What is the Best Way to Supervise the Quality of Medical Devices? Searching for a Balance Between *ex-ante* and *ex-post* Regulation

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This article discusses the legal remedies available for Competent Authorities, patients and healthcare professionals to prevent harmful incidents involving medical devices. It outlines a theoretical framework for ex-ante and ex-post regulation of medical devices. It then focuses on certain aspects of ex-post regulation. Participation by Competent Authorities with a supervisory role, healthcare professionals and patients in ex-post regulatory legal processes is analysed in the light of the current European Union legal framework and the revised framework proposed by the European Commission. It also discusses whether the proposed new legal framework enables the Competent Authorities, patients and healthcare professionals to prevent the harm caused by unsafe medical devices. Ex-ante regulation might prevent the entrance on the market of unsafe devices whereas ex-post regulation might dismiss the unsafe devices. The contribution concludes by suggesting a number of improvements to the supervisory system of medical devices in Europe.

I. Introduction

Triggered by the PIP breast implants scandal[1], the European Parliament adopted on 14 June 2012 a Resolution on defective silicone gel breast implants. The Resolution called upon the European Commission to develop an adequate legal framework to guarantee the safety of medical devices.[2] In September 2012, the European Commission proposed two new Regulations, which are currently under discussion in the European Parliament and Council.[3] In May 2013, the European Parliament formulated 907 amendments to the European Commission's proposed Regulation regarding medical devices.[4] Another 76 amendments were proposed to the draft Regulation concerning in vitro diagnostic medical devices.[5] Some of the amendments intended the introduction of a new regulatory element, that is, ex-ante regulation in the form of pre-market approval. Parliament proposed also a number of amendments to reinforce ex-post regulation by Competent Authorities. The Parliamentary Committee for Environment, Public Health and Food

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1 Poly Implant Prothèse (PIP) was a French company started in 1991 that produced breast implants. PIP went into liquidation in 2011. The company produced circa 100,000 implants per year, during circa 20 years. Approximately 400,000 women worldwide may have been implanted with PIP gel products. <http://en.wikipedia.org/wiki/Poly_Implant_Proth%C3%A8se> (last accessed on 4 November 2013).

2 European Parliament Resolution No 2012/2621(RSP), P7_TA-PROV(2012)0262, available online at <http://www.europarl.plenary/en/texts-adopted.html europa.eu/> (last accessed on 4 November 2013).

3 Commission 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) 542; Commission Proposal for a Regulation of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, COM(2012) 541.

4 European Parliament Committee on the Environment, Public Health and Food Safety, Draft Report 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: Dagmar Roth-Behrendt. The report is available on the internet at <http://www.europarl.europa.eu/committees/en/envi/draft-reports.html?linkedDocument=true&ufolderComCode=ENVI&ufolderLegId=7&ufolderId=10806&urefProcYear=&urefProcNum=&urefProcCode=#menuzone> (last accessed on 4 November 2013).

5 European Parliament Committee on the Environment, Public Health and Food Safety, Draft Report 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)), available on the internet at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-506.196+01+DOC+PDF+V0//EN&language=EN> (last accessed on 4 November 2013).

Safety (ENVI), i.e., the committee in charge of the medical devices file, was focused until 25 September 2013 on the issue of pre-market authorisation, which overshadowed the other issues in the deliberations about the new regulatory framework for medical devices. ENVI adopted a form of pre-market authorisation by special Notified Bodies under the supervision of the European Medicines Agency that might be classified as an instrument of *ex-ante* regulation. On 22 October 2013, the European Parliament accepted the proposal put forward by the European Commission with many amendments bundled together in a draft European Parliament Legislative Resolution.[6]

The amendments proposed by the Parliament have to be endorsed also by the Council of the European Union to ensure that the proposed new Regulations enter into force. Having in mind that the outcome of the deliberations in the Council are uncertain at this point, this article will describe the main aspects of the recent legal framework for medical devices as defined in the European Commission proposals. It will focus on the changes proposed to the Medical Devices Directive and not on the revision of the In Vitro Diagnostic Medical Devices Directive.[7] The analysis will start by defining some of the concepts used. It will then describe the main legal framework and the process of placing the medical devices on the EU market. Later on, it will focus on the rules concerning *ex-ante* and *ex-post* supervision of medical devices by Competent Authorities in the current and the newly proposed legal framework.

II. The current legal framework for medical devices in the European Union

European legislation regarding medical devices does not set forth any form of pre-market approval at the European level. EU Member States do not work with market authorisations, either. The main legal framework for medical devices is defined in the Medical Device Directive 42/93/EC (MDD), Directive 90/385/EC concerning Active Implantable Medical Devices and Directive 98/79/EC concerning In Vitro Diagnostic Medical Devices[8]. The Medical Device Directive (MDD) is praised for its contribution to innovation. It combines the goal to safeguard the freedom of trade and goods with the aim to ensure public health and safety of the products.[9] Medical devices in the European Union fall under the competence of the Directorate-General for Health and Consumers of the European Commission. Regulation of medical devices is discussed in the Parliamentary Committee for Environment, Public Health and Food Safety (ENVI) and in the Council Committee of Employment, Social Policy and Health Ministers.

The current legal framework for medical devices has its basis in the Council Resolution 85/C 136/01 of 7 May 1985[10] that formulated the so-called new approach to technical harmonisation and standardisation.[11] This Council Resolution establishes a

6 European Parliament Report 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)), available on the internet at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0324+0+DOC+XML+V0//EN> (last accessed on 4 November 2013).

7 The incidents with medical devices occurred with implantable medical devices. In Vitro Diagnostic medical devices are mostly not used by the patients themselves. For this reason I will not focus on the In Vitro Diagnostic Directive.

8 Council Directive 93/42/EEC on Medical Devices, OJ 1993 L 169/1, also known as the "Medical Device Directive"; Council Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices, OJ 1990 L 189/17; Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, OJ 1998 L 331/1 The Medical Device Directive was last amended by European Parliament and Council Directive 2007/47/EC, OJ EC 2007 L 247/21.

9 See also the Council Conclusions on Innovation in the Medical Device Sector, 2011/C 202/03, available on the internet at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:202:0007:0009:EN:PDF> (last accessed on 4 November 2013).

10 Council Resolution on a New Approach to Technical Harmonization and Standards, OJ C 136, 4.6.185, available on the internet at <http://eur-lex.europa.eu/JO-Html.do?uri=OJ:C:1985:136:SOM:EN:HTML> (last accessed on 4 November 2013).

