

Thursday 23 April 2009

Patient safety *

P6_TA(2009)0287

European Parliament legislative resolution of 23 April 2009 on the proposal for a Council recommendation on patient safety, including the prevention and control of healthcare associated infections (COM(2008)0837 – C6-0032/2009 – 2009/0003(CNS))

(2010/C 184 E/74)

(Consultation procedure)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(2008)0837),
 - having regard to Article 152(4) of the EC Treaty, pursuant to which the Council consulted Parliament (C6-0032/2009),
 - having regard to Rule 51 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0239/2009),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to alter its proposal accordingly, pursuant to Article 250(2) of the EC Treaty;
 3. Calls on the Council to notify Parliament if it intends to depart from the text approved by Parliament;
 4. Asks the Council to consult Parliament again if it intends to amend the Commission proposal substantially;
 5. Instructs its President to forward its position to the Council and Commission.

TEXT PROPOSED BY THE COMMISSION

AMENDMENT

Amendment 1**Proposal for a recommendation****Recital 2**

(2) It is estimated that in EU Member States between 8 % and 12 % of patients admitted to hospitals suffer from adverse events whilst receiving healthcare.

(2) It is estimated that in EU Member States between 8 % and 12 % of patients admitted to hospitals suffer from adverse events whilst receiving healthcare; **the numbers affected range from 6,7 million to 15 million hospital in-patients, along with more than 37 million primary care patients.**

Amendment 2**Proposal for a recommendation****Recital 2 a (new)**

(2a) 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.

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Amendment 3**Proposal for a recommendation
Recital 3**

(3) Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. A large proportion of adverse events are preventable, both in the hospital sector and in primary care, with systemic factors appearing to account for a majority of them.

(3) Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. A large proportion of adverse events, **including those resulting from misdiagnosis and/or inappropriate treatment**, are preventable, both in the hospital sector and in primary care, with **limited financial resources and** systemic factors appearing to account for a majority of them.

Amendment 4**Proposal for a recommendation
Recital 6 a (new)**

(6a) Among the adverse events associated with healthcare, HCAIs are easily avoidable. Member States need to provide the means to enable the number of persons a year in the European Union affected by adverse events to be reduced by 20 %.

Amendment 5**Proposal for a recommendation
Recital 7**

(7) Evidence suggests that EU Member States are at different levels in the development and implementation of effective and comprehensive patient safety strategies. Therefore, this initiative intends to create a framework to stimulate policy development and future action in and between Member States to address the key patient safety issues confronting the EU.

(7) Evidence suggests that EU Member States are at different levels in the development and implementation of effective and comprehensive patient safety strategies. Therefore, this initiative intends to create a framework to stimulate policy development and future action in and between Member States to address the key patient safety issues confronting the EU, **above all the responsibility of healthcare establishments and institutions for people's health. In accordance with Article 152 of the EC Treaty, however, there must be no encroachment upon Member States' competences.**

Amendment 6**Proposal for a recommendation
Recital 8**

(8) Patients should be informed and empowered by involving them in the patient safety process; they should be informed of levels of safety and on how they can find accessible and comprehensible information on complaints and redress systems.

(8) Patients should be informed and empowered by involving them in the patient safety process; they should be informed of levels of safety and on how they can find accessible and comprehensible information on complaints and redress systems. **The individual Member State should, however, be competent for the type and method of compensation.**

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Amendment 7**Proposal for a recommendation
Recital 10**

(10) Comparable and aggregate data should be collected at Community level to establish efficient and transparent patient safety programmes, structures and policies, and best practices should be disseminated among the Member States. To facilitate mutual learning, a common terminology for patient safety and common indicators need to be developed through cooperation between Member States and the European Commission, taking into account the work of relevant international organisations.

(10) Comparable and aggregate data should be collected at Community level to establish efficient and transparent patient safety programmes, structures and policies, and best practices should be disseminated among the Member States. ***These data should only be used for the purposes of patient safety with respect to the control of HCAs.*** To facilitate mutual learning, a common terminology for patient safety and common indicators need to be developed through cooperation between Member States and the European Commission, taking into account the work of relevant international organisations.

Amendment 8**Proposal for a recommendation
Recital 11**

(11) Information and communication technology tools, such as electronic health records or e-prescriptions, can contribute to improve patient safety, for instance by systematically screening for potential medicinal product interactions or allergies.

(11) Information and communication technology tools, such as electronic health records or e-prescriptions, can contribute to improving patient safety, for instance by systematically screening for potential medicinal product interactions or allergies, ***as has been recognised in Commission Recommendation 2008/594/EC of 2 July 2008 on cross-border interoperability of electronic health record systems*** ⁽¹⁾.

⁽¹⁾ OJ L 190, 18.7.2008, p. 37.

Amendment 9**Proposal for a recommendation
Recital 12 a (new)**

(12a) Older people are more likely to succumb to infectious diseases whilst in hospital; therefore their needs as a specific group should be researched and steps taken to meet them so as to promote their rehabilitation and return to good health.

