en/

rates for infected patients; whereas the American Centre for Disease Control and Prevention has raised awareness of the issue; whereas this specific issue is conspicuously absent in the European One Health Action Plan against AMR;

O. whereas active screening programmes using RDTs have been proven to contribute significantly to the management of HAIs and to limiting their spread within hospitals and between patients[1];

P. whereas the use of antibiotic compounds in non-clinical consumer products has been shown to increase the risk of generating drug-resistant bacteria strains[2];

Q. whereas good hand hygiene, in the form of effective hand washing and drying, can contribute to preventing AMR and the transmission of infectious diseases;

R. whereas the use of medical devices can prevent surgical site infections and therefore prevent and control the development of AMR[3];

S. whereas there are successful examples of programmes that have improved global access to drugs in HIV, tuberculosis (TB) and malaria;

T. whereas nosocomial infections pose a major threat to preserving and guaranteeing basic healthcare throughout the world;

U. whereas if the current trend continues, AMR could cause more deaths than cancer by 2050[4];

V. whereas the ECDC and EFSA have reiterated that AMR constitutes one of the greatest threats to public health[5];

W. whereas drug-resistant TB is the leading cause of death from AMR;

X. whereas in its report of March 2017, the World Bank warned that by 2050, drug-resistant infections could cause global economic damage on a par with the 2008 financial crisis;

Y. whereas AMR must be seen and understood as a threat to human, animal and planetary health and as a direct threat to the achievement of several of the Sustainable Development Goals (SDGs) outlined in the 2030 Agenda for Sustainable Development, including, but not limited to, SDG 1, SDG 2, SDG 3 and SDG 6;

Z. whereas the objectives of the One Health approach are to ensure that treatments for human and animal infections remain effective, to stem the emergence and spread of

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1 Celsus Academie voor Betaalbare Zorg, 'Cost-effectiveness of policies to limit antimicrobial resistance in Dutch healthcare organisations', January 2016. Available at: https://goo.gl/wAeN3L

2 http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_021.pdf

3 World Health Organisation, 'Global guidelines on the prevention of surgical site infection', 2016. Available at: http://www.who.int/gpsc/ssi-guidelines/en/

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

5 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5182/epdf

AMR and to enhance the development and availability of new effective antimicrobials in the EU and the rest of the world;

AA. whereas the Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance[1] ask the Commission and the Member States to align the strategic research agendas of existing EU R&D initiatives on new antibiotics, alternatives and diagnostics within a One Health Network on AMR;

AB. whereas the Charter of Fundamental Rights of the European Union recognises the fundamental right of citizens to health and medical treatment; whereas the right to health is the economic, social and cultural right to universal minimum standards of healthcare, to which all natural persons are entitled;

AC. whereas a key pillar of any EU-wide strategy for AMR must be to ensure the continued training of healthcare professionals in the latest developments in research and best practices in relation to the prevention and spread of AMR;

AD. whereas the World Health Assembly estimates that sepsis – a syndromic response to infectious diseases – causes approximately 6 million deaths worldwide every year, most of which are preventable;

AE. whereas as per their joint mandate, the ECDC, EFSA and the EMA are currently working to provide outcome indicators for AMR and the consumption of antimicrobials among food-producing animals and humans;

AF. whereas nature provides us with a plethora of powerful antibiotics, which could be harnessed to a far greater degree than is presently the case;

AG. whereas the latest EMA data show that action to reduce veterinary antimicrobial use has been inconsistent across the EU[2]; whereas some Member States have achieved significant reductions in the use of veterinary antimicrobials over a short period of time thanks to ambitious national policies, as illustrated by a series of fact-finding missions carried out by the Commission's Health and Food Audits and Analysis Directorate[3];

AH. whereas AMR is a cross-border threat to health, but the situation varies greatly from one Member State to another; whereas the Commission must therefore identify and act in areas that bring high European added value, while respecting the powers of the Member States, which are responsible for determining their own health policies;

AI. whereas effective action against AMR must be part of a broader international initiative engaging as many international institutions, agencies and experts as possible, as well as the private sector;

AJ. whereas the main causes of AMR are inappropriate use and abuse of antimicrobials, weakness of systems for the quality assurance of medicines, use of antimicrobials in

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1 http://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-antimicrobial-resistance/

2 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/10/news_detail_002827.jsp&mid=WC0b01ac058004d5c1

3 http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

livestock to promote growth or prevent diseases, deficiencies in the prevention and control of infections, and weaknesses in surveillance systems, among others;

AK. whereas patients should have access to healthcare and treatment options, including complementary and alternative treatments and medicines, in accordance with their own choices and preferences;

AL. whereas it is estimated that the cost of taking global action on AMR is up to USD 40 billion over a 10-year period;

AM. whereas AMR-related challenges will increase in the years ahead and effective action is reliant on continued, cross-sectoral investments in public and private research and innovation (R&I) so that better tools, products and devices, new treatments and alternative approaches can be developed following a One Health approach;

AN. 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;

AO. 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, TB 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;

AP. 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;

AQ. whereas there are positive spillover effects of new antimicrobials on public health and science;

AR. whereas the use of antibiotics for zootechnical purposes – as growth promoters, for example – represents misuse of these health products and is denounced by all international health organisations, which recommend its prohibition in the fight against AMR; whereas the use of antibiotics as growth promoters in food-producing animals has been banned in the EU since 2006;

AS. whereas numerous diseases caused by microbes can be combated effectively not with antibiotics, leading to drug resistance, but through early diagnosis combined with new and existing medicines and other treatment methods and practices permitted in the EU, thereby saving the lives of millions of people and animals EU-wide;