11 Council Resolution, ibid. 10. The Resolution establishes four fundamental principles:
1. Legislative harmonisation is limited to essential safety requirements (or other requirements in the general interest) with which products put on the market must conform and which can therefore enjoy free movement throughout the European Union;
2. The task of drawing up technical production specifications is entrusted to organisations competent in industrial standardisation, which take the current stage of technology into account when doing so;
3. These technical specifications are not mandatory and maintain their status of voluntary standards;
4. The authorities are obliged to recognise that products manufactured in conformity with harmonised standards are presumed to conform to the essential requirements established by the Directive. If the producer does not manufacture in conformity with these standards, he has an obligation to prove that his products conform to the essential requirements. Two conditions have to be met in order that this system may operate:
a. The standards must guarantee the quality of the product;
b. The public authorities must ensure the protection of safety (or other requirements envisaged) on their territory. This is a necessary condition to establish mutual trust between Member States.

number of fundamental principles[12] to be applied in the European Union to harmonise the essential requirements of products. Manufacturers have to ensure that their products comply with the harmonized standards. The principle of mutual recognition has the purpose to eliminate the technical obstacles to the free movement of goods within the EU market.

Harmonisation according to this approach is limited to essential requirements ensuring the safety and performance of medical devices placed on the European Union market. Since 1992, the European Union, the United States of America, Canada and Japan have been working together in the Global Harmonization Task Force (GHTF) to harmonize medical device regulatory practices. Since 2011, the responsibilities of the GHTF have been taken over by the International Medical Device Regulators Forum (IMDRF), a voluntary group with officials representing the Competent Authorities of the countries mentioned above.[13] In Europe the European Committee for Standardization formulates harmonized standards.[14] The European Commission publishes temporarily a list of titles and references with harmonised standards under Directive 93/42/EEC for Medical Devices and the other two related Directives.[15] The Competent Authorities assume that a certain medical device meets the essential requirements if the product complies with these published harmonized standards.[16] The two new Regulations proposed by the European Commission build further on this system.

The current legal framework delegates ex-post regulation and all supervisory activities after the market introduction of a medical device to Member States. Member States designate Competent Authorities to supervise the medical devices, as stated in Annex II, paragraph 5 of the Directive for medical devices. Also there are Guidelines regarding surveillance by manufacturers, Competent authorities and Notified Bodies, but these Guidelines have to be classified as soft law[17] (i.e., legally non-binding instruments). On the 14th of November 2013 the French Court of Toulon Rules a Notified Body liable for not fulfilling its tasks put down in Annex II of the directive. The victims of PIP implants and the distributors proved the certification organization did excercise the task of surveillance inadequate, what is the main reason for Liability. Because Notified Bodies are not part of a public administration, this article cannot classify this supervisory task as an "ex-post regulatory task", as it is understood in this piece. Also there will be an appeal which makes it difficult to estimate the effect of this ruling on the "ex post" instruments.[18] Supervisory authority is further on conferred upon the Competent Authorities operating in the Member States. There is no specific agency for medical devices operating at the European level.[19] On 8 May 2008, the European Commission published a public consultation document to explore the

12 A procedure for the provision of information in the field of technical standards the Member States undertake to keep a constant check on the technical regulations which are applied so as to withdraw those which are deemed obsolete or superfluous; and the Member States ensure the mutual recognition of the results of tests and establish harmonised rules on the operation of certification bodies (the mutual recognition principle).

13 International Medical Device Regulators Forum, available on the internet at <http://www.imdrf.org/index.asp> (last accessed on 4 November 2013).

14 These are the so called CEN-norms formulated by the European Committee for Standardization and published in the Official Journal of the European Union, available on the internet at <http://www.cen.eu/cen/pages/default.aspx> (last accessed on 4 November 2013).

15 European Standards on Medical devices, available on the internet at <http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/> (last accessed on 4 November 2013).

16 There is no obligation to use the "harmonized standards" in the conformity assessment procedure.

17 "Soft law" such as guidelines and recommendations is not considered binding by Parliament and Council. However, "soft law" can impose binding obligations on Member States to supervise their implementation according to the principle of sincere cooperation set forth in Art. 4(3) of the Consolidated version of the Treaty on European Union, OJ C 326 .55, 26.10.2012: "*Pursuant to the principle of sincere cooperation, the Union and the Member States shall, in full mutual respect, assist each other in carrying out tasks which flow from the Treaties. The Member States shall take any appropriate measure, general or particular, to ensure fulfilment of the obligations arising out of the Treaties or resulting from the acts of the institutions of the Union. The Member States shall facilitate the achievement of the Union's tasks and refrain from any measure which could jeopardise the attainment of the Union's objectives*".

18 The Notified body involved in this case was TÜV Rheinland, which had provided the CE-mark for PIP-breast implants. TÜV Rheinland announced an appeal against the Ruling.

19 The Draft Report of the European Parliament proposes some amendments to the Commission proposals to attribute more authorities to the European Medicines Agency (EMA). The proposed Regulation distinguishes a centralized procedure for innovative medical devices to be carried out by EMA and a decentralized procedure for high-risk devices to be carried out by the Competent Authority. In addition, one of the amendments proposes a multi-disciplinary European advisory committee of experts and representatives of stakeholder and civil society organisations. The Committee on the Internal Market and Consumer Protection sent its draft opinion to the Committee on the Environment, Public Health and Food Safety (ENVI) with several proposed amendments. 2012/0266(COD) 4.4.2013.

views of different stakeholders on the revision of the legal framework for medical devices. As noted above, triggered by the PIP breast implants scandal and the subsequent European Parliament Resolution adopted on 14 June 2012, the European Commission presented in September 2012 a proposal for a new legal framework for medical devices, in the form of two new Regulations: one regarding Medical Devices and one regarding In Vitro Diagnostic Medical Devices.[20] The PIP scandal and the European Parliament Resolution have strengthened the focus on supervision and pre-market approval as part of the revision agenda.

