Basic information

2014/2207(INI) INI - Own-initiative procedure	Procedure completed
Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance **Subject** 4.20.01 Medicine, diseases 4.20.06 Health services, medical institutions 4.20.07 Medical and para-medical professions 4.60.08 Safety of products and services, product liability	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
ENVI Environment, Public Health and Food Safety	PEDICINI Piernicola (EFDD)	12/11/2014
	Shadow rapporteur BUŞOI Cristian-Silviu (PPE) SCHALDEMOSE Christel (S&D) PAULSEN Marit (ALDE)	

European Commission

Commission DG	Commissioner
Health and Food Safety	ANDRIUKAITIS Vytenis Povilas

Key events

Date	Event	Reference	Summary
19/06/2014	Non-legislative basic document published	COM(2014)0371	Summary
17/12/2014	Committee referral announced in Parliament		
14/04/2015	Vote in committee		
04/05/2015	Committee report tabled for plenary	A8-0142/2015	Summary
18/05/2015	Debate in Parliament		
19/05/2015	Decision by Parliament	T8-0197/2015	Summary
19/05/2015	Results of vote in Parliament		
19/05/2015	End of procedure in Parliament		

Technical information	
Procedure reference	2014/2207(INI)
Procedure type	INI - Own-initiative procedure
Procedure subtype	Initiative
Legal basis	Rules of Procedure EP 55
Other legal basis	Rules of Procedure EP 165
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/8/01521

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE549.124	04/02/2015	
Amendments tabled in committee		PE549.474	09/03/2015	
Committee report tabled for plenary, single reading		A8-0142/2015	04/05/2015	Summary
Text adopted by Parliament, single reading		T8-0197/2015	19/05/2015	Summary

European Commission

Document type	Reference	Date	Summary
Non-legislative basic document	COM(2014)0371	19/06/2014	Summary
Commission response to text adopted in plenary	SP(2015)470	24/09/2015	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	PT_PARLIAMENT	COM(2014)0371	22/07/2015	

Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance

2014/2207(INI) - 19/06/2014 - Non-legislative basic document

PURPOSE: presentation of Commission's Second Report on the implementation of Council Recommendation 2009/C 151/01 on patient safety, including the prevention and control of healthcare associated infections.

CONTENT: Council Recommendation 2009/C 151/01 set out a series of measures on general patient safety and healthcare-associated infections (HAI) and invited the Commission to report on whether the measures are working effectively and to consider the need for further action.

Results of 1st implementation report: the Commission's first report, which was published in 2012, demonstrated satisfactory progress in the development of national policies and programmes on patient safety. It showed, however, uneven progress across the EU. Some Member States reported that implementation had been slowed by financial constraints resulting from the economic crisis. The Commission therefore proposed that its monitoring of the implementation of the general patient safety provisions be extended for another two years.

Second report on patient safety: Member States have made progress on developing policies on patient safety since the Recommendation was adopted. 26 countries developed or are finalising patient safety strategies or programmes, either free-standing or under other national policies. Most gave examples of indicators to evaluate the strategies. However, the report states that the Recommendation has had **less of an impact in increasing patient safety culture at healthcare setting level,** i.e. encouraging health professionals to learn from errors in a blame-free environment.

Furthermore, the impact on empowering patients is only partial. According to countries' self-assessments, the Recommendation raised awareness about patient safety at healthcare setting level. Only half of countries judged that it had had an impact on empowering patient organisations and individual patients.

The report sets out the measures that have been taken at EU level and notes that the Commission's Green Paper on mHealth highlights benefits of using **telemedicine and mHealth solutions** for ensuring patient safety.

Amongst the results set out in the report, the following are noted :

1) Education and training of health professionals: in this area, the report notes that further effort is required. Most countries reported that they encouraged multidisciplinary training on patient safety in healthcare settings, but three quarters do not provide information about the actual delivery of such training in hospitals.

2) Public perception: the Recommendation did not change EU citizens' perception of the safety of care. As in 2009, over 50% of respondents thought that patients could be harmed by hospital and non-hospital care. Also, 25% of respondents said that they or their family experienced an adverse event. Patients now report considerably more adverse events than in 2009 (46% vs. 28%). Most respondents felt, however, that such reporting does not lead to specific action being taken.

3) Areas of interest identified by Member States and stakeholders: in their contributions to the report, Member States identified the following areas for further cooperation at EU level:

- patient safety policies and programmes;
- the development of blame-free reporting and learning systems and encouraging reporting by both health professionals and patients; and
- the development and review of patient safety standards.