AT. whereas the gap between growing AMR and the development of new antimicrobial agents is widening; whereas drug-resistant diseases could cause 10 million deaths a year worldwide by 2050; whereas it is estimated that every year in the EU at least 25 000 people die of infections caused by resistant bacteria, at an annual cost of EUR 1.5 billion, while only one novel class of antibiotics has been developed in the past 40 years;

AU. whereas if antibiotics reserved exclusively for human use are to continue to be effective and the risks of AMR against these crucial antibiotics are to be minimised, the use of certain antibiotic families must be banned in veterinary medicine; whereas the Commission should specify which antibiotics or groups of antibiotics are to be reserved for the treatment of certain infections in humans;

AV. 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;

AW. whereas the oft-cited figures of 25 000 AMR-related deaths in the EU per year and related costs of over EUR 1.5 billion date back to 2007 and whereas continuously updated information on the real burden of AMR is required; emphasises that the magnitude of the problem is evidence of the clear need for a European One Health Action Plan Against AMR;

The EU as 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 and the environment 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 special consideration the food chain and the environment, which can be another source of resistant microorganisms; underlines the important role of the Commission in coordinating and monitoring national action plans implemented by Member States and the importance of cross-administrative cooperation;

2. Stresses the need for a time frame for the European One Health Action Plan; calls on the Commission and the Member States to include measurable and binding AMR objectives with ambitious targets, both in the European One Health Action Plan and in national action plans, to enable benchmarking;

3. Stresses that the correct 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, making the coordination of national plans with specific objectives set crucial; highlights that the Commission plays a key role in coordinating and monitoring national strategies; underlines the need for a cross-sectoral (particularly in the next EU research and innovation framework programme (FP9)) and cross-media implementation of the concept of One Health, which has not yet been sufficiently achieved in the Commission's action plan; insists that the use of antibiotics for preventive purposes in veterinary medicine should be strictly regulated, in accordance with the provisions of the forthcoming regulation on veterinary medicinal products;

4. Recommends that the newly-created One Health Network and the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) should also involve other key relevant stakeholders in addition to Member States;

5. Calls on the Commission to conduct and publish a mid-term evaluation and ex-post evaluation of the One Health Action Plan and to involve all relevant stakeholders in the evaluation procedure;

6. Stresses that joint EU action to tackle the increasing threat to human and animal health and the environment posed by antibiotic-resistant bacteria can only succeed if it is based on standardised data; calls on the Commission, therefore, to develop and propose appropriate procedures and indicators to measure and compare progress in the fight against AMR and to ensure the submission and evaluation of standardised data;

7. Notes that the recently adopted EU indicators helping Member States to monitor their progress in combating AMR only focus on antibiotic consumption and do not reflect appropriateness of use; calls on the ECDC to amend the EU indicators accordingly;

8. Calls on the Commission to collect data on and report the volume of antibiotics produced by manufacturers;

9. Calls on the Commission and the Member States to align surveillance, monitoring and reporting of AMR patterns and pathogens and to submit this data to the Global Antimicrobial Resistance Surveillance System (GLASS); underlines, furthermore, that the systematic collection of all relevant and comparable data on the volume of sales is of the utmost importance; calls on the Commission to draft, in consultation with the EMA, EFSA and the ECDC, an EU priority pathogen list (PPL), taking into account the WHO's global PPL, for both humans and animals, thereby clearly establishing future R&D priorities; asks the Commission, furthermore, to encourage and support Member States in putting in place and monitoring national targets for the surveillance and reduction of AMR/HAIs;

10. Calls on the Commission to develop standardised surveys for the collection of data on HAIs and to examine the risks to large human and animal populations during epidemics and pandemics;

11. Highlights that better sharing of local, regional and national information and data on emerging issues in human and animal health together with the use of early warning systems can assist Member States in adopting appropriate containment measures to limit the spread of resistant organisms;

12. Calls for the expansion of the role and the human and financial resources of all the relevant EU agencies in the fight against AMR and HAIs; believes that close collaboration between EU agencies and EU-funded projects is paramount;

13. Urges the Commission and the Member States to submit regular and accurate reports on the number of confirmed cases of AMR in humans along with correct and up-to-date AMR mortality statistics;

14. Emphasises that monitoring animal husbandry for agriculture and the food industry, infection prevention, health education, biosecurity measures, active screening programmes 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; stresses the need for mandatory reporting to public health authorities of all patients who are found to be infected with or identified as carriers of highly resistant bacteria; stresses the need for guidelines on isolation of hospitalised carriers and the creation of a multidisciplinary professional taskforce reporting directly to national ministries of health;

15. Highlights the need for an EU system for the collection of data on the correct use of all antibiotics; asks for the development of protocols for the prescription and use of antibiotics at EU level, recognising the responsibility of veterinarians and primary care doctors, among others, in this matter; asks, furthermore, for the compulsory collection, at national level, of all antibiotic prescriptions and for their registration in a database controlled and coordinated by experts in infections, so as to disseminate knowledge on how best to use them;

16. Deplores the fact, in this context, that the Commission did not propose a strategic approach to the pollution of water with pharmaceuticals sooner, as required by the Water Framework Directive[1]; urges the Commission and the Member States, therefore, to draw up an EU strategy for tackling drug residues in water and the environment without delay, devoting sufficient attention to monitoring, data collection and better analysis of the impact of AMR on water resources and the aquatic ecosystem; draws attention to the usefulness of an integrated chain approach to drug residues and AMR in the environment[2];

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1 Article 8(c) of Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy (OJ L 226, 24.8.2013, p. 1).

2 As formulated in the Netherlands by the Ministry of Infrastructure and Public Works, the National Institute for Public Health and the Environment (RIVM), the water industry and water boards.

