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P8\_TA(2015)0197

## Safer healthcare in Europe

### European Parliament resolution of 19 May 2015 on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance (2014/2207(INI))

(2016/C 353/02)

*The European Parliament,*

- having regard to its position of 23 April 2009 on the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare-associated infections <sup>(1)</sup>,
- having regard to the Council recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare-associated infections <sup>(2)</sup>,
- having regard to Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare,
- having regard to the Commission communication of 15 November 2011 entitled 'Action plan against the rising threats from Antimicrobial Resistance' (COM(2011)0748),
- having regard to the Council conclusions of 22 June 2012 on 'The impact of antimicrobial resistance in the human health sector and in the veterinary sector — a "One Health" perspective',
- having regard to its resolution of 11 December 2012 on 'The Microbial Challenge — Rising threats from Antimicrobial Resistance' <sup>(3)</sup>,
- having regard to the reports of 13 November 2012 and 19 June 2014 from the Commission to the Council on the basis of Member States' reports on the implementation of the Council recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections (COM(2012)0658 and COM(2014)0371),
- having regard to its resolution of 22 October 2013 on the report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections <sup>(4)</sup>,
- having regard to Decision No 1082/2013/EU of the European Parliament and the Council of 22 October 2013 on serious cross-border threats to health,
- having regard to the Special Eurobarometer 411, 'Patient safety and quality of care',
- having regard to the Progress report on the Action plan against the rising threats from Antimicrobial Resistance (SANTE/10251/2015),
- having regard to the proposal, of 10 September 2014, for a Regulation of the European Parliament and of the Council on veterinary medicinal products (2014/0257(COD)),
- having regard to the 'Conceptual framework for the international classification for patient safety' drawn up by the World Health Organisation (WHO),
- having regard to the Latvian Presidency's efforts in addressing the issue of antimicrobial resistance, in particular with regard to tuberculosis and multi-drug resistant tuberculosis (MDR-TB),
- having regard to the Council conclusions of 1 December 2014 on patient safety and quality of care, including the prevention and control of healthcare-associated infections and microbial resistance,

<sup>(1)</sup> OJ C 184 E, 8.7.2010, p. 395.

<sup>(2)</sup> OJ C 151, 3.7.2009, p. 1.

<sup>(3)</sup> Texts adopted, P7\_TA(2012)0483.

<sup>(4)</sup> Texts adopted, P7\_TA(2013)0435.

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- having regard to the first ECDC/EFSA/EMA joint report on the integrated analysis of the consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals (Joint Interagency Antimicrobial Consumption and Resistance Analysis — JIACRA),
  - 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 (A8-0142/2015),
- A. whereas the key to overall healthcare quality lies in patient safety, the essential elements of which are a healthcare culture and the management of adverse events;
  - B. whereas the volume of data available on the prevalence and incidence of adverse events in Member State healthcare systems is at present limited, but is steadily growing, and whereas the latest available data date back to 2008;
  - C. whereas it is estimated that between 8 % and 12 % of patients admitted to hospitals in the EU suffer from adverse events while receiving healthcare, and whereas nearly half of these events could be avoided;
  - D. whereas the most common healthcare-related adverse events are healthcare-associated infections (HAIs), medication-related events and complications arising during or after surgical operations;
  - E. whereas patient safety and the quality of healthcare require decent working conditions and safety at work for healthcare professionals, and whereas, in particular, ensuring patient safety, prevention and control of HAIs and prevention of the spread of multidrug-resistant bacteria is very difficult in overcrowded and understaffed healthcare environments;
  - F. whereas the current economic crisis has placed increased pressure on Member State healthcare budgets, hence having an impact on patient safety, as many Member States, instead of properly addressing efficiency, have reduced budgets and staffing levels in their healthcare systems with rather harsh cuts;
  - G. whereas the economic crisis has further deepened existing inequalities with regard to access to health services;
  - H. whereas continuous training of doctors and other healthcare professionals is crucial to avoid adverse events, including adverse drug events (ADEs), which are estimated to cost the EU healthcare systems some EUR 2,7 billion per year in care expenses and account for 1,1 % of all hospitalisations in the Union;
  - I. whereas patient-centred electronic health (e-Health) and home-care medical treatments have a high potential for improving the quality and efficiency of medical treatments while contributing to better healthcare performance;
  - J. whereas a multidisciplinary approach increases the chances of positive outcomes of medical treatments;
  - K. whereas patients, families and patient organisations play a key role in advocating for safer care, and their role should be promoted through patient empowerment and participation in the healthcare process and policy at all levels;
  - L. whereas home-care medical treatments can help patients psychologically and result in better healthcare performance;
  - M. whereas it has been noted that less-informed people use antibiotics more frequently, while full knowledge of antibiotics could encourage people to consume them more responsibly;
  - N. whereas 30 to 50 % of patients do not take the medicines prescribed for them by doctors or do not take them as directed by the doctor's prescription;

