

Opinion of the European Economic and Social Committee on the ‘Proposal for a regulation of the European Parliament and of the Council on medical devices and amending Directive 2001/83/EC and Regulations (EC) No 178/2002 and (EC) No 1223/2009’

COM(2012) 542 final — 2012/0266 (COD)

‘Proposal for a regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices’

COM(2012) 541 final — 2012/0267 (COD)

and

‘Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals’

COM(2012) 540 final

(2013/C 133/10)

Rapporteur: **Mr STANTIČ**

On 15 October 2012 and on 22 October 2012 respectively, the Council and the European Parliament decided to consult the European Economic and Social Committee, under Article 114 and 168(4)(c) of the Treaty on the Functioning of the European Union, 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

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*Proposal for a Regulation of the European Parliament and of the Council on *in vitro* diagnostic medical devices*

COM(2012) 541 final – 2012/0267 (COD).

On 26 September 2012 the Commission decided to consult the European Economic and Social Committee, under Article 304 of the Treaty on the Functioning of the European Union, on the

*Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Safe, effective and innovative medical devices and *in vitro* diagnostic medical devices for the benefit of patients, consumers and healthcare professionals*

COM(2012) 540 final.

The Section for the Single Market, Production and Consumption, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 5 February 2013.

At its 487th plenary session, held on 13 and 14 February 2013 (meeting of 14 February 2013), the European Economic and Social Committee adopted the following opinion by 136 votes and 5 abstentions.

1. Conclusions and recommendations

1.1 The EESC highlights that health is a high priority for Europe's citizens and reaffirms that *medical devices* (hereafter MD) ⁽¹⁾ and *in vitro diagnostic medical devices* (hereafter

IVD) ⁽²⁾ play a crucial role in prevention, diagnosis and treatment of diseases. They are central to our health and to the quality of life of people suffering and managing their diseases and disabilities.

⁽¹⁾ Medical devices (MDs) include products such as sticking plasters, contact lenses, hearing aids, dental fillings, hip replacements, sophisticated devices like x-ray machines, pacemakers, etc.

⁽²⁾ In vitro diagnostic medical devices (IVDs) include products used to ensure the safety of blood tests, detect infectious diseases (e.g. HIV), monitor diseases (e.g. diabetes) and perform any kind of blood chemistry.

1.2 The EESC welcomes the recast of the current regulatory system by the Commission that goes beyond a mere simplification of the framework and puts in place more effective rules, strengthening the pre-market approval procedures and in particular the post-market surveillance. As regards the recent scandal on defective breast implants, which resulted in a European Parliament Resolution of June 2012, as well as other major problems with high-risk medical devices and implants, the EESC, like the European Parliament ⁽³⁾, advocates in addition a high quality procedure prior to their placement on the market. This responds to the needs of citizens for patient safety and efficacy.

1.3 High-risk MDs (class III and implantable products) and IVDs must be subject to an adequate, high quality, EU-wide uniform approval procedure before entering the market, in which safety, efficacy and positive risk-benefit balance must be proven by the results of high quality clinical investigations. The full results should be stored in a publicly accessible central database. For high-risk medical devices and IVDs already on the market, compliance with Article 45 of the proposed Regulation has to be ensured in order to demonstrate safety and efficacy of the device.

1.4 The EESC strongly supports the legal form of a **'Regulation'** instead of a **'Directive'** so as to reduce the room for diverging interpretation by individual Member States, providing more equality for European patients and a level playing field for suppliers.

1.5 Beside safety, **fast access to the latest medical technologies** also represents an important benefit for patients. Considerable delays in accessing the new devices would harm patients by reducing their treatment choices (possibly life-supporting) or at least prevent them from reducing their disabilities and improving their quality of life.

1.6 The EESC highlights that MD and IVD sectors, characterised by high innovation capacity and high-skilled jobs, represent an important part of the European economy and can substantially contribute to the implementation of the EU 2020 Strategy and its Flagship initiatives. Therefore appropriate legislation is fundamental, not just to ensure the highest

possible level of health protection, but also to provide an innovative and competitive environment for the industry in which 80 % of manufacturers are small to medium and micro enterprises.

