The ethics of biomedical innovation:
The case of medical device legislation in the EU

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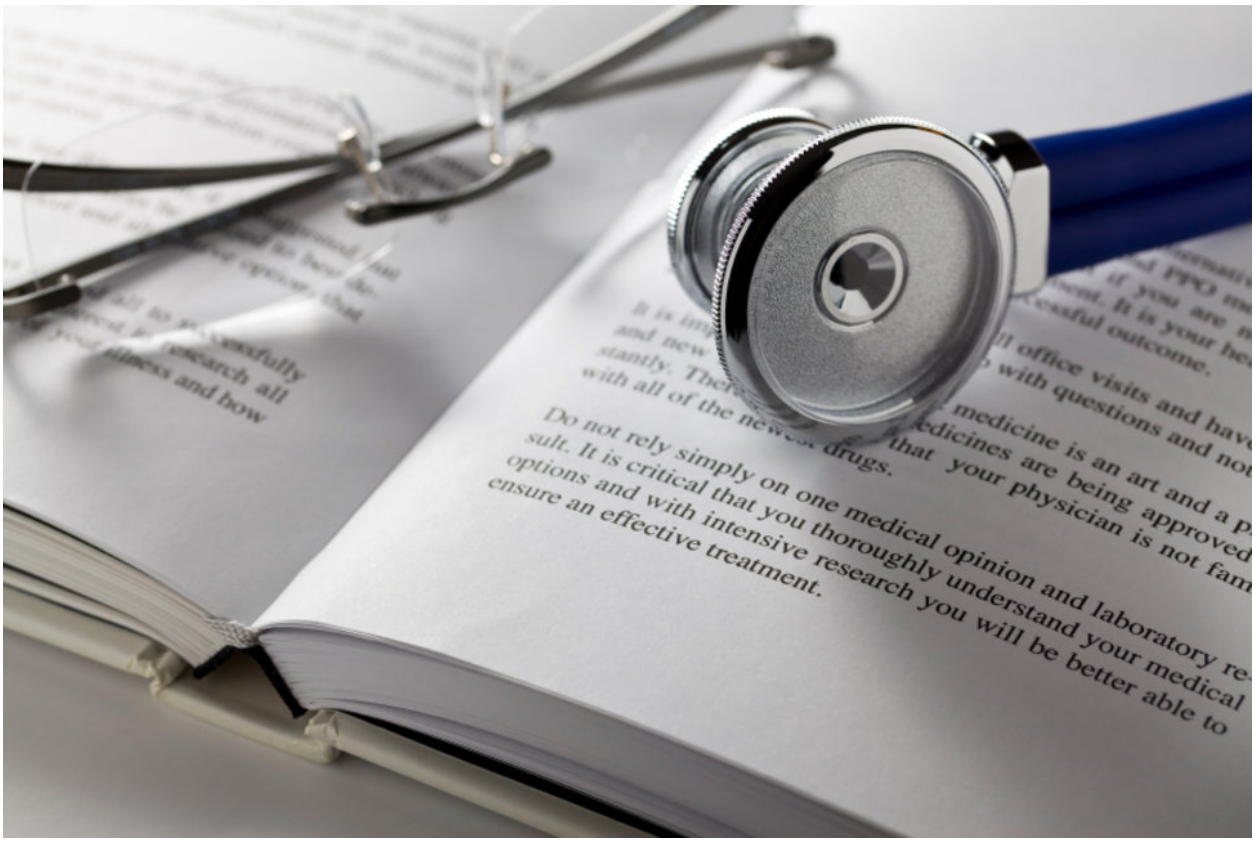

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Abstract

Recently, there have been several controversies in the medical devices sector, of which the ruptured PIP breast implants got most public attention. Several experts in the field believe these controversies to be possible due to the current legal and regulatory framework of medical devices, which is not very demanding. There are several differences with the pharmaceutical legal and regulatory framework.

In 2008, the European Commission started a review process of the current legislation on medical devices, resulting in a proposal for new medical device regulation in September 2012. Since then, the topic has been discussed by the relevant stakeholders, who agreed upon a draft text for a Medical Devices Regulation in June 2016. It is of interest to investigate whether ethical notions addressed in the literature, such as patient safety, the availability of information about medical devices to health care professionals and patients, the lack of trust of patients in the healthcare system due to the recent controversies, the legal uncertainty that may arise due to the regulatory differences between pharmaceuticals and medical devices, and methodological challenges that typically arise in the context of investigating medical devices, have been taken into account in the new Regulation. The main question of this thesis consequently is: to what extent have the ethical notions on medical device legislation been taken into account in the new European Regulation on Medical Devices?

In order to answer this question, a literature study is performed to identify the main ethical notions on medical devices. As it is also of interest to investigate whether the ethical notions are discussed during parliamentary debates, a discourse analysis on the transcripts of debates is performed. Third, a comparison is made between the current Medical Device Directive and the proposed Medical Device Regulation. Fourth, a policy analysis is performed in which it will be discussed to what extent the ethical notions can be considered to have been taken into account in the new Regulation.

It is concluded that most of the ethical notions addressed in literature have been discussed during the parliamentary debates. The theme of safety versus innovation has been frequently discussed as well. In the new Medical Devices Regulation, the notion of patient safety can be considered to be partially taken into account, the notion of reliable and responsible clinical research to not be taken into account, the notion of transparency to be taken into account, and the notion of legal certainty and patients' trust to, at most, be slightly taken into account.

Based on these results, it is recommended that an ethical discussion be performed on the balance between safety and innovation, and on the extent to which medical device legislation should be similar to medicinal products. In addition, it is recommended that the effectiveness of the new Regulation be monitored and, where necessary, notions concluded to be 'not taken into account', or 'partially taken into account', be taken into account in future versions of the Regulation on medical devices, preferably before any new controversies have happened. This approach might help to restore patients' trust, while ensuring more medical devices to be safe for patients.

It is hoped that this thesis provides valuable information on the ethical notions on medical devices - medical device legislation in particular- for policy makers, politicians, and other actors involved in future regulation of medical devices.

Contents

1 Introduction

'Flexible rules and pursuit of profit cause 'Wild West' culture in the medical devices industry,'[1] is the headline of an article in a Dutch newspaper after revealing an incident with medical devices in the biggest academic hospital in the Netherlands.[2] This incident, in which patients were not informed about being part of academic research concerning a new medical device, is the most recent issue in quite a list of controversies related to medical devices, which were broadly covered in the media during the last decade.

One of the most notorious recent issues with faulty medical devices has been the PIP scandal, involving ruptured *Poly Implant Prothèse* (PIP) breast implants, which resulted in more than 80.000 women being affected around Europe between 2001 and 2012,[3] due to a fraud, but also due to a defective shell.[4] Another controversy, which has been broadly covered by the media since 2010, considers the metal-on-metal hip implants. While these controversies have received a lot of public attention, according to public health experts, they are the tip of the iceberg. 'If the breast implant PIP scandal has called the attention of the media and the public on medical devices' security, many other incidents have not been covered by the media such as faulty stent grafts or elbow implants.'[5]

What are the reasons for so many controversies in the medical device sector? Experts, politicians and the journalists of the Dutch newspaper article seem to agree that the current rules in this sector are not strict enough, in order to prevent public health issues from happening.[6] That is, in comparison with other medical products, such as pharmaceuticals, the legal and regulatory framework of medical devices is much less demanding. There are several differences with the pharmaceutical legal and regulatory framework. For example, where the market introduction of pharmaceuticals is regulated by strict protocols, in which safety, efficacy, and long-term effects are tested during extensive clinical studies (after being tested on animals), market introduction of medical devices lacks such procedures. In the case of medical devices, manufacturers merely need to have a 'Conformité Européene' (CE)-mark before their device is allowed on the European market. Such CE-marks are provided by so-called notified bodies, which are privately funded institutes that provide all sorts of products and machines with CE-marks, from fridges to toys to medical devices. And these medical devices not only include low risk products, such as plasters and bandages, but also high-risk products, such as implantable heart valves and medical devices containing an active pharmaceutical ingredient, of which the risks are comparable to other pharmaceuticals. Notified bodies do perform tests on products before providing a CE-mark, so-called 'conformity assessments', but

[1] Literal translation of: http://www.nrc.nl/nieuws/2016/09/25/soepele-regels-en-winstbejag-oorzaak-van-wild-west-bij-medische-hulpmiddelen-4452398-a1523305.
[2] http://www.nrc.nl/nieuws/2016/09/25/soepele-regels-en-winstbejag-oorzaak-van-wild-west-bij-medische-hulpmiddelen-4452398-a1523305.
[3] See for example: Scientific Committee on Emerging and Newly Identified Health Risks, September 2013, p. 12; Hancher & Foldes, 2013, p. 432.
[4] Scientific Committee on Emerging and Newly Identified Health Risks, September 2013, p. 12; Hancher & Foldes, 2013, p. 432; http://www.euractiv.com/section/health-consumers/opinion/medical-devices-rules-patients-safety-must-be-reinforced/.
[5] http://www.euractiv.com/section/health-consumers/opinion/medical-devices-rules-patients-safety-must-be-reinforced/.
[6] Roscam Abbing, 2012, p. 420; Hancher & Foldes, p. 432 and Fouretier & Bertram, 2014, p. 352.

specific requirements and test protocols are lacking or vague[7], do not test the efficacy of the product for patients,[8] and notified bodies do not need to have, and consequently often do not have, specific expertise on the products they assess, like medical knowledge in the case of medical devices.[9] To make things worse, medical devices in the lowest risk class, like plasters, do not need to be assessed by notified bodies; manufacturers are allowed to perform conformity assessments themselves. To make things even worse, at the moment every notified body of each Member State of the European Union is allowed to approve medical devices of every risk category on the whole European market, while there are known to be differences in assessment quality and fees to be paid among the different notified bodies, even within one Member State.[10] Given these conditions, one can imagine that patient safety could easily be at stake and that patients could –unknowingly- be used as guinea pigs in the development of medical devices. Surprisingly, these undemanding conditions are unique for Europe; in the United States for example, pharmaceuticals and medical devices alike, have to undergo a centralized authorization procedure, performed by the FDA, before they are allowed on the market. [11]

Surprise about this un(der)demanding European legal framework, that potentially creates unsafe and harmful circumstances for patients, was the main motivation to write this thesis about the ethical notions related to medical devices. Further investigation into this topic showed that patient safety and lack of information to patients were not the only ethical notions at stake with the current legal framework. Several experts have, amongst others, warned about the lack of post-marketing surveillance and monitoring of medical devices on the market,[12] lack of access to information for the public and transparency on medical devices available on the EU market,[13] problems of classification and legal certainty of so-called 'borderline products' (i.e. products which have characteristics of medical devices, but also of, for example, pharmaceuticals), due to the large regulatory difference between medical devices and pharmaceuticals,[14] and the potentially harmful re-use of devices which are officially labelled as single-use devices.[15]

The European Union has not been deaf to these worries. From 2008 till 2012, after the most recent update of the Medical Device Directive (MDD) in 2007, but already before the PIP scandal in 2010, the European Commission performed a process of recast and review of the existing legislation concerning medical devices. In September 2012, the Commission published a proposal for a new Medical Device Regulation (MDR), which consequently has been discussed by the relevant legislative stakeholders, i.e. the European

[7] Fraser et al, p. 9; Hulstaert et al., 2012, p. 281; Boudard et al, 2013, p. 697; http://www.nrc.nl/nieuws/2016/09/25/soepele-regels-en-winstbejag-oorzaak-van-wild-west-bij-medische-hulpmiddelen-4452398-a1523305.

[8] For example: McCulloch et al., 2009, p. 7 & 8; Fraser et al., 2011, p. 13; Vinck et al., 2011, pp. 479-481; Hulstaert et al., 2012, p. 282; Mooijen et al., 2014, p. 2116; Harmon et al, 2015, p. 249.

[9] For example Fouretier & Bertram, 2014, p. 353; Vinck et al., p. 481; Cohen & Billingsley, 2011, p. 2.

[10] Vinck et al., p. 481; Cohen & Billingsley, 2011, p. 2.

[11] For example: Vinck et al, p. 483; Altenstetter, 2013, p. 464.

[12] For example: Mooijen et al, 2014, p. 2117; Cohen & Billingsley, 2011, p. 3; Cohen, 2011, p. 5; Fouretier & Bertram, pp. 355-356.

[13] See for example: Foldes, 2012, pp. 12-18; Sim, 2008, p. 67; Thompson, 2011, pp. 2-3; Singh, 2013, p. 475; Fouretier & Bertram, pp. 356-357; Harmon et al, 2015, pp. 249-250; Fraser et al, 2011, p. 12; Vinck et al, 2011, pp. 485-486; Cohen, 2011, p. 3; Cohen & Billingsley, 2011, p. 3.

[14] See for example: Chowdhury, 2013, pp. 141-160; Foldes, pp. 18-23; Fraser et al, 2011, p. 9; Tseliou, 2015, p. 24.

[15] See for example: Dunn, 2002, p. 993; Roth et al., 2002, p. 1091.

Parliament and the Council of the European Union. In June 2016, the European Parliament and the European Union agreed upon a draft text for the Medical Device Regulation.

From the perspective of the worries raised by experts in the field, such as ethicists and (legal) scholars, it is of interest whether these ethical concerns will be taken into account in the new Regulation. In this thesis, I will therefore examine to what extent the ethical notions addressed in the literature have indeed been taken into account into the new legislative text. Thus, the aim of the thesis is to provide an overview of the ethical notions that should be taken into account according to the experts, and to provide substantiated reasoning for the extent to which the ethical notions actually have been taken into account in the new Regulation on medical devices. This overview is hoped to offer valuable information on the ethical notions on medical devices -medical device legislation in particular- for policy makers, politicians, and other actors involved in future regulation of medical devices.

In making this overview, it is relevant to identify the most important ethical notions that the experts believe should be taken into account. In addition, it is of interest to investigate whether the ethical notions addressed by experts have been discussed during debates of the main European institutions involved in legislation. As only the debates of the European Parliament are publicly available, those debates will be used to investigate whether the ethical notions addressed by experts have been discussed, and if so, which specific themes have been addressed by which European political group. Since the recent controversies with medical devices received a lot of public attention, it is expected that at least the improvement of patient safety has been discussed extensively. Also, it is important to investigate whether and how each of the ethical notions has been taken into account in the new Regulation. The main question of this thesis consequently is: to what extent have the ethical notions on medical device legislation been taken into account in the new European Regulation on Medical Devices? The sub-questions to be answered are: 1) What are the most important ethical notions discussed in literature with respect to current European directives on medical devices? 2) To what extent and by whom have these notions been addressed during the parliamentary debates on the review of the legislation? 3) What are the main differences between the current Directive on Medical Devices and the proposed Regulation on Medical Devices? And 4) To which extent has each of the ethical notions discussed in the literature been taken into account in the new Medical Device Regulation?

To answer these questions, I will use the following research methods: first, I will perform a literature study on ethical notions related to medical devices, as expressed by scholars and experts in the field. Second, I will perform a discourse analysis on the transcripts of parliamentary debates, in order to determine whether the ethical notions identified by experts, are discussed during the debates, to identify which specific notions are addressed, and to touch upon striking similarities or striking dissimilarities between certain notions addressed by specific political groups, and the presumed position of the political groups with respect to free-market versus regulated-market. Third, I will compare the texts of the current Medical Devices Directive and the proposed Medical Device Regulation and describe the main differences. Finally, I will perform a policy analysis, in which I will discuss to what extent I consider the ethical notions to be taken into account in the new Regulation. This will be done by discussing for each ethical notion identified during the literature study, whether, based on the comparison between the current and the proposed legislation, it should be considered to be not taken into account at all, to be partially taken into account, or to be (mostly) taken into account.

I will discuss the methods employed and their limitations in more detail in the Methods chapter. Afterwards, I will discuss the results of the different analyses in the Results & Discussion chapter. Finally, I will finish with the Conclusion in which I will summarize the answers to the main question, and provide the main recommendations. Yet, before we are able to delve into the ethical notions addressed during the review process and to fully grasp the limitations of the research methods and the outcomes of the analyses, it is important to obtain more knowledge on the legislative process in the European Union, the medical device sector and the development of the Medical Device Directive. For that reason, I will start providing some background information on those important issues.

