






Procedure file

Basic information		
CNS - Consultation procedure Recommendation	2009/0003(CNS)	Procedure completed
Patient safety, prevention and control of healthcare associated infections		
Subject		
4.20 Public health		
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
	 Environment, Public Health and Food Safety		15/01/2009
		PPE-DE SARTORI Amalia	
	Committee for opinion	Rapporteur for opinion	Appointed
	 Employment and Social Affairs	The committee decided not to give an opinion.	
	 Internal Market and Consumer Protection	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Employment, Social Policy, Health and Consumer Affairs2947		08/06/2009

Key events			
15/12/2008	Legislative proposal published	COM(2008)0837	Summary
03/02/2009	Committee referral announced in Parliament		
31/03/2009	Vote in committee		Summary
03/04/2009	Committee report tabled for plenary, 1st reading/single reading	A6-0239/2009	
23/04/2009	Results of vote in Parliament		
23/04/2009	Debate in Parliament		
23/04/2009	Decision by Parliament	T6-0287/2009	Summary
08/06/2009	Act adopted by Council after consultation of Parliament		
08/06/2009	End of procedure in Parliament		

Technical information	
Procedure reference	2009/0003(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Recommendation
Legal basis	EC Treaty (after Amsterdam) EC 152-p4
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/72156

Documentation gateway					
Legislative proposal		COM(2008)0837	15/12/2008	EC	Summary
Document attached to the procedure		SEC(2008)3004	15/12/2008	EC	
Document attached to the procedure		SEC(2008)3005	15/12/2008	EC	
Committee draft report		PE419.906	30/01/2009	EP	
Amendments tabled in committee		PE421.189	02/03/2009	EP	
Economic and Social Committee: opinion, report		CES0632/2009	24/03/2009	ESC	
Committee report tabled for plenary, 1st reading/single reading		A6-0239/2009	03/04/2009	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0287/2009	23/04/2009	EP	Summary
Commission response to text adopted in plenary		SP(2009)3507	25/06/2009	EC	
Non-legislative basic document		COM(2012)0658	13/11/2012	EC	Summary
Follow-up document		SWD(2012)0366	13/11/2012	EC	
Non-legislative basic document		COM(2014)0371	19/06/2014	EC	Summary

Additional information	
European Commission	EUR-Lex

Final act
EP/Council Recommendation 2009/703 OJ C 151 03.07.2009, p. 0001 Summary

Patient safety, prevention and control of healthcare associated infections

PURPOSE: proposal on general patient safety issues as well as on the prevention and control of healthcare associated infections.

PROPOSED ACT: Council Recommendation.

BACKGROUND: it is estimated that between 8% and 12% of patients admitted to hospitals in the EU suffer from adverse events whilst receiving healthcare. The Commission, through the 7th Framework Programme for Research and Development, supports research in health systems. The [White Paper](#) "Together for Health: A Strategic Approach for the EU 2008-2013" identifies patient safety as an area for action.

CONTENT: this proposal sets out recommendations for specific actions that Member States can take, either individually, collectively or with

the Commission, to improve the safety of patients.

With regard to general patient safety issues, Member States should:

- support the development of national policies and programmes by : designating the competent authority responsible for patient safety; embedding patient safety as a priority issue in health policies; and supporting the development of safer systems, processes and tools;
- empower and inform citizens and patients by involving patient organisations in the development of policies on patient safety, and disseminating information to patients on risk, levels of safety and measures in place to reduce or prevent errors, and ensure informed consent to treatment;
- strengthen reporting and learning systems on adverse events that provide adequate information on the extent, types and causes of errors, adverse events and near misses, and encourage healthcare workers actively to report;
- promote education and training of healthcare workers on patient safety by encouraging multi-disciplinary patient safety education and training of all health professionals and ensuring that patient safety receives proper attention in the higher education curricula;
- adequately classify, codify and measure patient safety, by working with the European Commission to develop common definitions and terminology, and to share comparable data on patient safety outcomes;
- share knowledge, experience and best practice at European level.

With regard to the prevention and control of healthcare associated infections, Member States should implement a national strategy for the prevention and control of healthcare associated infections, pursuing certain specified objectives. These include: implementing prevention and control measures to support the containment of healthcare associated infections; enhancing infection prevention and control at the level of the healthcare institutions; and supporting research.

Lastly, the Recommendation states that Member States should consider the establishment of an inter-sectoral mechanism for the coordinated implementation of the national strategy as well as for the purposes of information exchange and coordination with the Commission, the ECDC and the other Member States.

Patient safety, prevention and control of healthcare associated infections

The Committee on the Environment, Public Health and Food Safety adopted the report drawn up by Amalia SARTORI (EPP-ED, IT) amending, under the consultation procedure, the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare associated infections.

The main amendments are as follows;

Scale: Members point out that the numbers affected range from 6.7 million to 15 million hospital in-patients, along with more than 37 million primary care patients. It is estimated that, on average, healthcare-associated infections (HCAIs) occur in one patient in twenty, that is to say, 4.1 million patients a year in the EU, and that about 37 000 deaths are caused every year by the after-effects of such infections.