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- O. whereas conflicts of interest related to the pharmaceutical industry exist in hospitals and among general practitioners and also veterinarians;
- P. whereas HAIs are a major public health problem in the Member States (according to figures compiled by the European Centre for Disease Prevention and Control (ECDC), 1 in 20 hospital in-patients on average suffer from an HAI in the EU, that is to say, 4,1 million patients annually, and every year 37 000 people in the EU die as a result of an HAI, although 20 to 30 % of those infections are considered to be preventable by intensive hygiene and control programmes), and this places a heavy burden on limited health service budgets;
- Q. whereas patients' experiences and inputs often differ from those of health professionals and can be of great value in finding new ways to reduce and prevent HAIs;
- R. whereas HAIs caused by multidrug resistant bacteria are increasing;
- S. whereas antimicrobial resistance has increased worldwide for bacterial pathogens, leading to increasing prevalence of HAIs and treatment failures in human and animal infectious diseases at national, European and international levels;
- T. whereas it is estimated that globally 10 million people will die every year because of antimicrobial resistance by 2050;
- U. whereas resistance to antibiotics that are commonly used to treat causative bacteria is at least 25 % or more in several Member States; whereas there is a growing gap between antimicrobial resistance and the development of new antibiotics and their introduction into clinical practice, and this is linked to scientific, regulatory and economic challenges;
- V. whereas the most recent studies show that, allowing for a few exceptions, antimicrobial resistance in hospitals has globally increased in the EU in recent years;
- W. whereas the EU estimates that every year at least 25 000 people die of infections caused by resistant bacteria, costing public health systems an estimated EUR 1,5 billion, according to data from 2011 collected by the ECDC;
- X. whereas the costs incurred by drug-resistant infections amount to an estimated EUR 1,5 billion annually, because of increases in healthcare expenditure costs and productivity losses; whereas patients who have caught resistant bacteria have to be isolated when treated in hospital, and this extra provision costs EUR 900 million and leads to 2,5 million extra bed days per year;
- Y. whereas one of the main causes of the spread of antimicrobial resistance in hospitals is lack of compliance with generally accepted infection prevention and control practices;
- Z. whereas first line drugs' effectiveness on bacterial pathogens is becoming increasingly limited by resistance and second or third line drugs are not always available and are often more toxic, more expensive and less effective than first line drugs;
- AA. whereas one of the main causes of antimicrobial resistance is the misuse of antimicrobials, including antibiotics, and in particular their systematic and excessive use;
- AB. whereas the high level of mobility between European healthcare systems and the increasingly cross-border nature of healthcare in Europe can promote the spread of resistant micro-organisms from one Member State to another;
- AC. whereas vaccination programmes are one effective tool in efforts to combat antibiotic resistance, because they can play a role in limiting the use of antibiotics and thereby the development of antimicrobial resistance;
- AD. whereas antibacterial research and development presents some unique challenges meaning that a long-term perspective is needed to develop the expertise and apply it in laboratories, and whereas it is regrettable that many researchers having such expertise have moved to other areas due to a lack of both private and public funding;

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- AE. whereas the failure to take basic personal hygiene precautions, both inside and outside hospitals, can cause pathogens — in particular antimicrobial-resistant ones — to spread;
- AF. whereas increasing scientific evidence shows that good hand hygiene in healthcare settings requires the use of methods to dry hands that do not facilitate microbial cross-contamination via airborne dissemination and aerosolisation;
- AG. whereas resistant bacteria can be found on medical devices even when the latter have been sterilised in accordance with the manufacturer's instructions;
- AH. whereas the use of antimicrobials in human and veterinary medicine contributes to a development of resistome in the environment which may serve as a source of resistance development in both humans and animals; whereas the same classes of antibiotics are used in both animal and human medicine and similar resistance mechanisms have emerged in both sectors;
- AI. whereas high-density farming may imply that antibiotics are improperly and routinely fed to livestock, poultry and fish on farms to promote faster growth and are also widely used for prophylaxis purposes, to prevent disease spreading owing to 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;
- AJ. whereas the One Health concept, endorsed by the World Health Organisation (WHO) and the World Organisation for Animal Health (OIE), recognises that human health, animal health and ecosystems are interconnected; whereas, in particular, animals and animal-derived food can serve as a direct main source of resistant zoonotic pathogens; whereas, therefore the use of antibiotics in animals, particularly those intended for consumption and kept in high-density farming, can affect antibiotic resistance in humans;
- AK. whereas, in the light of the One Health concept, an approach whereby both human and veterinary medical professionals undertake initiatives to prevent resistant infections and reduce the use of antibiotics can prevent HAIs, both inside and outside hospitals;
- AL. whereas, according to the WHO, antimicrobials are used much more in livestock than they are in human beings in a number of EU Member States <sup>(1)</sup>;
- AM. whereas, according to European consumer associations, over 70 % of meat products tested in six EU Member States were found to be contaminated with antibiotic-resistant bacteria, while in a further eight such bacteria were present in 50 % of all samples <sup>(2)</sup>;
- AN. whereas high levels of *Campylobacter* resistance to fluoroquinolones have been observed and most human *Campylobacter* infections come from the handling, preparation and consumption of chicken; whereas such high levels of resistance reduce the effective treatment options for human *Campylobacter* infections;
- AO. whereas in the EU the sub-therapeutic use of antibiotics, which involves low doses of antibiotics being fed to livestock to promote their growth, has been banned since 2006;
- AP. whereas the vast majority of medicated feed for farmed animals contains antimicrobials;
- AQ. whereas the use of antimicrobials in pets is an additional risk factor for the development and transmission of antimicrobial resistance in human beings, and whereas the upward trends in antibiotic resistance encountered at veterinary clinics for pets run parallel to similar trends at hospitals;

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<sup>(1)</sup> 'Tackling antibiotic resistance from a food safety perspective in Europe, WHO Europe, 2011'.