1.7 The EESC supports high standard approval procedures for high-risk MDs and IVDs before entering the market, in which safety and efficacy must be proven by the results of adequate clinical tests and investigations. However, the EESC expresses concerns against introducing a centralised pre-market authorisation system in Europe which would cause further delays in approval times, preventing the patients to have fast access to the latest medical technologies and considerably increasing the costs for SMEs and endangering their innovative capacity.

1.8 If any approval requirements for MDs and IVDs are to be increased, it must be done in a transparent and predictable way that does not further jeopardise the efficiency of the regulatory process and reduce future innovations.

1.9 The EESC welcomes the introduction of a **Unique Device Identification (UDI)** to be assigned to each device, allowing faster identification and better traceability. The EESC would also welcome a fully workable **central registration tool (Eudamed)** which would eliminate multiple registrations and considerably decrease the costs for SMEs.

1.10 The EESC supports the **strengthening of the patients'** position. In order to secure appropriate financial security in the event of harm being caused, injured parties must have the right to levy direct claims and receive full compensation. When patients have to prove the harm of a faulty medical device, the manufacturer should make available to the patient (and/or the payer liable for the cost of treatment) all necessary documentation and information regarding safety and efficacy of the device in question. In addition the EESC calls on the Commission to ensure through appropriate mechanisms the payment of compensation that does not lead to a substantial increase in the prices of medical devices.

1.11 The EESC acknowledges a rather **weak involvement of civil society** in the proposed regulation framework. The observer status of civil society in the temporary sub-groups, established by the newly formed Medical Device Coordination Group (MDCG), is not sufficient. The EESC proposes the establishment of an **'Advisory Committee'** made up of representatives of legitimate stakeholders organised at the European level. Such committee should act in parallel and work with the Medical Device Coordination Group (MDCG), advising the Commission and Member States on various aspects of medical technology and implementation of the legislation.

⁽³⁾ Resolution 14 June 2012 (2012/2621(RSP)); P7_TA-PROV(2012)0262.

1.12 The EESC would reiterate the need for appropriate provisions related to the **education and training of the professional healthcare staff** to be added to proposed regulations, following the recommendations expressed in the EU Council's Conclusions on Innovations in the Medical Devices Sector ⁽⁴⁾.

1.13 **Relevant Linkage with other legal dossiers and bodies:** The EESC highlights the need to ensure that the new rules for clinical performance studies for IVDs – Companion Diagnostics interact well with those which will come out of the currently discussed new framework for clinical trials with medicinal products, according to the EESC's recent opinion ⁽⁵⁾.

1.14 **In-house tests for IVDs:** the EESC recommends that the principle of assessing the risks and benefits of a healthcare device should apply to all products regardless of whether they are commercialised or developed and used solely inside an institution (in-house test).

1.15 The functioning of the regulations should be formally reviewed three years after entry into force, jointly by authorities and stakeholders from civil society to ensure that the objectives of the regulations are being met.

2. Introduction and background

2.1 MDs and IVDs play a crucial role in prevention, diagnosis and treatment of diseases. They are central to our health and to the quality of life of people suffering from disabilities.

2.2 MD and IVD sectors represent an important and innovative part of European economy. They generate annual sales of around EUR 95 billion (EUR 85 billion for MDs and EUR 10 billion for IVDs), investing heavily in research and innovations (EUR 7.5 billion annually). They employ more than 500 000 people (mostly highly skilled professionals) in about 25 000 companies. More than 80 % of them are small to medium and micro enterprises.

2.3 Fast demographic and societal changes, an enormous scientific progress, as well as the recent scandal involving the faulty silicone breast implants ⁽⁶⁾, problems with metal-on-metal hip implants and some other products ⁽⁷⁾, have all brought about and accelerated the need for a revision of current regulatory framework.

