

EUROPEAN PARLIAMENT

2004



2009

Session document

A6-0239/2009

3.4.2009

REPORT

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))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Amalia Sartori

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. In the case of amending acts, passages in an existing provision that the Commission has left unchanged, but that Parliament wishes to amend, are highlighted in **bold**. Any deletions that Parliament wishes to make in passages of this kind are indicated thus: [...]. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). Suggested corrections of this kind are subject to the agreement of the departments concerned.

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION.....	5
EXPLANATORY STATEMENT.....	27
PROCEDURE.....	29

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**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))**

(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.

Amendment 1

Proposal for a recommendation

Recital 2

Text proposed by the Commission

(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.

Amendment

(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.***

Justification

It is important to spell out, and understand the scale of, the problem and its public health implications.

Amendment 2

Proposal for a recommendation

Recital 2 a (new)

Text proposed by the Commission

Amendment

(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.

Justification

Healthcare-associated infections (HCAIs) are among the most frequent and destructive causes of unintended harm.

Amendment 3

Proposal for a recommendation

Recital 3

Text proposed by the Commission

Amendment

(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.

Justification

Unless there is a steady increase in resources for the health system, systemic factors and organisational solutions will not change anything.

The impact assessment (SEC(2008)3005) has shown that medical errors and misdiagnosis are one of the main causes of adverse events associated with healthcare.

Amendment 4

Proposal for a recommendation

Recital 6 a (new)

Text proposed by the Commission

Amendment

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

Justification

Commission studies show that a 20% reduction in adverse events would be achievable, since infection control methods are well practised and quick to implement. Healthcare-associated infections cause about 37 000 deaths every year. That being the case, a reduction target should be set for Member States, which should be called upon to meet it by 2015.

Amendment 5

Proposal for a recommendation

Recital 7

Text proposed by the Commission

Amendment

(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.

Justification

Healthcare providers' responsibility towards patients needs to be stressed.

Support is given to avoiding the duplication of work. Close attention should be paid to WHO activities and the Council of Europe recommendations in the field of patient safety and any additional measures at Community level should be dovetailed to provide synergies. Detailed requirements and guidelines on patient safety issues at European level are, however, rejected with reference to Article 152.

Amendment 6

Proposal for a recommendation

Recital 8

Text proposed by the Commission

(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.

Amendment

(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.***

Justification

It is important that members of the public who have suffered as a result of healthcare failures receive sufficient compensation. The Rome I and Rome II Regulations already determine the applicable law for cross-border cases within the EU. There must be no encroachment upon Member States' competences.

Amendment 7

Proposal for a recommendation

Recital 10

Text proposed by the Commission

(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.

Amendment

(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.

Justification

Data protection rules must be followed when collecting these data. There should be no misuse.

Amendment 8

Proposal for a recommendation

Recital 11

Text proposed by the Commission

(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.

Amendment

(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 systems¹.***

¹ OJ L 190, 18.7.2008, p. 37.

Amendment 9

Proposal for a recommendation Recital 12 a (new)

Text proposed by the Commission

Amendment

(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.

Justification

Older people are likely to have weaker immune systems and are more likely than younger people to pick up infectious diseases if they have hospital care. Research should be conducted into their unique needs because older patients should not receive a lower standard of healthcare than other citizens, and the aim should be to rehabilitate all citizens.

Amendment 10

Proposal for a recommendation Recital 15

Text proposed by the Commission

Amendment

(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.

Justification

Surveillance systems need to be improved in order to obtain more complete data on HCAs and determine what correlations exist between the policies, systems, and arrangements laid down and the results achieved. This will help to raise the standard of patient care and reduce hospital-acquired infections.

Amendment 11

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

Text proposed by the Commission

Amendment

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

Justification

Commission studies show that approximately 8700 nurses specialising in infection control need to be recruited if healthcare-associated infections are to be reduced rapidly and effectively. The optimum ratio is one specialist HCAI nurse for every 250 hospital beds.

Amendment 12

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

Text proposed by the Commission

Amendment

(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)

Text proposed by the Commission

Amendment

(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.

Justification

An increased number of healthcare professionals specialising in infection control is needed to improve patient safety standards. However, the specific number of staff required will depend on the type of treatment being carried out at the hospital and so targets should be set at the local and national level.

Amendment 14

Proposal for a recommendation Recital 16 a (new)

Text proposed by the Commission

Amendment

(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

Text proposed by the Commission

Amendment

REDUCTION TARGETS

Amendment 16

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

Text proposed by the Commission

Amendment

(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.