<sup>(2)</sup> 'Antibiotic use in livestock: Time to act' (position paper), BEUC (European Consumer Organisation).

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- AR. whereas the risk of transmission of antimicrobial resistance from pets to human beings cannot be fully quantified, and whereas further research into this is needed;
- AS. whereas it is acknowledged that the current legislation on veterinary medicines does not provide sufficient tools to ensure that risks to human health arising from the use of antimicrobials in animals are adequately managed;
- AT. whereas the issue of off-label use of antibiotics is a concern for animal medicine as well as human medicine;
- AU. whereas pharmaceutical companies tend to add new antibiotics within existing classes of antibiotics rather than discover and develop truly new antibacterial agents, and as a result, resistance to these new agents will emerge faster than for drugs with a truly new mechanism of action;
- AV. whereas it is necessary to encourage pharmaceutical laboratories to develop new antibiotics by giving thought to the creation of incentives and alternative economic models to reward innovation;
- AW. whereas it is of paramount importance to encourage pharmaceutical companies to invest and to continue investing in the development of new antimicrobial agents, in particular those active against diseases for which antimicrobial resistance is a serious concern, in particular:
- diseases caused by prevalent multidrug-resistant Gram-negative bacteria (such as *K. pneumoniae* and *Acinetobacter* or *E. coli*), or by other multidrug-resistant bacteria like *Staphylococcus aureus* or tuberculosis;
  - other diseases caused by viruses (such as HIV), or by parasites (such as malaria);
- as well as developing other methods to fight HAIs without using antibiotics;
- AX. whereas this can be achieved by addressing some of the key scientific, regulatory and economic challenges that have hampered the development of antimicrobials, and in particular by incentivising investment in research and development and focusing it on the greatest public health needs, while preserving the sustainability of national health systems;
- AY. whereas paragraph 2 of Article 4 of Directive 2001/18/EC sets a deadline for the use of genes conferring antibiotic resistance to transgenic plants;
- AZ. whereas product specialists should never perform therapeutic treatments, but should only support medical staff when and if required by the latter, for example to perform operations of assembling or disassembling specific instruments;
- BA. whereas the provisions of Directive 2011/24/EU on patient mobility are being implemented throughout the EU, making it more pertinent that European patients should be informed on patient safety in the various Member States;
- BB. whereas it is vital to ensure patients' rights and public confidence in health services, by ensuring that Member States have systems in place to provide fair financial compensation in the case of negligence arising from faulty medical provision;
- BC. whereas the internet is the biggest unregulated pharmaceuticals market in the world; whereas 62 % of pharmaceuticals bought online prove to be fake or non-compliant with standards; whereas a very large proportion of operators operating online do so illegally and the annual global turnover from the illegal online sale of prescription medicines is estimated at around USD 200 billion;
- BD. whereas Article 168 of the Treaty on the Functioning of the European Union stipulates that Union action must complement national policies and must be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health;

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*Implementation of the Council's recommendations on patient safety**Feedback on the Commission's second implementation report*

1. Recalls that the EU pharmaceutical legislation was put in place to protect patient safety; recalls its above-mentioned resolution of 22 October 2013 on the report from the Commission to the Council on the basis of Member States' reports on the implementation on the Council Recommendation (2009/C 151/01) on patient safety, including the prevention and control of healthcare-associated infections;
2. Welcomes the improvement of the HAI surveillance system in the EU and the other recent measures put in place by certain Member States to improve general patient safety and reduce the incidence of HAIs, and more particularly the progress made by Member States in developing patient safety strategies and programmes, including patient safety in health legislation, and in developing reporting and learning systems;
3. Notes, however, that the second implementation report still shows uneven progress among Member States on patient safety, and regrets the fact that some Member States have obviously slowed down implementation of the Council recommendations among others, possibly as a consequence of financial constraints resulting from the economic crisis;
4. Regrets that austerity measures have seen a reduction in the level of cleaning staff in hospitals and other healthcare settings across Europe, given the critical role cleaning staff have in ensuring high levels of hygiene;
5. Calls on Member States to make sure, in this period of economic crisis, that patient safety is not affected by austerity measures and that healthcare systems remain adequately funded and, in particular, to avoid the most damaging of measures, such as short-term savings, which would lead to high costs in the medium to long term, and instead to concentrate on the further development of high-quality and high-efficiency healthcare systems; calls on Member States to ensure that there are a sufficient number of healthcare professionals trained or specialised in infection prevention and control, as well as hospital hygiene, with a view to a more patient-centred approach;
6. Calls on Member States to set specific and ambitious quantitative targets for reducing the use of antibiotics;
7. Welcomes the work of the EU Working Group on Patient Safety and Quality of Care, which brings together representatives from all 28 EU Member States, EFTA countries, international organisations and EU bodies, and assists in developing the EU's patient safety and quality agenda;
8. Calls on the Commission to continue monitoring the implementation of the provisions on patient safety in the Member States, and where necessary to develop new guidelines accordingly;