2.4 As high-risk devices, implants are of considerable importance, e.g. 400 000 PIP silicone implants have been sold world-wide. Many women in the UK (40 000), France (30 000), Spain (10 000), Germany (7 500) and Portugal (2 000) have received PIP silicone breast implants with a rupture rate of 10-15 % within 10 years of implementation ⁽⁸⁾. In Germany alone in 2010, around 390 000 hip and knee prostheses were implanted, of which barely 37 000 were exchange operations where artificial joints had to be exchanged ⁽⁹⁾.

2.5 Summary of the main shortcomings of the existing system as acknowledged by the EESC:

- EU countries interpret and implement the rules in different ways, causing inequality among EU citizens and create obstacles to the Single Market;
- It is not always possible to trace medical devices back to the supplier;
- Patients and healthcare professionals do not have access to essential information on clinical investigations and evidence;
- Lack of coordination between national authorities and with the Commission;
- Regulatory gaps with regard to certain products ⁽¹⁰⁾.

3. Gist of the new package of the revised regulatory framework for MDs and IVDs

3.1 The package consists of the Communication ⁽¹¹⁾, a proposal for a Regulation on medical devices ⁽¹²⁾ (replacing Directive 90/385/EEC regarding active implantable MDs and Directive 93/42/EEC regarding MDs) and a proposal for a Regulation on *in vitro* diagnostic MDs ⁽¹³⁾ (replacing Directive 98/79/EC regarding *in vitro* diagnostic medical devices).

⁽⁴⁾ OJ C 202, 8.7.2011, p. 7.

⁽⁵⁾ EESC opinion 'Clinical trials on medicinal products for human use', OJ C 44, 15.2.2013.

⁽⁶⁾ French firm Poly Implant Prothèse (PIP) have violated the regulations by using unapproved industrial-grade silicone in some of its implantable products.

⁽⁷⁾ http://www.aok-bv.de/presse/medienservice/politik/index_06262.html

⁽⁸⁾ EP Resolution of 14 June 2012 (2012/2621(RSP)); P7_TA-PROV(2012)0262.

⁽⁹⁾ Information from the German AOK-federal board, 12.1.2012.

⁽¹⁰⁾ Products utilising non-viable human tissues or cells, genetic tests, implants for aesthetic purposes, etc.

⁽¹¹⁾ COM(2012) 540 final.

⁽¹²⁾ COM(2012) 542 final.

⁽¹³⁾ COM(2012) 541 final.

3.2 Main new elements of the proposed Regulations include:

- Wider and clearer scope of the legislation, extended to include implants for aesthetic purposes and genetic tests as well as medical software
- Stronger supervision of assessment (notified) bodies by national authorities in order to insure an efficient pre-market assessment of devices
- Clearer rights and responsibilities for manufacturers, importers and distributors
- Extended centralised European database on MDs and IVDs (EUDAMED), accessible to healthcare professionals, patients and partially to the public at large
- Better traceability of devices throughout the supply chain, including a Unique Device Identification system (UDI), enabling fast and effective response to any safety concerns
- Stricter requirements for clinical evidence and evaluation throughout the life of the device
- Stricter provisions for governing market surveillance and vigilance
- Better coordination between national authorities with scientific support by the Commission, in order to ensure a uniform implementation of the legislation
- Alignment to international guidelines in order to better adapt to the global market of MDs.

3.3 The MD and IVD sectors, characterised with the high degree of innovation and high-skilled job creation potential, can substantially contribute to the objectives of the **Europe 2020 Strategy**. Both sectors occupy a central place in several Flagship initiatives, in particular Digital Agenda for Europe ⁽¹⁴⁾ and Innovation Union ⁽¹⁵⁾.

4. General comments

4.1 The EESC strongly supports the form of Regulations, which are directly applicable and eliminate the risk of

divergent transposition and interpretation by individual Member States. It is a useful way to achieve more equality for patients across EU and a level playing field for suppliers.

4.2 Approval system and assessment procedures

4.2.1 High-risk MDs (class III and implantable products) and IVDs must be subject to an adequate high quality, EU-wide uniform approval procedure before entering the market, in which safety, efficacy and positive risk-benefit balance must be proven by the results of high quality clinical investigations. The full results should be stored in a publicly accessible central database. For high-risk medical devices and IVDs already on the market, compliance with Article 45 of the proposed Regulation has to be ensured in order to demonstrate safety and efficacy of the device.