2 Background information

2.1 Medical device sector in the EU

The medical technology industry in the European Union is characterized by heterogeneity of products, a constant flow of innovations and a huge involvement of small and medium-sized enterprises. According to the WHO, the size of the European medical technology market can be estimated at roughly €100 billion.[16] As said, the sector can be characterized as very innovative, which is shown by the fact that medical technology products typically have a lifecycle of only 18-24 months, before an improved product becomes available.[17] In addition, the innovative nature of the industry is shown by the fact that for example in 2014 more than 11.000 patent applications were filed with the European Patent Office in the field of medical technology. This apparently is more than any other sector in Europe. In comparison, circa 5300 patent applications were filed in the area of pharmaceuticals and 5900 in the biotechnology industry.[18] Moreover, numbers of patent applications over the last decade show that the amount of patents filed in the medical technology industry has doubled, while the amount of patents in pharmaceutical and biotechnology industry remained relatively constant.[19] This indicates that the medical technology sector is increasingly innovative.

One of the factors adding to the innovative atmosphere in the field of medical technology is the fact that the industry consists of so many small and medium-sizes enterprises, which commonly are focusing on a restricted product portfolio and can switch quickly if opportunities turn out to lay in other direction. According to a recent factsheet by MedTech Europe, an alliance organization of European medical technology associations, almost 95% of the 25.000 medical technology companies in Europe are small and medium-sized enterprises (SMEs), the majority of which employ less than 50 people (small and micro-sized companies).[20] All these companies provide a lot of jobs: the European medical technology industry employs more than 575.000 people. In comparison, the US medical technology industry employs circa 520.000 people, and the European pharmaceutical industry employs 675.000 people. Consequently, this high level of employment is one of the reasons why not only the products of the medical technology industry, with potentially improved public health and reduced healthcare costs, but also the amount of European citizens employed is important for the European institutions.

Medical devices comprise a large part of the medical technology industry. In current EU legislation, a medical device is defined as “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human being for the purpose of:

[16] WHO Global Health expenditure Database, Eurostat, Eucomed calculations based on the data obtained from National Associations of 15 countries for the latest year available. In: MedTech Europe, The European Medical Technology industry.
[17] MedTech Europe, The European Medical Technology industry, p. 13.
[18] MedTech Europe, The European Medical Technology industry, p. 13.
[19] European Patent Office, Eucomed calculations. Medical technology as defined by World Intellectual Property Organization (based on the WIPO IPC-Technology concordance as revised in August 2014). In: MedTech Europe, The European Medical Technology industry.
[20] MedTech Europe, The European Medical Technology industry, p. 21.

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."[21]

This definition encompasses a lot and a large variety of products, from simple and low-risk devices like plasters, gowns and gloves, to high-risk invasive or implantable devices like knee implants, medical devices administering an active pharmaceutical ingredient devices and deep brain stimulators, and complex machines like heart-lung machines and PET-CT scanners. Medical devices are commonly classified into four different risk categories: from the lowest risk-class, class I, via medium-risk classes IIa and IIb to the highest risk-class, class III.[22] In 2012, the European association representing the medical device sector, *Eucomed*, estimated the total number of different medical devices on the European market to be around 500.000.[23] And MedTech Europe estimated that the number of medical devices that received CE-marking was more than 4500, around 500 of which were class III devices.[24]

Even though the medical devices definition encompasses a lot of devices, many products in the healthcare sector and related sectors, like the food-supplement and cosmetic products sector, are excluded as well. In-vitro diagnostic devices (device used in-vitro for the examination of specimens derived from the human body), pharmaceuticals, food-supplements, and cosmetic implants amongst others are not included by the medical device definition, and consequently the medical device directive does not apply to them. On the one hand this is understandable, because these products in general do differ significantly and have their own directives and regulations applied to them. For example, in the case of in-vitro diagnostic medical devices (IVDs), the European Commission has concluded, preparing the recent revision of the medical device directive by a public consultation, that it was better to keep regulating IVDs in a separate legislative act, even though both directives share horizontal aspects and have common challenges, because in this way the 'specificities of the products (different risks and functioning)'[25] would be respected.[26] On the other hand, however, treating these products in separate legislative acts, might be a source of discussion and might encourage developers to look for a leeway in the system, especially if rules and procedures of the different legal acts do differ significantly. That is, with the development of science and technology in the field of healthcare products, products tend to become more and more complex and not seldom they tend to be products in which properties of, for example, pharmaceuticals and medical devices are combined. Not surprisingly those products are called 'combination products'. The problem of these combination products is that they have to be categorized under one of the legal acts, and that they can be categorized under one act only, while their properties actually tend to be in the grey area of -at least- two legal acts. That is why some of these combination products are also considered to be so-called 'borderline products', because they are situated on the borderline between different legal acts. If these

[21] Article 1, sub 1 under (a), Directive 2007/47/EC (MDD Directive).
[22] See Annex IX of Directive 2007/47/EC on the classification criteria.
[23] Eucomed cited in European Commission, Impact assessment, *Part I*, p.19.
[24] MedTech Europe, The European Medical Technology industry, p. 10.
[25] European Commission: Impact assessment, *Part IV,* Appendix 10, p. 2.
[26] European Commission: Impact assessment, *Part IV,* Appendix 10, p. 2.

legal acts differ significantly, it obviously matters a lot which act the product is determined to belong to. The ethical issues related to borderline products, i.e. legal certainty and patients' trust, will be discussed in paragraph 4.1.4. I would like to finish this paragraph by stating that even though it is important to realize that borderline products are a challenge in the field of medical device legislation, in this thesis I will focus only on all the products (so, also some borderline products) which are determined to be medical devices, under the current medical device legislation. Consequently, I will only focus on the current medical device directive and its developments for the future. The reasons for this demarcation are, first, because it allows me to study the development of and issues related to a single piece of legislation, which will make issues more tangible, and second, that the largest group of healthcare products, which are non-pharmaceuticals, are covered by this piece of legislation.[27]

2.2 History of regulation in the medical device sector

Regulation of medical devices on a European scale only dates back to the beginning of the 1990s, when the European Union adopted three main directives: Directive 90/385/EEC concerning active implantable medical devices, commonly called the Active Implantable Medical Devices Directive (AIMDD),[28] Directive 93/42/EEC concerning medical devices, commonly called the Medical Devices Directive (MDD),[29] and Directive 98/79/EC concerning in-vitro diagnostic medical devices, commonly called the In-Vitro Diagnostic Devices Directive (IVDDD).[30]

Prior to the harmonization through European directives, there was great diversity amongst European countries in how medical devices were regulated.[31] One common feature however of most nation-wide regulations, was that regulation of medical devices evolved within the pharmaceutical regulatory framework, before ultimately splitting into an autonomous legal framework.[32] The adoption of the *New Approach* to legislative harmonization by the European Commission in 1985 stimulated the view that medical devices were different from pharmaceuticals and needed their own legislative framework. This *New Approach* to technical harmonization and standardization was a legislative strategy adopted to ensure that European Directives would provide for merely 'essential requirements' and that corresponding technical standards and specifications would be drawn up by European Standardization bodies, consequently being considered as 'harmonized standards' that would carry a presumption of conformity.[33] The *New Approach* can accordingly be characterized by three fundamental aspects. First, private organizations competent in the standardization area have the duty of drawing up the so-called 'harmonized standards' required for the production and placement on the market of products that are in

[27] Chowdhury, p. 102.
[28] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, O J L 189 , 20 July 1990, p. 17 – 36.
[29] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, commonly known as the Medical Device Directive, O J L 169/1, 12 July 1993.
[30] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, O J L 331, 7 December 1998, p. 1 – 37.
[31] Chowdhury, p. 101; Altenstetter & Permanand, 2007, pp. 389-390; Jefferys, p. 230; Foldes, p. 7; Tseliou, p. 7.
[32] Chowdhury, p. 101.
[33] European Commission, Guide to the Implementation of Directives Based on the New Approach and the Global Approach, Luxembourg: Office for Official Publications of the European Communities, 2000. The New Approach dates back to the 1985 adoption of the Council Resolution on a New Approach to Technical Harmonization and Standards, OJ 1985 C 136, 4 June 1985.

conformity with the 'essential requirements', as specified in the Directives.[34] Second, those harmonized standards maintain their status as voluntary standards,[35] so the standards are not mandatory nor legally binding. Third, national authorities (overseeing the notifying bodies) will presume that products do conform with the 'essential requirements' if they are manufactured in conformity with the harmonized standards drawn up by notified bodies. Since conforming to the harmonized standards is not obligatory, the producer consequently could choose to manufacture not in accordance with the harmonized standards. In that case however, the producer has an obligation to prove that his/her product conforms to the 'essential requirements' of the Directive, which obviously are legally binding.[36]

Due to these aspects, the *New Approach* to legislation is significantly different from earlier, much more prescriptive legal approaches, wherein 'detailed rules were provided in legislations and there was a greater risk of it being rendered redundant when the product turnover was high and driven by incremental innovation.'[37] As discussed in paragraph 2.1, the innovation cycles in the medical device sector are short, typically 18-24 months, and generally much shorter than in the pharmaceutical industry. In that sense, the *New Approach* would suit the medical device sector. Also, unlike the pharmaceuticals sector, wherein product differentiation is based on different combinations of chemical compounds, the medical device sector is highly diverse in its range of products.[38] This wide range of products and product types obviously make it more difficult to adopt product-specific norms or standards. Consequently, a legislative approach that is limited to harmonization of essential requirements related to the safety and performance of all the products regulated, following the *New Approach* to legislation, might be much more workable. All these factors are the reasons why the medical device sector was deemed distinct from the pharmaceutical sector, and why autonomous, non-prescriptive directives for the medical device sector were deemed necessary, in accordance with the *New Approach* to legislation.[39]

The medical device Directives then, aimed at balancing two major goals: first, ensuring the free movement of medical devices as goods in the internal market, and second, guaranteeing a high level of protection of public health and patient safety.[40] Consequently, legislative harmonization has been limited to essential requirements with respect to safety and performance of medical devices.[41] As well in line with the *New Approach,* the EU regulatory framework on medical devices has been complemented by several guidance documents that are legally non-binding and reflect the consensus of major stakeholders regarding technical standards and the interpretation of the directives. Such guidelines include the European Commission Guidance documents providing explanations to the directives (such as the Blue Guide[42]), the

[34] Chowdhury, p. 102; Jefferys, p. 230; Altenstetter & Permanand, 2007, pp. 389-390; Hancher & Foldes, p. 431; Singh, pp. 466-467.
[35] Chowdhury, p. 102; Jefferys, p. 230; Altenstetter & Permanand, 2007, pp. 389-390; Hancher & Foldes, p. 431; Singh, pp. 466-467.
[36] Chowdhury, p. 102; Jefferys, p. 230.
[37] European Commission, Guide to the implementation of directives based on the new approach and the global approach, i.e. 'Blue Guide', 2000, in: Chowdhury, p. 102.
[38] See for example Parvizi & Woods, pp. 6-8; Altenstetter & Permanand, 2007, p. 402; Jefferys, p. 234; Foldes, pp. 4-5.
[39] Foldes, p. 5; Chowdhury, p. 101; Altenstetter & Permanand, 2007, p. 390; Jefferys, p. 234; Parvizi & Woods, p. 8.
[40] Hancher & Foldes, p. 431; Foldes p. 5; Fouretier & Bertram, p. 351; Tseliou, p. 5; Singh, p. 466-467.
[41] Hancher & Foldes, p. 431; Foldes p. 5; Fouretier & Bertram, p. 351.
[42] European Commission, 'Blue Guide', 2016.

MEDDEV guidelines and consensus statements published by the Medical Device Expert Group (MDEG)[43], and the NB-MED Guidance documents issued by the Notified bodies[44]. *Eucomed*, the organization representing the manufacturers, designers and suppliers of medical devices at EU level, has also adopted a set of non-binding rules for its members.[45,46]

The directives themselves have only been amended and supplemented since 2005. In that year, the European Commission proposed amendments to the Active Implantable Medical Device Directive and the Medical Device Directive, which led to the adoption of Directive 2007/47/EC,[47] the Medical Device Directive up to the in which the present day. In this directive, the AIMDD and MDD were combined into one legal act; the In-Vitro Medical Device Directive remained separate and was not amended.

Even though the Medical Device directive was amended, the core legal framework of the directive remained unchanged. Consequently, the *New Approach* is still valid for medical devices,[48] which implies that, despite advancements in science and technology over the past twenty years due to which quite a lot of medical devices have become more complex and/or more like pharmaceuticals, the medical device sector and the pharmaceutical sector are still considered to be very distinct industries, and regulated in a significantly different way. Although the medical device industry itself has been happy with the non-prescriptive nature of the legal framework on medical devices,[49] criticism on the flexible nature of the directive has been raised as well, for example by patient organizations, politicians and academia. It is probably due to this criticism that the European Commission already in May 2008, only a few months after the most recent version of the medical device directive came into force, launched a public consultation for a 'recast' of the medical devices legislations.[50] Though it was intended to merely be a recast, after the PIP scandal in 2010, the process was turned into a process of review. The (legal) difference between recast and review is that the former is referred to 'when the legislator does not propose to substantially amend the law but consolidate in one legal text different legislative instruments—e.g. directives—in the same area. To the contrary, review alludes to substantial legislative revision that would change the nature and quantum of legal obligations for regulatees.'[51] So, clearly the fundamental effectiveness of the legislations was questioned due to the PIP scandal and too many (ethical) issues seemed to be at stake to leave the legal framework the way it had always been.

Since the review involves controversial topics, different political parties, European institutions involved in legislation (and different lobby groups) are expected to have very distinct views on these, and might need

[43] MEDDEV guidelines can be downloaded from meddev.info. See on Guidance documents also: http://ec.europa.eu/growth/sectors/medical-devices/guidance_nl.
[44] NB-MED Guidance Documents can be downloaded from http://www.team-nb.org/nb-med-documents/.
[45] Eucomed, *About Eucomed*, 2013.
[46] Foldes, p. 6; Jefferys, p. 231; Vinck et al., p. 479; Singh, p. 467.
[47] Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market, O J L 247, 21 September 2007.
[48] Tseliou, pp. 7-9; Singh, p. 467.
[49] See for example Eucomed Medical Technology, *Eucomed Position ahead of the trialogue on the Medical Devices Regulation*, 2015.
[50] See for example Chowdhury, p. 99; Hanches & Foldes, p. 432; Foldes, pp. 9-10; Fouretier & Bertram, pp. 351-352; Singh, pp. 467-368.
[51] Chowdhury, p. 99, footnote 1.

to have fierce discussions in order to reach a compromise for a new regulation on medical devices. To facilitate a proper agreement to be reached, each European institution involved in legislation has its own rights and responsibilities in the legislative process. The main European institutions involved in legislation, and the legislative process, will be discussed in the next paragraphs.

2.3 European Institutions involved in legislation

The main institutions involved in the European legislative process are the European Commission, the European Parliament, and the Council of the European Union. These institutions will be discussed in the upcoming subparagraphs.