Justification

Commission studies show that adverse events could be reduced by 900 000 cases a year, since infection control methods are well practised and quick to implement. Healthcare-associated infections cause some 37 000 deaths a year. It is therefore important to set a reduction target for Member States to meet by 2015.

Amendment 17

Proposal for a recommendation Part I – Chapter II – point 1 – subparagraph a

Text proposed by the Commission

Amendment

(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;

Justification

Bodies responsible for coordinating public health measures at regional level do not exist in all the Member States (e.g. Poland).

Amendment 18

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

Text proposed by the Commission

Amendment

(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.

Justification

The development of systems, processes, and tools should allow for the needs and abilities of their users.

Amendment 19

Proposal for a recommendation
Part I – Chapter II – point 2 – subparagraph b a (new)

Text proposed by the Commission

Amendment

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

Justification

In the new Member States, many people are unaware of their rights and of the remedies they can obtain and from whom. Moreover, they do not know to whom they should turn in order to assert their rights.

Amendment 20

Proposal for a recommendation
Part I – Chapter II – point 3 – subparagraph a

Text proposed by the Commission

Amendment

(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;***

Justification

Patients must know exactly who is responsible for what.

Amendment 21

Proposal for a recommendation

Part I – Chapter II – point 3 – subparagraph b a (new)

Text proposed by the Commission

Amendment

(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 – subparagraph b a (new)

Text proposed by the Commission

Amendment

(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.

Justification

Healthcare workers need to have the best possible knowledge about the proper functioning and use of the products they use in treatments. Only this knowledge enables them to minimise the risks for patients and themselves which could arise from wrong application of medical devices, for example by reusing devices which are designed and manufactured for one use on one patient only.

Amendment 23

Proposal for a recommendation
Part I – Chapter II – point 5 – subparagraph c

Text proposed by the Commission

Amendment

(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 HCAs through common learning.***

Justification

The cooperation sought between Member States and the Commission with respect to classification, codification and data collection should not result in the Commission obtaining the right to draw conclusions from the data collected.

Amendment 24

Proposal for a recommendation
Part I – Chapter II – point 6 – subparagraph b a (new)

Text proposed by the Commission

Amendment

(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 – subparagraph -a (new)

Text proposed by the Commission

Amendment

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

additional precautionary measures.

Justification

It is vitally important that patients are assessed prior to admission, and that those carrying infections, such as MRSA, are quickly diagnosed and treated, to safeguard their health and to prevent them passing infections on to other patients and to healthcare staff.

Amendment 26

Proposal for a recommendation

Part I – Chapter III – point 1 – subparagraph -a a (new)

Text proposed by the Commission

Amendment

(-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;

Justification

Healthcare staff risk potentially fatal infections every day and can spread infections amongst patients and out into the community.

Amendment 27

Proposal for a recommendation

Part I – Chapter III – point 1 – subparagraph -a b (new)

Text proposed by the Commission

Amendment

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

Justification

It is important that long-term nursing homes are not overlooked. Close living proximity, building design, multiple medications, pressure sores and catheter usage all make nursing homes ideal for breeding and spreading MRSA and other infections.

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

Text proposed by the Commission

Amendment

(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;

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

(iii) as regards patient care facilities;

Justification

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.

Amendment 29

**Proposal for a recommendation
Part I – Chapter III – point 1 – subparagraph b – new indent**

Text proposed by the Commission

Amendment

- promote hand hygiene among health professionals;

Justification

Infection is usually spread on the hands of healthcare staff and other people who come into contact with infected patients or with environmental surfaces.

Proposal for a recommendation

Part I – Chapter III – point 1 – subparagraph b – new indent

Text proposed by the Commission

Amendment

- 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;

Justification

Medical and paramedical personnel are not just exposed to the danger of catching diseases and healthcare-associated infections, but are also potential carriers. 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.

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

Text proposed by the Commission

Amendment

(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**;

Justification

The fact that viruses are resistant to antibiotics is one of the main reasons for nosocomial infections and should feature prominently in the training provided to healthcare personnel at every level. To enable nosocomial infections to be reduced, all staff working in healthcare facilities need to be given thorough training on a continuing basis.

Amendment 32

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

Text proposed by the Commission

Amendment

(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**;

Justification

Patients need to be fully informed about risks, degrees of safety, and the measures applied to avert errors and nosocomial infections. Information campaigns should consequently be organised at regular intervals, using the various types of media.

Amendment 33

Proposal for a recommendation

Part I – Chapter III – point 1 – paragraph f

Text proposed by the Commission

Amendment

(f) Support research.

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

Justification

Nanotechnologies have many applications, those in the health field being among the most promising. For example, altering surface nanostructures of hospital building materials so as to make surfaces clean or sterile could be a helpful way to control healthcare-associated infections.