4) EU action relating to healthcare-associated infections: the Recommendation provides that Member States should use case definitions agreed at EU level to allow consistent reporting of HAI. Commission Decision 2012/506/EU of 8 August 2012 includes in its annex **general and specific systemic case definitions of HAI**, including reporting instructions for each of the conditions. These case definitions of HAI will help not only to considerably improve surveillance across the EU, but will allow assessing the impact at EU level of the preventive measures undertaken.

In particular, the ECDC's Europe-wide point prevalence survey of HAI and antimicrobial use in 2011-12 contributed to the improved collection of data on HAI, even in Member States that had not previously started with this activity. Since the Recommendation was published, one EU-wide point prevalence survey was organised in acute care hospitals in 2011-12 (ECDC PPS) and two in long-term care facilities. **Overall, the level of participation in the European HAI surveillance modules was considered high in nine countries or regions** (AT, DE, ES, FR, IT, LT, MT, PT and UK-Scotland), medium in 13 (BE, CZ, EE, FI, HU, LU, NL, NO, RO, SK, UK-England, UK-Northern Ireland and UK-Wales) and low in 11 countries (BG, CY, DK, EL, HR, Iceland, IE, LV, PL, SE and SI).

The point prevalence report and the Commission's first implementation report indicate that

Member States should focus their efforts on ensuring the **targeted surveillance of HAI in surgical site infections, intensive care units and nursing homes** and other long-term care facilities.

Further measures by Member States are needed to improve the routine case ascertainment of HAI, through the development of national diagnostic guidelines, continued training of healthcare workers in applying case definitions of HAI and the reinforcement of laboratory and other diagnostic capacity in healthcare institutions. The report also discusses the need to establish: (i) adequate numbers of specialised infection control staff in hospitals and other healthcare institutions; (ii) sufficient isolation capacity for patients infected with clinically relevant microorganisms in acute care hospitals; (iii) standardised surveillance of alcohol hand rub consumption.

Other measures required in improving patient safety and quality of care : the report concludes with a series of additional measures that could be of particular relevance for further EU work, in close collaboration with Member States and stakeholders:

- common definition of quality of care and further support for the development of common terminology, common indicators and research on patient safety;
- EU collaboration on patient safety and quality of care to exchange good practices and effective solutions. This could build on the current joint action and be extended to other topics identified by Member States and stakeholders;
- developing guidelines on how to provide information to patients on quality of care;
- development with Member States of an EU template on patient safety and quality of care standards to achieve common understanding of this concept in the EU;
- reflection with Member States on the issue of redress as provided for in Directive 2011/24/EU ;

- encouraging the development of training for patients, families and informal carers using ICT tools;
- encouraging reporting as a tool to spread a patient safety culture;
- regular updating and dissemination of the guide on the setting-up and functioning of reporting and learning systems.

Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance

2014/2207(INI) - 19/05/2015 - Text adopted by Parliament, single reading

The European Parliament adopted by 637 votes to 32 with 10 abstentions a resolution on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance.

It recalled that globally, **10 million people would die every year because of antimicrobial resistance by 2050,** and that resistance to antibiotics that were commonly used to treat causative bacteria was at least 25 % or more in several Member States.

Ensuring patient safety during economic crisis: Parliament called on Member States to make sure, in this period of economic crisis, that **patient safety was not affected by austerity measures** and that healthcare systems remained adequately funded. Member States were further asked to avoid short-term savings, which would lead to high costs in the medium to long term and to ensure that there were a sufficient number of healthcare professionals specialised in infection prevention and control, as well as hospital hygiene, with a view to a more patient-centred approach. Amongst other things, the resolution called on Member States to set specific and ambitious quantitative targets for **reducing the use of antibiotics.**

At the same time, Parliament set out the state of play on the Council's recommendations on patient safety and the Commission's second implementation report on the matter (please see the summaries set out in procedure reference 2013/2022(INI)). Members feedback and proposals for improvements include the following:

- ensure that health managers were appointed on the basis of merit and not of political affiliation;
- ensure **basic training** of all healthcare personnel, even those who were not in direct contact with patients;
- ensure the appropriate and up-to-date training of doctors and other healthcare professionals, as well as the exchange of best practices;
- ensure the adoption of a multidisciplinary approach in medical treatments;
- lighten the burden on healthcare facilities by promoting care and medical treatment at home;
- ensure that medical professionals inform patients when a medicine was used off-label and provide patients with information on the potential risks in order to enable them to give informed consent;
- **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;
- **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';
- develop EU guidance for patients' involvement in patient safety strategies.