17. Stresses that pollution of water and soil by human and veterinary antibiotic residues is a growing problem and that the environment itself is a potential source of new resistant micro-organisms; calls on the Commission, therefore, to pay significantly more attention to the environment as part of the One Health concept;

18. Recalls that the oft-cited figures of 25 000 AMR-related deaths in the EU per year and related costs of over EUR 1.5 billion date back to 2007 and that continuously updated information on the real burden of AMR is required;

19. Recalls that health is a factor of productivity and competitiveness, and is one of the issues of most concern for citizens;

20. Calls on the Commission to expand its funding to EUCAST, which deals with the technical aspects of phenotypic in vitro antimicrobial susceptibility testing and functions as the breakpoint committee of the EMA and the ECDC;

21. Urges the Commission to allocate additional funding specifically for research into non-therapeutic feed alternatives for application in animal husbandry in the 2021-2027 Multiannual Financial Framework (MFF);

22. Supports, as a minimum, the Council's response to the draft Codex Alimentarius Code of Practice to Minimise and Contain Antimicrobial Resistance, and its principles 18 and 19 on the responsible and prudent use of antimicrobials;

23. Encourages a focus on compliance with infection control guidelines, integrating infection rate reduction targets and supporting good practices to help to address patient safety in the hospital environment;

24. Calls on the Commission, the ECDC and the Member States to encourage the use of single-use handtowels in hygiene-sensitive locations, such as healthcare institutions, food processing facilities and nurseries;

25. Recalls that food is one of the possible vehicles for transmission of resistant bacteria from animals to human beings and, furthermore, that drug-resistant bacteria can circulate in populations of human beings and animals through water and the environment; takes note of the risks of infection with resistant organisms by contaminated crops treated with antimicrobial agents or by manure, and farmyard run-offs into groundwater; points out, in this context, that the spread of such bacteria is influenced by trade, travel and both human and animal migration;

26. 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 responsible use and handling of antibiotics, particularly prophylactic use; underlines the importance of promoting 'health literacy', since it is crucial that patients understand healthcare information and are able to follow treatment instructions accurately; stresses that preventive measures, including good hygiene, should be scaled up to reduce the human demand for antibiotics; stresses that awareness of the perils of self-medication and over-prescription should be a core component of a preventive strategy;

27. Calls on the Member States to develop public health messages to raise public awareness of the link between infections and personal hygiene; emphasises that an effective means

to reduce the use of antimicrobials is to stop infections from spreading in the first place; encourages the promotion of self-care initiatives in this regard;

28. Calls on the Commission and the Member States to develop strategies to support patients' adherence to and compliance with antibiotic and other appropriate treatments as prescribed by medical professionals;

29. Urges the Commission to propose guidelines, following the One Health approach, setting out best practices for the development of harmonised quality standards to be implemented in EU-wide curricula in order to foster interdisciplinary education, infection prevention and training programmes for healthcare professionals and the public, to ensure the proper conduct of health professionals and veterinary practitioners in relation to the prescription, dosage, use and disposal of antimicrobials and AMR-contaminated materials[1] and to ensure the establishment and deployment of multidisciplinary antibiotic stewardship teams in hospital settings;

30. Emphasises that one third of prescriptions are made out in the primary care sector and therefore that this sector should be considered a priority in use protocols; stresses the need for specialists in infectious diseases in the elaboration of these protocols and in their control and follow-up; calls on the Commission to draft guidelines for the use of these protocols in the field of human health; calls on the Member States to review all existing protocols, especially for prophylactic use during surgery; welcomes current projects at national level, such as the PIRASOA programme, as examples of good practice with regard to rational use in primary care and hospitals; encourages the development of mechanisms through which to share best practices and protocols;

31. 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 effective and accurate decision-making;

32. Encourages Member States to prevent the spread of infection by resistant bacteria by implementing active screening programmes with rapid diagnostic technologies in order to quickly identify patients infected with multi-drug resistant bacteria and to put in place appropriate infection control measures (such as patient isolation, cohorting and reinforced hygiene measures);

33. Is aware that the cost of RDTs may exceed the price of antibiotics; calls on the Commission and the Member States to propose incentives for the industry to develop effective, inexpensive and efficient testing methods and the use of RDTs; stresses that RDTs are only available nationwide in 40 % of OECD countries; calls on health insurance carriers to cover the extra cost arising from the use of RDTs, given the long-term benefits of preventing the unnecessary use of antimicrobials;

34. Calls on the Commission and the Member States to restrict the sale of antibiotics by the human and animal health professionals who prescribe them and to remove any incentives – financial or otherwise – for the prescription of antibiotics, while continuing to ensure sufficiently rapid access to emergency veterinary medicine; stresses that many antimicrobials are used in both humans and animals, that some of these antimicrobials are critical for preventing or treating life-threatening infections in humans, and that their

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[1] Article 78 of the forthcoming regulation on veterinary medicinal products.

use on animals should therefore be banned; stresses that these antimicrobials should be reserved for the treatment of humans alone in order to preserve their efficacy in the treatment of infections in humans for as long as possible; considers that Member States should be allowed to implement or maintain stricter measures regarding the restriction of sales of antibiotics;

35. Calls on the Commission and the Member States to take firm action against the illegal sale of antimicrobial products or their sale without a doctor's or veterinarian's prescription in the EU;

36. Highlights the value of vaccines and diagnostic tools in combating AMR and HAIs; recommends the integration of targets for life-long vaccination and infection control in the population, particularly in high-risk groups, as a key element of national action plans on AMR; stresses the importance, furthermore, of accessible information and awareness raising among the general public to boost the vaccination rate in human and veterinary healthcare and thus tackle diseases and AMR cost-effectively;

