EUROPEAN PARLIAMENT 2009 - 2014

Committee on Employment and Social Affairs

2012/0266(COD)

20.6.2013

OPINION

of the Committee on Employment and Social Affairs

for the Committee on the Environment, Public Health and Food Safety

on the proposal for a regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
(COM(2012)0542 – C7-0318/2012 – 2012/0266(COD))

Rapporteur: Edite Estrela

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SHORT JUSTIFICATION

On 26 September 2012, the Commission adopted a package on innovation in health consisting of a Communication on safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals, a Proposal for a Regulation of the EP and of the Council on medical devices, and a Proposal for a Regulation of the EP and of the Council on *in vitro* diagnostic medical devices. These proposals aim to update the existing European legislation in light of technological and scientific progress and to address recently voiced concerns over certain aspects of patient safety.

The proposal for a Regulation on medical devices, which will replace Directive 90/385/EEC regarding active implantable medical devices, and Directive 93/42/EEC, regarding medical devices, aims to regulate the standards of safety, quality and efficiency of medical devices which can be placed on the market in the European Union.

Under this proposed legislation, the hundreds of thousands of different types of medical devices currently on the market in the European Union, ranging from sticking plasters, syringes, catheters and blood sampling devices to sophisticated implants and life-support technologies, are required to be safe not only for patients but also for the healthcare professionals who use or handle them and for lay persons who come into contact with them.

As laid down in Recital 71 of the proposal, the objective of this Regulation is to ensure high standards of quality and safety for medical devices allowing for a high level of protection of health and safety for patients, users and other persons. The term "user" is defined in the current proposal as "any healthcare professional or lay person who uses a device" and the Regulation recognises that users are an essential component in providing safe health to patients. Medical devices are used mainly in hospital settings by healthcare professionals but also in other environments, including long-term care homes, patients' homes and prisons. Those at risk include healthcare workers who use the products, ancillary workers (such as laundry, cleaning and refuse collection staff) as well as patients and the general public. As such, safe medical devices contribute directly to working conditions and need to provide for the safest possible working environment.

"Health and safety" is mentioned throughout the Regulation as an overarching goal. In this spirit, the proposal includes, in Annex I, the general safety and performance requirements for medical devices. Under point 8 of Annex I it explicitly states that "the devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and where applicable other persons". Point 11 of the same Annex also underlines the need for devices to avoid risk of injury to patients, users and other persons.

The relationship between safe and high quality medical devices and the overarching goal of ensuring health and safety for users, patients and other persons allows for this proposed Regulation to synergise with applicable EU legislation on occupational health. The Regulation should therefore incorporate explicit references to legislation providing for high

levels of safety for users and patients in healthcare settings and take into account design and performance characteristics of medical devices cited in relevant EU Directives on occupational health. This is certainly the case with Directive 2010/32/EU on the prevention from sharp injuries in the hospital and healthcare sector, which aims to improve occupational safety following a Framework Agreement between the social partners at EU level which recognises the need to provide medical devices which incorporate safety-engineered protection mechanisms in order to limit the risk of injuries and infections from medical sharps. Therefore, it is entirely logical for such a provision to be recognised in the general safety and performance requirements of the medical devices Regulation.

It is not only frontline medical staff, such as nurses and doctors, who are at risk, but also caregivers in outpatient and alternative healthcare settings, laboratory staff and support workers such as cleaners, laundry workers, prison staff, etc.

Healthcare institutions need to make sure that their employees receive the necessary training for the correct use of medical devices, tools and practices that help reduce needlestick injuries, the transmission of healthcare associated infections and other adverse effects in order to ensure the safe use of new medical technology and surgical techniques.

All healthcare workers should also receive adequate protection, 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.

The proposals put forward in this draft opinion take into account the previous work of the Employment and Social Affairs committee and its resolutions adopted to ensure the safety of workers in the healthcare environment, namely:

- European Parliament resolution on the mid-term review of the European strategy 2007-2012 on health and safety at work adopted on 15 December 2011,

- European Parliament resolution on the proposal for a Council directive implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU adopted on 11 February 2010,

- European Parliament resolution on the Community strategy 2007-2012 on health and safety at work adopted on 15 January 2008,

- European Parliament resolution with recommendation to the Commission on protecting European healthcare workers from blood-borne infections due to needlestick injuries adopted on 6 July 2006.