4.2.2 In this context the EESC supports the strengthening of the existing regulatory framework for high-risk medical devices, based on the concept of conformity assessment and decentralised regulatory bodies, as provided for in proposed regulations. We support stricter requirements to obtain a conformity certificate as regard to documentation and other conditions, including pre-clinical and clinical data, clinical evaluations and investigations, risk/benefit analysis, etc. ⁽¹⁶⁾. They can considerably raise the existing approval standards in the EU, without scarifying too much a fast access to new products.

4.2.3 The EESC strongly supports strict and high level pre-market approval procedures but expresses concerns against introducing a centralised Pre-market Authorisation System (PMA) in Europe, as known in the USA. Such system would bring delays in approval times. For patients it would mean a time lag in accessing the latest lifesaving medical technologies. On the other hand a centralised PMA system would negatively impact most European SMEs in the MD sector, considerably increasing their costs and seriously endangering their innovative capacity. They would have difficulties to finance and survive lengthy market approvals.

4.2.4 *Newly proposed mechanism for scrutiny* – (Art. 44 / 42): The EESC notes that the Medical device Coordination Group (MDCG) can interfere with its opinion on the application file submitted by the Notified body. The EESC is well aware

⁽¹⁴⁾ COM(2010) 245 final/2 and OJ C 54, 19.2.2011, p. 58.

⁽¹⁵⁾ COM(2010) 546 final and OJ C 132, 3.5.2011, p. 39.

⁽¹⁶⁾ See Annexes II, III, V, IX, XII, XIV, specifying requirements to obtain EU certificate of conformity.

of the importance of patient safety. In order to avoid additional and unpredictable delays for manufacturers (and consequently for the patients) this must be done in a transparent and predictable way that does not jeopardise the efficiency of the regulatory process and reduce future innovation.

4.3 *Vigilance and market surveillance*

4.3.1 The EESC welcomes the proposed improvement and strengthening of the vigilance system, particularly the introduction of an **EU portal** where manufacturers should report serious incidents and corrective actions to reduce the risk of recurrence (Art. 61/59). The automatic availability to all national authorities concerned will allow better coordination among them.

4.3.2 To further guarantee safety of medical devices, and in particular with a view to picking up long-term safety issues related to implants, the legislation needs to be strengthened in the post-market provisions and, in particular, post-market clinical follow-up, vigilance and market surveillance.

4.4 *Transparency*

4.4.1 For the EESC one of the most significant issues in both recasts of regulations is the proposal for an increased transparency of the whole system.

4.4.2 In this respect the EESC supports the introduction of a **Unique Device Identification (UDI)** to be assigned to each device, allowing faster identification and better traceability to support the European Parliament Resolution of 14 June ⁽¹⁷⁾.

4.4.3 The EESC considers the establishment of a fully workable **Eudamed** as a very suitable tool for increased transparency. The establishment of such central registration tool (Eudamed) will eliminate multiple registrations throughout Member States and thus help reducing the administrative costs for applicants by up to EUR 157 million.

4.5 *Strengthening the position of patients harmed*

4.5.1 The current Product Liability Directive 85/374/EEC establishes medical device manufacturers' liability. However, the person harmed (or the payer liable for the cost of treatment) has to prove the harm and the faultiness of the MD. The patient often lacks the information required to prove such faultiness. Therefore, the manufacturer should be obliged to make all

necessary documents and information regarding safety and efficacy of a device available to the person harmed.

4.5.2 The EESC also recognises that a mechanism should be put in place to compensate patients harmed by faulty medical devices or IVDs. In order to secure appropriate financial security in the event of harm being caused, the injured parties must have the right to levy direct claims and receive full compensation. The burden of proof as to whether a defective medical device is the cause of harm to health or not must be shifted from the patient to the manufacturer. It should only still be incumbent upon the patient to provide proof of the objective possibility of cause of harm by the medical device. Accordingly, the EESC calls on the Commission to ensure through appropriate mechanisms the payment of compensation that does not lead to a substantial increase in the prices of medical devices.