2.3.1 European Commission

The European Commission is a politically independent (at least in theory, according to Versluis et al.[52]) executive institution, that represents the interests of the EU as a whole, and can therefore be considered as 'the voice of the common interest'.[53] The European Commission promotes this common interest of the EU by proposing and enforcing legislation, as well as by implementing and managing EU policies, and allocating the EU budget.[54] In addition, the European Commission is representing the European Union on the international stage.[55] The European Commission consists of a 'College' of 28 Commissioners (one from each Member State), and is supported by about 24000 civil servants.[56]

2.3.2 European Parliament

The European Parliament (EP) is an EU body, directly elected by the EU voters every 5 years,[57] that represents the interests of the people of Europe, and is therefore also considered to be the 'voice of the people'.[58] The European Parliament has three main roles: 1) it has the power to legislate (shared with the Council of the European Union), 2) it exercises democratic supervision over all EU institutions, and 3) it has the authority (also together with the Council of the European Union), to establish and approve the EU's budget.[59] In total, the European Parliament in total consists of 751 Members of Parliament (MEPs); that is, 750 MEPs plus the President. For each Member State, the number of MEPs is roughly proportionate to its population, but this is by digressive proportionality: no Member State can have less

[52] Versluis et al., p. 34.
[53] Versluis et al., p. 34.
[54] https://europa.eu/european-union/about-eu/institutions-bodies/european-commission_en, retrieved on 26 June 2017.
[55] Versluis et al., p. 34.
[56] https://europa.eu/european-union/about-eu/institutions-bodies/european-commission_en, retrieved on 26 June 2017; Versluis et al., p. 34.
[57] https://europa.eu/european-union/about-eu/institutions-bodies/european-parliament_en, retrieved on 26 June 2017.
[58] Versluis et al., p. 35.
[59] https://europa.eu/european-union/about-eu/institutions-bodies/european-parliament_en, retrieved on 26 June 2017; Versluis et al., p. 35.

than 6 or more than 96 MEPs.[60] In the Parliament, MEPs are however not grouped by nationality, but by political affiliation. Currently, there are 8 so-called 'political groups' in the European Parliament.[61] Political groups at EU level are different from national political parties, as they consist of members from several political parties from several Member States.[62] These political groups are (ordered by current size in the EP):[63]

1) Group of the European People's Party (EPP) (Christian Democrats)
2) Group of the Progressive Alliance of Socialists & Democrats (S&D)
3) European Conservatives and Reformists Group (ECR)
4) The Alliance of Liberals and Democrats for Europe (ALDE)
5) Confederal Group of the European United Left – Nordic Green Left (GUE/NGL)
6) Group of the Greens/European Free Alliance (Verts/ALE)
7) Europe of Freedom and Direct Democracy (EFDD)
8) Europe of Nations and Freedom Group (ENF)

Some MEPs don't belong to a group, and are registered as 'Non-Attached Members'.[64]

As there are merely 8 political groups, while some national parliaments already have 13 political parties, several MEPs within a group are likely to share some general views, but might at the same time have rather different views on specific topics. For example, two Dutch liberal parties are both member of the same liberal political group in the EP, while one party is generally considered to be more progressive than the other one. Consequently, categorizing political groups on presumed political orientation, can merely be done on a rather general level.

In this thesis, we will make a distinction between political groups that are in favor of a free market and political groups that are in favor of a regulated market. The ENF, EFDD, ALDE, ECR, and EPP are presumed to be (more) in favor of a free market, while the S&D, the GUE/NGL, and the Verts/ALE are presumed to be (more) in favor of a regulated-market.

2.3.3 Council of the European Union

The Council of the European Union, commonly called 'the Council', is an EU body that represents the interests of the governments of the Member States, and is therefore also considered to be the 'voice of the Member States'.[65] The Council consists of government ministers from each EU Member State, according to the policy area to be discussed.[66] The Council comes together in ten different 'configurations'

[60] https://europa.eu/european-union/about-eu/institutions-bodies/european-parliament_en, retrieved on 26 June 2017.
[61] http://www.europarl.europa.eu/meps/en/crosstable.html; http://www.europarl.europa.eu/EPRS/EPRS-Briefing-542150-European-Parliament-Facts-and-Figures-FINAL.pdf (This is however about the 8th Parliamentary term, from 21st of November 2014 onwards).
[62] http://www.itsyourparliament.eu/groups/, retrieved on 26 June 2017.
[63] http://www.europarl.europa.eu/meps/en/crosstable.html; (N.B. Current size means during the 8th Parliamentary term, from 21st of November 2014 onwards)
[64] http://www.europarl.europa.eu/meps/en/crosstable.html
[65] Versluis et al., p. 38.
[66] https://europa.eu/european-union/about-eu/institutions-bodies/council-eu_en, retrieved on 27 June 2017.

for different policy fields.[67] The ministers have the authority to commit their governments to the actions agreed on in the meetings. During the meetings, laws are discussed and adopted, and policies are coordinated. So, together with the European Parliament, the Council has the power to legislate, and can be seen as the principal decision-making body of the EU.[68]

2.4 Legislation process EU

2.4.1 Commission proposal

New EU legislation starts with a legislative proposal. Legislative proposals are prepared by the European Commission.[69] The European Commission can do so on its own initiative or at the request of other EU institutions or Member States, or following a citizen's initiative, often after public consultations have taken place. The final legislative proposal is sent to the European Parliament, the Council of the European Union and the national parliaments simultaneously. In some cases, when applicable, the proposal is also sent to two advisory bodies, i.e. the Economic and Social Committee (ESC) and the Committee of the Regions (CoR), who are then asked to give their opinion on the proposal.[70]

2.4.2 1st reading in the European Parliament

After the European Parliament has received the legislative proposal, the process of 1st reading in the European Parliament starts. Subsequently, the President of the European Parliament refers it to a relevant (based on the subject-matter) parliamentary committee. Other parliamentary committees might be offered the possibility to offer their opinion on the proposal if the subject matter also concerns them. The responsible parliamentary committee appoints a rapporteur from among its members. Other political groups may appoint a shadow rapporteur, who is responsible for preparing the position of the political group and for monitoring the work of the rapporteur. The rapporteur is responsible for presenting a draft report to the committee, including his/her amendments to the Commission proposal. The parliamentary committee usually meets several times to examine the draft report. During those debates, the European Commission may defend its proposal and answer questions from the members of the committee. After the rapporteur's draft report is presented, any Member of Parliament can table amendments to the report before the deadline set by the committee. All the amendments are subject to a vote in the responsible committee, which votes by a simple majority. Once the report is adopted in the responsible committee, it is placed on the agenda of the plenary European Parliament ('plenary').[71]

[67] Versluis et al., p. 38.
[68] Versluis et al., p. 38; https://europa.eu/european-union/about-eu/institutions-bodies/council-eu_en, retrieved on 27 June 2017.
[69] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *Commission Proposal.*
[70] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *Commission Proposal.*
[71] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *1st reading in European Parliament.*

The plenary then discusses and votes, by simple majority, on the legislative proposal on the basis of the report drawn up by the responsible committee, including any proposed amendments, and an explanatory statement by the rapporteur. The Parliament then can either reject the proposal as a whole, or approve the proposal without amendments, or approve it subject to amendments. The result is the Parliament's 1st reading position, which is consequently forwarded to the Council of the European Union.[72]

2.4.3 1st reading in Council

The Council of the European Union receives the Commission proposal at the same time as the European Parliament. Preparatory work on the position of the Council thus runs in parallel with the European Parliament, but the Council may only formally conducts its 1st reading based on the Parliament's position. The Council can either accept the position of the Parliament, or adopt changes to the Parliament's position, which leads to a Council's 1st reading position. This position is consequently sent to the Parliament for a 2nd reading.[73]

This process can continue up to a 3rd reading of the European Parliament and Council. If by then no legislative proposal is adopted, the legislation falls and the procedure is ended. It can only be restarted with a new proposal from the European Commission.

Although this seems to be a very long process, all the steps after the first readings are restricted in time. In practice however, Parliament and Council often aim for an agreement after the 1st reading.[74] Since this process has no time limit, it still can become a long-lasting process.

It is worthwhile to note that when the European Parliament and the Council are aiming for a 1st reading agreement, they often organize informal, unrecorded meetings, so-called 'trialogues', which are attended by representatives of the Parliament (rapporteur, and, if applicable, shadow rapporteurs), the Council (chair of the working party, i.e. the Member State holding the Presidency of the European Union at that time,[75] and/or representatives from the COREPER (civil servants involved in the working groups)[76]), and the Commission (department responsible for the dossier and the Commission's Secretariat-General), in order to negotiate a compromised text which all parties can agree on.[77]

Once both European Parliament and the Council have approved the final text of a legislative proposal, it is jointly signed by both institutions. After signature, the texts are published in the Official Journal of the

[72] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *1st reading in European Parliament.*
[73] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *1st reading in Council.*
[74] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *1st reading in European Parliament.*
[75] Personal communication with Thomas van der Valk, political assistant to Dutch MEP Sophie in 't Veld (ALDE).
[76] Versluis et al., p. 37.
[77] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *1st reading in Council.*

EU and become official.[78] The adopted proposal then, can have three different forms, being a regulation, a directive or a decision:

- Regulations are directly binding in their entirety throughout all Member States as of the date set down in the Official Journal. At the moment regulations come into force, they override all national laws of the Member States dealing with the same subject matter.[79]
- Directives bind Member States to end results to be achieved, but the means of achieving that result, that is, the choice of form and method, are left to be determined by each Member State. While regulations are directly binding, directives first need to be transposed into national legislation. Each directive specifies the date by which the national laws must be adapted to the end result.[80]
- Decisions are fully binding rules for those (for example particular authorities or individuals) to whom they are addressed.[81]

[78] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *Proposal adopted.*
[79] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *Proposal adopted*; Versluis et al., p. 58.
[80] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *Proposal adopted*; Versluis et al., p. 58.
[81] http://www.europarl.europa.eu/aboutparliament/en/20150201PVL00004/Legislative-powers, *Proposal adopted*; Versluis et al., p. 58.

3 Methods

In order to investigate what the ethical notions are with respect to the current European regulatory framework on medical devices, and to investigate to what extent these notions have been taken into account in the new Regulation on Medical devices, several analyses will be performed. In the remainder of this chapter, I will describe the analyses performed and will also discuss the limitations of the methods employed.

3.1 Analyses performed

First of all, the ethical notions with respect to the current legislative framework on medical devices are identified. In order to do so, a literature study is performed. Relevant academic literature on ethical notions related to European medical device legislation is searched for. Google Scholar with subscription of Utrecht University is used as academic database. Keywords used for the search are "medical devices" "European Regulation" "93/42" "2007/47" "ethical" OR "ethics", both in the title, and in the article. Initially, the search is limited to articles from the period 2007-2016, as during this period the review process of the medical device regulation has taken place. Relevant articles are selected based on title and abstract. If the article is considered useful, the reference list is checked for other potentially useful articles. Regarding some specific themes/notions identified, such as surgical innovation, the learning curve, the learning healthcare system, and borderline cases, extra articles are searched for, in order to have some more in-depth knowledge. Based on the study of the articles, for each ethical notion identified, several aspects were recognized, which should be taken into account in the new Regulation on Medical Devices.

Second, the debates of the main European institutions involved in legislation are investigated. Searching databases of the European institutions on all documents related to Directive 93/42/EEC and Directive 2007/47/EC, and by a request for public access[82] at European institutions involved in legislation, it was found that only the debates of the European Parliament and the parliamentary committees are publicly available. Debates of the European Commission and the Council of the EU are not recorded. Consequently, it was decided to merely analyze the debates of the parliamentary committees in charge and the plenary. Reviewing those documents, however, it became clear that no verbatim of the relevant debates were available, which are necessary to analyze to what extent and by whom ethical notions on medical devices are addressed during the parliamentary debates. Fortunately, some written statements, for example explanations of votes, and the recordings of the meetings are available online. In order to be able to investigate the recordings, the movies have been transcribed. On these transcribed documents, a discourse analysis will be performed, providing an overview of the main themes addressed during the debates. In addition, for each theme, it is analyzed by which political groups the theme is addressed. Subsequently, it is indicated whether there is an overlap between the presumed position of the political group(s) regarding regulation of the market, and the theme addressed. The presumed position of the political groups regarding regulation of the market is discussed in paragraph 2.3.2: three European political groups are considered to be in favor of a (more) regulated market, while five political groups are considered to be (more) in favor of a free market. It is assumed that groups in favor of a free market generally strive for as little rules for the industry as are deemed necessary, want to encourage innovation,

[82] A request for public access at the European institutions is comparable to what we in Dutch call a 'WOB verzoek'.

and are supportive of free trade, while groups in favor of a regulated market are assumed to prefer strict rules for the industry, and to not want innovation at all costs. These points of view will be taken into account discussing the overlap the main themes addressed during the parliamentary debates.

Third, in order to investigate the main differences between the current Medical Device Directive and the proposed Regulation on medical devices, a comparison will be made between these legislative texts. To be more precise, an analysis will be made, comparing the contents of Medical Device Directive 93/42/EEC, amended by Directive 2007/47/EC, with the 'tentatively agreed consolidated compromise text of the proposed Regulation on medical devices resulting from the negotiations between the Council and the European Parliament,'[83] which dates back to the 15th of June 2016.

Fourth, the outcomes of the literature study, discourse analysis, and the comparison between the legislative texts will be used for the final analysis of this thesis: the policy analysis. It will be analyzed to what extent the ethical notions that have been addressed in the academic literature, and the ambitions that have presumably been addressed by the politicians during the parliamentary debates, have been taken into account in the tentatively agreed consolidated compromise text of the proposed Regulation on medical devices resulting from the negotiations between the Council and the European Parliament. This analysis will be performed by assessing, for each aspect of each ethical notion identified during the literature study, whether and based on what arguments, the aspect can be considered to be taken into account. Aspects can be considered to have not at all been taken into account, to have partially been taken into account, or to have been (mostly) taken into account. Subsequently, for each ethical notion, an average outcome of the aspects is determined qualitatively, which indicates whether overall, the ethical notion can be considered to not be taken into account, to be partially taken into account, or to be mostly taken into account. Based on these conclusions, some recommendations for future research and for future legislation will be given.

3.2 Limitations of the methods

In order to judge the scientific validity of the analyses performed, it is important to know their limitations. First of all, it is debatable whether the literature study performed will provide all the relevant ethical issues related to medical devices. The outcome of a literature study depends on the database and keywords used, and obviously on the articles available. As it is assumed that most of the articles related to the regulatory framework of medical devices will concern regulatory and policy issues, rather than ethical notions, it is important to be critical on the outcomes of the literature analysis and to keep an open mind on potential gaps in the ethical literature related to medical devices. Conversations with ethicists in the field will help to ensure that the most important issues are addressed.

Second, discourse analysis normally is performed on written texts. In this case, the discourse analysis will be performed on some written statements, but mainly on transcripts of recorded parliamentary debates, since verbatim of the debates is either not available or only available in the native language of the Member of Parliament, which I am frequently not able to understand. Consequently, transcribing the debates can be considered the best option available, since the recordings are offered in all the official languages of the European Union, English included. The quality of the transcripts, however, is limited due to the facts that

[83] Tentatively agreed consolidated compromise text of the proposed Regulation on medical devices resulting from the negotiations between the Council and the European Parliament, 15 June 2016.

English usually is not a native language of the MEPs, that English is not my native language, and that the translating time for the professional translators is limited. Consequently, the transcripts will not perfectly represent the original contributions intended by the speakers, but should be accepted as the best material available.

With respect to the third analysis, in the ideal case, one would like to analyze every draft version between the Directive 93/42/EEC, lastly amended by Directive 2007/47/EC, and the tentatively agreed consolidated compromise text of the proposed Regulation on medical devices resulting from the negotiations between the Council and the European Parliament, provided by the European Commission, the European Parliament and the Council, in order to analyze the differences and the reasoning behind every decision. Not only is this not realistic timewise, but also hardly possible in practice, due to the fact that many documents are not publicly available nor the reasoning behind every decision or preference is explained. The discussions during the trialogue phase for example, are recorded nor publicly accessible, because negotiations take place on legislative paragraphs, none of the parties involved wants to be held accountable for.[84] Also, the documents available after filing a request for public access at the relevant European institutions often do not contain any reasoning behind preferences for certain phrases or formulations. For those reasons, and due to the fact that the main motivation of the comparative analysis is to find out what the differences between the current version and the proposed new version are, I have decided to limit the analysis to a comparison between this first and final version.

The overview of differences and similarities will then be used for the fourth analysis, the policy analysis, in which it will be analyzed to what extent the ethical notions addressed can be considered to be taken into account. The main limitation of this kind of analysis is that, although it is based on the data provided by the previous analyses, and should be based on sound and valid argumentation, there is always a subjective dimension. Consequently, the conclusions drawn might not be agreed with. Inherent to most analyses, this problem can't be solved, but I will try to reduce the subjective dimension as much as possible, by providing data, literature, and argumentation.

[84] Personal conversation with Thomas van der Valk.

4 Results & Discussion

In this chapter, I will present the results of the analyses introduced in the previous chapter. First, I will discuss the ethical notions identified in literature with respect to the current regulatory framework on medical devices (Paragraph 4.1), then I will discuss the results of the discourse analysis on the parliamentary debates (Paragraph 4.2), after which the most important differences between the current and the proposed legislative framework will be described (Paragraph 4.3). I will finish with the policy analysis of the ethical notions (Paragraph 4.4).

4.1 Ethical notions related to medical devices' regulatory framework

Most of the ethical issues at stake with the medical device directive, have already been addressed by scholars and experts in the field. In this paragraph, I will shortly discuss the most important ethical challenges with respect to the current legal framework on medical devices.