AMENDMENTS

The Committee on Employment and Social Affairs calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.	(2) This Regulation aims to ensure the functioning of the internal market as regards medical devices, taking as a base a high level of protection of health ***for patients, users and operators***. At the same time, this Regulation sets high standards of quality and safety for medical devices to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 TFEU, this Regulation harmonises the rules for the placing on the market and putting into service of medical devices and their accessories on the Union market which may then benefit from the principle of free movement of goods. As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for those medical devices by ensuring, among other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

Amendment 2

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety.	(3) Key elements of the existing regulatory approach, such as the supervision of notified bodies, conformity assessment procedures, clinical investigations and clinical evaluation, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding devices should be introduced, to improve health and safety ***for health professionals, patients, users and operators, including in the waste disposal chain***.

Amendment 3

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health protection, free movement of goods ***and*** legal certainty for manufacturers, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles that can be released to the human body and those devices should be subject to the most severe conformity assessment procedure.	(13) There is scientific uncertainty about the risks and benefits of nanomaterials used for medical devices. In order to ensure a high level of health ***and safety*** protection ***for health professionals, operators and patients, as well as*** free movement of goods***,*** legal certainty for manufacturers ***and responsibility on their part***, it is necessary to introduce a uniform definition for nanomaterials based on Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial, with the necessary flexibility to adapt this definition to scientific and technical progress and subsequent regulatory development at Union and international level. In the design and manufacture of medical devices, the manufacturers should take special care when using nanoparticles that can be released to the human body and those devices should be subject to the most severe conformity assessment procedure.

Amendment 4

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) This Regulation includes requirements regarding the design, safety and performance characteristics of medical devices intended to prevent occupational injuries as laid down in Council Directive 2010/32/EU of 10 May 2010 implementing the Framework Agreement on prevention from sharp injuries in the hospital and healthcare sector concluded by HOSPEEM and EPSU[1].
	[1] OJ L 134, 1.6.2010, p. 66.

Amendment 5

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No […/…] on European standardisation should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.	(19) To recognise the important role of standardisation ***and traceability*** in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No […/…] on European standardisation should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as quality and risk management.

Amendment 6

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) The Directive 2013/35/EU of the European Parliament and of the Council of 26 June 2013 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (electromagnetic fields) (20th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)[1] should be the reference text for ensuring that people working in the vicinity of magnetic resonance imaging equipment when it is functioning are properly protected.
	[1] OJ L ..., ..., p. ... (not yet published in the OJ).

Amendment 7

Proposal for a regulation
Recital 32

Text proposed by the Commission	*Amendment*
(32) Patients who are implanted with a device ***should*** be given essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.	(32) Patients who are implanted with a device ***must*** be given ***clear and easily accessible*** essential information related to the implanted device allowing it to be identified and containing any necessary warnings or precautions to be taken, for example indications as to whether or not it is compatible with certain diagnostic devices or with scanners used for security controls.

Amendment 8

Proposal for a regulation
Recital 36

Text proposed by the Commission	*Amendment*
(36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.	(36) One key aspect is the creation of a central database that should integrate different electronic systems, with the UDI as an integral part of it, to collate and process information regarding medical devices on the market and the relevant economic operators, certificates, clinical investigations, vigilance and market surveillance. The objectives of the database are to enhance overall transparency, to streamline and facilitate the flow of information between economic operators, notified bodies or sponsors and Member States as well as between Member States among themselves and with the Commission, to avoid multiple reporting requirements and to enhance the coordination between Member States. ***The database will also facilitate the traceability of medical equipment donated or exported to countries outside the Union.*** Within an internal market, this can be ensured effectively only at Union level and the Commission should therefore further develop and manage the European databank on medical devices (Eudamed) set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Amendment 9

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) For high-risk medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.	(39) For high-risk medical devices, manufacturers should summarise the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available ***and easily accessible***.

Amendment 10

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection and citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.	(40) The proper functioning of notified bodies is crucial for ensuring a high level of health and safety protection ***for health professionals, users and operators, including in the waste disposal chain,*** and ***for ensuring*** citizens' confidence in the system. Designation and monitoring of notified bodies by the Member States, in accordance with detailed and strict criteria, should therefore be subject to controls at Union level.

Amendment 11

Proposal for a regulation
Recital 52

Text proposed by the Commission	*Amendment*
(52) In order to better protect health and safety regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.	(52) In order to better protect ***the*** health and safety ***of health professionals, patients, users and operators, including in the waste disposal chain,*** regarding devices on the market, the vigilance system for medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.

Amendment 12

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(53) Healthcare professionals and patients	(53) Healthcare professionals and patients

should be empowered to report suspected serious incidents at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.	should be empowered to report suspected serious incidents ***which affect the safety of patients, care givers, healthcare professionals or other persons***, at national level using harmonised formats. The national competent authorities should inform manufacturers and share the information with their peers when they confirm that a serious incident has occurred in order to minimise recurrence of those incidents.

