EUROPEAN PARLIAMENT 2009 - 2014

Committee on Employment and Social Affairs

2012/0267(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 in vitro diagnostic medical devices
(COM(2012)0541 – C7-0317/2012 – 2012/0267(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 in vitro diagnostic 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 devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union, this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic 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) of the Treaty on the Functioning of the European Union, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical performance studies is protected.	(2) This Regulation aims to ensure the functioning of the internal market as regards in vitro diagnostic 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 devices to meet common safety concerns as regards those products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union, this Regulation harmonises the rules for the placing on the market and putting into service of in vitro diagnostic 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) of the Treaty on the Functioning of the European Union, this Regulation sets high standards of quality and safety for those devices by ensuring, among other things, that data generated in clinical performance studies is reliable and robust and that the safety of subjects participating in clinical performance studies 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, risk classification, conformity assessment procedures, clinical evidence, vigilance and market surveillance should be significantly reinforced, whilst provisions ensuring transparency and traceability regarding in vitro diagnostic medical 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 in vitro diagnostic medical 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 a (new)

Text proposed by the Commission	*Amendment*
	(13a) 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 4

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve ***purchase-policy and stock-management by hospitals***.	(27) The traceability of in vitro diagnostic medical devices by means of a Unique Device Identification (UDI) system based on international guidance should significantly enhance the effectiveness of the post-market safety of in vitro diagnostic medical devices due to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against counterfeit devices. Use of the UDI system should also improve ***purchasing and waste disposal policies and hospitals' management of stock***.

Amendment 5

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) Transparency and better information are essential to empower patients ***and*** healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.	(28) Transparency and better information are essential to empower patients**,** healthcare professionals ***and all others concerned,*** and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system.

Amendment 6

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) 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 in vitro diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, 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) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.	(29) 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 in vitro diagnostic medical devices on the market and the relevant economic operators, certificates, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies, 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) by further developing the databank set up by Commission Decision 2010/227/EU of 19 April 2010 on the European Databank for Medical Devices.

Amendment 7

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) In order to better protect health and safety regarding devices on the market, the	(48) In order to better protect health and safety regarding devices on the market, the

vigilance system for in vitro diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions.	vigilance system for in vitro diagnostic medical devices should be made more effective by creating a central portal at Union level for reporting serious incidents and field safety corrective actions ***within and outside the Union***.

Amendment 8

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) 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.	(49) Healthcare professionals and patients should be empowered to report suspected serious incidents ***which affect the safety of patients, 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 9

Proposal for a regulation
Article 2 – paragraph 1 – subparagraph 1 – point 55

Text proposed by the Commission	*Amendment*
(55) ‘field safety notice’ means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;	(55) ‘field safety notice’ means the communication sent by the manufacturer to users***, waste disposal operators*** or customers in relation to a field safety corrective action;

Amendment 10

Proposal for a regulation
Article 39 – 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 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 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 59 to 73, the Commission***, having consulted relevant stakeholders, including healthcare professionals' organisations, and manufacturers' associations,*** shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:

Amendment 11

Proposal for a regulation
Article 42 – paragraph 6 a (new)

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

Amendment 12

Proposal for a regulation
Article 49 – paragraph 6 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	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 13

Proposal for a regulation
Article 59 – 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 14

Proposal for a regulation
Article 61 – 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 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.	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 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer. ***The competent authority shall take into account the views of all relevant stakeholders, including patient and healthcare professionals' organisations and manufacturers' associations.***

Amendment 15

Proposal for a regulation
Annex 1 – part III – point 17 – point 17.3 – point 17.3.2 – point i a (new)

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

PROCEDURE

Title	In vitro diagnostic medical devices
References	COM(2012)0541 – C7-0317/2012 – 2012/0267(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	+: 44 –: 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, Licia Ronzulli, Elisabeth Schroedter, Joanna Katarzyna Skrzydlewska, Jutta Steinruck, Traian Ungureanu, Inês Cristina Zuber
Substitute(s) present for the final vote	Sergio Gutiérrez Prieto, Richard Howitt, Jelko Kacin, Ria Oomen-Ruijten, Birgit Sippel
Substitute(s) under Rule 187(2) present for the final vote	Jorge Chatzimarkakis, Ricardo Cortés Lastra, Jürgen Klute