*Leads for improvements*

9. Welcomes the work cofinanced by the EU and performed by the OECD on comparable indicators to assess patient safety; calls on the Member States to implement such indicators with a view to assessing patient safety;
10. Notes the importance of including patient safety in the education, on-the-job-training and continuing training of healthcare workers and health professionals in all Member States;
11. Highlights the potential benefits of eHealth in reducing adverse events by tracking information flows and improving the understanding of medical processes, as well as through digital prescriptions and alerts on drug interaction; calls on the Commission and the Member States to further explore the possibilities offered by eHealth in the area of patient safety, including the introduction of electronic patient records, and to step up the level of cooperation so as to share their experiences, knowledge and good practices in this sector;
12. Calls on the Commission and the Member States to assess the potential of mobile health (mhealth) in relation to efficiency of care, incidence of hospitalisation and the reduction of annual per capita healthcare costs;

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13. Notes that the use of antibiotics and the prevalence of antimicrobial resistance vary widely between Member States, and encourages Member States to apply best practices;
14. Underlines the urgent need to promote veterinary research and innovation at EU and national level;
15. Urges the Member States to implement or develop the following measures:
  - (a) continue their efforts to improve patient safety by taking the necessary measures in order to fully implement the Council's recommendations;
  - (b) regularly collect data, in accordance with standardised surveys, on the prevalence and incidence of adverse events in their own territory, and enhance early warning alert systems and coordinate exchanges of these data effectively;
  - (c) ensure that health managers are appointed on the basis of merit and not of political affiliation;
  - (d) ensure the continuous improvement and ongoing evaluation of working conditions for healthcare professionals with a view to improving patient safety;
  - (e) ensure basic training of all healthcare personnel, even those who are not in direct contact with patients, in infection prevention and control before they start working in a hospital or other healthcare facility, and regularly afterwards;
  - (f) ensure the appropriate and up-to-date training of doctors and other healthcare professionals, as well as the exchange of best practices, in order to keep pace with the latest technology in place and best hospital hygiene practices, and set up monitoring systems to verify that their competences are up-to-date, especially regarding the implementation of the WHO Surgical Safety Checklist; this would reduce the prevalence of medical errors (including HAIs) caused by partial knowledge and failure to keep up with new technological advances;
  - (g) ensure the adoption of a multidisciplinary approach in medical treatments;
  - (h) ensure better coherence and continuity in patients' progress through the system, focusing on transition between sectors and the transmission of information, for example from the hospital to the primary care sector;
  - (i) lighten the burden on healthcare facilities by promoting care and medical treatment at home;
  - (j) ensure that medical professionals inform patients when a medicine is used off-label and provide patients with information on the potential risks in order to enable them to give informed consent;
  - (k) exchange among themselves information on the best approach with regard to combating antibiotic resistance in order to implement the most effective approach throughout Europe;
  - (l) ensure equal access to health services and medical treatment for patients in order to combat existing health inequalities;
  - (m) promote information campaigns for patients concerning the risks of adverse events in the healthcare system and concerning possible preventive measures, starting with basic hygiene measures, and launch awareness-raising campaigns and health education courses in schools concerning the rational use not only of antibiotics but of all pharmaceuticals and the risks entailed by the rise of antibiotic resistance; these campaigns should address parents and carers responsible for young children as well as for elderly people, and should be followed by an assessment of their outcomes;
  - (n) emphasise the importance of prevention of HAIs in healthcare settings by means of containment of spread through patient and contact screening as well as infection control measures, and continue promoting good hygiene practices (like hand-washing);



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- (o) step up hygiene precautions, making greater use of hygiene specialists to monitor all aspects of health and hygiene relating to healthcare facilities, patients and relations between patients and outside 'guests';
  - (p) actively and formally involve patients' organisations and representatives at all stages and levels of policies and programme development;
  - (q) develop EU guidance for patients' involvement in patient safety strategies and actions in collaboration with stakeholders, particularly patient organisations;
  - (r) provide them with appropriate support to carry out patient safety activities;
16. Calls on Member States to investigate possible malpractice involved in the refurbishment and re-use of medical devices originally designed and labelled for single use;
17. Urges Member States to improve awareness programmes for medical professionals, other healthcare workers, veterinary practitioners and the general public focusing on antibiotic use and prevention of infections;
18. Calls on the European Medicines Agency (EMA) to develop guidelines on the off-label/unlicensed use of medicines based on medical need, as well as to compile a list of off-label medicines in use despite licensed alternatives;
19. Calls on the Commission and the ECDC to develop guidelines for healthcare professionals, patients and their families on effective hand washing and drying and encouraging the use of hand drying methods that do not facilitate microbial cross-contamination via airborne dissemination and aerosolisation;
20. Underlines the need for major improvements in communication and in education and training aimed at both veterinarians and farmers;
21. Urges the Commission once again to present, as soon as possible, a legislative proposal for the mandatory addition of the drug-fact-box to the package leaflet; the information provided by the drug-fact-box should be presented in a form that is clearly legible, prominent and clearly distinguishable from the rest of the text; this drug-fact-box should contain a short description of the necessary facts concerning the medicine in order to enable the patient to understand the utility and possible risks of the medicinal product and in order to apply the medicinal product safely and in the right way; this includes inter alia advice on how to use antibiotics in the right and proper way;
22. Calls on the Commission and the Member States to promote the introduction of the European logo provided for by Implementing Regulation (EU) No 699/2014 in order to identify clearly online pharmacies which offer medicines for sale to the public remotely while safeguarding consumers against the purchase of fake medicines, which are often a health hazard;
23. Points out that, on the basis of Decision No 1082/2013/EU on serious cross-border threats to health, Member States must provide the Commission with updates on the latest situation with regard to their preparedness and response planning at national level, and calls on Member States to submit the information concerned in accordance with the timetable established by that decision;