4.1.1 Patient safety should be ensured

First and foremost, it is fair to say that the notion that patient safety should be ensured can be considered the most important notion with respect to medical devices, because, as the recent controversies with for example the PIP implants have shown, unsafe medical devices could cause serious harm for patients.[85] As these incidents were able to happen though, it indicates that safety for patients cannot be ensured under the current legislative framework. In the literature, one could distinguish several reasons why experts consider patient safety to not be ensured. These entail the lack of requirements regarding clinical efficacy, the lack of a definition for patient safety, the minimal control, varying capacities and lack of centralization of notified bodies, the limited level of post-market surveillance and vigilance, and finally, the re-use of single-use devices. I will discuss these reasons in consecutive paragraphs.

4.1.1.1 The CE-mark: no evidence of clinical efficacy

In accordance with the *New Approach*, medical devices are regulated such, that they have to adhere to essential requirements on safety and performance, and that devices of medium and high risk classes are assessed by a notified body on their conformity to harmonized standards.[86] If this is the case, the devices are provided with a conformity mark, the 'Conformité Européene' (CE-mark), and are allowed on the European market.[87] As Mooijen describes, this conformity approval guarantees that, for example, implants do not fall apart, perform in lab situations as they are supposed to, and have no harmful material in them.[88] 'However, a Conformité Européenne approval will not guarantee that the medical device will work in patients, or that it does not cause harm in other ways, such as higher reoperation rates as

[85] Singh, p. 471.
[86] Directive 2007/47/EC, Article 11.
[87] Directive 2007/47/EC, Article 17 in conjunction with Article 4 sub 1.
[88] Mooijen et al., p. 2116.

compared with other interventions.'[89] 'In other words, it is not mandatory for the manufacturer to prove that the device actually treats the condition of the patient and brings about significant therapeutic benefits such as reduction of symptoms.'[90] So, the safety for the patient, the (clinical) efficacy of the device and the long-term effects are often not tested, or not sufficiently, before the device is allowed on the market.[91] Consequently, novel medical devices can be introduced on the market, and thus in patients, without sound evidence, especially in comparison with pharmaceuticals, where rigorous safety and comparative effectiveness research is needed before they are allowed on the market.[92] As Vinck contends: 'From an ethical point of view, the unlimited dissemination of CE-marked implants without having first conducted the necessary controlled trials may be a source of considerable harm,'[93] as the recent controversies have shown. Consequently, we can conclude that the notion of patient safety has not been taken into account in the current legislation on medical devices, due to the lack of requirements for sound evidence of clinical performance before devices are put on the market.

4.1.1.2 Lack of clear definition (patient) safety

The lack of clinical data on efficacy of devices is however not the only reason why patient safety cannot be considered to be taken into account. Something that might add to unsafe devices entering the market, is the fact that even though the MDD states frequently that safety and performance of the device should be tested,[94] and that devices should not compromise the safety of patients,[95] the concept of (patient) safety is not defined in the Directive. Consequently, it might not always be clear whether certain devices pose a risk to the safety of patients and should be removed from the market. As Singh describes, '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.'[96] Lack of a definition of patient safety might thus contribute to patient unsafety.

4.1.1.3 Varying capacities of notified bodies

The potential unsafety due to the lack of data on clinical efficacy is increased due to a related problem; the lack of centralization and harmonization in the bodies involved in premarket evaluation of devices.[97] The assessment of conformity with the essential requirements concerning medical devices is checked by a notified body; a for profit organization certified by a Competent Authority of a Member State.[98] Notified bodies do not have equal capacities in terms of personnel, expertise, medical knowledge, technical

[89] Mooijen et al., p. 2116.
[90] Foldes, p. 8.
[91] See amongst others: Mooijen et al., p. 2115; Foldes, p. 8; Singh, p. 471; Vinck et al., pp. 479-481; Harmon et al., pp. 249-252; Hulstaert et al., p. 280.
[92] Mooijen et al., p. 2116; Fraser et al, p. 9; Sim, p. 65; Hulstaert et al., p. 280; McCulloch et al., p. 1111; Harmon et al., pp. 249-252; Altenstetter & Permanand, 2007, p. 400; Vinck et al., pp. 479-481; Singh, p. 471.
[93] Vinck et al., p. 481.
[94] Directive 2007/47/EC, Annex X.
[95] Directive 2007/47/EC, Annex I.
[96] Singh, p. 476.
[97] Vinck et al, p. 481.
[98] Vinck et al., p. 481.

capabilities or reviewing process.[99] This variation is not optimal to guarantee patient safety in a uniform way.[100] Especially not, since companies are free to choose any of the designated notified bodies in the European Union and may consequently select a notified body that is the fastest, cheapest or least stringent.[101] Consequently, the same type of medical device might be evaluated as being conform by one notified body, whereas it will be rejected by another body.[102] As however merely one notified body is needed for providing a CE-mark, which allows the device on the entire European market,[103] one can imagine that the market entrance of a medical device having safety issues, will not always be prevented. The fact that notified bodies are private/commercial organizations, which are supported in part by the fees paid by device companies,[104] due to which notified bodies see themselves as clients on behalf of manufacturers,[105] might create a conflict of interest.[106] This does not necessarily encourage independent evaluation of devices, and consequently harmful medical devices might be allowed to enter the market, which were known to be unsafe.

4.1.1.4 Limited post-market surveillance

The lack of proper pre-market testing however, is not the only reason why patient safety cannot be ensured. Even though it is said that the European system relies more on post-market surveillance than it does on pre-market testing,[107] under the current legislation it appears that no public body, neither European nor national, actually monitors the safety of medical device after they are placed on the European market.[108] Currently, the responsibility for post-market surveillance and vigilance is basically completely conferred upon private parties.[109] That is, manufacturers are obliged to implement a 'medical device vigilance system' to monitor their products once they are on the market.[110] This is monitored by the notified bodies and audited by Competent Authorities of Member States.[111] In this context, a potential conflict of interest might rise again.[112] Even more pressing is the fact that there are no requirements with respect to the vigilance system. Consequently, rather than perform large post-marketing studies, manufacturers may rely simply on feedback from users.[113] Neither is it necessary to report incidents with medical devices to Competent Authorities.[114] This lack of (post-)market surveillance in the current system

[99] Hulstaert et al., p. 280; Vinck et al., p. 481; Cohen & Billingsley, p. 2; Fouretier & Bertram, p. 354.
[100] Vinck et al., p. 481; Cohen & Billingsley, p 2; Fouretier & Bertram, p. 353.
[101] Fraser et al., p. 3; Vinck et al., p. 481; Hulstaert et al., p. 280; Cohen & Billingsley, p. 2; Fouretier & Bertram, p. 354.
[102] Fouretier & Bertram, p. 354.
[103] Vinck et al., p. 482.
[104] Fraser et al., p. 3;
[105] Cohen & Billingsley, p. 2.
[106] Fraser et al., p. 10.
[107] Cohen & Billingsley, p. 3.
[108] Singh, p. 472.
[109] Singh, p. 472.
[110] Cohen & Billingsley, p. 3.
[111] Cohen & Billingsley, p. 3.
[112] Fraser et al., p. 10.
[113] Cohen & Billingsley, p. 3.
[114] Singh, pp. 472-473; Foldes, p. 11.

does not help to quickly trace incidents with a medical device, nor to study negative side-effects or long-term effects,[115] and consequently adds to the possibility that patients are harmed.

4.1.1.5 Harmful re-use of single-use devices

Lastly, another important issue with respect to patient safety is the fact that under the current legislation it is allowed to re-use products, even if they are labelled as single-use by manufactures. Although re-users, often hospitals, are assumed to at least clean and/or sterilize the products intended for single-use, research shows that these processes are often not effective.[116] Consequently, the patient does not receive the standard of care and is harmed unnecessarily.[117] So, apart from liability issues in those cases, the safety of patients might be endangered by re-using single use devices.

4.1.2 Clinical research should be responsible and reliable

In paragraph 4.1.1.1, we discussed that the notion of patient safety currently cannot be considered to be taken into account, due to the fact that medical devices are not required to be tested for clinical benefit and efficacy. In comparison with pharmaceuticals, for which randomized clinical trials (RCTs) are the golden standard, clinical trials with medical devices have some limitations, due to the nature of devices (as discussed in paragraph 4.1.2.1). Also, medical devices have some practical difficulties, such as the learning curve, which will be discussed in paragraph 4.1.2.2. Thirdly, some experts, though acknowledging some limitations of RCTs with medical devices, believe that the lack of clinical evidence on medical devices cannot be fully explained by the limited research methodologies, but is also attributable to the lack of requirements regarding clinical investigations. As discussed in paragraph 4.1.2.3, they consider the notion that clinical research should be responsible and reliable, another notion that is currently not taken into account in the current directive. Due to the limited amount of clinical evidence before a device is introduced on the market, devices are basically tested when used in clinical practice. Consequently, research and practice can blur, and this practice is often not reviewed by ethics committees, as discussed in paragraphs 4.1.2.4 and 4.1.2.5 respectively.

4.1.2.1 Methodological challenges of randomized clinical trials

Double-blind randomized controlled clinical trials, commonly used for studies on pharmaceuticals are considered the 'gold standard' for establishing the efficacy and safety of medical products.[118] Designing randomized clinical trials for medical devices, however, poses challenges that do not arise with clinical trials for pharmaceutical products.[119] As Black points out, there are several limitations with clinical trials for medical devices: RCTs may be unnecessary, inappropriate, or impossible.[120] Trials might be unnecessary when an advance or effect of an intervention is clear and substantial and cannot be explained

[115] Mooijen et al., p. 2117.
[116] See for example Roth et al., p. 1091; Heeg et al., 2001, p. 548.
[117] See for example Dunn, 2002, p. 993; Roth et al., 2002, p. 1091.
[118] See for example Boudard et al., p. 700; Black, p. 1; Hulstaert et al, p. 279.
[119] Parvizi & Woods, p. 9.
[120] Black, pp. 2-5; Siebert et al., p. 737; McCulloch et al., p. 1107.

by either chance or bias.[121] Trials may be inappropriate when a medical device is used for a relatively small patient population, or when some of the examined effects of a device can only be observed during a long-term follow-up period.[122] RCTs might be impossible due to the reluctance and refusal of clinicians and/or key patients to participate.[123] Another reason why trials might be impossible is due to technical limitations and ethical objections. For example, randomization is particularly difficult when comparing surgical medical devices with other therapeutic alternatives,[124] as some patients then have to undergo surgeries with potential complications, while others don't. Also, double blinding is difficult to achieve, especially for implantable or surgical medical devices, but also for comparisons between medical devices and drug treatments,[125] as the surgeon simply has to know the treatment they are performing.[126] Also, the use of placebo or sham interventions is difficult in many instances for medical devices.[127] Sham surgery as a comparator for proving device efficacy may be considered unethical, as patients are exposed to potential risks and complications.[128]

4.1.2.2 Practical challenges of medical device research

In addition to methodological challenges, research on medical devices is complicated due to practical challenges. The most important challenge is that 'medical device safety and effectiveness are, in part, determined by the user's skill and patient selection; training in the use of the medical device can substantially affect outcomes.'[129] This problem is called the problem of the learning curve, which is defined as 'the time or number of procedures required for an average surgeon to be able to perform a procedure independently with an acceptable outcome.'[130] Due to devices having a learning curve, in particular implantable devices, there might be variability in experience or mastery of the technique between surgeons implanting a new device or using a new surgical technique.[131] Ethical considerations, on for example patient safety, require that 'all reasonable precautions are taken to avoid harm to patients during the learning curve, including, when possible, mentoring.'[132] Consequently, clinical research on medical devices should not just study the device itself, but the complete system around it. This includes the most optimal procedures for handling the device, and ways of shortening the learning curve.[133]

[121] McCulloch et al., 1107; Black, p. 2; Siebert et al., p. 737.
[122] Black, pp. 2-3; Siebert et al., p. 737.
[123] Black, p. 3; McCulloch et al., p. 1108; Niemansburg et al., p. 5.
[124] Boudard et al., p. 700.
[125] Boudard et al., p. 700; Niemansburg et al., p. 5; Parvizi & Woods, p. 9; De Faoite & Wilhelmi, p. 82.
[126] De Faoite & Wilhelmi, p. 82.
[127] Boudard et al., p. 701; Parvizi & Woods, p. 9; De Faoite & Wilhelmi, p. 82
[128] Hulstaert et al., p. 280; De Faoite & Wilhelmi, p. 82.
[129] Parvizi & Woods, p. 9.
[130] Subramonian, K. & Muir, G. (2004) The 'learning curve' in surgery: what is it, how do we measure it and can we influence it? British Journal of Urology International, 93 (9), 1173–1174, in: Boudard et al., p. 701.
[131] Niemansburg et al., p. 5.
[132] McCulloch et al., p. 1107.
[133] Hulstaert et al, p. 279.

4.1.2.3 Lack of requirements regarding clinical evaluation

Despite the methodological and practical difficulties with randomized clinical trials on medical devices, several authors state that high quality randomized controlled trials have been performed successfully,[134] 'even if these trials involve no or only the partial blinding of patients, physicians, or outcome assessors.'[135] For that reason, these authors seem to believe that the practical and methodological challenges are not the reason why so little clinical trials are performed with medical devices, and why clinical efficacy is hardly tested for in the European Union. Rather, they believe the European regulatory system itself is the cause thereof. That is, for the demonstration of device performance, a RCT is neither necessary nor appropriate, whereas it is essential for the demonstration of clinical efficacy in a controlled way.[136] Even though Directive 2007/47/EC states that in case of implantable and class III devices some human clinical investigations shall be performed,[137] these do not need to be randomized clinical trials nor evaluate effectiveness.[138] Also, no specific requirements are provided regarding the depth and extent of clinical evaluations or the design of RCTs.[139] Furthermore, the directive allows manufacturers to use clinical data of other similar devices to support their application for CE marking.[140,141] However, the directive does not specifically define the criteria to determine equivalence.[142] This consequently enables manufacturers to overuse equivalence as the basis for approval.'[143] If a manufacturer is claiming equivalence, clinical data can involve as little as 'a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristic and intended purpose of the device.'[144,145] So, by a simple demonstration of equivalence with another device subject to clinical evaluation, a manufacture can avoid having to carry out clinical investigations for high-risk medical devices. As the decision on equivalence is left to the manufacturer and the notified bodies,[146] the problems raised about them (paragraph 4.1.1.3) are likely to be valid in this context as well. It thus seems to be attributable to the current regulatory system on medical devices in Europe, that the clinical efficacy of devices is not properly tested and consequently, as discussed in paragraph 4.1.1.1, that patient safety is at stake.

4.1.2.4 Blurring of research and clinical practice

A consequence of the lack of specific requirements regarding clinical research, and subsequently the lack of clinical evidence before devices are allowed on the market, is that medical devices are actually evaluated from the moment they are introduced in clinical practice. Otherwise phrased, 'patients may be treated with a high risk medical device on an experimental basis, outside the context of a clinical trial.'[147]

[134] Parvizi & Woods, p. 9; McCulloch et al., p. 1108; Hulstaert et al., p. 279.
[135] Hulstaert et al., p. 279.
[136] Hulstaert et al., p. 280.
[137] Directive 2007/47/EC, Annex X, 1.1a.
[138] Cohen & Billingsley, p. 2; Fraser et al., p. 3; Byrne et al., p. 3.
[139] Hulstaert et al., p. 281; Vinck et al., pp. 480-481, 485.
[140] Directive 2007/47/EC, Annex X, 1.1a.
[141] Boudard et al., p. 701.
[142] Boudard et al., p. 701.
[143] Fraser et al., p. 9.
[144] Henegan & Thompson, pp. 186-187.
[145] Cohen & Billingsley, p. 2.
[146] Henegan & Thompson, p. 186.
[147] Vinck et al., p. 488.

In that sense, one could argue that clinical research is actually performed in clinical practice. Currently though, a sharp distinction is made between clinical research and clinical practice in legislations and research ethics.[148] Regulations and oversight in clinical research are generally much more stringent than in clinical practice.[149] Some scholars believe this distinction to be obsolete,[150] and argue for a learning healthcare system (LHS).[151] The rationale behind a learning healthcare system is to improve the quality of health care by embedding research within clinical care.[152] The moral framework of LHS focuses on a broad spectrum of learning activities, which include clinical trials, quality improvement practices, and comparative effectiveness research.[153] So, it is clear that in a proper system in which the sharp distinction between research and practice is blurred, continuous evaluation of the quality of care should take place.[154] This implies amongst others that pre-market evaluation and post-market surveillance should be of high quality. Otherwise, the patients might be used, to put it bluntly, as guinea-pigs. Unfortunately, we have seen in paragraphs 4.1.2.3 and 4.1.1.4 that both pre-market evaluation and post-market surveillance in the case of medical devices are often limited. In addition, there are perverse financial incentives in the system.[155] For example, '[t]he sale of devices is not usually evidence based. It is based on recommendation from opinion leaders, many of whom have undeclared competing interests.'[156] In such a system, the blurring of research and practice might not improve the quality of healthcare, but rather put patients unnecessarily at risk of serious harm.