Amendment 10**Proposal for a recommendation
Recital 15**

(15) Insufficient data on healthcare associated infections are available to allow meaningful comparisons between institutions by surveillance networks, to monitor the epidemiology of healthcare associated pathogens and to evaluate and guide policies on the prevention and control of healthcare associated infections. Therefore, surveillance systems should be established or strengthened at the level of healthcare institutions and at regional and national level.

(15) Insufficient data on healthcare associated infections are available to allow meaningful comparisons between institutions by surveillance networks, to monitor the epidemiology of healthcare associated pathogens and to evaluate and guide policies on the prevention and control of healthcare associated infections. Therefore, surveillance systems should be established or strengthened at the level of healthcare institutions and at regional and national level. ***Better information gathering at regional, national and European level should make it possible to determine more easily what direct correlations exist between the quality of the patient safety policies, systems and arrangements laid down and the results achieved in that field.***

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Amendment 11**Proposal for a recommendation
Recital 15 a (new)**

(15a) Member States need to be able to reduce the number of persons affected by HCAIs. As regards the possible means to that end, it is essential to recruit more nurses specialising in infection control.

Amendment 12**Proposal for a recommendation
Recital 15 b (new)**

(15b) Furthermore, Member States and their healthcare institutions should consider the use of link staff to support specialist nurses at clinical level in acute and community facilities.

Amendment 13**Proposal for a recommendation
Recital 15 c (new)**

(15c) In order to reduce adverse events resulting from healthcare, Member States should be encouraged to 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.

Amendment 14**Proposal for a recommendation
Recital 16 a (new)**

(16a) The Commission should bring forward proposals to prevent the circulation of counterfeit drugs and harm to patients and health workers from needlestick injuries.

Amendment 15**Proposal for a recommendation
Part I – Chapter I a (new) – title****Ia. REDUCTION TARGETS****Amendment 16****Proposal for a recommendation
Part I – Chapter I a (new) – point 1**

(1) 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.

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Amendment 17**Proposal for a recommendation
Part I – Chapter II – point 1 – point a**

- (a) Designating the competent **authority or** authorities responsible for patient safety on their territory;
- (a) Designating the competent authorities **at the various levels of state and local government administration** responsible for patient safety **and supervision and coordination of measures to improve public health** on their territory;

Amendment 18**Proposal for a recommendation
Part I – Chapter II – point 1 – point c**

- (c) Supporting the development of safer systems, processes and tools, including the use of information and communication technology.
- (c) Supporting the development of safer, **user-friendly** systems, processes and tools, including the use of information and communication technology.

Amendment 19**Proposal for a recommendation
Part I – Chapter II – point 2 – point b a (new)**

- (ba) Informing patients about treatment risks and introducing legal mechanisms to facilitate the lodging of claims for damage to health, including against pharmaceutical companies.**

Amendment 20**Proposal for a recommendation
Part I – Chapter II – point 3 – point a**

- (a) Provide adequate information on the extent, types and causes of errors, adverse events and near misses;
- (a) Provide adequate information on the extent, types and causes of errors, adverse events and near misses **and identify those responsible;**

Amendment 21**Proposal for a recommendation
Part I – Chapter II – point 3 – point b a (new)**

- (ba) Provide for confidential sharing of information between health authorities in different Member States on health professionals who have been found guilty of negligence or malpractice.**

Amendment 22**Proposal for a recommendation
Part I – Chapter II – point 4 – point b a (new)**

- (ba) Providing 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.**

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Amendment 23**Proposal for a recommendation
Part I – Chapter II – point 5 – point c**

(c) To gather and share comparable data and information on patient safety outcomes in terms of type and number at EU level to facilitate mutual learning and inform priority setting.

(c) To gather and share comparable data and information on patient safety outcomes in terms of type and number at EU level to facilitate mutual learning and inform priority setting. *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.*

Amendment 24**Proposal for a recommendation
Part I – Chapter II – point 6 – point b a (new)**

(ba) Promoting 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.

Amendment 25**Proposal for a recommendation
Part I – Chapter III – point 1 – point -a (new)**

(-a) Provide effective risk assessment mechanisms, including pre-admission diagnostic screening of patients, in order to rapidly identify conditions requiring additional precautionary measures.

Amendment 26**Proposal for a recommendation
Part I – Chapter III – point 1 – point -a a (new)**

(-aa) Provide 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;

Amendment 27**Proposal for a recommendation
Part I – Chapter III – point 1 – point -a b (new)**

(-ab) Provide effective infection prevention and control in long-term nursing and rehabilitation facilities.