#### *Reporting and accountability/liability issues*

24. Urges Member States to encourage regular information input from health professionals advising patients on how to minimise risks to their safety through contact with the healthcare system;
25. Encourages the Member States to set up independent bodies to liaise with professionals in order to ensure the raising of awareness and the dissemination of alerts regarding threats to patient safety;
26. Calls on the Member States to improve their reporting systems for adverse events and medical errors by developing measures that encourage accurate, blame-free and anonymous reporting by health professionals and patients, and to consider establishing an e-system which could facilitate and improve reporting by patients;



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27. Calls on the Member States to adopt measures that would improve the quality — and not just the quantity — of reporting on adverse events, so that reporting contains robust information that would really improve patient safety, and to establish a system in which data could be easily retrieved and which would ensure comprehensive and systematic evaluation;
28. Calls on the Commission to develop standardised surveys for collecting data on HAIs;
29. Calls on the Member States to be more rigorous in verifying and enforcing the ban on non-medical external staff performing medical treatment;
30. Calls on Member States to inform patients about the risks and preventive measures relating to adverse events in healthcare, and about the complaint procedures and legal options available should an adverse event occur, via, for example, a patients' rights representative;
31. Calls on the Member States to take the necessary measures to avoid any conflict of interests affecting doctors and veterinarians in relation to prescription and sale of medicines;
32. Calls on the Member States to ensure that full information on existing mechanisms for complaint and redress is readily available to patients who have suffered an HAI or a medical error;
33. Invites the Commission to report on national practices of collective redress in HAI-related cases;
34. Recognizes the value of citizens' initiatives, such as the European Charter of Patients' Rights based on the Charter of Fundamental Rights of the European Union, and the European Patients' Rights Day, which has been organised every year on 18 April since 2007; invites the Commission and the Member States to support the European Patients' Rights Day at local, national and EU level;

#### *Fighting antimicrobial resistance*

##### *State of play and promising solutions*

35. Welcomes the Commission's work on antimicrobial resistance and on the prevention and control of HAIs, as well as the coordination and surveillance efforts of the ECDC, in particular in the framework of the European Antimicrobial Resistance Surveillance Network (EARS-Net), the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) and the Healthcare-Associated Infections surveillance Network (HAI-Net);
36. Welcomes the joint work of coordination and surveillance on antimicrobial resistance of the ECDC, the EMA and the European Food Safety Authority (EFSA);
37. Notes with concern that between 2010 and 2013 the percentages of *K. pneumoniae* resistant to fluoroquinolones, third-generation cephalosporins and aminoglycosides, as well as combined resistance to all three antibiotic groups and resistance to carbapenems, a last-line group of antibiotics, significantly increased in many Member States and at EU level; also notes that during the same period resistance to third-generation cephalosporins also significantly increased in many Member States and at EU level for *E. coli*; further notes that in certain regions of Europe MDR-TB accounts for as many as 20 % of all new tuberculosis cases, while treatment outcomes for MDR-TB are alarmingly low;
38. Notes with concern that in countries with high levels of multi-drug resistance, including resistance to carbapenems, only a few therapeutic options are available, among these being polymyxins; emphasises that in those countries the presence of bacteria resistant to polymyxins is a major warning that options for the treatment of infected patients are becoming even more limited;
39. Notes that infections caused by antimicrobial resistant bacteria are very likely to entail costly prolonged hospital stays as well as the use of alternative and more expensive therapeutic treatments which will place an increased burden on the Member States' healthcare systems;