4.6 *Notified bodies and competent authorities*

4.6.1 The EESC supports tightening up the **designation and monitoring of Notified Bodies** to ensure a uniform high level of competence throughout the Union. The central oversight of their designation by Member States is also welcomed.

4.6.2 The EESC supports all proposals to reinforce the rights and obligations of competent authorities (better coordination and clarification of procedures, on-site and unannounced inspections) on the one hand and the suppliers on the other hand (request for a 'qualified person').

4.6.3 The EESC appreciates the unification of high-quality standards and competences for Notified bodies across Europe but expresses concern that this goal cannot be achieved if the number of notified bodies remains as high as it is now (80). The EESC recommends high quality instead of quantity.

4.7 *Education and training*

4.7.1 The EESC notes that the Members States in its EU Council Conclusions on innovations in the Medical Devices Sector ⁽¹⁸⁾ invited the Commission to improve information and training for healthcare professionals, patients and patients' families regarding the proper use of devices. MDs work only if they are used correctly. Their effectiveness relies on the skills and experience of the physician and lab personnel using them.

4.7.2 Therefore the EESC invites Member States to include appropriate provisions related to the education and training of the professional staff in the proposed regulations.

⁽¹⁷⁾ See footnote 3.

⁽¹⁸⁾ See footnote 4.

4.8 *Involvement of civil society*

4.8.1 The EESC believes that the proposed Medical device coordination group (MDCG) does not provide enough involvement of all stakeholders. According to proposed regulations, MDCG may establish standing or temporary sub-groups, but the EESC considers it insufficient, if organisations representing the interests of consumers, health professionals and medical device industry at the Union level will be invited in such sub-groups only in the capacity of observers. Their active role as consultants must be assured.

4.8.2 Experience has shown that progress in the EU is only possible when the different players share a common vision and a common direction. The system benefits today from an active 'Advisory Committee' as part of Medical Device Expert Group (MDEG). This should be kept and given explicit reference in the legislation. Otherwise decisions and policy may lack an early and rightful input of patients, health professionals, industry and other parts of civil society.

4.9 *Review clause*

4.9.1 A review of the functioning of the Regulations would be necessary to ensure that its intent is truly being met. At some point, no longer than three years after the entry into force of the proposals, the functioning of the Regulation should be formally reviewed jointly by authorities and stakeholders from civil society to ensure that the objectives of the regulations are being met.

5. **Specific comments on IVD regulation related to Companion Diagnostics (CDx)**

5.1 **Definition:** The EESC is concerned that the definition of companion diagnostic as proposed in Article 2 (6) is too broad

and could lead to legal uncertainty. The EESC proposes the following definition: '*companion diagnostic means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for treatment with a specific medicinal product*' (instead of 'eligible for a targeted therapy').

5.2 **Clinical evidence:** The IVD Regulation proposal contains a comprehensive set of rules on performing clinical performance studies with IVDs and also introduces the possibility for 'sponsors' of interventional multi-national clinical performance studies to submit a single application through an electronic portal to be set up by the Commission.

5.2.1 However, the proposed Regulation should ensure that the new rules for clinical performance studies interact well with those which will come out of the currently discussed new framework for clinical trials with medicinal products, according to the previous opinion of the EESC ⁽¹⁹⁾. The EESC also holds the view that the databases for registering trials need to be interoperable.

5.3 **'In-house tests':** According to the IVD Regulation proposal, high-risk (class D) in-house tests are subject to the same requirements as commercial class D tests. But for in-house tests in other classes (including class C and CDx), the IVD Regulation does not apply fully. The EESC recommends that the principle of assessing the risks and benefits of a healthcare product should apply to all products regardless of whether they are commercialised or developed and used solely inside an institution (in-house test).

Brussels, 14 February 2013.

The President
of the European Economic and Social Committee
Staffan NILSSON

⁽¹⁹⁾ EESC opinion 'Clinical trials on medicinal products for human use', OJ C 44, 15.2.2013.