It appears that some members of the European Parliament have demanded more fundamental changes in the legal framework for medical devices. Some of the amendments formulated by Parliament in May 2013 introduced a form of pre-market review that does not exist in the current legal framework. A number of amendments intended to establish a centralized EU-wide pre-market review process for "innovative" high-risk devices and a decentralized pre-market review to be carried out in Member States for high-risk devices. This is called the (centralized or de-centralized) marketing authorisation procedure. Further to the ENVI vote that took place on 25 September 2013, a new procedure was proposed for the plenary vote in Parliament. According to this procedure, the European Medicines Agency would be in charge of designating special Notified Bodies that would assess the highest risk medical devices (such as hip implants). Furthermore, a new expert body called the Assessment Committee for Medical Devices (ACMD) was proposed to control the Notified Bodies. In addition, the ENVI Committee enhanced ex-post market monitoring. The ENVI proposals were endorsed by Parliament during the plenary vote that took place on 22 October 2013, and the proposed changes were bundled in a Legislative Resolution on the draft Regulation, adopted by Parliament on the same day.[21]

There are other notable changes proposed by the European Parliament. They include the proposal to create a multidisciplinary advisory committee of experts and representatives of stakeholder and civil society organisations as well as an expert team at the European Medicines Agency in charge of medical devices. Furthermore, one of the amendments asks for defining safety as "the avoidance of risk or harm caused by the medical device or associated with its use". Parliament's wish for some form of pre-market approval may cause a clash with the Commission proposal and prompt critical reactions on behalf of the medical technology industry. Eucomed, the organization representing the medical technology industry in Europe, has already criticized the outcome of the ENVI vote.[22]

The plenary vote results will be deliberated in the Council. During the meeting of the Council Committee on Employment, Social Policy, Health and Consumers held on 20 and 21 June 2013, the Council representatives discussed the two draft Regulations proposed by the European Commission. All delegations attending this meeting expressed general reservations on the proposed legal framework.[23] As a next step, the Council has to deliberate on the amendments made by the European Parliament. The outcome of this deliberation is still uncertain.

The European Commission's reform proposal did not introduce any form of pre-market approval. The proposed new Regulations continue the legal framework set forth in the current Directives although they formulate much more clearly the competences, authorities and responsibilities for manufactures and Notified Bodies compared to the Directives.[24] The proposed new Regulation for Medical Devices introduces the Medical Device Coordination Group (MDCG) that has the authority to scrutinize pre-market assessment reports drawn up by the Notified Bodies for certain devices that are classified as high-risk prior to their placement on the mar-

20 European Parliament Resolution No 2012/2621(RSP), P7_TA-PROV(2012)0262, available on the internet at <http://www.europarl.europa.eu/plenary/en/texts-adopted.html> (last accessed on 4 November 2013).

21 <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A7-2013-0324+0+DOC+XML+V0//EN> (last accessed on 4 November 2013).

22 Eucomed, "Rushed deal leaves patients and jobs in second place", 25 September 2013, available on the internet at <www.eucomed.org/newsroom/117/187/Rushed-deal-leaves-patients-and-jobs-in-second-place?cntnt01template=detail-pr> (last accessed on 4 November 2013).

23 A report of this meeting is available on the internet at <http://register.consilium.europa.eu/pdf/en/13/st10/st10360.en13.pdf> (last accessed on 4 November 2013).

24 Council Directive No 93/42/EC on medical devices, supra note 8; Council Directive 90/385/EEC on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices, OJ 1990 L 189/17; Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices, OJ 1998 L 331/1.

ket.[25] This proposal will still be discussed in the Council.

III. The concepts of ex-post and ex-ante regulation

The concept ex-ante regulation is applied in competition law and to liberalised markets like telecommunication and energy.[26] In these sectors liberalisation of the former state monopolies needed specific legislation to establish a level playing field for the new competitors. If there is a level playing field, then ex-ante regulation will be taken over by ex-post regulation.

The contribution will use the concepts "ex-post" and "ex-ante" regulation to trespass the debate between the introduction of pre-market approval for medical devices and the European system currently in place, which does not require pre-market authorisation. Therefore, the concept of "ex-ante regulation" refers to the market admittance to get a device placed on the market and the related competences and instruments available for Competent Authorities. Ex-ante regulation might prevent unsafe medical devices from entering the European market. Ex-post regulation might correct the entry of unsafe medical devices by removing them from the market or compensate for the harm that a medical device has caused.[27] Private liability claims are also considered ex-post regulatory mechanisms.

The article will use the concept "ex-post regulation" to discuss the instruments and competences that Competent Authorities have when a medical device is already placed on the market. With the court ruling of 14 November 2013, Notified Bodies carry a responsibility regarding Class III medical devices for surveillance after certification. Because Notified Bodies are not part of a public administration this article can not classify this supervisory task as an "ex-post regulatory task", as understood in this article. Also there will be an appeal which makes it difficult to estimate the effect of this ruling on the "ex post" instruments. Vigilance and market surveillance are part of ex-post regulation, which has to be carried out mainly by manufactures according to both the Directives and the proposed new Regulations. In Europe, the Competent Authorities are not involved in the process of placing medical devices on the market. Notified Bodies, which are private companies, are in charge of ex-ante regulation by carrying out the conformity assessment process. Only a little related competence is attributed to the Competent Authorities, i.e., to record incidents according to Article 10 of the Medical Device Directive (MDD). The recently proposed, new legal framework sets forth some additional instruments for Competent Authorities, such as reasoned requests for information to manufactures and Notified Bodies. In addition, Competent Authorities should encourage healthcare professionals, users and patients to report suspected serious incidents.[28]

For the purposes of this analysis, competences conferred upon Competent Authorities and the instruments available to them will be called "remedies". From an economic perspective, not all remedies that are meant to correct infringements of the legal framework by manufacturers should be applied exclusively by governmental bodies such as Competent Authorities. Such remedies should be available also to patients and healthcare providers to compensate for harm caused by medical devices or prevent inappropriate performance of unsafe devices.

In economics an externality is a cost or benefit that results from an activity or transaction, and that affects an otherwise uninvolved party who did not choose to incur that cost or benefit.[29] Economists may define incidents with medical devices as negative externalities. An externality is the result of an economic activity that does not financially affect the producer of a device but influences the standard of living of the society or individuals (examples include

25 Art. 44 sets forth the mechanism for scrutiny of certain conformity assessments. The "scrutiny mechanism" has been discussed in the Council and the issue is likely to be discussed again by the Council following the plenary vote in the European Parliament.

26 Commission Recommendation No C(2007) (5406) on Relevant Product and Service Markets within the Electronic Communications Sector Susceptible to Ex-ante Regulation in Accordance with Directive 2002/21/EC of the European Parliament and of the Council on a Common Regulatory Framework for Electronic Communications Networks and Services, OJ L 344, 28.12.2007, pp. 65–69.