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40. Regrets that the past 25 years have witnessed both a lack of awareness of the importance of rational use of antimicrobial agents, and antibiotics in particular, and a stagnation in drug development in the field of antimicrobial medicines, due in particular to the emergence of scientific, economic and regulatory barriers;
41. Notes that both Horizon 2020 and the EU Third Public Health Programme have placed emphasis on HAIs and antimicrobial resistance;
42. Notes that some existing and effective antibiotics are not available in several Member States, resulting in inappropriate selection of drug therapy, and therefore calls on the Member States and the Commission to examine how to keep effective antibiotics on the market;
43. Points out that antibiotic resistance often holds up treatment with the right antibiotics and that, when they are given the wrong antibiotics or treatment starts too late, patients with serious infectious diseases suffer grave complications which in some cases can be fatal;
44. Notes with great concern the high number of animals infected with bacteria that are resistant to antibiotics, and the risk of carry-over of these bacteria from infected meat to consumers;
45. Notes with great concern the link between veterinary use of antimicrobials and the development of antimicrobial resistance in farmers, and the risk of this resistance being spread by hospital treatment;
46. Welcomes initiatives and actions taken by the Member States, animal health professionals and animal owners aimed at ensuring responsible use of antimicrobials in animals and reducing antimicrobial use in animal husbandry;
47. Considers research for new antimicrobial drugs to be of the utmost importance, and calls on the Commission to use the European Fund for Strategic Investments (EFSI) to stimulate research by, for instance, supporting existing structures such as the Innovative Medicines Initiatives (IMI);
48. Calls for greater attention to be focused on the development of new antimicrobial agents aimed at new targets;
49. Welcomes and encourages further research into genuinely new antimicrobial drugs, in particular antibiotics with activity against prevalent multidrug-resistant Gram-negative bacteria and against diseases that are particularly prone to antimicrobial resistance, such as *K. pneumoniae*, *Acinetobacter*, *E. coli*, HIV, *Staphylococcus aureus*, tuberculosis and malaria; insists, however, that it is of primary importance to first of all ensure the responsible and sensible use of antimicrobials; welcomes and encourages further research into alternative methods aimed at fighting HAIs without using antibiotics and at combating MDR-TB;
50. Calls on the Commission and the Member States to accelerate research and development activities with a view to providing new tools to fight bacterial infections that are increasingly prevalent in Europe;
51. Calls on the Commission and the Member States to strengthen incentives for public and private sector cooperation to reinvigorate antibiotic development R&D;
52. Calls on the Member States to step up the level of cooperation with regard to patient safety and combating antimicrobial resistance, in order to limit and reduce the spread of resistant micro-organisms from one Member State to another;
53. Calls on the Commission and the Member States to use 'adaptive pathways' schemes and other regulatory tools for earlier patient access to innovative antibacterials to treat resistant infections;

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54. Calls on the Commission and the Member States to make use of the 'adaptive pathway' programme of the European Medicines Agency and to use all the regulatory tools at their disposal to enable more rapid access to innovative antibacterial treatment for patients;

55. Highlights the need for patients to be at the centre of any health policy, and encourages health literacy and patient involvement in treatment decision-making;

56. Considers it of paramount importance that the Commission should ensure the continuation of the EU Action Plan on Antimicrobial Resistance post-2016, emphasising how to overcome the scientific, regulatory and economic challenges associated with antimicrobial resistance, while including the prevention and control of healthcare-associated infections;

*Recommendations regarding antibiotic use in human medicine*

57. Recalls that self-medication with antibiotics should be strictly prohibited and stresses the necessity of enforcement of a 'prescription only' policy for antibacterials by the national competent authorities of the Member States;

58. Calls on the Member States to take suitable actions to ensure the responsible and sensible use in human medicine of all antimicrobial agents and in particular of antibiotics that are considered to be last-line treatment of bacterial infections in hospitals, bearing in mind that improper use of antibiotics for preventive purposes (including in hospitals) is one of the main contributory factors in the emergence of antibiotic resistance;

59. Calls on the Member States to promote access to high-quality drugs as well as adherence to full treatment circles for all patients, with specific support for the most vulnerable, as a way to prevent the development of resistance;

60. Urges Member States also to conduct research into so-called 'forgotten' antibiotics so that the range of pharmaceuticals from which to choose can be enlarged;

61. Calls on the Commission to engage in the work of the WHO in developing a new economic model in order to take into consideration public health concerns and needs;

62. Calls on the Member States and the Commission to start a reflection process to develop a new economic model, that de-links the volume of sales from the reward paid for a new antibiotic, which would reflect the societal value of a new antibiotic and allow for sufficient return on investment for the company, while the purchaser would gain the right to use the product and have full control over volumes;

63. Urges the Member States to implement or develop the following measures:

(a) remind physicians of the paramount importance of ensuring that the prescription of antibiotics for treatment is appropriate and responsible;

(b) ensure that, whenever possible, appropriate microbiological diagnosis is systematically performed before prescribing antibiotics, for instance by using new diagnostic tools that could allow point-of-care rapid diagnosis, and/or antibiograms, especially in the case of diseases which have a tendency to relapse, as well as work to abolish hurdles that prevent proper microbiological diagnosis, especially in the ambulant sector;

(c) regulate the prescription of antibiotics for treatment, and in particular strictly implement laws prohibiting the provision of antibiotics for treatments without prescription, so that an appropriate use of medicines is ensured, specifying the therapeutic objective and selecting the appropriate drug therapy;

(d) implement responsible marketing practices avoiding conflicts of interest between producers and prescribers of medicine;

(e) encourage the development of new revenue models whereby economic returns for companies are de-linked from prescribed volumes of antibiotics, while encouraging pharmaceutical innovation and balancing it with the sustainability of health systems;