37. Stresses that the European One Health Action Plan against AMR observes that immunisation by means of vaccination is a cost-effective health intervention in efforts to combat AMR[1] and that, in the Action Plan, the Commission announces incentives to promote the use of diagnostics, antimicrobial alternatives and vaccines[2], but that the relatively higher costs of diagnosis, antimicrobial alternatives and vaccination compared with conventional antibiotics are an obstacle to increasing the vaccination rate, as the Action Plan aims to do[3]; underlines that various Member States already regard vaccination as an important policy measure, both to prevent outbreaks of animal diseases across borders and to restrict further risks of contagion for the EU agricultural market, and have therefore introduced it as such;

38. Calls on Member States to step up efforts to prevent and control infections that can lead to sepsis; calls on Member States to include targeted measures to improve the prevention, early identification and diagnosis, and clinical management of sepsis in their national AMR action plans;

39. Calls on the Commission to explore how best to leverage the potential of the European Reference Networks for rare diseases and to assess their possible role in AMR research;

40. Highlights that the pollution of the environment by human and animal antibiotic residues, particularly by livestock farming, hospitals and households, is an emerging problem that requires coherent policy measures to prevent the spread of AMR among ecosystems, animals and people; encourages further research into transmission dynamics and the relative impact of this pollution on AMR; calls, therefore, for the development of synergies between the One Health approach and existing environmental monitoring data, in particular in the form of monitoring watch lists under the Water Framework Directive, in order to improve knowledge of the occurrence and spread of antimicrobials in the environment;

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1 European Commission, 'A European One Health Action Plan against Antimicrobial Resistance (AMR)', June 2017, p. 10.
2 Ibid., p. 12.
3 Ibid., p. 15.

41. Notes that bacteria exposed to herbicides respond differently to clinically relevant antibiotics; notes the frequency of changes in resistance to antibiotics induced by the use of approved herbicides and antibiotics and that the effects of these changes escape regulatory oversight;

42. Calls on the Commission to take appropriate steps to address the release of pharmaceuticals, including antimicrobials, into the environment through wastewater and wastewater treatment plants, as a major factor in the emergence of AMR;

43. Calls for a review of the environmental risk assessments as part of the marketing authorisation process for antimicrobials, as well as for older products already on the market; calls for strict adherence to the EU Good Manufacturing Practices (GMPs) and green procurement rules as regards the production and distribution of pharmaceuticals and the release of antibiotics into the environment;

44. Urges the Commission and the Member States to address the issue of rapidly rising levels of multi-drug resistant fungi by reviewing the use of fungicides in the agricultural and industrial sector;

45. Calls on the Commission and the Member States to phase out the use of antimicrobial compounds or chemicals in non-clinical settings, such as in everyday cleaning products and other consumer goods;

46 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;

47. Points out, in this connection, that a thorough ex-ante assessment of the social costs of an ‘end of pipe’ approach is necessary;

48. Calls on the Commission and the Member States to revise their codes of good agricultural practice and relevant best available techniques under the Industrial Emissions Directive[1] to include provisions for the handling of manure containing antibiotics/microorganisms resistant to antimicrobials;

49. Calls on the Commission and the Member States to encourage the development of sustainable medicinal products with a low impact on the environment and water, and to encourage further innovation in the pharmaceutical industry in this area;

50. Stresses that not all Member States possess sufficient resources to develop and implement comprehensive national AMR strategies; urges the Commission to provide Member States with clear information about the EU resources available to tackle AMR and to make more dedicated funding available for this purpose;

51. Calls on the Commission to review and revise the best available techniques reference documents (BREFs) under the Industrial Emissions Directive that relate to emissions from plants manufacturing antibiotics;

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1 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

52. Urges the Commission to effectively deploy available legislation in all AMR-related areas to ensure that the threat is being tackled in all policies;

53. Underlines the importance of a life cycle assessment approach, from production and prescription to the management of pharmaceutical waste; asks the Commission to address the issue of the disposal of antibiotics, where alternatives to incineration, such as gasification, should be explored;

54. Calls on the Commission and the Member States to ensure that environmental issues are introduced into the pharmacovigilance system for human pharmaceuticals and strengthened for veterinary pharmaceuticals, particularly in relation to AMR;

55. Calls on the Commission and Member States to set quality standards (threshold values) or risk assessment requirements to ensure that manure, sewage sludge and irrigation water contain safe concentrations of relevant antibiotics and AMR microorganisms before they can be spread on agricultural fields;

56. Calls on the Commission to launch, in cooperation with the Member States, an EU-wide information campaign for consumers and businesses on aquaculture in general, and in particular on the differences between the stringent and comprehensive standards on the EU market and the standards applicable to products imported from third countries, with a particular emphasis on the problems caused for food safety and public health by the introduction into the Union of particularly resistant micro-organisms and AMR;

57. Calls for the phasing out of the routine prophylactic and metaphylactic use of antimicrobials in groups of farm animals and calls for the use of last-resort antibiotics to be banned altogether in food-producing animals; emphasises that good animal husbandry, hygiene practices, farm management and investments in these areas contribute to the prevention of infections and thereby to the reduction of the use of antibiotics; urges the Commission to present a new EU strategy on animal welfare as advocated by the European Parliament, with the long-term aim of creating an animal welfare law; urges the Commission to implement the points outstanding from the EU Strategy for the Protection and Welfare of Animals 2012-2015 without delay;

58. Underlines that good farm management, bio-security and animal husbandry systems underpin the health and welfare of food-producing animals and, when applied appropriately, minimise susceptibility to bacterial disease and the need for antibiotic use in animals;