With regard to the need to **fight against antimicrobial resistance**, Parliament considered research for new antimicrobial drugs to be of the utmost importance, and called on the Commission to use the European Fund for Strategic Investments to stimulate research by, supporting existing structures such as the **Innovative Medicines Initiatives**. It called for greater attention to be focused on the development of new antimicrobial agents aimed at new targets. With regard to sales of antibiotics, Parliament called on Member States and the Commission to start a reflection process to **develop a new economic model, that de-linked 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.

Parliament also proposed the following measures:

- remind physicians of the paramount importance of ensuring that the prescription of antibiotics for treatment was appropriate and responsible;
- ensure that, whenever possible, appropriate microbiological diagnosis was systematically performed before prescribing antibiotics;
- regulate the prescription of antibiotics for treatment;
- **encourage the development of new revenue models whereby economic returns for companies were de-linked from prescribed volumes of antibiotics**, and at the same time, while encouraging pharmaceutical innovation;
- regulate the sale and distribution of antibiotics;
- intensify infection control, in particular from a cross-border perspective, and especially by carefully monitoring potential carriage of multidrug-resistant bacteria;
- improve safety standards, especially for medical devices that are resistant to sterilisation (e.g. endoscopes);
- **launch awareness campaigns targeting a wide audience**
- increase public funding and create new academic positions to focus on exploring and validating new approaches for treating bacterial infections.
- make the records of hospitals and other healthcare facilities with regard to HAIs publicly available, so that patients can make informed choices;

Parliament also asked 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.

Parliament also made a series of recommendations regarding antibiotic use in veterinary medicine in general and in husbandry in particular, notably:

- introduce legal tools to restrict the use of antibiotics in animals if a significant risk to public health is identified;
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- implement tougher controls to limit the use of antibiotics in veterinary medicine, 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;
- 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.

The Plenary did not adopt the position of its competent committee which had urges consideration of the possibility of banning antibiotics in medicated feed in the upcoming discussions on veterinary medicine and medicated feed legislation.

On the other hand, Parliament agreed with its competent committee in calling on co-legislators, when negotiating the proposal for a regulation on veterinary medicinal products (2014/0257(COD)), to ensure that standards of quality, safety and efficacy of veterinary medicinal products were not lowered with the new legislation and to **prohibit the on-line sale of antimicrobials.** Parliament also called for 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.

It went on to make recommendations on collaborative approaches within the EU, calling on Member States to cooperate on defining minimum patient safety standards and indicators for safety and quality of healthcare at the EU level. The Commission and the Member States were asked to further engage in a dialogue with all stakeholders and develop a coordinated, comprehensive and sustainable EU strategy for patient safety. They were also asked to optimise EU partnerships between academia and the pharmaceutical industry, and Members encouraged pharmaceutical companies, governments and academia to contribute with their best assets (infrastructure, compounds, ideas and financial resources) to ground-breaking fundamental research.

The resolution asked 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.

It also encouraged 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.

Lastly, Parliament stressed that **antimicrobial resistance had become a serious problem** that needed to be urgently tackled. It called on the Commission to consider proposing legislation on the prudent use of antibiotics if little or no progress had been made in Member States within five years of the publication of these recommendations.

Safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance

2014/2207(INI) - 04/05/2015 - Committee report tabled for plenary, single reading

The Committee on the Environment, Public Health and Food Safety adopted the own-initiative report by Piernicola PEDICINI (EFDD, IT) on safer healthcare in Europe: improving patient safety and fighting antimicrobial resistance.

Members recalled that globally, **10 million people would die every year because of antimicrobial resistance** by 2050, and that resistance to antibiotics that were commonly used to treat causative bacteria was at least 25 % or more in several Member States.

In this context, Members set out the state of play on the Council's recommendations on patient safety and the Commission's second implementation report on the matter (please see the summaries set out in procedure reference 2013/2022(INI)). Members feedback and **proposals for improvements** include the following:

- ensure that health systems and healthcare facilities were managed independently of political choices, and that managers were appointed on the basis of merit and not of political affiliation;
- ensure basic training of all healthcare personnel, even those who were not in direct contact with patients;
- ensure the appropriate and up-to-date training of doctors and other healthcare professionals, as well as the exchange of best practices;
- ensure the adoption of a multidisciplinary approach in medical treatments;
- lighten the burden on healthcare facilities by promoting care and medical treatment at home;
- ensure that medical professionals inform patients when a medicine was used off-label and provide patients with information on the potential risks in order to enable them to give informed consent;
- 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;
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With regard to the need to **fight against antimicrobial resistance**, Members proposed the following measures:

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They were also asked to optimise EU partnerships between academia and the pharmaceutical industry, and Members encouraged 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. The EU should take part in any global initiative aimed at improving ways of combating antibiotic resistance.

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