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- (f) regulate the sale and distribution of antibiotics so that patients can only obtain the specific quantity of antibiotics as prescribed by their doctors, because in some Member States rules still exist which authorise the sale of antibiotics in bigger package sizes than those intended for a specific treatment;
- (g) ensure greater levels of patient adherence to and compliance with antibiotic and other appropriate treatments prescribed by medical professionals, and develop strategies aimed at increasing patient understanding of the importance of the responsible use of antibiotic treatments and the risks of increasing antimicrobial resistance;
- (h) monitor antibiotic resistance and the use of antibiotics in hospitals and ensure that antibiotics when used in hospitals are only used according to the correct indications, at the correct dose and for the shortest duration possible as recommended by evidence-based guidelines;
- (i) intensify infection control, in particular from a cross-border perspective, and especially by carefully monitoring potential carriage of multidrug-resistant bacteria, through proper screening of patients transferred from a country/region/hospital known for its high prevalence of multidrug-resistant bacteria, and isolating positive patients in individual rooms or by implementing 'cohort nursing';
- (j) develop a multi-stakeholder strategy on MDR-TB to encompass key aspects such as prevention, awareness-raising, diagnosis, appropriate treatment, and adherence and compliance to prescribed medication;
- (k) improve safety standards, especially for medical devices that are resistant to sterilisation (e.g. endoscopes), and undertake careful monitoring to ensure that medical devices originally designed and CE-marked for single use, if regenerated, meet all safety standards in order to protect consumer health;
- (l) launch awareness campaigns targeting a wide audience, including health education courses in schools on the rational use of antibiotics and the risks entailed by increasing antibiotic resistance and the importance of developing good personal hygiene practices; these campaigns should target the young and old, as well as parents and carers, and should be followed up by outcome assessments, keeping in mind the opportunities offered by e-health systems in this regard;
- (m) increase public funding and create new academic positions to focus on exploring and validating new approaches for treating bacterial infections;
- (n) increase, in particular, the incentives for research and development of new antimicrobials;
- (o) invite the ECDC to carry out field missions to give Member States scientific and technical assistance and training on antimicrobial resistance as foreseen in Article 9 of the ECDC Regulation (Regulation (EC) No 851/2004); those Member States that have not yet done so, and especially those in which antimicrobial resistance is already high or is increasing alarmingly, are particularly urged to invite the ECDC to carry out such missions;
- (p) make the records of hospitals and other healthcare facilities with regard to HAIs publicly available, so that patients can make informed choices;

64. Calls on the Commission to reflect on the consequences of the increased mobility provided for in Directive 2011/24/EU with regard to the enhanced antimicrobial resistance that could result from patients travelling throughout Europe for treatment;

*Recommendations regarding antibiotic use in veterinary medicine in general and in husbandry in particular*

65. Expresses concern that the joint report by EFSA and ECDC on antimicrobial resistance shows that bacteria which most frequently cause food-borne infections such as *Salmonella* and *Campylobacter* have exhibited significant resistance to common antimicrobials;

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66. Repeats its call made in its resolution of 27 October 2011 on the public health threat of antimicrobial resistance<sup>(1)</sup> for a phase-out of the prophylactic use of antibiotics in livestock farming, stressing that the livestock and intensive fish-farming sectors should focus on preventing disease through good hygiene, housing and animal husbandry, as well as strict bio-security measures, rather than the prophylactic use of antibiotics;

67. Calls on the Member States to introduce or develop the following measures:

- (a) promote and foster the responsible and sensible use in veterinary medicine, including medicated feed, of all antimicrobial agents, by allowing their use only for treatment after veterinary diagnosis, with specific additional consideration to antibiotics that are on the WHO list of critically important antimicrobials for human medicine;
- (b) introduce legal tools to restrict the use of antibiotics in animals if a significant risk to public health is identified;
- (c) implement tougher controls to limit the use of antibiotics in veterinary medicine; one of the ways to achieve this would be by restricting the right to prescribe antibiotics to professionally qualified veterinarians and by decoupling the veterinarians' right to both prescribe and sell antibiotics so as to eliminate all economic incentives;
- (d) launch awareness campaigns on the responsible use of antimicrobials for animals, including pets;
- (e) reduce the need for antibiotics by improving animal health through biosecurity measures, disease prevention and good management practices, and establish strong and clearer methodologies and priorities in the fight against the development of antimicrobial resistance;
- (f) ensure that livestock farming and aquaculture focus on disease prevention through good hygiene, housing and animal husbandry and on strict biosecurity measures, rather than the prophylactic use of antibiotics; it is known that sounder farm management and animal husbandry procedures can be achieved through a review of provisions on maximum animal density in livestock farming, as current herd sizes often prevent individual or smaller animal group treatment, thus incentivising prophylactic use of antimicrobials;
- (g) restrict the use of antibiotics in intensively reared livestock and encourage organic or extensive models of livestock rearing;
- (h) reduce the use of antibiotics in animals by progressively eliminating their use for prophylactic purposes where antibiotics are administered to animals for disease prevention, and minimise the need for metaphylaxis, i.e. the mass medication of animals to cure sick specimens on farms whilst preventing infections in healthy animals;
- (i) develop and implement national strategies or action plans for countering AMR, which would include, inter alia:
  - (i) implementation of national guidelines on the animal antimicrobial treatment to ensure responsible use of antimicrobials based on specific evidence and conditions in the respective Member States;
  - (ii) implementation of preventative animal health policies aimed at improving animal health status and reducing the need for use of antimicrobials in animal husbandry;
  - (iii) definition of the responsibilities of veterinarians in terms of animal health management and decision-making on the use of antimicrobials;

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<sup>(1)</sup> OJ C 131 E, 8.5.2013, p. 116.