59. Believes that adequate funding for on-farm investments, such as in quality housing, ventilation, cleaning, disinfection, vaccination and bio-security, must be encouraged and should not be undermined in the future common agricultural policy (CAP); recognises, in that respect, the importance of awareness among members of the farming community of animal welfare, animal health and food safety; notes the importance of promoting and applying good practices at all stages of the production and processing of food products and the importance of safe and nutritionally balanced feed, specific feeding strategies, feed composition, feed formulations and feed processing;

60. Calls on the Commission and the Member States — including in the context of the reform of the CAP — to bring about more synergies and, in accordance with the findings set out in its One Health Action Plan against AMR, to provide effective

financial incentives and support for livestock farmers who can demonstrate that they have significantly reduced their use of antibiotics and achieved a high vaccination rate among their animals or livestock;

61. Stresses that good sanitation and hygiene on farms is fundamental; asks the Commission to develop guidelines on the use of antibiotics in animals and on the hygiene conditions of farms; calls on the Member States to draw up specific plans and to strengthen control over sanitary conditions;

62. Recalls the preventative measures to be used before resorting to antimicrobial treatment of entire groups (metaphylaxis) of food-producing animals:

– using good, healthy breeding stock that grows naturally, with suitable genetic diversity,

– conditions that respect the behavioural needs of the species, including social interactions and hierarchies,

– stocking densities that do not increase the risk of disease transmission,

– isolation of sick animals away from the rest of the group,

– (for chickens and smaller animals) subdivision of flocks into smaller, physically separated groups,

– implementation of existing rules on animal welfare already in cross compliance as set out in statutory management requirements (SMRs) 11, 12, 13 of Annex II to Regulation (EU) No 1306/2013[1];

63. Believes that requirements to ensure that labelling makes reference to antibiotic use would improve consumer knowledge and enable consumers to make a more informed choice; calls on the Commission to create a harmonised system for labelling based on animal welfare standards and good animal husbandry practices as already envisaged in 2009[2],

64. Draws attention, furthermore, to recent scientific findings (February 2018) that show that extended-spectrum beta-lactamases (ESBLs) are only transferred to people from

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1 Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008, OJ L 347, 20.12.2013, p.549), applying rules laid down in Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (OJ L 221, 8.8.1998, p. 23); Council Directive 91/630/EEC of 19 November 1991 laying down minimum standards for the protection of pigs (OJ L 340, 11.12.1991, p. 33); Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves (OJ L 340, 11.12.1991, p. 28).

2 https://ec.europa.eu/food/sites/food/files/animals/docs/aw_other_aspects_labelling_ip-09-1610_en.pdf

livestock farming and meat consumption to a limited extent and that the transmission of ESBLs mainly occurs from person to person[1];

65. Stresses that high-density farming may involve antibiotics being improperly and routinely fed to livestock and poultry on farms to promote faster growth, and that they are also widely used for prophylactic purposes, to prevent disease spreading as a result of the cramped, confined and stressful conditions in which the animals are kept, and which inhibit their immune systems, and to compensate for the unsanitary conditions in which they are raised;

66. Considers that our understanding of the spread of AMR from animals in farms to humans is already quite solid and that this has not been properly recognised in the Action Plan; notes that the Action Plan merely calls for further investigation and for closing the knowledge gaps on the issue, which might possibly postpone much-needed action;

67. Calls on the Commission and Member States to distinguish between livestock and pets, particularly in the development of mechanisms to monitor and assess the use of antimicrobials in veterinary medicine, and in the development of measures to address their use;

68. Stresses that comprehensive monitoring of antibiotics in farming has been developed in cooperation with veterinarians, which comprehensively documents the use of antibiotics and further improves their application; regrets that there is, as yet, no comparable system in relation to human medicine;

69. Notes that the existence of a correlation between resistance to antibiotics found among food-producing animals (e.g. broiler chickens) and a large proportion of bacterial infections in humans, which comes from the handling, preparation and consumption of the meat of these animals, has also been confirmed by EU agencies[2];

70. Stresses that research shows that interventions that restrict antibiotic use in food-producing animals are associated with a reduction in the presence of antibiotic-resistant bacteria in these animals[3];

71. Calls on the Commission and the Member States, in the light of this recent research[4], to take care and maintain a sense of proportion when adopting measures, and to carefully assess and classify antibiotics and antimicrobial resistance in all relevant legislation so as not to restrict unnecessarily the availability of remedies to combat certain protozoa, such as coccidia, in European livestock farming and thus unintentionally cause an

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1 Mevius, D. et al., 'ESBL-Attribution-Analysis (ESBLAT). Searching for the sources of antimicrobial resistance in humans', 2018. Available at: http://www.1health4food.nl/esblat

2 The European Centre for Disease Prevention and Control, and the European Food Safety Authority: https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/antimicrobial-resistance-zoonotic-bacteria-humans-animals-food-EU-summary-report-2014.pdf

3 http://www.thelancet.com/pdfs/journals/lanplh/PIIS2542-5196(17)30141-9.pdf

4 Mevius, D. et al., 'ESBL-Attribution-Analysis (ESBLAT). Searching for the sources of antimicrobial resistance in humans', 2018. Available at: http://www.1health4food.nl/esblat

increase in the risks of contamination of human beings with dangerous bacteria such as salmonella and microbes from food;

72. Regrets that the European One Health Action Plan against AMR lacks any allocation of resources and that it is not making more ambitious use of legislative tools; calls on the Commission to be more ambitious in any future action plan it develops and to make more determined efforts to implement it in its entirety;

73. Regrets that the Commission's strategic approach, which is basically right, is all too often limited to declarations of intent and calls on the Commission to spell out its approach;

74. Calls on the Commission to coordinate and monitor national strategies to enable sharing of best practices among Member States;