Amendment 13

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 45

Text proposed by the Commission	*Amendment*
(45) ‘corrective action’ means action ***taken*** to eliminate the cause of ***a potential or real non-conformity or other undesirable situation***;	(45) ‘corrective action’ means action to eliminate the cause of ***non-conformities in order to prevent recurrence***;

Amendment 14

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 46

Text proposed by the Commission	*Amendment*
(46) ***‘***field safety corrective action***’ means*** corrective action taken by ***the*** manufacturer ***for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market***;	(46) Field Safety Corrective Action ***(FSCA): A field safety*** corrective action ***is an action*** taken by ***a*** manufacturer ***to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device***;

Amendment 15

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 47

Text proposed by the Commission	*Amendment*
(47) 'field safety notice' ***means the*** communication sent ***by the*** manufacturer ***to users or customers*** in relation to a field safety corrective action;	(47) 'field safety notice'***: a*** communication sent ***out by a*** manufacturer, ***or its representative to the device users or waste disposal operators*** in relation to a Field Safety Corrective Action;

Amendment 16

Proposal for a regulation
Article 4 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.	***deleted***

Justification

The above text should be deleted because the Commission is only allowed to amend or supplement a legal text via delegated acts on non-essential elements. The safety and performance requirements are among the most essential elements of the proposed Regulation and should therefore not be changed via delegated acts.

Amendment 17

Proposal for a regulation
Article 8 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.	***deleted***

Justification

The second part of the above Article should be deleted because the Commission is only allowed to amend or supplement a legal text via delegated acts on non-essential elements. The elements which shall appear in the technical documentation are among the most essential elements of the proposed Regulation.

Amendment 18
Proposal for a regulation
Article 41 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following:	4. In the light of technical progress and any information which becomes available in the course of the vigilance and market surveillance activities described in Articles 61 to 75, the Commission***, having consulted relevant stakeholders, including healthcare professionals' organisations,*** shall be empowered to adopt delegated acts in accordance with Article 89 as regards the following:

Amendment 19

Proposal for a regulation
Article 44 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. Throughout the scrutiny process, the views of all relevant stakeholders, including patient, healthcare professionals and caregivers' organisations, shall be taken into account.

Amendment 20

Proposal for a regulation
Article 51 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. An ethics review shall be carried out. The Commission shall facilitate the coordination between stakeholders, as well as the sharing of best practices and the development of quality standard for ethics review across the Union.

Amendment 21

Proposal for a regulation
Article 61 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.	The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients. ***Member States shall nevertheless maintain other formats for reporting suspected serious incidents to national competent authorities.***

Amendment 22

Proposal for a regulation
Article 63 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together	1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 61 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. ***The competent***

with the manufacturer.	***authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations.***

Amendment 23

Proposal for a regulation
Article 94 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.	4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application ***provided that the relevant delegated and implementing acts have entered into force***.

Justification

Implementing and delegated acts which are necessary for the correct implementation of this Regulation shall be ready before this Regulation is applied to any device.

Amendment 24

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – introductory part

Text proposed by the Commission	*Amendment*
7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are

carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***and*** which ***are*** identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .	carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 , and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health ***or*** which ***have been*** identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) ***or are known or presumed endocrine disrupters pursuant to Commission Recommendation (2013/.../EU) on criteria for the identification of endocrine disrupters***.

Amendment 25

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
If devices, or parts thereof, that are intended	Devices, or parts thereof, that are intended

Amendment 26

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.4 – paragraph 1 – indent 3 – paragraph 1

Text proposed by the Commission	*Amendment*
contain, in a concentration of 0.1% by mass ***of the plasticised*** material ***or above, phthalates*** which are classified as	***shall not*** contain, in a concentration of 0.1% ***or above*** by mass ***per homogeneous*** material***, substances*** which are classified

carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing ***phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women,*** the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for ***these patient groups*** and, if applicable, on appropriate precautionary measures.	as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, ***or substances identified as endocrine disrupters pursuant to the first subparagraph, unless the manufacturer can show that there are no suitable safer substances or devices without these substances.***
	Where the manufacturer can show that there are no suitable safer substances or devices without these substances, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing ***substances which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B or substances identified as endocrine disrupters.*** The manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for ***patients*** and, if applicable, on appropriate precautionary measures.

Justification

CMR substances are banned in cosmetic products and CMR phthalates are banned in toys. Similar restrictions should apply for medical devices where exposure in inevitable, unless

there are no safer alternatives. Where no alternatives exist, manufacturers should label the devices and provide specific justification as to the compliance with the safety provisions of the regulation. The same should also apply for known endocrine disrupters. As the Commission is in the process of adopting a recommendation for the identification of endocrine disrupters, a reference to it should be added.