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- (iv) implementation of continuous training for animal health professionals and animal owners;
- (j) confirm the prohibition of the use of antibiotics as growth promoters in livestock;
68. Urges the Member States to regulate any conflicts of interest and financial incentives involving veterinarians who both sell and prescribe antibiotics;
69. Calls on the European Medicines Agency to draw up a list of antibiotics used in animals for which a significant risk to public health has been identified;
70. Urges national authorities and the EMA to take or develop the following measures:
- (a) reinforce the existing risk assessment of new veterinary antimicrobial substances by identifying the main potential risks to public health at a very early stage of authorisation;
- (b) monitor the development of resistance in specific bacteria according to plans agreed between regulators and companies when a new antimicrobial substance is first approved in veterinary medicine;
- (c) monitor changes in the use of antimicrobials in animals as part of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project (led by the EMA) for measuring the impact of the actions implemented;
71. Calls on the co-legislator, when negotiating the proposal for a regulation on veterinary medicinal products (2014/0257(COD)), to follow a course of action that is in line with the One Health principle, and more particularly:
- to adopt provisions banning the off-label use in animals of antimicrobials authorised only in human medicine;
  - to support mandatory recording of the quantities of all antimicrobials used in livestock farming, to be communicated to the competent national authorities and made public by them on an annual basis;
  - to ensure that standards of quality, safety and efficacy of veterinary medicinal products are not lowered with the new legislation on such products and that those high standards are guaranteed throughout the veterinary medicinal product life-cycle;
  - to create an EU database with information on when, where, how and on which animals antimicrobials are used;
  - to prohibit the on-line sale of antimicrobials;
72. Calls on the co-legislator, when negotiating the proposal for a regulation on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC (2014/0255(COD)) to ensure that it includes provisions aiming to substantially limit the use of medicated feed containing antimicrobials for food-producing animals, and in particular to strictly prohibit the preventive use of antimicrobials included in medicated feed;
73. Calls on the Commission and the ECDC to carry out research into the potential direct or indirect damage arising from by the use of antimicrobials in pets, and to develop mitigation measures to reduce the risk of potential transmission of antimicrobial resistance from pets to people;
74. Points out that some Member States have already successfully phased out prophylactic use at farm level; calls on the Commission, therefore, to come forward with legislation to phase out the prophylactic use of antibiotics;

*Collaborative approaches within the European Union*

75. Calls on the Member States to cooperate on defining minimum patient safety standards and indicators for safety and quality of healthcare at the EU level, in consultation with all relevant stakeholders including patient organisations;

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76. Calls on the Commission and the Member States to further engage in a dialogue with all stakeholders and develop a coordinated, comprehensive and sustainable EU strategy for patient safety, as well as to put forward concrete solutions to be implemented at EU, national, regional, local and/or primary care levels;
77. Calls on the Member States and the Commission to start a reflection process together with the WHO in order to develop a new economic model that de-links the volume of antibiotics sales from the reward paid for a new antibiotic, ensuring a fair return on investment for the companies while safeguarding the sustainability of national health systems;
78. Calls on the Commission, the Member States and the pharmaceutical industry to optimise EU partnerships between academia and the pharmaceutical industry, as exemplified by the Innovative Medicines Initiative (IMI);
79. Encourages pharmaceutical companies, governments and academia to contribute with their best assets (infrastructure, compounds, ideas and financial resources) to ground-breaking fundamental research and pre-competitive joint projects; believes that the Innovative Medicine Initiative (IMI) should be given the flexibility to explore any new findings emerging from those projects;
80. Asks the Commission to consider a legislative framework to encourage the development of new antibiotic drugs, for example in the form of an instrument governing antibiotics for human use similar to that already proposed for antibiotics for animal use;
81. Encourages the further pursuit of private-public collaborations, such as the Innovative Medicine Initiative (IMI) programmes 'New Drugs for Bad Bugs', COMBACTE, TRANSLOCATION, Drive AB or ENABLE, in order to harness the power of collaboration;
82. Welcomes the Joint Programme Initiative on Antimicrobial Resistance, which allows Member States to agree on research needs so as to avoid duplication, and calls for an increase in funding for the development of new medicines as an alternative to antibiotics, in order to combat antimicrobial resistance;
83. Encourages the EU to join the global innovation fund that has been proposed by the 'Antibiotic Resistance Review' conducted in the UK, with the aim of supporting 'blue sky science';
84. Asks the Commission and the Member States to support easy-to-apply diagnostic tools in order to ensure greater availability of proper diagnosis before an antibiotic is prescribed or administered, especially in the ambulant sector;
85. Encourages the EU to promote and take part in any global initiative aimed at improving ways of combating antibiotic resistance, and to support research in this field;
86. Calls on the Commission to prepare, in collaboration with the Member States, recommendations on the food safety standards to be applied with respect to the presence of (multi)resistant pathogens and/or specified resistance determinants;
87. Stresses that antimicrobial resistance has become a serious problem that needs to be urgently tackled; calls on the Commission to consider proposing legislation on the prudent use of antibiotics if little or no progress has been made in the Member States within five years of the publication of these recommendations;

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88. Instructs its President to forward this resolution to the Council, the Commission, the Committee of the Regions and the Member States.
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