75. Urges Member States to develop ambitious national strategies to tackle AMR in the animal production sector, to include quantitative reduction targets for the use of veterinary antimicrobials, while taking local circumstances into account; stresses that all sectors all along the food chain should be involved in their implementation;

76. Notes that some Member States have legally defined professionally qualified animal medicine advisors authorised to prescribe certain veterinary medicines by the relevant authorities; underlines that national action plans on AMR should not prohibit these persons from prescribing and supplying certain veterinary medicines, where necessary, given the vital role these persons can play in isolated rural communities;

77. Underlines the importance of exchanges of best practices among Member States and the coordination of such exchanges by the Commission; welcomes, in this context, the reduction of the use of antibiotics in animal husbandry in the Netherlands by 64.4 % in the period 2009-2016 and the stated national ambition to further reduce it by 2020; calls on the Commission and the Member States to apply this example of public-private cooperation between public authorities, industries, scientists and veterinary surgeons in other parts of the Union as well;

78. Urges the Member States to consider the implementation of positive (tax exemptions for farmers) and negative (taxes on antibiotic sales such as those successfully introduced in Belgium and Denmark) tax incentives on antibiotics used in husbandry for non-therapeutic purposes;

Boosting research, development and innovation with regard to AMR

79. Points out that with an investment of EUR 1.3 billion in AMR research, the EU is a leader in this domain, and that EU achievements include the launch of the New Drugs for Bad Bugs (ND4BB) programme[1] and the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR)[2]; underlines the need for the efficiency and coordination of research actions; welcomes initiatives, therefore, such as ERA-NET for establishing synergies between the JPIAMR and Horizon 2020; highlights that more

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

2 http://www.jpiamr.eu

than 20 new classes of antibiotics were developed until the 1960s and notes with concern that no truly new antimicrobial classes have been introduced in recent years;

80. Urges the Commission to consider a new legislative framework to stimulate the development of new antimicrobials for humans, as already requested by Parliament on 10 March 2016 in its amendments to the proposal for a regulation on veterinary medicinal products and in its resolution of 19 May 2015; notes that in the European One Health Action Plan against AMR, the Commission also commits itself to '[analysing] EU regulatory tools and incentives – in particular orphan and paediatric legislation – to use them for novel antimicrobials';

81. Welcomes the fact that EFSA and the EMA recently reviewed and discussed a number of alternatives to the use of antimicrobials in food-producing animals, some of which have been shown to yield promising results in the improvement of animal health parameters during experimental studies; recommends, therefore, giving new impetus to scientific research on alternatives and designing an EU legislative framework that would stimulate their development and clarify the pathway for their approval;

82. Recalls that the traditional generation of antibiotics, which is based on a series of techniques for the modification of antibiotics obtained from nature, has been exhausted and that R&D investments in the creation of a new generation should break the traditional antibiotic paradigm; welcomes the new techniques that have already been developed, such as monoclonal antibodies that reduce the virulence of bacteria, not by killing them, but by rendering them useless;

83. Points out that science and research play a crucial role in the development of standards in the fight against AMR;

84. Welcomes recent research projects into alternative antibiotic therapies such as bacteriophage therapy, for example 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 framework for bacteriophage therapy based on the latest scientific research;

85. Notes the recent research into the development of next-generation probiotics for concomitant use with antibiotic treatment in clinical settings, which has been shown to reduce HAIs caused by bacteria highly resistant to antibiotics[1];

86. Notes that R&D in the field of novel approaches to the treatment and prevention of infections is equally important and that these approaches can include the use of substances to strengthen the immune response to bacterial infection, such as pre- and probiotics;

87. Encourages the EMA in collaboration with EFSA and the ECDC to review all available information on the benefits and risks of older antimicrobial agents, including antibiotics in combination, and to consider whether any changes to their approved uses are required; stresses that early dialogue between innovators and regulatory authorities should be encouraged in order to adapt the regulatory framework where necessary so as

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1 Pamer, E. G., 'Resurrecting the intestinal microbiota to combat antibiotic-resistant pathogens', *Science*, Vol. 352(6285), 2016, pp. 535-538.

to prioritise and speed up the development of antimicrobial medicines and allow for faster access;

88. Encourages the Commission to introduce a fast-track procedure whereby the use antimicrobials approved for industrial or agricultural purposes but suspected of having a severe negative impact on AMR can be temporarily prohibited until further studies on the impact of the antimicrobial have been carried out;

89. Recalls that the poor quality of medical and veterinary products with low concentrations of active ingredients and/or their long-term use encourages the emergence of resistant microbes; calls, therefore, on the Commission and Member States to improve and design laws that ensure that medicines are of assured quality, safe and effective, and that their use will follow strict principles;

90. Calls on the Commission to increase funding for early cross-sectoral and interdisciplinary R&I in epidemiology and immunology of AMR pathogens and the screening of HAIs, in particular the pathways of transmission between animals and humans and the environment; calls on the Commission to support research into hand hygiene and the impact of different hand washing and hand drying methods on the transmission of potential pathogens;

91. Calls on the Commission to invest equally in the development of non-antibiotic alternatives for animal health, including growth promoters, and in the development of new molecules for the development of new antibiotics; stresses that new antibiotics must not be used for animal health promotion or growth promotion and that industries receiving public funds for the development of new antibiotics must stop distributing and/or using antibiotics for animal health promotion and growth promotion;

92. Welcomes recent cross-border research projects into antimicrobial stewardship and the prevention of infection, such as the EU-funded i-4-1-Health Interreg project; calls on the Commission to increase research funding for measures to prevent HAIs;

93. Calls on the Commission to further support R&D efforts in the field of AMR, including with regard to global health infections as defined in the SDGs, in particular drug-resistant TB malaria, HIV and neglected tropical diseases, as part of the next EU research and innovation framework programme, including by dedicating a specific mission under the programme to the global fight against AMR;