4.1.2.5 Limited review by ethics committees

Another consequence of the limited number of clinical trials performed on medical devices, in combination with the sharp distinction between clinical research and clinical practice, might be a limited review by ethics committees. That is, clinical investigations under the current Directive may merely commence 'insofar as the relevant ethics committee has issued a favorable opinion on the program of investigation in question, including its review of the clinical investigation plan.'[157] However, if no clinical investigation is performed, for example if the manufacturer demonstrates equivalence of his/her device to a device already on the market,[158] it will not be reviewed by the ethics committee either.[159] Consequently, in practice the review by ethics committees is limited.

It might also be the case that the first clinical use of a device is after CE-marking, perhaps when the device is applied to the ethics committee for 'post-market review'.[160] As Humphreys has experienced, such studies might not be clinical trials at all, but investigations the purpose of which is merely to demonstrate

[148] See for example Faden et al., 2013, p. 16.
[149] See for example Faden et al., 2013, p. 16.
[150] Faden et al., p. 2011.
[151] See for example Olsen et al, 2007; Faden et al, 2013; Broekman et al, pp. 19-20; McCulloch et al, pp. 1110-1111.
[152] Broekman et al., p. 19.
[153] Faden et al., 2011, p. 2; Broekman et al., p. 20.
[154] Faden et al, 2013, p. 18.
[155] See for example: Cohen, 2011, p. 3.
[156] Wilmshurst, p. 1093.
[157] Directive 2007/47/EC, Article 15 sub 2 & 3.
[158] As described in paragraph 4.1.2.3.
[159] Humphreys, p. 45.
[160] Humphreys, p. 47.

that the device can do what it is claimed to do.[161] If the device in such cases is applied for review, the ethics committee will not have an easy task, as they also have to assess the safety of the investigation itself, and thus the adequacy of arrangements for the device's safety, the suitability of its design and its material composition, while they, according to Humphreys, often do not possess specific knowledge on these topics.[162] It should be noted as well, that during such investigations clinical efficacy is not evaluated, and consequently, if clinical efficacy is evaluated afterwards in clinical practice, it might not be have been reviewed by the ethics committees.

4.1.3 Transparency should be encouraged to enable informed decision-making

Related to the notions patient safety and inadequate clinical evaluations is another ethical notion: the need for transparency of clinical data towards patients, healthcare professionals, independent investigators and the general public. The current medical device legislation lacks rules on providing information to the public. That is, apart from rules concerning device packaging, leaflet and label, the current Directive does not regulate information to the public on medical devices, and contains no harmonized standards for information content and presentation.[163] The public includes physicians and caregivers as well, who are responsible for treating patients according to the best clinical standards, and have the duty to inform and advice patients on the available treatment options.[164] Patients subsequently, based on the ethical principle of informed consent, which entails that autonomous patients should consciously agree with treatments and interventions after being sufficiently informed by their caregiver(s),[165] have the right to be informed before they make any decision with respect to a medical intervention or participation in research.[166] Lack of transparency of clinical data makes it impossible to make an informed decision.

Rather than encouraging to provide information to the public though, the Directives on medical devices emphasize confidentiality.[167] 'Staff members of notified bodies are obliged to ensure professional secrecy with regard to all information gained in the course of their duties. […] Confidentiality extends to data resulting from clinical investigations of medical devices (if performed at all, AG) as well as claims submitted by manufacturers to notified bodies, assessment reports, and evaluation of the device by notified bodies.'[168]

In contrast to rules on confidentiality, the current legislation lacks rules on public access to objective data and information on medical devices (at the same time, EU law does allow for direct-to-consumer advertising of medical devices, even though non-promotional data is hardly accessible).[169] Consequently, there is, for example, no publicly available list of medical devices approved for the European market; not even a list on merely the high-risk devices[170]. 'Even Competent Authorities have to rely on a Google

[161] Humphreys, p. 47.
[162] Humphreys, p. 46.
[163] Foldes, p. 13.
[164] Harmon et al., pp. 249-250; Fouretier & Bertram, p. 356.
[165] See for example Beauchamp & Childress, pp. 121-122.
[166] Beauchamp & Childress, pp. 121-122.
[167] Vinck et al., p. 486; Hulstaert et al., p. 281.
[168] Foldes, p. 13; Fraser et al., p. 12.
[169] Foldes, p. 15.
[170] Vinck et al., p. 486; Singh, p. 475.

internet search to identify the class III devices being marketed, as there [is still] no comprehensive list or database.'[171]

So, it is currently very hard for the public to get any information on device malfunctioning and/or deterioration which might lead to death or serious health damage.[172]

Even though Member States have been obliged since May 2011 to report to EUDAMED, a European Databank on Medical Devices,[173] data on 'registration of manufacturers, authorized representatives and devices, certificates issued, modified, supplemented, suspended, withdrawn or refused according to the EU conformity procedures, clinical investigations and post-marketing surveillance,'[174] these databases are not open to the public.[175]

The confidentiality of and lack of access to the databases thus implies that trials are not publicly registered before the first patient is tested, nor that results of clinical investigations are available to the public. This is remarkable, as the Medical Device Directive at the same time requires that clinical trials respect the Declaration of Helsinki,[176] which implies that clinical trials should be entered in a publicly available trial registry before the first patient is investigated, and that positive and negative results of clinical trials/investigations should be published or otherwise made publicly available.[177] Clearly, this requirement of the MDD is often not respected.[178]

Consequently, the current legislation makes it very difficult, if not impossible, for physicians to fulfill their duty of informing their patients, and for patients to make a well-informed decision. Evidently, the notion that more transparency and access to information is needed in order to enable informed decision-making, should be taken into account in the new Regulation.

4.1.4 Legal certainty should be increased to restore patients' trust

A notion that basically follows from the challenges identified with respect to medical devices, such as the lack of pre-market evaluation, control and information available, while other products in healthcare are much more - or even less - strictly regulated, is the problem of borderline products. As Chowdhury describes, 'borderline products refer to products that escape regulatory categorization, in other words products which may fall under two or more regulatory product categories.'[179] In the case of healthcare products, one can generally distinguish five different regulatory categories: pharmaceuticals, medical devices, in-vitro diagnostic medical devices, cosmetics and food supplements. In terms of the scale of regulatory burden, it is the highest with respect to the pharmaceuticals, followed by the two different categories of medical devices, and finally the cosmetics. I am not sure about the regulatory burden of food

[171] Hulstaert et al., p. 281.
[172] Foldes, p. 15; Fraser et al., p. 12; Harmon et al., p. 249; Singh, p. 475.
[173] Fouretier & Bertram, p. 357.
[174] Foldes, p. 9.
[175] Foldes, p. 15; Fouretier & Bertram, pp. 356-357.
[176] World Medical Association Declaration of Helsinki; Ethical Principles for Medical Research Involving Human Subjects.
[177] Vinck et al., pp. 485-486; Hulstaert et al., pp. 282-283; Sim, p. 67.
[178] Hulstaert et al., p. 283.
[179] Chowdhury, p. 141.

supplements, but I assume it is comparable to, or slightly stricter than cosmetics (since no pre-market authorization is needed and products are freely available, but food is invasive and cosmetics are generally not).

Borderline products pose legal challenges, in the sense that legal frameworks are binary: a product is either included in a certain legal act, or it is not.[180] EU law is also mutually exclusive: a healthcare product can merely belong to one category only.[181] Yet the development of science and technology increasingly leads to complex, so-called 'combination products'[182], that include aspects of both medical devices and medicines.[183] Consequently, one can image it is a legal challenge to classify these products in the proper category (if there is any). Borderline products however do not only pose legal (classification) challenges, but also ethical ones. For example, due to the classification challenges, legal certainty is at stake, because (in the eyes of the public and manufacturers) seemingly similar borderline products could be categorized on different sides of the borderline. Therefore, manufacturers of borderline products can never be sure beforehand, to which directive their products will be assigned. The fact that currently national authorities of each Member State are allowed to make this classification on a case-by-case basis,[184] definitely does not add to legal certainty. Legal uncertainty not only poses problems for manufacturers, but also for patients, physicians and the public in general, because they often do not know how a product is classified, especially if a product can belong to different categories. Since currently there is quite a regulatory difference between medicines and medical devices,[185] it does matter significantly how products are categorized with respect to, as we have seen, clinical evaluation, informed decision-making and direct-to-consumer marketing. Categorization of borderline products thus potentially infringes patients' trust, since patients might assume that certain combination products are tested more stringently (because they are perceived as pharmaceuticals), than is actually required under current legislation (because they are categorized as medical devices). Therefore, it is recommended that in the proposed Regulation, legal certainty of borderline products should be increased, in order to enhance patients' trust.

Having concluded so, it might be that patients' trust is endangered by other factors than merely legal uncertainty regarding borderline products. The meaning of the CE mark for example, is often misunderstood.[186] 'It may be interpreted by clinicians and patients as meaning that clinical effectiveness has been established, for example from clinical trials, whereas it simply implies conformity with essential requirements including an acceptable risk/benefit ratio.'[187] This confusion might add to a general distrust in healthcare products. Furthermore, the recent controversies with medical devices, broadly covered in the media and public debates, are likely to have made clear to the public that there commonly is no stringent testing being done, which clearly caused harm to patients, and can consequently also harm the patient's trust in healthcare products/the healthcare sector. In addition, the lack of transparency might lead to misunderstanding and mistrust.[188] All these aspects diminishing patients' trust are obviously is not helpful for patients whose physical well-being depends on healthcare products, but also not helpful for

[180] Tseliou, p. 19.
[181] Tseliou, p. 19.
[182] See for example Foldes, p. 18.
[183] See for example Jefferys, pp. 234-235; Foldes, p. 18; Tseliou, p. 14, 19
[184] Chowdhury, p. 145; Tseliou, pp. 18-19.
[185] Tseliou, p. 20.
[186] Fraser et al., p. 11.
[187] Fraser et al., p. 11.
[188] Cohen & Billingsley, p. 3.

the medical device sector as such, who might see their sales decrease. Consequently, it is a common interest of the public, the European Union and the industry to make sure that patients' trust is restored, and that this notion is properly taken into account in the new Regulation.[189]

In conclusion, according to experts in the field, there are several ethical notions that should be taken into account in medical device legislation. These entail the notion of enhancing patient safety, of responsibly and reliably performing clinical investigations, of increasing transparency of clinical information towards health-care providers and patients, and restoring patients' trust by amongst others increasing the legal certainty of borderline products. It is obviously in the interest of the patients and the healthcare providers, but also in the interest of the medical device industry, that these notions are properly taken into account in the new Regulation. In the remainder of this chapter, I will analyze and discuss the changes in the legislative framework on medical devices and the extent to which the ethical notions identified, have been touched upon during the debates and are taken into account in the new Regulation.

4.2 Analysis of parliamentary debates

In this paragraph, I will analyze the main themes discussed during the parliamentary debates. I will first provide some background information on the debates (paragraph 4.2.1), then discuss the main themes and the outcome of the discourse analysis (paragraph 4.2.2), and finish with a summary of the main themes and a discussion on the extent to which the themes overlap with the ethical notions addressed by the experts (paragraph 4.2.3).

4.2.1 Background information on the debates

After the European Parliament received the draft proposal on Regulation of medical devices from the European Commission, published on 26 September 2012, the Parliament, at the beginning of October 2012, appointed a committee responsible (the Environment, Public Health and Food Safety Committee (ENVI)), and also appointed other relevant committees to provide their opinion (the Employment and Social Affairs Committee (EMPL), the International Trade committee (INTA), the Industry Research and Energy committee (ITRE), and the Internal Market and Consumer Protection committee (IMCO)).[190] They also appointed a rapporteur of the committee responsible, with the responsibility to collect input and proposals for any amendments to the proposed Medical Device Regulation. This rapporteur was Mrs. Dagmar Roth-Behrendt of the Progressive Alliance of Socialists and Democrats (S&D). The other political groups also appointed shadow rapporteurs:

- Mairead McGuinness for the European People's Party (Christian Democrats/EPP)
- Holger Krahmer for the Alliance of Liberals and Democrats for Europe (ALDE)
- Michèle Rivasi for the Group of the Greens/European Free Alliance (Verts/ALE)

[189] Henegan & Thompson, p. 187.

[190] http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2012/0266%28COD%29#tab-0. NB. The Industry, Research and Energy committee and the International Trade committee decided to not provide an opinion on this piece of legislation.

- Marina Yannakoudakis for the European Conservatives and Reformists Group (ECR)
- Alda Sousa for the European United Left/Nordic Green Left (GUE/NGL)

It apparently took some time to plan and or prepare a debate, since the first meeting in the ENVI committee on the subject of medical devices took place at the end of March 2013. Two other meetings in the ENVI committee followed, one on 24th of April 2013 on the report written by the rapporteur, and one on the 29th of May 2013, after the amendments to the report had been submitted by the political groups. The amendments were voted for after the summer recess (no debate takes place during voting), after which the Committee report was tabled for plenary. On the 22nd of October 2013, the debate in plenary was held, and consequent the document was partially voted for. It took until the 2nd of April 2014 before the complete text was voted for and adopted in the Parliament. Only then the Council was allowed to officially prepare their position, after which trialogue meetings could be held. This latter process has taken another two years (actually a bit more, since the tentatively agreed consolidated compromise text of the proposed Regulation on medical devices dates only back to the 16th of June 2016). Due to the elections to the European Parliament in 2014, and the fact that Mrs. Roth-Behrendt was not available for re-election, a new rapporteur had to be appointed, who would be representing the Parliament during the trialogue process. This new rapporteur was Mrs. Dame Glenis Willmott, also, like her former colleague, from the Progressive Alliance of Socialists and Democrats (S&D).

In this subchapter, I will however only focus on the parliamentary debates available, which are the three committee meetings and the plenary debate (each about 1 to 1,5 hours in length). For all these debates, Mrs. Dagmar Roth-Behrendt has been the rapporteur in charge. This is important to know, since the rapporteur has the most speaking time during the debate. He or she introduces or updates the subject and is allowed to have the final word with respect to the agenda item. Generally, the debates are structured as follows: after the rapporteur has introduced the subject, the shadow rapporteurs are allowed to state their opinions. Then, every member of the committee (or, in case of plenary, every MEP) who wants to, is allowed to have the floor to state their opinion. This is followed by speaking time for the representative of the European Commission, who is allowed to explicate the Commissions' point of view. Finally, as said, the rapporteur is allowed to make his/her final remarks. This set structure is chaired by the President of the committee, in case of the ENVI committee Matthias Groote (S&D), or of the Parliament, in this case Miguel Angel Martínez Martínez (S&D), who, more importantly, also do the timekeeping of the speaking time of the Members of Parliament. The speaking time is strictly set and, generally, the more important you are with respect to the topic at hand, the more speaking time you get, but this is very limited still. Consequently, the speakers only focus on the main points they want to address, talk as fast as possible, are cut off, or argue with the President why the speaking time they have is not reasonable. Combined with the fact that the speeches are held subsequently, rather than speakers debating with each other, it should be of no surprise that the debates are mere listings of main points of view rather than debates questioning each other, providing detailed argumentation, and/or striving for compromises. Consequently, we will mainly be analyzing main positions and issues, rather than technical details and fierce debates. The MEPs are aware of this themselves, and as the shadow rapporteurs contend this is a very technical and complex piece of legislation, most of the technical details will be discussed during the unrecorded shadow rapporteurs' meetings. This doesn't mean the debates are very dull or superficial, though. I was surprised by the passion, theatre and drama with which the speakers, especially the rapporteur, argued for their positions. Although I don't know whether the level of passion

and drama is unusual for debates in European Parliament, I believe it showed that the issue of medical devices lies close to the heart of the Members of Parliament involved.