27 Christa Altenstetter uses the concepts ex-post and ex-ante regulation in: Christa Altenstetter, "Medical Device Regulation: Demystifying the Role of the FDA 1976–2012", presentation held at the Conference "Revising Medical Devices Regulation, the Legal Challenges", Tilburg, 29 January 2013.

28 See the proposed Regulation on Medical Devices, *supra* note 3, Chapter VII, Surveillance in recent and proposed legal framework is set up in a form of self-regulation by economic operators, defined in Art. (1)23.

29 This definition comes from James Buchanan and Craig Stubblebine, "Externality", 29(116) *Economica* (1962), pp. 371 *et sqq*.

damages caused to the environment and health). The production and trading in unsafe medical devices in economic theory may be defined as negative externalities, which has to be compensated for.[30] In general, economists apply the concept "ex-ante regulation" to Competent Authorities' competences to regulate an economic activity before an accident occurs. Ex-ante regulation in economic theory is seen as a substitute for ex-post policies (exposure to tort liability) for correcting externalities.[31] Ex-post regulation such as tort liability, may correct the negative externalities. Ex-ante regulation might prevent negative externalities, such as accidents. Several economists have investigated the effectiveness of ex-post and ex-ante regulation.[32] Robert Innes concludes that ex-ante regulation might be more effective than ex-post liability.[33] One of his conclusions is the following: "*the direct ex-ante regulation of care can be more efficient than imposing ex-post liability for harm even when the government's cost of monitoring care (as required under ex-ante regulation) is significantly higher than the cost of monitoring accidents (as needed under ex-post liability).*"

Manufacturers of false implants have a high risk for bankruptcy, which frustrates the tort liability. Both the current and the newly proposed legal framework confer the ex-ante regulation competences on the Notified Bodies and not on the Competent Authorities. The ENVI proposals of 26 September 2013 also set forth that the Notified Bodies would be responsible for market admittance of medical devices.

IV. Ex-ante third party conformity assessment

The European regulatory framework for medical devices is quite different from the legal framework existing in the United States (US). In the US, pre-market approval for medical devices by the US Food and Drug Administration (FDA) is compulsory. Several procedures are applied in the US for pre-market approval, but the FDA takes the final decision on whether a medical device may be placed on the market and used in the US or not.[34]

In Europe, both the currently existing legal framework and the newly proposed framework set forth that the conformity assessment of a medical device intended for the European market shall be carried out by private bodies that are not part of public administration. Those private bodies are designated by Member States as Notified Bodies. The manufacturer that wants to introduce a medical device in Europe has to contract a Notified Body for a conformity assessment. Conformity assessment means that the Notified Body has to assess if a medical device complies with the essential requirements of safety and performance, if possible by referring to the harmonized standards published by the European Commission. The Notified Body has to rely on the document that the manufacturer provides. For the purposes of the conformity assessment the manufacturer should perform a quality assurance system for its working process. The Notified Body must assess the documentation about the quality assurance system and the devices provided by the manufacturer.

The most important document for the assessment, according to the current as well as the newly proposed legal framework, is the manufacturer's declaration that the products meet the essential require-

30 Stefano Bartolini, "Beyond Accumulation and Technical Progress: Negative Externalities as an Engine of Economic Growth", Quaderni Università degli Studi di Siena DIPARTIMENTO DI ECONOMIA POLITICA n. 390 – Luglio, available on the internet at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=467002> (last accessed on 4 November 2013). The author gives a description of negative externalities on the environment.

31 Charles D. Koldstad, Thomas S. Ulen and Gary V. Johnson, "Ex Post Liability for Harm vs. Ex ante Safety Regulation: Substitutes or Complements?", 80(4) *The American Economic Review* (1990), pp. 888 *et sqq*.

32 One of the first law and economics studies was done by Steven Shavel in 1884: Steven Shavell, "A Model of the Optimal Use of Liability and Safety Regulation", 15 *Rand Journal of Economy*, pp. 271 *et sqq*. Also: Steven Shavell, "Liability for Harm versus Regulation for Safety", 13 *Journal of Legal Studies*, pp. 357 *et sqq*.

33 Robert Innes, "Enforcement Costs, Optimal Sanctions, and the Choice between Ex-post Liability and Ex-ante Regulation", 24 *International Review of Law and Economics* (2004), pp. 29 *et sqq*. One of his conclusions is the following: "The direct ex-ante regulation of care can be more efficient than imposing ex-post liability for harm even when the government's cost of monitoring care (as required under ex-ante regulation) is significantly higher than the cost of monitoring accidents (as needed under ex-post liability)."

34 [FDA Overview of Device Regulation] Available on the internet at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> (last accessed on 4 November 2013): Even for the pre-market notification according to the 510(k) Food, Drug and Cosmetic Act, the FDA still has to approve the admittance of the device. 510 (K) constitutes fastest procedure in the United States to place a medical device on the market. [Overview of Device Regulation], available on the internet at <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/default.htm> (last accessed on 4 November 2013).

ments set forth in the Directives concerning medical devices. The Notified Body has to check the manufacturer's declaration on the basis of the documents submitted to it. This may encourage the manufacturer to provide unilaterally positive documents about the product. In practice it is very hard to determine whether this happens or not, because patients and healthcare professionals have no access to the documents that are relevant to the conformity assessment procedure. These documents are not available to the public, which results in lack of transparency with regard to the process and the outcome of the conformity assessment. Moreover, neither the current nor the newly proposed legal framework includes a role for Competent Authorities to supervise this process. However, the proposed Regulations specify more details with regard to the documents that a manufacturer has to send to the Notified Body.[35]

If a medical device intended by the manufacturer for the EU market complies with the essential requirements, then the Notified Body assigns the CE mark to the device concerned. After the conformity assessment and the assignment of the CE mark, the device may be placed on the market, put into circulation and traded throughout Europe. The Medical Device Directive currently in force does not impose requirements for the use of medical devices. National legislation may provide obligations and professional standards for users (mostly physicians), patients, and healthcare facilities.[36]

Neither the currently existing legal framework nor the newly proposed one provides any general requirement for manufacturers to conduct clinical trials of medical devices. It is only for the highest risk medical devices falling in Class III that the manufacturer must carry out his or her own clinical research and submit this information to the Notified Body. Only a small share of medical devices fall into Class III, which means that the market admission of most medical devices does not depend on clinical research.[37] The essential requirements for medical devices are set forth in the current Directives in rather general terms, such as "eliminate or reduce risks as far as possible" and "take any appropriate measures to protect against risks that cannot be excluded." Any risks of the product should be "balanced" against the benefits of the device for the patient. The proposed Regulations provide as part of the general safety and performance requirements, a much more detailed list for essential requirements compared to the current Directives.