94. Calls on the Commission to put in place restrictions on live animal transport from zones where antimicrobial-resistant strains of bacteria have been identified by the current monitoring system;

95. Notes that some plant protection products might also have antimicrobial properties, which would affect the spread of AMR; calls for further research on the possible link between exposure to commercial formulations of pesticides and herbicides and the development of AMR; recognises that herbicides are routinely tested for toxicity but not for sublethal effects on microbes, and stresses, for the reasons cited above, the importance of giving consideration to conducting such tests routinely;

96. Calls on the Commission and the Member States to promote early and continuous dialogue with all stakeholders to elaborate appropriate incentives for R&D in the field

of AMR; acknowledges that there is no 'one-size-fits-all' approach; urges the Commission to formally include civil society in One Health discussions, for example by setting up and funding a dedicated stakeholder network;

97. Stresses the need for different models of collaboration led by the public sector and with the involvement of industry; recognises that the capacities of industry play a key role in R&D in the field of AMR; stresses that, notwithstanding the above, further public prioritisation and coordination are required for R&D in this urgent field; calls on the Commission, therefore, to launch a public platform for publicly funded R&D projects in AMR and for the coordination of all R&D actions;

98. Stresses, therefore, that the current innovation framework does not effectively encourage R&D into AMR, and calls for the adjustment and harmonisation of the intellectual property regime at European level, in particular in order to better match the duration of protection with the period requested for the innovative medicine in question;

99. Believes that research into fighting AMR is already taking place in many different parts of the Union, without there being any adequate overview of the state of research in the EU as a whole; suggests, therefore, that a dedicated platform be established at EU level to enable research resources to be used more efficiently in the future;

100. Recalls the value of developing coalitions between academia and biopharmaceutical companies in terms of developing new antibiotics, rapid diagnostics and novel therapies;

101. Welcomes the conclusions of the WHO, World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO) Joint Technical Symposium entitled 'Antimicrobial Resistance: How to foster innovation, access and appropriate use of antibiotics'[1], where new R&D models were discussed to incentivise R&D while delinking the profitability of antibiotics from volume sold;

102. Recalls that the Clinical Trials Regulation[2] 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;

103. Calls on the Commission and the Member States to support the development and uptake of new economic models, pilot projects and push and pull incentives to boost the development of new therapies, diagnostics, antibiotics, medical devices, vaccines and alternatives to using antimicrobials; believes that these are meaningful when they are sustainable, needs-driven and evidence-based over the long term, target key public priorities and support appropriate medical use;

104. Calls on the Commission to assess the efficiency of current hygiene practices and sanitation methods in hospitals and healthcare environments; asks the Commission to explore the use of probiotics and other sustainable hygiene technologies as efficient sanitation approaches to prevent and reduce the number of HAIs attributed to AMR;

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1 http://www.wipo.int/publications/en/details.jsp?id=4197

2 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

105. Encourages the uptake of cost-effectiveness technologies that reduce the impact of HAIs in hospitals and help to prevent the spread of multi-resistant microorganisms;

106. Encourages Member States to promote alternative reimbursement systems to facilitate the uptake of innovative technologies in national healthcare systems;

107. Notes that the usual business model for developing medicines is not suitable for antibiotic development since resistance can evolve over time and since they are meant to be used temporarily and as a last resort; reminds the industry of its corporate and social responsibility to contribute to work to tackle AMR by finding ways to extend the life of antibiotics, thereby making the supply of effective antibiotics sustainable, and calls for incentives for this research and for the definition of the regulatory pathway;

108. Recalls that both Parliament and the Council have asked for a review of current incentives (i.e. those established in the Orphan Regulation[1]), owing to their misuse and high final prices; calls, therefore, on the Commission to analyse current R&D incentive models, including the 'transferable market exclusivity' model, with a view to designing new ones and defining the regulatory pathway;

109. Calls on the Commission and the Member States to develop, in cooperation with researchers and industry, new incentive models that delink payment from prescribing volume and stimulate investment across the entire product development and production period; highlights that guaranteeing affordability and access to quality antibiotics must be the final aim of R&D incentives;

110. Acknowledges the key role of pharmacists in raising awareness of the appropriate use of antimicrobials and in the prevention of AMR; encourages Member States to expand their responsibilities by allowing exact quantity dispensing and enabling the administration of certain vaccines and rapid diagnostic tests within pharmacies;

111. Calls for transferable market exclusivities and market entry rewards to be considered as options for sustainable incentives;

112. Calls on the Commission to take the global lead in advocating evidence-based best practice models for early diagnosis to tackle AMR;

Shaping the global agenda

113. Underlines that without harmonised and immediate action on a global scale, the world is heading towards a post-antibiotic era in which common infections could once again kill;

114. Recalls that owing to the complexity of the problem, its cross-border dimension, the severe consequences for the environment and human and animal health, and the high economic burden, AMR requires urgent and coordinated EU, global and intersectoral action; asks, therefore, for a clear commitment on the part of the EU and the Member States to building European and international partnerships and launching a crosscutting global strategy to combat AMR, covering policy areas such as international trade, development and agriculture;

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[1] Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

115. Welcomes the WHO's ranking list of the 20 worst antibiotic-resistant pathogens[1]; calls for urgent R&D projects on this priority list of antibiotic-resistant bacteria in order to develop drugs to fight them; highlights, however, that research on new drugs is not the only action needed and that misuse and overuse must be tackled in both humans and animals;