Reduction targets: Member States should provide the means necessary to bring about a 20% reduction in the number of persons in the European Union affected annually by adverse events resulting from healthcare, the target thus being to reduce such events by 900 000 cases a year by 2015.

Informing patients: patients should be informed about treatment risks and Member States should introduce legal mechanisms to facilitate the lodging of claims for damage to health, including against pharmaceutical companies. They must also identify those responsible for errors.

Education and training of healthcare workers: the report adds that Member States should provide adequate education and training for all healthcare workers so that they use medical technology appropriately in accordance with the function and specifications outlined in the instruction manuals in order to prevent health risks and adverse effects, including those arising from unintended reuse of devices.

Cooperation with the Commission: the scale and cost of the data collection, and use of the data collected, should not be disproportionate to the expected benefits. The data should only be collected in order to achieve the objective of reducing HCAIs through common learning.

Best practice: Members States should promote opportunities for cooperation and exchange of experience and best practice between hospital managers, clinical teams and patient groups across the European Union on patient safety initiatives at the local level.

Prevention and control of healthcare associated infections: the committee stressed the need to provide: (a) effective risk assessment mechanisms, including pre-admission diagnostic screening of patients; (b) adequate protection for healthcare staff, through vaccination, post-exposure prophylaxis, routine diagnostic screening, provision of personal protective equipment and the use of medical technology that reduces exposure to blood-borne infections; effective infection prevention and control in long-term nursing and rehabilitation facilities.

It also stressed that, to prevent nosocomial infections, all equipment with which patients come into contact has to meet the highest possible standards of cleanliness, hygiene, and, where necessary, asepsis.

Member States should therefore seek to guarantee the safety of staff as well as patients. As regards the ways of reducing the incidence of healthcare-associated infections, it would be useful to organise specifically targeted staff vaccination campaigns. Education and training of healthcare and paramedical workers at Member State level and at the level of healthcare institutions should focus in particular on nosocomial infections and viral antibiotic resistance.

Member States should also report every healthcare-associated infection outbreak affecting a significant number of patients to the European Centre for Disease Prevention and Control. They should Conduct awareness campaigns for the public and for healthcare workers with the aim of reducing practices which lead to antimicrobial resistance.

Actions by the Commission: the Commission should consider where existing Community legislation could be strengthened to improve patient safety, for example by ensuring that, when healthcare professionals cross borders within Europe, the professional regulators share information about any disciplinary procedures concluded or pending against individuals, and not just their initial qualifications.

Using the practical guide drawn up by the World Health Organisation in 2002, entitled 'Prevention of hospital-acquired infections', the Commission is invited to produce a document aimed at patients on the prevention of nosocomial infections.

Patient safety, prevention and control of healthcare associated infections

The European Parliament adopted by 521 votes to 6, with 5 abstentions, a legislative resolution amending, under the consultation procedure, the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare associated infections.

The main amendments are as follows:

Scale: Members point out that the numbers affected range from 6.7 million to 15 million hospital in-patients, along with more than 37 million primary care patients. It is estimated that, on average, healthcare-associated infections (HCAIs) occur in one patient in twenty, that is to say, 4.1 million patients a year in the EU, and that about 37 000 deaths are caused every year by the after-effects of such infections.

Reduction targets: Member States should provide the means necessary to bring about a 20% reduction in the number of persons in the European Union affected annually by adverse events resulting from healthcare, the target thus being to reduce such events by 900 000 cases a year by 2015. They should also set local and national targets for recruitment of health professionals specialising in infection control, taking into account the recommended target ratio of one nurse for every 250 hospital beds by 2015.

Informing patients: patients should be informed about treatment risks and Member States should introduce legal mechanisms to facilitate the lodging of claims for damage to health, including against pharmaceutical companies. There should also be confidential sharing of information between health authorities in different Member States on health professionals who have been found guilty of negligence or malpractice.

Education and training of healthcare workers: Member States should provide adequate education and training for all healthcare workers so that they use medical technology appropriately in accordance with the function and specifications outlined in the instruction manuals in order to prevent health risks and adverse effects, including those arising from unintended reuse of devices.

Cooperation with the Commission: the scale and cost of the data collection, and use of the data collected, should not be disproportionate to the expected benefits. The data should only be collected in order to achieve the objective of reducing HCAIs through common learning.

Best practice: Member States should promote opportunities for cooperation and exchange of experience and best practice between hospital managers, clinical teams and patient groups across the European Union on patient safety initiatives at the local level.

Prevention: the Parliament stressed the need to provide: (a) effective risk assessment mechanisms, including pre-admission diagnostic screening of patients; (b) adequate protection for healthcare staff, through vaccination, post-exposure prophylaxis, routine diagnostic screening, provision of personal protective equipment and the use of medical technology that reduces exposure to blood-borne infections; (c) effective infection prevention and control in long-term nursing and rehabilitation facilities.