V. Problems with the current legal framework

The incidents with faulty breast implants and unsafe hip implants[38] demonstrate that the current legal framework has not been able to prevent a number of serious incidents involving medical devices. Cases involving hip implants, PIP implants and meshes have shown that unsafe medical devices could cause serious harm for patients. The European Commission's proposed new legal framework for medical devices has the aim to prevent similar incidents from re-occurring.

The PIP case illustrates that the current legal framework is vulnerable to fraud. In this case the manufacturer used non-medical grade silicones in breast implants whereas the CE mark was given for other silicon material. Unlike the manufacturers of PIP implants, the manufacturers of the metal ASR hip implants did not cause harm by fraud. The metal-on-metal hip implants tend to create tiny particles

35 See the Commission Proposal for a regulation concerning Medical Devices, *supra* note 3.

36 Par. 13 of Annex I of the Medical Device Directive specifies the information that should be provided by the Manufacturer. Instructions for the use of the medical device must be understandable for the medical specialist; however, some requirements for the patients are also formulated.

37 The Medical Devices Directive sets forth a system for the classification of medical devices in Classes I, IIa, IIb and III. For each class, there is a specific procedure for conformity assessment. When a product is classified in Class I, the manufacturer shall perform the conformity assessment mainly through self-assessment. For Classes IIb, IIa and III, the procedures set by the chosen Notified Body must be followed. Class III products are high-risk, Class IIa and IIb products have an average risk and Class I products have low risk. A decision of the European Commission determined in 2003 that breast implants fall in Class III: Commission Directive No 2003/12/EC on the Reclassification of Breast Implants in the Framework of Directive 93/42/EEC on Medical Devices, OJ L 28, 4.2.2003, pp. 43–44.

38 Daily main reporter, "Thousands to Undergo Blood Tests after Fears Replacement Metal Hips are Poisoning Them", 17 June 2011, Mail Online, available on the internet at <http://www.dailymail.co.uk/health/article-2004218/Thousands-hip-op-patients-fear-poisoned-metal-prosthetics.html> (last accessed on 4 November 2013): "In April 2010, the United Kingdom's (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) issued a medical device alert that included specific follow-up recommendations for patients with MoM hip replacements. The recommendations included blood tests and imaging for patients with painful MoM hip implants. In February 2012, MHRA published a medical device alert and updated it in June 2012 with advice on the management and monitoring of patients with MoM hip systems."

that can damage tissue, muscle and bone, and release toxic metals to the blood. In the Netherlands several incidents with meshes have been reported.[39] Such incidents show that there is a problem with the current regulation of medical devices. Serious shortcomings of the current system have also been highlighted by the *British Medical Journal* (*BMJ*)[40]: The *BMJ* and the *Daily Telegraph* reported how a non-existing hip implant has been successfully placed on the European market in the framework of the current legislation.[41]

It appears that no public body, neither European nor national, actually monitors the safety of a medical device after it gets placed on the European market. As there is no EU level monitoring of devices that are already on the market, supervision is delegated to the Competent Authorities operating in the Member States. European legislation knows no centralized regulation regarding medical devices. To supervise and maintain the safety of medical devices, a Competent Authority needs to be authorized by national legislation for legitimate law enforcement and monitoring of compliance with national legislation. Neither the current nor the proposed new European legal framework for medical devices can confer specific authorities upon Competent Authorities for law enforcement and legitimate monitoring of compliance.[42] It is left for the national constitutional and administrative legislation to confer competences for legitimate ex-post and ex-ante supervision and law enforcement upon the Competent Authorities. Due to the differences between the constitutional and administrative systems, the instruments and sanctions available to Competent Authorities to correct infringements of the law differ across Member States.

In particular, there are large differences across the Member States in terms of organization of ex-post supervision. It is not always clear who should report an incident related to a medical device. In the PIP case it appears that healthcare professionals and patients had complained about the PIP implants already before the European authorities recalled those implants in 2010. Several rumours about the failures of the PIP implants have been reported in Europe since 2006.[43] For example, in the Netherlands an increase in the number of incidents with PIP breast implants has been recorded by the Dutch Health Care Inspection, but because of lack of capacity no coordination on this issue has taken place so far.[44] Only in 2010 the French Competent Authority AFSSAPS published a Notification of Vigilance under the Medical Device Directive (MDD).[45] So it took at least three years before the fraud was notified. The PIP case demonstrates that the safety of medical devices cannot be fully guaranteed in the current legislative framework.

The Directives currently in force confer the competence of ex-post regulation upon private parties. The manufacturers are supposed to carry out the post-market surveillance themselves. They are also responsible for setting up a vigilance system. Manufacturers have to report incidents to the Competent Authority in the Member States concerned. The European Commission formulated on 8 January 2013 its Guidelines on a Medical Devices Vigilance System (MEDDEV 2.12-1 rev) to set forth the respective responsibilities of manufacturers and Competent Authorities regarding incidents and field safety corrective actions.[46] These Guidelines are soft law instruments, which means that they are not officially binding upon the manufacturers and the Notified Bodies.

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39 Lensen EJ, Withagen MI, Stoutjesdijk JA, Kluivers KB, Vierhout ME., "The use of synthetic mesh in vaginal prolapse surgery: a survey of Dutch urogynaecologists" 262(1), *Eur J Obstet Gynecol Reprod Biol,* May;162(1):113–115 (2012), [starting page 113: doi: 10.1016/j.ejogrb.2012.02.004. Epub 2012 Mar 6. Avaibable online at <http://www.ncbi.nlm.nih.gov/pubmed/22397742> (last accessed on 4 November 2013). Metal Hips were recalled by NHRA.

40 "Europeans are left to their own devices", *BMJ* 2011; 342 doi: http://dx.doi.org/10.1136/bmj.d2748 (Published 15 May 2011) Cite this as: BMJ 2011;342:d2748

41 "Medical Device Regulation, How a fake hip showed up failings in European device regulation," *BMJ* 2012; 345, doi: <http://dx.doi.org/10.1136/bmj.e7090> (Published: 24 October 2012). Cite this as: BMJ 2012;345:e7090

42 One can argue that Arts. 63, 67, 69, 70 and 72 of the proposed Regulation regarding medical devices formulate concrete tasks for Competent Authorities.