4.2.2 Main themes

4.2.2.1 Safety

With respect to the main positions and issues considering medical devices, analyzing the debates, it becomes clear that the theme addressed most is patient safety. Although no-one defines patient safety nor explains what they exactly mean with it, both the European Commission and the political groups state that patient safety is the number one priority.

For example, the European Commission on 24th of April:

'[T]his is a proposal that we revamp, exactly because patient safety was in our head. So, there I think we all agree and I am grateful that this has been the theme under which all the proposals have been made. … all the work that we have done in our proposal was with one issue in mind: how to increase and strengthen patient safety through the process?'[191]

And in the debate on 29th of May:

'[F]rom what we heart here today, I think one thing is for sure and one thing is common, that the fundamental objective is to ensure the highest level of safety for patients in Europe, and that we should all see how such safety, when it comes to medical devices that are placed in the market, is to the highest possible level. And where we can strengthen it, we should. And the Commission is very conscious of its duty in that direction … This is our duty to safety, because safety is the priority issue.'[192]

And during the plenary debate on 22nd of October:

'[T]he two proposals on medical devices and in vitro diagnostics that we are debating today, are of the highest importance for patient safety.'[193]

With respect to the political groups, the rapporteur states in the plenary debate on the 22nd of October 2013 that '[w]ell, if listened carefully to today's debate, I think all colleagues have spoken in favor of more safety for patients and they have all said that we need to improve the system.'[194] Analyzing the contributions of the different political groups, we can indeed observe that (almost)[195] all groups state several times that they consider patient safety to be the first priority.

Statements of the political groups:

- European Conservatives and Reformists Group (ECR):

[191] European Commission, 24 April 2013, ~55'.
[192] European Commission, 29 May 2013, ~52'.
[193] European Commission, Neven Mimica, 22 October 2013, opening remarks.
[194] Dagmar Roth-Behrendt, 22 October 2013 (closing remarks).
[195] The only group which doesn't state that safety is of main importance to them is the Europe of Freedom and Democracy group (EFD), currently, in the 8th Parliamentary term the Europe of Freedom and Direct Democracy group (EFDD), which however merely has one contribution in the Plenary debate by a MEP who states that he is a libertarian: 'I am against this report because I am a libertarian,' Derek Roland Clark, EFD Group, 22 October 2013.

'[S]afety needs to be right into the center … So, safety is top of the list.'[196]
'[F]or me, what matters most, is of course patient safety.'[197]
'I voted in favor of putting patient safety as the top priority.'[198]

- Alliance of Liberals and Democrats for Europe (ALDE):
  'Patients in Europe, I think, are rightly expecting that if they need to use medical devices, they should be safe.'[199]
  'I should say that the leading on issue should be the safety issue.'[200]
  '[W]e should not compromise with the safety.'[201]
  '[T]his report on medical devices is a balanced one which, like the in vitro report, puts patient safety first.'[202]

- Group of the European People's Party (Christen Democrats) (EPP):
  'We have increased patient safety at the core of our work.'[203]
  '[W]hat we have agreed upon is that the patient security has to be the first priority here.'[204]
  'Where are the controversies in this house? Well there are none, because the patient is the key element of the process here. The patient is the most important element, so if we are discussing the fact that the producers need to have certain rights, because otherwise their products will not be able to be sold on the market, we are not trying to understand the people! The people who really need our help very often.'[205]
  '[W]e are all responsible for patient's health. That's our ultimate aim as we deal with this.'[206]
  '[W]e therefore voted in favor for this text, which has, as its primary goal, the defense of European patient's health.'[207]

- The Progressive Alliance of Socialists and Democrats (S&D):
  '[T]o make sure that patient safety is the highest impact and that only medical devices get on the market which are safe and which are prudently looked at.'[208]
  'Health and safety are issues which are mentioned throughout the proposal as fundamental objective, so which need to be reached.'[209]
  '[To] ensure that patient security and safety lies at the very heart of the provision, particularly in terms of implants as well.'[210]

[196] Anna Rosbach, 20 March 2013, ~22'.
[197] Anna Rosbach, 29 May 2013, ~41'.
[198] Anna Rosbach, 22 October 2013, Oral explanation of vote.
[199] Holger Krahmer, 22 October 2013.
[200] Antonyia Parvanova, 20 March 2013, ~34'30''.
[201] Antonyia Parvanova, 24 April, 2013, ~46'30''.
[202] Marian Harkin, 22 October 2013, Oral explanation of vote.
[203] Mairead McGuinness, 29 May 2013, ~16'30''.
[204] Richard Seeber, 22 October 2013.
[205] Jolanta Emilia Hibner, 22 October 2013.
[206] Thomas Ulmer, 22 October 2013.
[207] Paolo Bartolozzi, 22 October 2013, Oral explanation of vote.
[208] Dagmar Roth-Behrendt, 29 May, ~6'.
[209] Edite Estrela, 20 march 2013, ~24'.
[210] Gilles Pargneaux, 22 October 2013.

- The Greens/European Free Alliance (Greens/EFA):
  '[W]e need to reject the system, we need more guarantees for patient safety, that is what we need, my true concern.'[211]
  'We will have a safe system which also will encourage Member States to criminalize the industries that are not sufficiently safe, because we are dealing with the health of our population.'[212]

- Confederal Group of the European United Left/Nordic Green Left (GUE/NGL):
  '[T]he issue of safety, safety of persons who are ill. That is of capital importance.'[213]
  'These are pieces of legislation which effect the security of our citizens. And they put the safety of our patients at the very center of our attention.'[214]

- Democratic Unionist Party/No Group (NI):
  '[T]he health and wellbeing of our constituents are a top priority for all of us as legislators.'[215]

The observation that safety seems to be the main objective of the political groups, is being supported by the fact that the phrase 'safety' is used most frequent, in comparison with other themes (discussed in upcoming paragraphs). Even neglecting synonyms for safety, and including synonyms for 'transparency' (i.e. 'traceability), 'innovation' (i.e. 'industry' and 'competitive/competitiveness'), and 'trust' (i.e. 'confidence'), 'safety' is used much more frequent than the other terms. To be precise, 'safety' is mentioned 107 times, while 'innovation' related phrases are used 73 times, 'transparency' related phrases 43 times, and 'trust' related phrases 20 times.

This observation might not be very surprising, since, especially after the public controversies with medical devices, it is politically incorrect, and MEPs might be accused of not representing the public interest (while being representative of the European people), if they did not state to consider patient safety (at least) very important. Besides, one of the tasks of the European Union is the protection of public health. Obviously, safe devices on the internal market are needed in order to fulfill this aim.

4.2.2.2 Safety versus innovation discourse

Even though almost all political groups state that patient safety is of utmost importance and absolute priority, for the European Commission and several political groups this doesn't mean that they don't consider another theme to be important as well, sometimes equally important, even. This theme is rapid innovation of medical devices and the competitiveness of the European medical devices sector.

[211] Michèle Rivasi, 29 May 2013, ~28'.
[212] Margrete Auken, 22 October 2013.
[213] Alda Sousa, 20 March 2013, ~29'.
[214] Alda Sousa, 22 October 2013.
[215] Diane Dodds, 22 October 2013, Oral explanation of vote.

The European Commission then, though it considers patient safety to be the first and fundamental objective, also states, in their proposal and in the debates, that actually three objectives have to be fulfilled in the new regulation:

> 'The three objectives were to strengthen protection of health and safety, the well-functioning of the internal market, and the support for innovation and competitiveness of the sector.'[216]

In the next debate, the Commission again mentions the importance of the industry:

> 'So, it is about patient safety, it is not just about the competitiveness of the sector, which is equally important of course.'[217]

Also in the plenary debate, the Commission stresses the importance of balancing patients' interest and the interests of the industry:

> 'My guiding principle will be the aim of ensuring the highest level of patient and consumer safety, whilst making sure that innovation continues to flourish.'[218]

> 'We all have to work on what is not an easy balance between patient safety and the industry's need – especially that of SMEs – to keep the existing innovative and competitive edge of European manufacturers. This balance would be easier to strike if our point of departure and arrival were to/would remain one of no compromise on patient safety.'[219]

So, patients' safety should be at its highest level, but not at all costs; industries' interests should not be forgotten about either. Apparently these interests do not neatly fit together, since a balance has to be struck between patient safety and the industry's need.

Some political groups do share these points of view, others don't. Especially the groups that are more in favor of a free market, stress the importance of a competitive sector.

The European Conservatives and Reformists Group, for example, states that:

> 'Yes, we have an obligation to patient safety. We also have an obligation to have a system that is going to work, that is not over bureaucratic and will not stop getting people the care they need.'[220]

And the ALDE contends that:

> 'Today we have helped to ensure the continuation of those jobs while at the same time putting patient safety first.'[221]

The EPP in its turn, also stresses the importance innovation, but seems to suggest the schism between those two is not as big as some other political groups and the Commission might present:

[216] European Commission, 20 March 2013, ~41'.
[217] European Commission, 20 March 2013, ~56'.
[218] European Commission, Neven Mimica, 22 October 2013, opening remarks.
[219] European Commission, Neven Mimica, 22 October 2013, closing remarks.
[220] Marina Yannakoudakis, 29 May, ~28'30''.
[221] Marian Harkin, 22 October 2013, Oral explanation of vote.

> 'I think that there are two key points that we have to deal with […] first is to restore consumer and patient safety and confidence in the system, and [second?, AG] to secure the industry's ability to innovate, and put products on the marketplace.'[222]

> 'So, I think that on the whole we can say we are making a huge step forward. A step forward to better patient safety, without endangering innovation in the industry.'[223]

> 'At the same time, a great attention needs to be paid to the medical devices sector, in order to guarantee fair competition, which is very important in terms of jobs, considering the situation, whilst protecting the health of patients.'[224]

The more regulated-market oriented S&D, however, seems to disagree and believes that industries' interests might hamper or even harm patient safety.

> 'But the right wing of this Parliament has considered industry more than patients.'[225]

> 'Clearly, patients are those who have benefitted the most and that is why we have to encourage all inventions. But of course, that should never have repercussions in terms of patient's safety. Patients have to have the guarantees that the devices given to them are the best.'[226]

> 'The rapporteur has done its utmost to reach a compromise and the proposal clearly increases patient safety in the EU. It could however do more if there was [not?, AG] strong pressure from some stakeholders that the proposal was "balanced". This means in practice, as suggested by some MPs, that it should find a solution that would suit both patients and entire sectors of production, distribution and sale of medical devices. In my view, however, the safety of patients in the first place and their confidence strengthened as a compromise, but clear rules that effectively prevent similar scandals.'[227]

The Confederal Group of the European United Left, on the other hand, seems to think that patient safety and innovation can go hand in hand:

> '[T]he issue of safety, safety of persons who are ill. That is of capital importance. And this is not something that runs counter to innovation, but what we do need is legislation that on the one side will guarantee safety, and on the other hand, […] should also allow for proper controls.'[228]

[222] Mairead McGuinness, 20 March 2013, ~14'.
[223] Peter Liese, 22 October 2013, opening remarks.
[224] Paolo Bartolozzi, 22 October 2013, Oral explanation of vote.
[225] Chistel Schaldemose, 22 October 2013.
[226] Biljana Borzan, 22 October 2013.
[227] Pavel Poc, 22 October 2013, Writing.
[228] Alda Sousa, 20 March 2013, ~29'.

And, later on:

> 'We have to bear in mind the needs of the patients and their health issues which are at stake, and try to introduce legislation in this area, which both takes into account what we are trying to achieve in terms of innovation, but this was never be at the cost of patient safety.'[229]

So, the debates in committee and plenary are mainly about the safety discourse and the innovation discourse, and to what extent these discourses overlap and differ with respect to the pressing policy issues about medical devices, in order to protect public health on the one hand, and on the other hand the internal market. The policy issues discussed from the perspectives of both discourses are market authorization, oversight by and quality of notified bodies, post-market surveillance and vigilance, and reprocessing of single-use devices. Especially with respect to market authorization, there is quite some disagreement between the political groups on the necessity of pre-market authorization and whether centralized authorization is needed in order to ensure patient safety, or whether it might unnecessary delay innovation and the introduction of new devices on the internal market. Particularly the more free-market oriented political groups, in favor of balancing the value of patient safety with the interests of industry, do not prefer the introduction of a centralized authorization procedure and stress the potential problems with such a system, especially for the industry, but ultimately for patients as well.

The ALDE for example, refers to a consultancy report[230] in order to show that patient safety might not necessarily be increased by a centralized authorization system:

> 'They compared the situation in the US and in Europe. In the US they have a centralized authorization system and the results of the study show that between the two markets, i.e. the American market and the European market, there is no difference. There are no significant differences when it comes to the frequency of medical devices, so and no more devices are withdrawn in Europe than in the US.'[231]

Consequently, the ALDE argues in another debate that:

> 'Now, every centralization decision we take, is one we should think twice about, because we have experience here. In the United States, for example, there is a centralized authorization process, which didn't stop the problems with hip implants. And so it is not just the case that centralizing authorizations will automatically lead to more product safety.'[232]

In addition to the presumed lack of safety increase, in the debate in plenary, Holger Krahmer of the ALDE uses related arguments, i.e. practical constraints and the assumed small percentage of manufacturers with a criminal intent, deliberately threatening patient safety (and consequently large percentage of trustworthy manufacturers), in order to argue against centralized market authorization:

> 'Now we have to ensure that what we do, can be implemented in practice. Now, what the committee, I think, has decided upon, this probably could not be implemented. So many

[229] Alda Sousa, 29 May 2013, ~31'.
[230] BCG, EU Medical Device Approval Safety Assessment, January 2011.
[231] Holger Krahmer, 24 April 2013, ~24'.
[232] Holger Krahmer, 20 March 2013, ~15'30''.

> committees, groups with unclear competences, and I think at the end of the day we are going to extend the time needed for procedures to be approved, products to be approved, but we are not necessarily improving the safety of those devices. Now, really, I think we have a tiny tiny percentage of quality products relating to the actual quality/quanty [?, unclear what word he uses here, AG] standards with the products, which can be attributed to the manufacturers. I think, really, with the implementation of these devices in hospitals, it is a lot to do with how they are actually used. And I don't know whether it is a good idea to have a debate here, which focusses on the black sheep in this; the people who have criminal intent. I mean there is just a tiny percentage of people on the market, because most other people want to market good products.'[233]

Another MEP from ALDE reasons from a utilitarian perspective, and uses arguments based on economic constraints in order to argue against a centralized procedure:

> 'I think that in relation to the discussion about pre-market approval or post-marketing surveillance, I think we need to consider whether the benefits gained in patient safety are enough to warrant the extra administration. And also, would we need to create a new agency, and would that be realistic, especially at time when actually we have been cutting, you know, reforming the staff regulations in the institutions.'[234]

The EPP is not in favor of a centralized authorization process, either. They use similar arguments as the ALDE, like the concern that patient safety might not necessary be improved with a centralized system, and practical, monetary and daily constraints, in order to reason against a centralized system.

> 'When we come back to the authorization process, which I think is a key part of our rapporteur's proposal, in my view it complicates the system without giving us absolute clarity that it gives us a better system. And therefore I would suggest that in my amendments, I would be looking at strengthening the Commission proposal, so that we get the results that we all are hoping to achieve. And that involves, in my view, post-market surveillance has to be greatly strengthened, the role and operation of the notified bodies needs to be absolutely strengthened, and the Competent Authorities need to do now, what they are currently not doing.'[235]

> '[W]hat we did not want was a state pre-authorization of products, what we did not want was central authorization by the EMA. That does not necessarily bring extra security, that applies to pharmaceutical products where we still have a long list of scandals. Various new forms of anti-baby pills etcetera. And we find huge new practical problems, there are big issues in ensuring that innovation is safe [?, unclear what word he uses here, AG] for patients. So we need to act actively, but there are lot of people at the industry who also say that we don't want any extra security, and we don't want a European expert group to have a look at our products.'[236]

[233] Holger Krahmer, 22 October 2013.
[234] Rebecca Taylor, 20 March 2013, ~29'30''.
[235] Mairead McGuinness, 24 April 2013, ~18'.
[236] Peter Liese, 22 October 2013, opening remarks.