It is also necessary to enhance infection prevention and control at the level of the healthcare institutions and ensure the highest standards of cleanliness, hygiene, and, where necessary, asepsis as regards medical equipment and patient care facilities.

In order to reduce nosocomial infections, it is also important to: (i) promote hand hygiene among health professionals; (ii) implement necessary staff vaccination campaigns; (iii) foster education and training of healthcare and paramedical, focusing in particular on nosocomial infections and viral antibiotic resistance; (iv) support research, for instance into potential medical applications of nanotechnologies and nanomaterials.

Member States should also: (i) report every healthcare-associated infection outbreak affecting a significant number of patients to the European Centre for Disease Prevention and Control; (ii) conduct awareness campaigns for the public and for healthcare workers with the aim of reducing practices which lead to antimicrobial resistance.

Actions by the Commission: the Commission should consider where existing Community legislation could be strengthened to improve patient safety, for example by ensuring that, when healthcare professionals cross borders within Europe, the professional regulators share information about any disciplinary procedures concluded or pending against individuals, and not just their initial qualifications.

Using the practical guide drawn up by the World Health Organisation in 2002, entitled 'Prevention of hospital-acquired infections', the Commission is invited to produce a document aimed at patients on the prevention of nosocomial infections. It is also called upon to bring forward proposals to prevent the circulation of counterfeit drugs and harm to patients and health workers from needlestick injuries.

Patient safety, prevention and control of healthcare associated infections

PURPOSE: to encourage Member States to take measures to improve patient safety, including the prevention and control of healthcare-associated infections.

ACT: Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.

CONTENT: it is estimated that in Member States between 8 % and 12 % of patients admitted to hospital suffer from adverse events whilst receiving healthcare. The European Centre for Disease Prevention and Control (ECDC) has estimated that, on average, healthcare associated infections occur in one hospitalised patient in 20, that is to say 4.1 million patients a year in the EU, and that 37 000 deaths are caused every year as a result of such infections.

The Community, through the seventh framework programme for research and development, supports research in the quality of healthcare provision. The Commission, in its [White Paper](#) 'Together for Health: A Strategic Approach for the EU 2008-2013?', identifies patient safety as an area for action.

This Recommendation lists the measures that Member States can take - alone, collectively or together with the Commission - in order to improve patient safety.

In terms of patient safety, Member States are called upon to:

- support the establishment and development of national policies and programmes by: (i) designating the competent authority or authorities responsible for patient safety on their territory; (ii) embedding patient safety as a priority issue in health policies and

- programmes; (iii) supporting the development of safer systems, including the use of information and communication technology; (iv) regularly updating safety standards and/or best practices; (v) encouraging health professional organisations to have an active role; (vi) including a specific approach to promote safe practices;
- empower and inform citizens and patients by: (i) involving patient organisations and representatives in the development of policies and programmes on patient safety; (ii) disseminating information to patients on: risk, safety measures which are in place to reduce or prevent errors and harm, and to facilitate patient choice and decision-making; complaints procedures and available remedies and redress and the terms and conditions applicable; (iii) considering the possibilities of development of core competencies in patient safety;
 - support the establishment or strengthen blame-free reporting and learning systems on adverse events;
 - promote education and training of healthcare workers on patient safety by: (i) encouraging multidisciplinary patient safety education and training of all health professionals; (ii) embedding patient safety in higher education, on-the-job training and the continuing professional development of health professionals; (iii) considering the development of the core knowledge, attitudes and skills required to achieve safer care; (iv) disseminating information to all healthcare workers on patient safety standards, risk and safety measures in place, including best practices; (v) collaborating with organisations involved in professional education in healthcare;
 - classify and measure patient safety by working with each other and with the Commission (to develop common definitions and terminology, develop a set of reliable and comparable indicators, and share comparable data and information at EU level);
 - share knowledge, experience and best practice by working with each other and with the Commission and relevant European and international bodies;
 - develop and promote research on patient safety.

In terms of the prevention and control of healthcare associated infections, Member States should:

- adopt and implement a national strategy, pursuing the following objectives: (i) implement prevention and control measures at national or regional level to support the containment of healthcare associated infections; (ii) enhance infection prevention and control at the level of the healthcare institutions; (iii) establish or strengthen active surveillance systems; (iv) foster education and training of healthcare workers; (v) improve the information to the patients by healthcare institutions; (vi) support research in fields such as epidemiology, the applications of nanotechnologies and nanomaterials, new preventive and therapeutic technologies and interventions and on the cost-effectiveness of infection prevention and control;
- consider the establishment, if possible by 9 June 2011, of an inter-sectoral mechanism or equivalent systems corresponding to the infrastructure in each Member State, collaborating with, or integrated into, the existing inter-sectoral mechanism as set up in accordance with Council [Recommendation No 2002/77/EC](#) on the prudent use of antimicrobial agents in human medicine.

The Commission is called upon to produce, by 9 June 2012, an implementation report to the Council assessing the impact of this Recommendation, on the basis of the information that Member States must provide by 9 June 2011.