43 Robert Mendick, Laura Donnelly and Harriet Alexander, "Breast Implant Scandal: Whe Whistleblowers", The Telegraph, 31 December 2011, available on the internet at <http://www.telegraph.co.uk/health/healthnews/8986746/Breast-implant-scandal-the-whistleblowers.html> (last accessed on 4 November 2013)

44 W. Sorgdrager, "Van incident naar effectief toezicht, Onderzoek naar de afhandeling van dossiers over meldingen door de Inspectie voor de Gezondheidszorg", in order by Dutch Health Minister published on 19 November 2012, p. 52.

45 Recall by the French Government according to Art. 10 of the Medical Device Directive saying the following: "Afssaps have registered an increase of reported incidents over the last three years concerning silicone filled breast implants manufactured by Poly Implant Prothese (PIP). The elements collected during this inspection showed that most of the breast implants manufactured since 2001 have been filled with a silicone gel different from the one described in the CE-marking file and the batch manufacturing files".

46 Medical Devices Vigilance System, January 2013, available on the internet at <ec.europa.eu/health/medical-devices/documents/guidelines/ under 2.12>.

Nevertheless, the European Union principle of sincere cooperation requires the Member States to follow these Guidelines.[47] Most of the content of the Guidelines will be included in the two proposed Regulations to bind all parties to a vigilance system. The court ruling of 14 November 2013 however stated that Notified Bodies have to fulfill the surveillance paragraph of Annex II of the Medical Devices Directive for class III medical devices.

Another problem with ex-post regulation is related to the market features in the medical devices sector. The majority of the manufacturers are small and medium sized enterprises (SME).[48] It might be difficult for smaller enterprises to set up a vigilance system. Ex-post liability such as tort liability is difficult to enforce in this sector. Most SME companies for medical devices go bankrupt after a recall is published. Bankruptcy after recall makes it difficult for patients to make use of the remedies to correct and compensate for harm. There is no compulsory product liability insurance for medical devices.

To start a tort liability procedure, patients need to know the address of the manufacturer or distributer. The label of a device must bear the name or trade name and address of the manufacturer. For devices imported into the EU the label shall contain also the name and address of the authorised representative.[49] However, this information is often not provided for implantable medical devices, which are yet another cause of serious problems related to tort liability. This shows that ex-post liability as an ex-post remedy for patients is very difficult to enforce under both the current and the newly proposed regulatory framework.

VI. Ex-post regulation in the current legal framework

The current Directives and Guidelines define several tasks for manufacturers and Notified Bodies regarding the vigilance of medical devices. The court ruling of 14 November 2013 however stated that Notified Bodies have to fulfill the surveillance paragraph of Annex II of the Medical Devices Directive for class III medical devices. To promote a common approach for manufactures, Notified Bodies and Competent Authorities, the European Commission formulated several Guidelines on vigilance.[50] These guidelines are, however, not legally binding on those parties as the principle of sincere cooperation is not binding on private parties, only on Member States.[51] Member States have to use their competences to make the manufacturers and the Notified Bodies comply with the Guidelines. As opposed to this, the proposed Regulations will be binding in their entirety on manufacturers and Notified Bodies and will apply directly in all Member States. [52]

According to the current legal framework, the ex-post regulation duty of the Competent Authorities can be formulated as follows: If a medical device does not comply with the essential requirements set forth in the Directives concerning medical devices, then the Member State concerned has to inform the European Commission about this.[53] This ex-post supervision in Member States is delegated to the Competent Authorities. Member States and Competent Authorities have to cooperate with each other and with the European Commission.

If one of the Member States reports non-compliance, then the European Commission has to ensure that other Member States are kept informed about the device concerned. Another ex-post supervision duty of the Competent Authorities is the obligation to record and evaluate any information brought to their knowledge regarding incidents concerning malfunctioning or deterioration of a device that led or might have led to the death of a patient or user.[54] Information regarding recalls by the manufacturer should also be recorded and evaluated by Member States.

47 See for the definition of the principle of sincere cooperation, Art. 3, par. 4 of the Treaty of the European Union, *supra* note 17.

48 Eucomed, "Innovation, Reseach & SMEs", available on the internet at <http://www.eucomed.org/key-themes/innovation-research-smes> (last accessed on 4 November 2013). According to Eucomed data, 95 % of all manufacturers of medical devices are Small and Medium Entreprises (SME).

49 Par. 13.3. states the following: The label must bear the following particulars: (a) the name or trade name and address of the manufacturer. For devices imported into the Community, in view of their distribution in the Community, the label, or the outer packaging, or instructions for use, shall contain in addition the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community.

50 European Commission, DG Health & Consumers, "Guidance MEDDEVs", available on the internet at <ec.europa.eu/health/medical-devices/documents/guidelines/> (last accessed on 4 November 2013).

51 See for the definition of the principle of sincere cooperation, Art. 3, par. 4 of the Treaty of the European Union, *supra* note 17.

52 According to Article 288 TFEU.

53 Article 8 of the Medical Device Directive, *supra* note 8.

54 Article 10 of the Medical Device Directive, *supra* note 8.

Yet another ex-post supervision task of Member States is to end the infringement caused by a manufacturer that affixed the CE marking unduly.[55] For medical devices falling in the highest risk class, Member States must fully record all serious adverse events and notify these immediately to all Competent Authorities of other Member States where a clinical investigation is being performed.[56] Ex-post supervisory authority is regulated in different ways in the diverse legal systems of Member States. Consequently, the position and competences pertaining to vigilance might differ across States.

Neither the current nor the proposed new legal framework formulates specific requirements for Competent Authorities. A specific responsibility of Member States is to inform the European Commission about the Notified Bodies that they designate for carrying out the conformity assessment procedure. Member States have to supervise the Bodies that they notify and have to withdraw the notification if a Body no longer meets the criteria stipulated in the Directives concerning medical devices.