Amendment 27

Proposal for a regulation
Annex 1 – part II – point 7 – point 7.6

Text proposed by the Commission	*Amendment*
7.6. The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks linked to the size and the properties of particles used. Special care shall be applied when devices contain or consist of ***nanomaterial*** that can be released into the patient's or user's body.	7.6. The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks linked to the size and the properties of particles used. Special care shall be applied when devices contain or consist of ***nanomaterials*** that can be released into the patient's or user's body. ***The manufacturer shall provide specific evidence that the use of nanomaterials complies with the general safety and performance requirements within the technical documentation and, within the instructions for use, information on residual risks for patients and, if applicable, on appropriate precautionary measures.***

Justification

When nanomaterials are being used in medical devices, manufacturers should provide specific evidence that their use complies with the general safety and performance requirements. This would greatly facilitate the application of the most severe conformity assessment as foreseen pursuant to Rule 19 and Recital 13.

Amendment 28

Proposal for a regulation
Annex 1 – part II – point 8 – point 8.1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) fully comply with the requirements of applicable Union Directives concerning

	occupational safety, such as Directive 2010/32/EU,

Amendment 29

Proposal for a regulation
Annex 1 – part II – point 8 – point 8.1 – point a – paragraph 1

Text proposed by the Commission	*Amendment*
and, where necessary,	***deleted***

Amendment 30

Proposal for a regulation
Annex 1 – part II – point 10 – point 10.3 – paragraph 1

Text proposed by the Commission	*Amendment*
In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons***, including in the waste disposal chain***. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

Amendment 31

Proposal for a regulation
Annex 1 – part II – point 11 – point 11.2 a (new)

Text proposed by the Commission	*Amendment*
	11.2a. Devices which can transfer potentially fatal blood-borne infections to healthcare staff, patients or other persons, by unintended cuts and pricks such as needle stick injuries, shall incorporate appropriate safety-engineered protection

	mechanisms in accordance with Directive 2010/32/EU. However the specificities relating to the dental profession must be respected.

Amendment 32

Proposal for a regulation
Annex 1 – part II – point 18 – point 18.2 – indent 1

Text proposed by the Commission	*Amendment*
– ensure that the device is easy to use by the intended user at all stages of the procedure, ***and***	– ensure that the device is easy to use by the intended user at all stages of the procedure,

Amendment 33

Proposal for a regulation
Annex 1 – part II – point 18 – point 18.2 – indent 1 a (new)

Text proposed by the Commission	*Amendment*
	– as laid out in Directive 2010/32/EU, reduce as far as possible the risk of injury and infection to other persons by incorporating safety-engineered protection mechanisms designed to prevent needle stick and other sharp injuries, and

Justification

Every year more than 1 million healthcare workers in the EU suffer life-changing and potentially fatal injuries involving medical devices that incorporate needles or other sharps. Not only are healthcare workers at risk of contracting blood-borne infections, they may also act as carrier to increase the risk of transmission to other patients.

Amendment 34

Proposal for a regulation
Annex 1 – part III – point 19 – point 19.3 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The instruction for use shall be lay-friendly and reviewed by the representatives of relevant stakeholders, including patient and healthcare professionals' organisations.

PROCEDURE

Title	Regulation on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009
References	COM(2012)0542 – C7-0318/2012 – 2012/0266(COD)
Committee responsible Date announced in plenary	ENVI 22.10.2012
Opinion by Date announced in plenary	EMPL 22.11.2012
Rapporteur Date appointed	Edite Estrela 21.11.2012
Discussed in committee	23.4.2013 29.5.2013
Date adopted	20.6.2013
Result of final vote	+: 43 –: 1 0: 0
Members present for the final vote	Regina Bastos, Edit Bauer, Heinz K. Becker, Jean-Luc Bennahmias, Phil Bennion, Pervenche Berès, Philippe Boulland, Milan Cabrnoch, David Casa, Alejandro Cercas, Ole Christensen, Derek Roland Clark, Marije Cornelissen, Emer Costello, Frédéric Daerden, Karima Delli, Sari Essayah, Richard Falbr, Thomas Händel, Marian Harkin, Nadja Hirsch, Stephen Hughes, Danuta Jazłowiecka, Martin Kastler, Ádám Kósa, Jean Lambert, Verónica Lope Fontagné, Olle Ludvigsson, Thomas Mann, Elisabeth Morin-Chartier, Csaba Őry, Sylvana Rapti, Licia Ronzulli, Elisabeth Schroedter, Joanna Katarzyna Skrzydlewska, Jutta Steinruck, Traian Ungureanu, Inês Cristina Zuber
Substitute(s) present for the final vote	Sergio Gutiérrez Prieto, Jelko Kacin, Ria Oomen-Ruijten, Birgit Sippel
Substitute(s) under Rule 187(2) present for the final vote	Jorge Chatzimarkakis, Jürgen Klute