The EPP also explicitly stresses the importance and unique characteristics of the medical devices sector as a reason to oppose (centralized) pre-market authorization. Since the point of view is so clearly stated, I provide the whole –pretty extensive- reasoning here:

> 'I think that people who believe that a central authority would avoid corruption is absolutely wrong; the central authorities have exactly the same failure rate as a regional authorities, on average. And medicine, medicinal products get onto the market 43 weeks earlier than the products in the USA, and I think now that is key for our patients and their health, because the faster these products are available, then the better it is for the patients. Of course, we need to ensure that there aren't any failings. We don't want unsatisfactory products to be implanted or anything like that. But we have the huge advantage of the European system, which is flexibility; we need to maintain that. And we need to continue to fine-tune our approach. I mean jobs don't justify everything, but we have to remember it is a fact that this is an innovative sector; it's a market of hundreds of billions of euros where tens of thousands of people work there. Huge numbers of patents coming from the sector every year. Seven percent of all patents are for medical devices. So, if we are going to get advantage from all of this innovation, all these new patents, we need to have a good system. We need a proposal that goes against all centralizing tends.'[237]

The political groups opposing pre-market authorization procedures thus seem to reason from both the perspective of increased patient safety and the innovation perspective. They clearly think both perspectives can and should be balanced in order to reach a compromise which is not likely to harm patients nor the internal market. The political groups (basically all the regulated-market oriented groups) in favor of (centralized) pre-market authorization on the other hand, either do not mention industry's interest when defending the proposed system, or state that any potential delay in market authorization of devices can be justified with respect to patient safety and/or the development time of devices. Michèle Rivasi of the Group of the Greens most clearly formulates this point of view:

> 'So, I mean this is why we are saying that we need to strengthen checks, but these certifying bodies, with all the experts that may be available to them... I mean, how are we going to make sure that they detect anything, knowing that all their funding comes from manufacturers! We need a public body to exercise oversight! We need a public body with checks, because these controlling bodies of course they carried out checks, on the ground, in Marseille [where the manufacturer of PIP implants is located, AG], but they did not detect anything. But, if they had looked at the accounting of this whole manufacturer in Marseille, they could have seen that the ingredients they used, did not actually correspond to those declared. They could just have seen it from that side. What we need, is to stop fraud. But there is still fraud. We have just seen another case, another implant using a European Community label. And the hospitals adjusted it to the device and they used it for patients, because they saw this European Community label. So it is the producers, the manufacturers who carry out fraud, and the certifying bodies are not a guarantee against fraud. So, I feel that for all implants, anything that we are going to insert into body, we need a market access authorization. And then of course there are certain devices that are high-

[237] Richard Seeber, 22 October 2013.

> risk, and who is going to pay when something goes wrong? Not the manufacturers. No! It is the taxpayer. So, we need market access authorizations, and we need clinical trials before anything is authorized. And people say, well/all well, this will waste the manufacturer's time, but what are two, three months compared to the harm to patients that are to receive a fraudulent implant?'[238]

Also rapporteur Dagmar Roth-Behrendt of the S&D, by stressing the importance of patient safety, by proposing a strict centralized pre-market authorization procedure, and by accusing the industry of bad lobbying, does not seem to support the industry's interests very much nor seems to strive for legislation that balances both interests. Consequently, the rapporteur -behind the scenes- is being accused of neglecting the importance of innovation and industry, which after all might in the long(er) term be in the patients' interest as well. In the committee meetings following the accusation, she responds by stating that:

> '[M]ore than innovation for the sake of innovation, which is not a sake in itself, I want to have quick access for patients, but I also want patient safety. And I have to underline, yes I do want quick access to the patients, because some of the companies mislead not only citizens, but as well members of Parliament by pretending that my proposal would prolong the market-access, which is a lie. I want to have quick access, but patient safety we all agree and I hope as well companies would agree and the industry would agree, is as important as that.'[239]

During a press conference at the 4th of April 2014 however, just before the final vote will take place in Parliament, she, frustrated about the delay of several months in the legislative process, and possibly also frustrated about the fact that the system of pre-market authorization has already been voted down by the Parliament, is much less friendly towards the industry:

> 'But we face a situation here, where the European industry pretends that that report would stop their innovation capacity, which is a ridiculous argument. Because when you speak about high-risk products, you normally speak about products which are produced or developed in a time-frame of some years. You do not produce, and develop, and invent a processor to implant into the brain in half a year. So to speak then, about perhaps two or three months of a certification process, is nothing in the development time! But the industry, the European industry, not for me understandable, had the approach to keep the status-quo if possible. So they were similar to the tobacco industry with two lines: no legislation at all, but if a legislation, as late and as weak as possible. And obviously, they were successful up till now, because as late as possible we are now.'[240]

To conclude, even though the last quotation shows that the rapporteur believes the text adopted in Parliament is not as responsible towards patients and their safety as she might have wanted, the passages cited all indicate that balancing the interests of the patients with the interests of the medical device industry, lies at the heart of the debates in Parliament.

[238] Michèle Rivasi, 29 May 2013, ~24'.
[239] Dagmar Roth-Behrendt, 24 April 2013, ~4'.
[240] Dagmar Roth-Behrendt, 4 April 2014, ~10'.

4.2.2.3 Patients' trust

In addition to the main themes of patient safety and innovation, other themes are discussed as well. One of these themes is related to the issue of patient safety, but also to the interests of industry, and potentially also to the interests and the image of the European Union with respect to the rest of the world: the theme of patients', consumers' and healthcare professionals' trust in the healthcare system, and more specifically in medical devices. This theme is related to patient safety, in the sense that the recent controversies with medical devices, after which medical devices turned out to not be as safe for patients as expected, are likely to have decreased the trust of patients in medical devices. Obviously, this is very unfortunate for the medical devices industry, as their sales are dependent on willingness of healthcare professionals, consumers and patients to use their products, and consequently they are dependent on the trust of customers in medical devices. The European Union itself also has interest in trust from patients and healthcare professionals in the healthcare system, since there has been quite a lot of discussion about the usefulness and the tasks of the European Union in the Member States. Effectively protecting public health of the citizens in all the Member States, and the citizens showing their trust in the healthcare system, might contribute to a positive judgement about the unification of Europe.

Interestingly, none of the political groups or the Commission provide an argument why regaining trust in the system is important. They merely state that it is something important to be achieved. Almost every political group though, has at least one MEP mentioning patients' and healthcare providers' trust as a key aspect of the new legislation.

The Commission, for example:

> 'These are just a few examples of why the revision is needed – and it is needed urgently in order to fully restore the trust of patients, consumers and healthcare professionals in the regulatory system.'[241]

The ECR:

> '[T]here has been a whole range of scandals with breast and hip implants. And that means that the people have lost trust in this sort of thing, and we need to be seen to restore trust.'[242]

The ALDE:

> 'Patients in Europe, I think, are rightly expecting that if they need to use medical devices, they should be safe, you know. When you go to the hospital, have to be seen (?), you trust the doctor and you trust what is used there, meets safety requirements.'[243]

The EPP:

> 'We need to improve their quality and safety, so patients can regain trust. That can only happen if we have a clear, safe reinforced legal framework.' [244]

[241] European Commission, Neven Mimica, 22 October 2013, opening remarks.
[242] Anna Rosbach, 20 March 2013, ~21'30''.
[243] Holger Krahmer, 22 October 2013.
[244] Roberta Angelilli, 22 October 2013, Oral explanation of vote.

The S&D:

> 'When a patient puts their life, their health in the hands of a doctor, the patient has to feel safe. And the doctor has to be able to trust the devices he is using.'[245]

> 'Europe's citizens expect that medical devices that are used in their countries, are safe. Their confidence has been undermined by a series of scandals […] clearly pointed to the fact that the current legislation is not able to ensure the safety of medical devices.'[246]

No group:

> 'Confidence in all aspects of health care, especially in the safety of medical devices and of medical procedures, is paramount to both healthcare professionals and patients.'[247]

Strikingly, the two other groups in favor of a regulated market (i.e. the Greens and the United Left) do not mention trust/confidence in the healthcare system as a point of attention during the debates. This might support the thesis that trust is important for the industry, as the political groups stressing the importance of keeping the interests of industry in mind, do mention the importance of regaining patients' and healthcare providers' trust as well.

4.2.2.4 Distrust in industry

A theme related to the theme of patients' trust in the healthcare system, is distrust in industry. This theme entails the issue that even though the healthcare system and medical devices turn out to be safe and are trusted (again) by patients and healthcare providers, it still tends to be that people, and some politicians, distrust the industry of healthcare products, presumably due to their commercial nature and the scandals in the past. Generally, it is assumed that political parties and groups that are in favor of a more regulated market, tend to have a more critical position towards industries, than groups in favor of a free market, which are assumed to be (more) supportive of industries. Consequently, one might expect that the political groups in the European Parliament that are considered to be in favor of a regulated market, tend to be more critical towards the medical devices industry and show more distrust. Interestingly enough, quite a lot of political groups provide critical notes towards the industry at some time during the debate, and there is no clear correlation with the ideology of the group. It should be noted however, that distrust in industry is not as explicitly stated by the MEPs as for example patient safety and patients' trust, so critical notes towards the industry are the only indicator for distrust available, but not necessarily an indicator for general distrust in the medical devices industry. It might perhaps be the case that some political groups are critical towards intentions or (expected) practices with respect to a certain topic, but are not critical towards the industry in general. The outcome of the analysis supports this thesis, as most of the examples shown below are related to the issue of reprocessing of single-use devices. Merely the Confederal Group of the United Left and the rapporteur (of the S&D) also provide critical notes which are

[245] Biljana Borzan, 22 October 2013.
[246] Pavel Poc, 22 October 2013, Writing.
[247] Diance Dodds, 22 October 2013, Oral explanation of vote.

not directly related to this policy issue, which might indicate that there is some correlation with the position of the political groups after all.

At least, the rapporteur Dagmar Roth-Behrendt, who seemingly is being accused of neglecting the importance of innovation and industry (as discussed in the paragraph 4.2.2.2 on the 'Safety versus innovation discourse'), provides the most critical notes towards the medical devices industry. For instance:

> 'The manufacturer is the one to say and to prove why it is single-use, why it is not reprocessable. Now, I am not naïve, I know that that is still a way of printing money, and I am sorry, I should not be so direct, and I know that that is a possibility for a manufacturer to pretend that it is single-use.'[248]

> 'I do not want colleagues to fall into that trap which the producers of medical devices try to pretend. They try to pretend that any other system will prolong the market access longer, and patients do not get access. Like one roof organization of producers did in a very moving way, describing that poor lady not getting the urgently needed device. Colleagues, we just always want to speak about the real facts.'[249]

The Confederal Group of the United Left:

> 'It is clear that all the experts who carry out this type of authorization, have to be completely independent. They cannot have an interest elsewhere, or be in the pay of other producing bodies. These organizations who are responsible for giving authorization, must, have to be completely independent, so that they don't end up being an easy pray for the pharmaceutical industry.'[250]

The other political groups show some signs of distrust towards the industry with respect to reprocessing of single-use devices:

The ECR:

> 'Let's have a look at what things look like in practice: I think it would be inappropriate to leave everything to the manufacturer, and to leave it up to the manufacturer to decide what medical devices should be single-use or should be understood to be single-use or not.'[251]

The ALDE:

> '[A]s regards to the single-use or double-use; there is the tendency in the companies to put a lots of plugs and switches etcetera as single-use, or part of the device which is unreplaceable, which makes actually a lots of spendings on the national health insurance, without necessarily being important for the patient's safety, but making it unique, so that the medical devices are not replaceable or compatible. This probably also needs to be considered and switch and plugs etcetera not to be made unique, or irreversible.'[252]

[248] Dagmar Roth-Behrendt, 24 April 2013, ~1:08:00.
[249] Dagmar Roth-Behrendt, 29 May 2013, ~56'.
[250] Alda Sousa, 29 May 2013, ~31'30''.
[251] Milan Cabrnoch, 24 April 2013, ~35'.
[252] Antonyia Parvanova, 20 March 2013, ~36'.

The EPP:

> 'The manufacturers of medical products say that these products should only be used once, although it can be used several times. Because they of course want to increase their turn-over.'[253]

4.2.2.5 Transparency & Traceability

Another important theme frequently discussed, is transparency about device performance and traceability of devices. This theme obviously is related to the theme of patient safety, as more information about the location of the device during its lifetime and about the device performance, both pre-market as post-market, is expected to provide the opportunity to know (at an earlier stage) when something goes wrong/different than predicted, and consequently to act (at an earlier stage) in order to prevent the patient from experiencing (more) harm. Therefore, transparency and traceability are expected to increase patient safety. Several political groups state the importance of increasing transparency, although they highlight different aspects of transparency and do not all explain why they believe it to be important.

The ECR indeed considers transparency important in order to detect mistakes. Also, they relate transparency to inform patients about devices:

> 'And there needs to be transparency, and openness, so that there is proper traceability possible for these medical products. One way or another, you need to be able to trace any mistakes.'[254]

> 'And patient information. Because I myself would preferably not want to be treated with re-used single-use devices or products. I would want to know. And I really think that patients are entitled to information, and we are all patients! Everyone here in this room is a patient and we are entitled to know whether the devices or the products that's been used on us are safe or not.'[255]

The ALDE relates transparency to information about and control of devices that are already on the market:

> 'We may also be able to agree with you [the rapporteur, AG] on issues related to how we deal with products which are already on the market, with a surveillance and follow-up. How can we get better information about necessary cases? I think we can reach a compromise on this and I think we could agree that we need more and more vigorous controls, especially for the producers. That is really the point where abuse, or criminal activity can be detected.'[256]

Transparency is also related to reporting about and detecting any defective devices (not the best English, unfortunately, but the general message will be clear):

> '[T]here have been number of tests of cases reported in which there are defective medical devices. There is no first of all traceability, but this defective medical devices, especially those which are for inter/intra corporal use, may cause further complications of the medical diagnosis,

[253] Horst Schnellhardt, 20 March 2013, ~32'.
[254] Anna Rosbach, 20 March 2013, ~22'30''.
[255] Anna Rosbach, 29 May 2013, ~41'30''.
[256] Holger Krahmer, 29 May 2013, ~18'.

> or may cause side-effects. And that is why it is necessary this cases to be reported and further actions to be taken.'[257]

The EPP focusses on sharing of information throughout the European Union:

> 'Furthermore, for high risk medical devices, in the interest of increased transparency, manufacturers should summarize the main safety and performance expert [?, unclear what word she uses here, AG]). Transparency of procedures should be ensured, where similar incidents have occurred, or failed safety corrective actions have to be carried out in more than in one Member States.'[258]

The S&D clearly connects transparency with improved patient safety:

> '[A]nd it [i.e. the proposal of Roth-Behrendt, AG] makes it quite clear that supervision has to guarantee that we have transparency and we have traceability for each products. And that manufacturer controls are strict and this can be implemented without a prior warning. I think this is something that the Parliament could do in order to ensure that the health of patients, our first objective, is respected. You know, we people have implants which stay in their bodies for the rest of their life.'[259]

The Group of the Greens pays most attention to the theme of transparency and even argues for guaranteeing full transparency ('so that we make sure that the people who try to cheat us won't be able to hide'[260]), wherever that might be realistic:

> 'And on clinical investigation we want transparency, no secrets, that is one of the best guaranties. If we have smooth authorization procedures, we can prevent, you know, real bad handling, if we guarantee full transparency. Then it is, will be more safe that the control is in place. And public accessibility of course, to the data, not only to the summaries and always tell industry that if they are able to make a fair summary, they are also able to have, then they have the date. Because they cannot make a fair summary if they don't have the data.'[261]

Also the Confederal Group of the European United Left pays quite a lot of attention to transparency, more specific, to provide information to the patient, the healthcare professional, and the public at large:

> '[I] t is very important to provide information to the public at large. People need information on the available medical devices, and this is something that really links into the issue of transparency, which is very important for this reason: the public needs to have access to information and this is of course of the most important to health workers. Health workers need to be able to have the information to assess the devices in order to make recommendations on the use of medical devices. But a review of current literature is not enough. I think we need to have a full overview

[257] Antonyia Parvanova, speaking English, 20 March 2013, ~35'.
[258] Zofija Mazej Kukovic, speaking English, 29 May 2013, ~35'30''.
[259] Andrés Perelló Rodriguez, 22 October 2013.
[260] Margrete Auken, 22 October 2013.
[261] Margrete Auken, 20 March 2013, ~19'.