VII. Ex-post supervision in the proposed new Regulations

As discussed above, the proposed new legal framework for medical devices will be set forth in two Regulations[57] that will replace the three currently existing Directives. European Regulations have far more binding effect for the manufactures than European Directives have. The new Regulations will bind the manufacturers and the Notified Bodies in their entirety and will be directly applicable in all Member States. Chapter VII of the proposed Regulation for Medical Devices deals with vigilance and market surveillance issues. It formulates several ex-post responsibilities for the Competent Authorities and imposes certain obligations for manufactures to ensure remedies for patients and healthcare professionals against negative externalities.

The proposed new Regulation for Medical Devices intends to introduce some form of ex-ante regulation, which prompted a debate about pre-market approval. Specifically, the proposed Regulation introduces the Medical Device Coordination Group (MDCG), which would play a central role in achieving a harmonised interpretation and implementation of the Regulation. The MDCG would be an expert committee bringing together representatives of Member States. According to the European Commission proposal, only the new MDCG would be authorized to scrutinise third-party pre-market assessment reports for certain high-risk medical devices prior to market introduction.[58] The Commission emphasises that this does not amount to "pre-market approval".

In its draft opinion submitted to the ENVI Committee of the European Parliament, the Parliamentary Committee on the Internal Market and Consumer Protection amended the original proposal to make this procedure compulsory for high risk devices.[59] The Council Committee on the Employment, Social Policy, Health and Consumers is still discussing this so-called scrutiny-procedure. As mentioned earlier in this article, the ENVI Committee proposed the introduction of a centralized marketing authorisation procedure for innovative and high-risk devices to be carried out by the European Medicine Agency and a decentralised market authorisation procedure for high-risk devices to be carried out by the Competent Authorities in the Member States. In Europe market authorisation means more or less the same as pre-market approval. Therefore, the pre-market authorization proposed by ENVI amounts to an instrument of ex-ante regulation. The European Parliament endorsed the ENVI proposal despite the highly controversial nature of the issue[60] and the criticism by the medical technology industry. In the Council, however, it seems at this point that only the French delegation is likely to support the market authorisation procedure.[61] Further to the ENVI vote and the plenary vote in Parliament, the amended proposal delegates the conformity assessment of im-

55 Article 18 of the Medical Device Directive, *supra* note 8.

56 Paragraph 2.3.5 of Annex X to the Medical Device Directive, *supra* note 8.

57 Commission Proposal, *supra* note 3.

58 See the proposed Art. 44 on the mechanism for scrutiny of certain conformity assessments.

59 (2012/0266(COD) 4.4.2013. In addition, the Committee on the Internal Market and Consumer Protection sent its DRAFT OPINION to the Committee on the Environment, Public Health and Food Safety (ENVI) with several proposed amendments, amendment 53 2012/0266(COD) 4.4.2013).

60 Henriette Jacobsen, "MEPs divided ahead of vote on medical devices", EurActiv special report, 5 July 2013, available on the internet at <http://www.euractiv.com/special-report-medical-devices-r/meps-divided-medical-devices-reg-news-529087> (last accessed on 4 November 2013).

61 Dutch 'kamerstuk' (Parliamentary documents), available on the internet at <https://zoek.officielebekendmakingen.nl/kst-21501-31-283.html> (last accessed on 4 November 2013).

plantable Class III medical devices to "Special Notified Bodies", which are private bodies under the supervision of the European Medicines Agency (EMA).

The following paragraphs will explore further the question whether the ex-post supervisory authorities of the Competent Authorities may compensate for and correct the externalities regarding medical devices when these are already placed on the European market.[62] Chapter VII of the proposed Regulation regarding Medical Devices defines ex-post regulation in the sections on vigilance and market surveillance.

First of all, one should note that the proposed Regulations formulate more legally binding obligations for the manufacturer and the Notified Bodies than the Directives. To include also distributors and authorized representatives the proposed Regulation uses the term "economic operators".

It is also noteworthy that the proposed Regulation concerning Medical Devices guarantees more information for patients. It sets forth that patients who are implanted with a device should be given essential information on the implanted product, including any necessary warnings or precautions to be taken. This obligation has been inserted with the intention to make it easier for the patient to choose between implants. However, the practice in Member States will be essential, because the hospitals and healthcare professionals will be responsible for providing the patients with the necessary information.

To improve the traceability of medical devices, manufacturers must complement their products with unique device identification.[63] Registration of a medical device in a central European database will be compulsory. The proposed Regulations introduce an EU portal where manufacturers must report serious incidents.[64] Economic operators have to report the corrective actions that they have started to reduce the risks. Manufacturers of high-risk devices and diagnostic devices must draw up a summary of their safety and performance with key elements of the clinical data available.[65] These obligations set forth for manufacturers should help patients to make use of the available legal remedies if a medical device fails.

The European Commission intends to ensure access for healthcare professionals and patients to the European database for the electronic system for vigilance.[66] Manufacturers will have the obligation to update their technical documentation with information on incidents received from healthcare professionals, patients and users.[67] Member States will be required to take all appropriate measures to encourage healthcare professionals, users and patients to report to their Competent Authorities the incidents with medical devices.[68] However, the position of patients and healthcare professionals might be different across Member States due to variations in national level regulation. The multidisciplinary advisory committee proposed by the European Parliament would involve patients and healthcare professionals along with experts, civil society organizations and other stakeholders to participate in the regulatory processes, which might strengthen the position of patients and users.[69]

Article 76 of the proposed Regulation regarding Medical Devices defines the role and responsibilities of the Competent Authorities designated by Member States. Member States have to entrust the Competent Authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. Article 28, paragraph 6 of the proposed Regulation sets forth that "the national authority responsible for Notified Bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks". Furthermore, Article 67 sets forth the following: "The Competent Authorities may require economic operators to make the documentation and information necessary for the purpose of carrying out their activities available and, where nec-

62 The draft report of the ENVI <Commission>{ENVI}Committee proposed an amendment to introduce an obligation for innovative medical devices and Class III devices to undergo a new procedure for marketing authorisation, carried out by the Competent Authority in the Member States: "*The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the devices referred to in Article 41a(1) throughout the Union.*" Also, "None of the following devices may be placed on the market of a Member State unless a national marketing authorisation has been granted by the competent authority of that Member State through the decentralised procedure referred to in Article 41d, and in accordance with the provisions of this Regulation".