Amendment 34

Proposal for a recommendation

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

Text proposed by the Commission

Amendment

(fa) Report every healthcare-associated infection outbreak affecting a significant number of patients to the European Centre for Disease Prevention and Control.

Amendment 35

Proposal for a recommendation

Part I – Chapter III – point 1 – subparagraph f b (new)

Text proposed by the Commission

Amendment

(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

Text proposed by the Commission

Amendment

PART II: **REPORT** BY THE
COMMISSION

PART II: **ACTIONS** BY THE
COMMISSION

Justification

Nanotechnologies have many applications, those in the health field being among the most promising. For example, altering surface nanostructures of hospital building materials so as to make surfaces clean or sterile could be a helpful way to control healthcare-associated infections.

Amendment 37

Proposal for a recommendation Part II – point 1 a (new)

Text proposed by the Commission

Amendment

(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 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

(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).

Justification

The WHO practical guidelines on infection control at points of care, drawn up in 2003, have proved to be very useful. They are, however, intended specifically for healthcare personnel. A European document aimed specially at patients might prove valuable from the point of view of nosocomial infection control, as well as enabling patients to gain a basic understanding of patient safety.

Amendment 39

**Proposal for a recommendation
Annex 2 – line 3 – column 2**

Text proposed by the Commission

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.

Amendment

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.

Justification

The definition of adverse events should also cover temporary impairment of a bodily structure or function.

Amendment 40

**Proposal for a recommendation
Annex 1 – line 4 – column 2**

Text proposed by the Commission

An institution where healthcare workers provide secondary or tertiary care.

Amendment

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

or tertiary care.

Justification

The definition given in the proposal fails to cover the various types of healthcare organisation existing within the EU and the fact that there are clinics, hospitals and palliative care centres that are run by religious orders, faith-based associations and charitable organisations and foundations.

Amendment 41

Proposal for a recommendation

Annex 1 – line 12 – column 2

Text proposed by the Commission

Amendment

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 – line 7 – column 2

Text proposed by the Commission

Amendment

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.

Justification

Preference should be given here to a more neutral definition in order to highlight the fact that infections can occur not just in hospitals but also in other healthcare sectors, such as doctors' practices. A high level of patient safety also has to be guaranteed in these sectors so that no further patients are put at risk during subsequent treatment.

Amendment 43

Proposal for a recommendation
Annex 2 – Chapter I – point 1 – subparagraph b a (new)

Text proposed by the Commission

Amendment

(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.

Justification

Enhancing healthcare workers' understanding of the proper functioning and use of medical products reduces the likelihood of misuse and therefore the risks for patients treated with these products. New ICT tools, such as electronic manuals, including pictures or films, could help raise the level of understanding of medical products significantly.

Amendment 44

Proposal for a recommendation
Annex 2 – Chapter I – point 4 – subparagraph c a (new)

Text proposed by the Commission

Amendment

(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.

Justification

Healthcare workers need to have the best possible knowledge about the proper functioning and use of the products they use in treatments. Only this knowledge enables them to minimise the risks of health of patients and themselves which could arise from wrong application of medical devices, for example by reusing devices which are designed and manufactured for one use on one patient only.

Amendment 45

Proposal for a recommendation Annex 2 – part 1 – point 7 – subpoint a a (new)

Text proposed by the Commission

Amendment

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

Justification

Nanotechnologies have many applications, those in the health field being among the most promising. For example, altering surface nanostructures of hospital building materials so as to make surfaces clean or sterile could be a helpful way to control healthcare-associated infections.

Amendment 46

Proposal for a recommendation Annex 2 – Chapter 2 – point 1 – subparagraph a – indent 2

Text proposed by the Commission

Amendment

- 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;***

Justification

Medical and paramedical personnel are not just exposed to the danger of catching diseases and healthcare-associated infections, but are also potential carriers. 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.

EXPLANATORY STATEMENT

Healthcare standards in Europe are continuing to rise, driven by the constant advances in medical science, which, among other things, are enabling hospital stays to be greatly shortened or even avoided altogether.

However, medical procedures can sometimes damage patients' health. Some adverse effects are associated with the risks inherent in operations or drugs, but others are caused by avoidable medical errors or by infections which arise in places of treatment.

Commission studies show that adverse events occur in between 8% and 12% of patients admitted to EU hospitals. In numerical terms, this amounts to 6.7 to 15 million hospital in-patients. Added to that there are some 37 million primary care patients a year who suffer adverse effects linked directly to the treatment administered to them.