116. Recognises that AMR is a transborder issue and that products enter Europe from all over the world; urges the Commission to collaborate with third parties to reduce the use of antibiotics in husbandry and associated environmental contamination; calls on the Commission, moreover, to implement collaborative research programmes with third countries to reduce the overuse of antibiotics; calls on the Commission, in the context of free trade agreements, to ban imports of food animal products when the animals have not been raised in line with EU standards, and notably with the ban on the use of antibiotic growth promoters;

117. Takes note of the report entitled 'Tackling drug-resistant infections globally: Final report and recommendations'[2], which estimates that taking global action on AMR will cost USD 40 billion over a 10-year period, which is a tiny amount in comparison with the cost of inaction and a very small fraction of what the G20 countries spend on healthcare today (around 0.05 %); calls on the Commission to analyse the possibility of imposing a tax on the industry for public health within the framework of its social responsibility;

118. Stipulates that in any future trade deal with the UK post-Brexit, AMR must be addressed and a condition set requiring the UK to follow up on further advancements in EU action to tackle AMR in order to protect consumers and workers in both the EU and the UK;

119. Welcomes the WHO Global Action Plan (GAP) on AMR, which was adopted unanimously in May 2015 by the 68th World Health Assembly; stresses the need for global, EU and national action plans to be in line with the GAP;

120. Welcomes the new WHO guidelines on use of medically important antimicrobials in food-producing animals[3]; highlights that in some countries, approximately 50-70 % of medically important antibiotics are consumed in the animal sector, largely for growth promotion in healthy animals; asks, in the framework of the One Health approach, for this topic to be included in the trade policy of the EU and in negotiations with international organisations such as the WTO and associated or third countries, shaping a global policy to ban the use of antibiotics for fattening healthy animals;

121. Notes that AMR is of serious concern in many poverty-related and neglected diseases (PRNDs), including HIV/AIDS, malaria, TB and diseases connected with epidemics and pandemics; highlights that about 29 % of deaths caused by AMR are due to drug-resistant TB; calls on the Commission and the Member States, as a matter of urgency, to increase their support for research into and the application of health tools to address PRNDs affected by AMR; calls on the Commission and the Member States to create partnerships, modelled on the Partnership for Research and Innovation in the

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1 http://www.who.int/mediacentre/news/releases/2017/bacteria-antibiotics-needed/en/
2 https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf
3 http://www.who.int/foodsafety/areas_work/antimicrobial-resistance/cia_guidelines/en/

Mediterranean Area (PRIMA) and the European and Developing Countries Clinical Trials Partnership (EDCTP), for international R&D projects on health, comprising different geographical regions and covering the most pertinent health topics, such as AMR, vaccines, cancer and access to medicines;

122. Underlines the importance of EU initiatives such as the ECDC programmes for infectious diseases, including AIDS, TB and malaria; points out that these initiatives are examples of good practice, demonstrating the EU's responsiveness and good functioning with a view to the need for new antibiotics, and that the ECDC should have a key role in the prioritisation of R&D needs, in the coordination of actions and the involvement of all actors, in enhancing cross-sectoral work and in capacity building through R&D networks;

123. Highlights the problem of the emergence of multiresistant bacteria that are resistant to several antibiotics at the same time and that can eventually become superbacteria, resistant to all available antibiotics, including last-line antibiotics; highlights the need for a database on these multiresistant bacteria, covering AIDS, TB, malaria, gonorrhoea, Escherichia coli and other drug-resistant bacteria;

124. Notes that the livestock raised for food in the US is dosed with five times as much antibiotic medicine as farm animals in the UK; underlines, therefore, the importance of controls of meat imports into the EU;

125. Calls on the Commission to advocate EU standards and measures for tackling AMR and for the appropriate use of antibiotics in trade agreements, and to work through the WTO to raise the issue of AMR; notes that the use of antibiotics as growth promoters in food-producing animals has been banned in the EU since 2006, but that in countries outside the EU antibiotics can still be used in animal feed as growth promoters; calls on the Commission to include a clause in all free trade agreements stipulating that food imported from third countries must not have been produced using antibiotics as growth promoters, with a view to ensuring a level playing field for EU livestock farming and aquaculture and in order to mitigate AMR; calls on the Commission to ban all food imports from third countries where these products come from animals treated with antibiotics or antibiotic groups that are reserved for the treatment of certain human infections in the EU;

126. Calls on the Commission and the Member States to strengthen measures to combat illegal practices related to the production, trade, use and disposal of antimicrobials; emphasises that actors involved in the life-cycle chain of antimicrobials must take responsibility for their actions;

127. Notes the impact of the universality and affordability of and broad access to existing antibiotics; believes that targeted treatment, using specific antibiotics, should be available to all in order to prevent the misuse of unsuitable antibiotics and the overuse of broad-spectrum antibiotics; calls on the Commission and the Member States to take stronger measures against the sale of large consignments of antimicrobials at dumping prices, in particular critical human antibiotics;

128. Calls for comprehensive checks to be carried out on producers of antibiotics so that withdrawal periods are adapted to reality, in order to ensure that no antibiotics are present in food products;

129. 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; highlights the opportunity for EU scientific bodies, such as the ECDC, to take on global stewardship roles; calls on the Commission to advocate collaboration between the EU and international organisations, including the WHO, the UN Food and Agriculture Organisation (FAO) and the World Organisation for Animal Health (OIE); welcomes the Davos Declaration on Combating Antimicrobial Resistance issued at the World Economic Forum in Davos on January 2016, in which pharmaceutical, biotechnology and diagnostics industries call for collective action to create a sustainable and predictable market for antibiotics, vaccines and diagnostics that enhances conservation for new and existing treatments;

130. Calls for the promotion and enhancement of, and the transition to, a mode of production based on agroecology;

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131. 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, the World Health Organisation and the World Organisation for Animal Health.