63 Commission proposal for a Regulation on Medical Devices, *supra* note 3, Annex I, par. 19.

64 Commission proposal for a Regulation on Medical Devices, *supra* note 3, Art. 62.

65 Commission proposal for a Regulation on Medical Devices, *supra* note 3, Annex VII.

66 Commission proposal for a Regulation on Medical Devices, *supra* note 3, Art. 62, par. 3.

67 Commission proposal for a Regulation on Medical Devices, *supra* note 3, Art. 65.

68 Commission proposal for a Regulation on Medical Devices, *supra* note 3, Art. 61, par. 5.

69 Commission proposal for a Regulation on Medical Devices, *supra* note 3 Art. 78a.

essary and justified, enter the premises of economic operators and take the necessary samples of devices. They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary". Competent Authorities have to coordinate their market surveillance activities. The new regulatory framework prescribes the possibility of sharing work and specialisation among the Competent Authorities operating in Member States.

Article 63 formulates the obligation for Member States to 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 brought to their attention will be evaluated centrally by their Competent Authority. The national Competent Authorities have to carry out a risk assessment with regard to reported serious incidents or field safety corrective actions and inform without delay the other Competent Authorities of the corrective action taken or envisaged by the manufacturer. The proposed new Regulation formulates in Article 63 the responsibilities for Member States to analyse serious incidents and field corrective actions. The European Parliament proposes several amendments to article 63, and one of them intends to ensure that all incidents are recorded.[70]

VIII. Amendments reinforcing ex-post regulation

Further to the discussion above on ex-post regulation and remedies, a number of recommendations will be put forward in this contribution with regard to reinforcing ex-post regulation by Competent Authorities and strengthening ex-post remedies for patients and healthcare professionals. Some amendments formulated by the European Parliament have to be discussed to address this issue. As part of the revision process, Parliament consulted the European Society of Cardiology (ESC), which asked for improvement of the system of post-market surveillance and introduced the concept of "conditional approval" towards this end. This concept makes it possible to introduce a time period during which the approval can be reviewed. Conditional approval might encourage healthcare professionals and patients to participate in the evaluation of a medical device. This might create a form of self-regulation that reduces the supervisory tasks of the Competent Authority.[71] Despite the ESC recommendation, not one of the 907 amendments formulated by the European Parliament took over this suggestion. However, several amendments endorsed by Parliament advocate for increasing the involvement of healthcare professionals in the implementation of the legal framework.[72] One important amendment concerns the definition of safety as "the avoidance of risk or harm caused by the medical device or associated with its use", which is relevant both for ex-ante and ex-post regulation.[73] Once safety is defined more clearly, it will be easier for the Competent Authorities to categorize risks and monitor them. As a result, Competent Authorities would be increasingly able to dismiss unsafe devices from the market.

Another important amendment to the articles on vigilance proclaims the following: "Member States shall take all appropriate measures, including targeted information campaigns, to encourage and enable healthcare professionals, users and patients to report to their Competent Authorities suspected serious incidents" to enforce the ex-post supervision.[74] To ensure effective ex-post remedies for patients, some amendments propose the introduction of compulsory insurance for manufacturers of medical devices with an appropriate or minimal coverage.[75] A number of amendments turn the burden of proof in favour of the patient, such as the following: "Manufacturers shall bear the cost to the health system of treatment, operations and diagnostic procedures practiced on patients as a result of defects in or malfunctioning of health devices detected by the health authorities or the manufacturers themselves."[76] Amendment 471 prescribes that the public and healthcare professionals should be enabled "to

70 Amendment 653, AM\\936128EN.doc

71 ESC's response to European Commission's Proposals for new regulation to govern medical devices, available on the Internet at <http://www.escardio.org/about/press/press-releases/pr-13/Pages/esc-proposals-medical-devices-directives.aspx> (last accessed on 4 November 2013).

72 Amendment (53) sets forth that Member States should take all necessary measures to raise awareness among healthcare professionals, users and patients about the importance of reporting suspected serious incidents. In the legislative Resolution this has been incorporated as Amendment 46.

73 Amendment 27 RMDD. In the legislative Resolution this has been incorporated as Amendment 81.

74 Amendment 98 Proposal for a regulation Article 61 – paragraph 3, in the legislative Resolution Amendment 61.

75 Amendment 165, in the legislative Resolution Amendments 25a, 87, 103, 106.

76 Amendments 321 and 438. This Amendment has not been registered in the legislative Resolution Amendment.

have an overview of vigilance data and market surveillance activities", which would be important for ex-post regulation. Once healthcare professionals are granted better access to information about medical devices, they will be able to supply vigilance data. Moreover, better access to data will enable healthcare professionals to better inform their patients about medical devices.

IX. Conclusion

The European Commission, European Parliament and Council are currently revising the European regulatory framework of medical devices. The debate on the revision process has been dominated so far by the issue of pre-market approval for certain categories of devices. Pre-market approval would be carried out by either an European agency or by special Notified Bodies.

This article examined the concept of pre-market approval by applying a number of economic terms to the context of medical device regulation. In economic theory health risks related to medical devices can be qualified as externalities. Both ex-ante regulation and ex-post regulation can, in principle, correct negative externalities. Some economists argue that ex-ante regulation can be more effective than ex-post regulatory instruments such as private liability claims.

The current EU rules set forth in the Directives concerning medical devices attribute no ex-ante regulation to Competent Authorities. Under the current system neither patients nor healthcare professionals have access to ex-ante and ex-post regulatory instruments, except private liability against the manufacturer. The current EU rules only give a few ex-post competences to the Member States that are delegated to the Competent Authorities.

This contribution argued for a better balancing of ex-ante and ex-post instruments with the aim to compensate for the negative externalities of medical devices in the proposed new Regulations. The analysis pointed out a number of serious shortcomings of the current European legal framework concerning medical devices. Notably, Competent Authorities are not involved in the process of placing medical devices on the market since conformity assessments are done by the Notifies Bodies. The new Regulations proposed by the European Commission do not address this issue and they do not give to the Competent Authorities any competence regarding the market entry of devices. However, the amendments proposed by the European Parliament envisage more control by the Competent Authorities over Notified Bodies and the designation of special Notified Bodies to assess implantable devices. At this moment the procedures for the designation of these special Notified Bodies are not specified. The exact ex-post regulatory competences for patients, healthcare professionals and Competent Authorities are not yet clear. It remains to be seen whether the deliberation and decision of the Council will bring further changes to the newly proposed regulatory framework.

For a fair balance between ex-ante and ex-post supervision in the new legislation at the European and national levels it will be necessary to strengthen the position of Competent Authorities, patients and healthcare professionals and empower them to work together for ensuring the safety of medical devices.