Among the most common adverse effects are infections contracted in hospitals and other points of care. On average, these occur in 1 hospital patient in 20, giving an annual total of 4.1 million patients.

Even more worryingly, nosocomial infections kill approximately 37 000 people every year; they are among the most frequent and destructive causes of unintended harm.

There are a number of factors which help to trigger, and contribute to the spread of, nosocomial infections, including:

- viral antibiotic resistance,
- a high bed occupancy rate,
- the increase in patient transfers,
- an inadequate staff to patient ratio,
- a failure to pay proper heed to hand hygiene and various other practices serving to prevent infections,
- incorrect use of medical devices.

In most cases, the adverse effects associated with healthcare in general, and nosocomial infections in particular, could be avoided. Every year 8% to 12% of patients suffer adverse effects on account of the treatment that they have undergone: that bracket can and must be made smaller.

To achieve that aim, the EU and the Member States need first of all to grasp the scale of the phenomenon by gathering information at regional, national, and European level. The data will make it possible to determine with greater certainty what correlations exist between the quality of the policies, systems, and arrangements laid down and performance in terms of greater patient safety.

It is also important for Member States to have clear-cut targets for improving the care delivered to their citizens. A 20% reduction in healthcare-associated infections by 2015 is, from that point of view, a desirable and feasible target, given that infection control methods are well practised and quick to implement. Public health is a prime asset and a right. Infections contracted as a result of treatment administered kill 37 000 people a year: that is too high a figure for EU citizens to accept.

To meet the target of reducing these infections by 900 000 cases a year (20% reduction), the Member States and the European institutions are called upon, in accordance with their respective responsibilities, to provide the necessary means. The policies to pursue could include the following:

- increasing the numbers of nurses specialising in infection control;
- encouraging education and training for healthcare and paramedical workers, focusing especially on nosocomial infections and the antibiotic resistance of the viruses which cause them;
- supporting research, laying particular emphasis on new technologies.

Without infringing the subsidiarity principle, the European institutions and the Commission in particular have to play a leading role in this area so as to facilitate the exchange of data and best practice. Specifically, the rapporteur believes that the Commission should be asked to produce a document aimed at patients on the prevention of nosocomial infections and submit it to Parliament and the Council.

Finally, she wishes to draw attention to the need for rapid practical solutions enabling nosocomial infections in Europe to be permanently reduced as and where necessary. She therefore believes that targets should be set for the Member States, even if they are not binding. Furthermore, the Commission should be called upon to report to Parliament in three years' time on the progress made by the Member States as well as at EU level.

PROCEDURE

Title	Patient safety	
References	COM(2008)0837 – C6-0032/2009 – 2009/0003(CNS)	
Date of consulting Parliament	23.1.2009	
Committee responsible Date announced in plenary	ENVI 3.2.2009	
Committee(s) asked for opinion(s) Date announced in plenary	EMPL 3.2.2009	IMCO 3.2.2009
Not delivering opinions Date of decision	EMPL 11.2.2009	IMCO 12.3.2009
Rapporteur(s) Date appointed	Amalia Sartori 15.1.2009	
Discussed in committee	17.2.2009	
Date adopted	31.3.2009	
Result of final vote	+	50
	-	0
	0:	0
Members present for the final vote	Adamos Adamou, Georgs Andrejevs, Margrete Auken, Liam Aylward, Pilar Ayuso, Irena Belohorská, Maria Berger, Johannes Blokland, John Bowis, Frieda Brepoels, Hiltrud Breyer, Martin Callanan, Dorette Corbey, Magor Imre Csibi, Chris Davies, Avril Doyle, Edite Estrela, Anne Ferreira, Alessandro Foglietta, Matthias Groote, Françoise Grossetête, Cristina Gutiérrez-Cortines, Gyula Hegyi, Marie Anne Isler Béguin, Dan Jørgensen, Christa Kläß, Urszula Krupa, Jules Maaten, Marios Matsakis, Linda McAvan, Péter Olajos, Miroslav Ouzký, Vladko Todorov Panayotov, Vittorio Prodi, Dagmar Roth-Behrendt, Guido Sacconi, Daciana Octavia Sârbu, Amalia Sartori, Bogusław Sonik, María Sornosa Martínez, Thomas Ulmer, Anja Weisgerber, Glenis Willmott	
Substitute(s) present for the final vote	Iles Braghetto, Nicodim Bulzesc, Christofer Fjellner, Milan Gaľa, Johannes Lebech	
Substitute(s) under Rule 178(2) present for the final vote	Christopher Heaton-Harris, Søren Bo Søndergaard	
Date tabled	3.4.2009	