Amendment 28**Proposal for a recommendation
Part I – Chapter III – point 1 – point b**

(b) Enhance infection prevention and control at the level of the healthcare institutions;

(b) Enhance infection prevention and control at the level of the healthcare institutions *and ensure the highest standards of cleanliness, hygiene, and, where necessary, asepsis:*

(i) as regards supplies used at the time of admission of patients or during their stay;

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(ii) *as regards medical and paramedical equipment, electro-medical devices used for patients, and dispensing of medicines;*

(iii) *as regards patient care facilities;*

Amendment 29

Proposal for a recommendation
Part I – Chapter III – point 1 – point b a (new)

(ba) *Promote hand hygiene among health professionals;*

Amendment 30

Proposal for a recommendation
Part I – Chapter III – point 1 – point b b (new)

(bb) *Enhance prevention and control of the spread of diseases among, and their transmission by, medical and paramedical personnel, to that end implementing the requisite prevention-oriented policies, including the necessary staff vaccination campaigns;*

Amendment 31

Proposal for a recommendation
Part I – Chapter III – point 1 – point d

(d) Foster education and training of healthcare workers at Member State level and at the level of healthcare institutions;

(d) Foster education and training of healthcare *and paramedical* workers at Member State level and at the level of healthcare institutions, *focusing in particular on nosocomial infections and viral antibiotic resistance;*

Amendment 32

Proposal for a recommendation
Part I – Chapter III – point 1 – point e

(e) Improve the information given to patients;

(e) Improve the information given to patients, *using the social and health network as well as by means of information campaigns conducted from time to time in the press and on the radio, television and the Internet;*

Amendment 33

Proposal for a recommendation
Part I – Chapter III – point 1 – point f

(f) Support research.

(f) Support research, *for instance into potential medical applications of nanotechnologies and nanomaterials;*

Amendment 34

Proposal for a recommendation
Part I – Chapter III – point 1 – point f a (new)

(fa) *Report every HCAI outbreak affecting a significant number of patients to the European Centre for Disease Prevention and Control;*

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Amendment 35**Proposal for a recommendation****Part I – Chapter III – point 1 – point f b (new)**

- (fb) *Conduct awareness campaigns for the public and for healthcare workers with the aim of reducing practices which lead to antimicrobial resistance.*

Amendment 36**Proposal for a recommendation****Part II — Title**PART II: **REPORT** BY THE COMMISSIONPART II: **ACTIONS** BY THE COMMISSION**Amendment 37****Proposal for a recommendation****Part II – point 1 a (new)**

- (1a) *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.*

Amendment 38**Proposal for a recommendation****Part II – point 1 b (new)**

- (1b) *Using the practical guide drawn up by the World Health Organisation in 2002, entitled ‘Prevention of hospital-acquired infections’⁽¹⁾, the Commission is invited to produce a document aimed at patients on the prevention of nosocomial infections.*

⁽¹⁾ WHO, ‘Prevention of hospital-acquired infections. A practical guide’, first edition, December 2002 (second edition published in 2008)

Amendment 39**Proposal for a recommendation****Annex 1 – Definitions – ‘Adverse event’ – column 2**

Incident which results in harm to a patient. Harm implies impairment of structure or function of the body and/or any deleterious effect which arises from that.

Incident which results in harm to a patient **while undergoing medical treatment**. Harm implies **permanent or temporary** impairment of structure or function of the body and/or any deleterious effect which arises from that.

Amendment 40**Proposal for a recommendation****Annex 1 – Definitions – ‘Healthcare institution’ – column 2**

An institution where healthcare workers provide secondary or tertiary care.

A public, non-public or charitable healthcare institution, where healthcare workers **or volunteers** provide secondary or tertiary care.

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Amendment 41

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Annex 1 – Definitions – ‘Patient safety’ - column 2

Freedom for a patient from unnecessary harm or potential harm associated with healthcare.

Absence of adverse events, where an adverse event is defined as a harmful incident due more to the treatment than to the illness. This adverse event may be avoidable or unavoidable.

Amendment 42

Proposal for a recommendation

Annex 1 – Definitions – ‘Infection control link staff’ - column 2

Health professionals working in *clinical wards/departments* who act as a liaison between their *wards/departments* and the Infection Prevention and Control Team. Infection control link staff *helps* promote infection prevention and control in their *wards/departments* and give feedback to the Infection Prevention and Control Team.

Health professionals working in *the corresponding sectors* who act as a liaison between their *work sector* and the Infection Prevention and Control Team. Infection control link staff *help* promote infection prevention and control in their *sectors* and give feedback to the Infection Prevention and Control Team.

Amendment 43

Proposal for a recommendation

Annex 2 – Chapter I – point 1 – point ba (new)

(ba) Accepting and facilitating the use of information and communication technology tools, such as electronic instructions for use, in order to improve the understanding of users of the medical products.

Amendment 44

Proposal for a recommendation

Annex 2 – Chapter I – point 4 – point ca (new)

(ca) Providing 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.

Amendment 45

Proposal for a recommendation

Annex 2 – Chapter 1 – point 7 – point aa (new)

(aa) Encouraging research, for example into medical applications of nanotechnologies and nanomaterials.

Amendment 46

Proposal for a recommendation

Annex 2 – Chapter 2 – point 1 – point a – indent 2

— Integrating infection prevention and control measures into patient care plans;

— Integrating infection prevention and control measures into patient care plans, *including the necessary staff vaccination campaigns;*