> of the medical devices. We need to see which medical devices have been withdrawn from the market, which are still on the market, which ones function well, which ones do not.'[262]

The rapporteur, finally, agrees with her fellow colleagues, but she also touches upon some specific issues related to the theme of transparency not discussed before:

> 'Concerning some bits what Margrete Augen and other said, yes, we need yes, we need more transparency on clinical data and we need more clinical data. For that we probably need more clinical trials, and we have to strengthen the procedure; from the first second on, we have to have the registration and then we continue.'[263]

But she also discusses the methodological challenges of achieving transparency, due to the unique nature of medical devices in comparison with for example pharmaceuticals:

> 'You know that on medical devices not only clinical data are more difficult to get, but as well the traceability and long-term studies are more difficult, because the device very often is implanted , so we have to be there very prudent.'[264]

Lastly, she discusses some particular issues with respect to transparency of information concerning, first, notified bodies, and second, data in the electronic system:

> 'And at the same time, what they do at the moment notified bodies, they subcontract. But nobody knows where they subcontract to. And I say therefore we have to ensure that subcontracting occurs only in a limited amount of cases, and the lists with the subcontractors have to be published. And disclosed. So we want to know naturally whether a notified body is responsible. Have they done it alone or have they had a subcontractor and who was the subcontractor?'[265]

> 'I want to make sure that reporting to the electronic system includes date and place of incidence, and where available as well data and information on the patient and user, healthcare professional. That is that the healthcare professionals want us, because they say the failure of a medical device can be the failure of a medical device, but as well, it can, it could be as well a failure of the healthcare professional and therefore we need as well all those data included.'[266]

To conclude, even though different aspects of transparency are highlighted by different groups, the theme in general seems to be important for almost all the political groups.

The analysis of the transparency issue finishes the discussion of the main themes of the parliamentary debates. In the remainder of this subchapter, I would like to discuss some issues, which are deemed important by some of the groups, and are closely related to the ethical issues concerning the legislation of medical devices, but are not broadly touched upon during the debates.

[262] Alda Sousa, 20 March 2013, ~30'.
[263] Dagmar Roth-Behrendt, 20 March 2013, ~55'.
[264] Dagmar Roth-Behrendt, 29 May 2013, ~6'.
[265] Dagmar Roth-Behrendt, 24 April 2013, ~14'.
[266] Dagmar Roth-Behrendt, 24 April 2013, ~16'.

4.2.2.6 Clear classification and legal certainty

The first issue discussed by some of the political groups is consistent classification and legal certainty. Although not always explicitly stated, the Parliament and Commission seem to struggle how to classify some healthcare products that can be considered borderline products. Also, one is discussing to what risk-class these products should be assigned, and under what regime they should be tested. Even though, as discussed before, not all the political groups are in favor of a centralized pre-market authorization procedure for medical devices, as is common in the case of pharmaceuticals, both the Commission and most of the political groups seem to believe that medical devices, especially those that can be considered high-risk, and pharmaceuticals are not as distinct as considered during the time of the *New Approach* (see background information on the *History of regulation in the medical device sector*, paragraph 2.2). Rapporteur Roth-Behrendt several times mentions the similarities between the two kinds of healthcare products:

> 'I don't mind to look how we can define it, but I believe personally, for everything which is implanted, and which stays in the body, and for everything which is connected with an active ingredient, with a pharmacological substance, that has to undergo a very similar procedure than a pharmaceutical. It is connected with your body, imagine that. It should deliver a pharmaceutical where you have to be safe that it does that.'[267]

And:

> 'That is not the way we should deal with products. Or if you find it appropriate, we should deal with that with pharmaceuticals as well.'[268]

She however seems to be in favor of distinct legislation of the different kinds of products and consequently pays some attention to the challenges borderline products might pose, and the equal level of risk on which the risk-classification should be based:

> '[W]e agree, naturally, that if it is something is a pharmaceutical, it should not be in the medical device, but if something is not in the pharmaceutical world and cannot be a pharmaceutical, because it does not fulfill the demands and it doesn't have a physiological effect, like some laxatives, some other products, then we have to find another solution for that. But clearly, it is not the right thing to say that some biologicals, which only change the pH value in parts of the body, are class III. Together with a high-risk product! […] if you have concern that there are products in there which are pharmaceuticals, we open them the role [?, unclear what word he uses here, AG] for the pharmaceutical line. But that is not the right way to approve. […]. At the moment they are forced to be medical devices, because they don't have a physiological effect.'[269]

[267] Dagmar Roth-Behrendt, 24 April 2013, ~1:03:00.
[268] Dagmar Roth-Behrendt, 29 May 2013, ~1:00:00.
[269] Dagmar Roth-Behrendt, 20 March 2013, ~50'.

The Commission actually, is the only one explicitly stating something about borderline products, although it is rather vague what the statement entails in practice:

> '[W]e need better clarity for innovative and borderline products.'[270]

The ALDE and the EPP then, are the groups referring to the importance of clear and consistent classification, i.e. legal certainty:

> 'When it comes to classification of products, there are one or two rules in the Commission's proposal, which I think are not clear enough and perhaps would create legal uncertainty in implementing this.'[271]

> '[T]he high-risk devices we need to look at public collegial [?, unclear what word he uses here, AG] monitoring. The commissioners looked at this on a case-by-case basis, but it is essential to get legal predictability on the part of the manufacturers.'[272]

As legal certainty with respect to classification is something of particular importance for the industries placing products on the market, it is consistent with our earlier observations that political groups (also) representing the interests of the industry explicitly refer to this principle.

4.2.2.7 Equality within internal market

A second issue touched upon by some political groups concerns the well-functioning of the internal market. Presumably based on the principles of fairness, equality and equal opportunity, the MEPs argue for similar procedures and requirements across all Member States.

The rapporteur, for example, argues that:

> 'And, I want to ensure that fees charged by national authorities for national activities are comparable across Member States, now made public. At the moment, you can notify an implantable hip for thousand euro in the European Union, in a half day, and you can pay 50.000 euro and have nine months. You have all that spectrum. And you would agree with me that that is not what we can expect and accept!'[273]

And a MEP of the EPP makes a comment which shows that she believes that not only the requirements should be the same across the borders, but also the opportunities and outcomes of policies:

> '[T]here are huge differences in terms of innovation between various Member States. And the European Union should make sure that all patients, in all Member States, no matter how rich or how poor, have access to the same innovating equipment.'[274]

[270] European Commission, Neven Mimica, 22 October 2013, opening remarks.
[271] Holger Krahmer, 24 April 2013, ~23'30''.
[272] Norra Berra, 22 October 2013.
[273] Dagmar Roth-Behrendt, 24 April 2013, ~13'.
[274] Petru Constantin Luhan, 22 October 2013.

The Confederal Group of the European United Left argues for something similar:

> '[W]e need a guarantee that there is no difference between the approval(s) system that applies for citizens in Lithuania or in Portugal. I think it is very important that it should be the same across the board/border. Everyone deserves the same level of protection.'[275]

4.2.2.8 Daily constraints

It is striking that just three political groups mention the importance of equality across the Member States, especially because the persons involved in the debates are politicians operating at the European level. It might however be the case that they don't believe it to be realistic to for example have similar access to the same innovating equipment everywhere across the internal market, because it is too expensive or takes too much time to realize. During the debates, several political groups reason from this perspective of daily, financial or practical constraints, in order to argue against measures proposed. In the discussion concerning the reprocessing of single-use devices, this kind of reasoning shows up several times:

The rapporteur for example:

> 'Nevertheless, we have to be clear amongst us how a single use, does single-use mean always only single-use and is it realistic? Is it realistic when we have an image building camera for a heart check, which costs 1000 euro, which where the check of the patient takes an hour; we all know that in 90% of those cases, even if it's a single-use product, it will be reprocessed.'[276]

And the ECR:

> 'Personally speaking, I think it would be better to look at reprocessing. I have experienced this on regular basis, where tubes for example were being washed or cleaned by the nurse, but at the time that was the only possibility we had.'[277]

Also in the discussion on centralized pre-market authorization, arguments based on practical constraints are used. The ALDE for example, argues that:

> 'And also, would we need to create a new agency, and would that be realistic, especially at time when actually we have been cutting, you know, reforming the staff regulations in the institutions.'[278]

And the EPP:

> 'I believe that if we have a completely new system, which is built up by the EMA, for surveillance of medical devices, well this is a Herculean task. We need experts on medical issues, financial experts, and I think that this alone would take far too much time. We have only got a transposition

[275] Alda Sousa, 22 October 2013.
[276] Dagmar Roth-Behrendt, 20 March 2013, ~5'.
[277] Milan Cabrnoch, 24 April 2013, ~37'.
[278] Rebecca Taylor, 20 March 2013, ~39'30''.

> period of three years foreseen in the Commission's proposal, and I don't think this will be possible.'[279]

Even though arguments provided based on this kind of reasoning might be valid, it could be a pity that they are used, as they often cause the debate to turn away from what should actually be discussed: whether a certain measure proposed in principle is worthwhile or not.

4.2.2.9 Criminal intent versus police state: realistic perspective

Related to the perspective of daily constraints, is the realistic perspective on the amount of influence legislation and control could have on criminal intent of the market. As discussed before in paragraph 4.2.2.2*,* the *opinio communis* in the Parliament is that patient safety is the first priority, but that innovation should not be stopped either. Consequently, patient safety is not absolute and in practice this means that it is not possible to check every single device for potential harm to patients. So, if someone deliberately wants to produce fraudulent devices and harm patients, it might not always be possible to prevent this. The rapporteur indeed reasons from this realistic perspective and states that:

> 'If somebody wants to be criminal, somebody can always be criminal. That led no legislation in the world will stop people to develop criminal activity. The only thing is we can try to do is, for those who do not do that, to have a clear, good framework and safety, and for the others, who want to cheat, and to fraud, and to do whatever, all the range between, between industrial jail, horse meat, all the vast way of cheating, there we need to have a good control system.'[280]

The Confederal Group of the European United Left states to believe that no police state is created:

> 'It is clear that with this legislation, or other legislation, we are not trying to introduce a police state around surveillance and control, but as said, it doesn't mean we should just forget about having solid guarantees.'[281]

The European Commission then, also agrees with the point of view that fraud cannot be prevented, but has verified whether it would be detected by the proposed system:

> 'When we had the PIP scandal, because this was a scandal, it was a, it was a fraud, it was pure fraud, we did a stress test[282] to see whether the proposals that we have tabled, would have, in fact, addressed the problem. Would we have saved the situation had we applied this legislation already back then? And that stress test was positive. And I think there we need to be reassured.'[283]

[279] Peter Liese, 29 May 2013, ~44'.
[280] Dagmar Roth-Behrendt, 2 April 2014, Press conference, ~17'.
[281] Alda Sousa, 29 May 2013, ~31'.
[282] European Commission, Impact Assessment on the revision of the regulatory framework for medical devices, Appendix 11.
[283] European Commission, 24 April 2013, ~59'.

4.2.2.10 Research ethics

Finally, an issue mentioned by some of the political groups, concerns research ethics and the involvement of ethics committees.

With respect to research ethics, and the challenge of clinical trials with medical devices, the rapporteur provides the best statement:

> 'Because when we speak implants, we will never have enough clinical data, and never enough clinical trial, so you will always have to follow in the real-life. But the real-life means in the patient! So, let's be honest, we partly use patients as guinea pigs. We have to accept that in some areas, but we need at the same time to have a balance with more clinical data. The real-life test only to look at, let's say, the implant outside of the body, again and again, that won't help us, because you wouldn't see anything else than at the beginning. So, we will have to do that.'[284]

The Confederal Group of the European United Left stresses that ethical aspects are important to be discussed:

'I think that, when we have the debate possibilities, we will be able to deal in more detail into some of the aspects. […] Clinical research and clinical tests, which could be used to provide data as to the usefulness and safety of medical equipment as well as of course […] ethical aspects too. And ethical […] opinions that's significant as well.'[285]

Lastly, the Parliament stresses the importance of ethics review by including the requirement for the approval of a clinical investigation by an independent ethics committee in one of its amendments to the Commission's proposal. The European Commission responds positively to the proposal:

> 'You propose, for example, strengthening the provisions on ethics committees or on minors and incapacitated patients. I am open to these changes, as long as they remain in line with the provisions that are currently being negotiated in the context of the proposed regulation on clinical trials on pharmaceuticals.'[286]

So, even though the theme is touched upon rather superficially, the parliamentary debates give us hope that ethical notions will be more substantially taken into account in the future.

4.2.3 Summary & Discussion

To conclude, several themes have been discussed during the parliamentary debates. The main themes turn out to be patient safety, rapid innovation of medical devices and the competitiveness of the European medical devices sector –and the potential conflict with patient safety-, patients' trust, distrust in industry, and transparency & traceability. These themes are discussed by basically all political groups. Some other themes, like consistent classification of medical devices and legal certainty, equality within the internal market, the theme of daily, financial and practical constraints, of a realistic perspective on fraudulent behavior, and finally, of research ethics, are discussed by merely some political groups, and can consequently be considered less important to the MEPs. If we compare these themes with the ethical

[284] Dagmar Roth-Behrendt, 20 March 2013, ~53'.
[285] Alda Sousa, 24 April 2013, ~38'.
[286] European Commission, Neven Mimica, 22 October 2013, opening remarks.

notions addressed in the literature (paragraph 4.1), we observe quite some overlap. All the main ethical challenges are addressed during the debates, except for the challenges with respect to clinical research. In comparison with the experts, it is striking though, how much attention is paid to the well-functioning of the internal market, and the support for innovation and competitiveness of the medical devices industry. Also, it should be noted that, especially in comparison with the literature, the themes are discussed rather superficially. That is, problems are merely addressed, and no solutions are offered, nor deliberated upon. Of course, this might be due to the limited speaking time, and the fact that most of the technical details are discussed during the unrecorded shadow rapporteurs' meetings.

Having discussed the extent to which the main themes of the parliamentary debates overlap with the ethical notions described in paragraph 4.1, it is of interest to see whether the themes are implemented in the new Regulation. In the next paragraph, I will provide an overview of the main differences between the current Directive 2007/47/EC and the proposed Medical Device Regulation.

4.3 Comparison Directive 2007/47/EC with proposed Medical Device Regulation

After a lengthy process of parliamentary debates and trialogue meetings, on the 16th of June 2016 a compromise text of the proposed Medical Device Regulation has been tentatively agreed on. This entails that representatives of the Council and the European Parliament reached an agreement on the text. However, this also implies that the official version of the legislation still has to be formally adopted by the Council and the Parliament before the Regulation enters into force.[287] Recent sources suggest that this process will take place in spring 2017.[288] After a transition period of 3 years, the new rules will officially apply.[289]

At the moment, the latest version of the legislation is the 'tentatively agreed consolidated compromise text of the proposed Regulation on medical devices' that thus dates back to the 16th of June 2016. Although this text is expected to not change a lot anymore, since it is merely to be confirmed by the legislative institutions and reviewed by legal linguists,[290] in theory changes are possible till the legislative text is published in the Official Journal of the European Union. As this text unfortunately is not available yet, we will be using the consolidated compromise text as best alternative available for our analysis of the main differences with Directive 2007/47/EC.

The first thing to notice when we compare both legislations is the amount of articles that have been added to the proposed Medical Device Regulation. In comparison, Directive 2007/47/EC consists of 23 Articles and 12 Annexes, which cover a total of 60 pages, while the Medical Device Regulation consists of 97 Articles, and 16 Annexes , which cover a total of about 350 pages (the font of the Medical Device Regulation is somewhat bigger, though). In Appendix C an overview is provided of all the articles which

[287] Council of the EU, Press release *Medical Devices,* 25 May 2016.
[288] Legislative Observatory, Forecast; https://www.emergogroup.com/blog/2016/12/european-commission-entry-force-mdr-ivdr-anticipated-late-may-2017; European Parliament, Press release *Medical Devices*, 15 June 2016; European Commission: Growth, Newsroom, 27 June 2016.
[289] Medical Device Regulation, Article 97 sub 2; European Commission: Growth, Newsroom, 27 June 2016
[290] Council of the EU, Press release *Medical Devices,* 25/05/2016.

are completely new to the proposed Regulation, which means that no paragraph overlaps with the current Medical Devices Directive.

Another clear difference between the legislative texts is the fact that the Directive has changed into a Regulation. As explained in paragraph 2.4 on the Legislation Process in the EU, the difference between a Regulation and a Directive is that the first is directly binding in all Member States, while the latter first need to be transposed into national legislation. The change consequently indicates that the new legislation will be applied more consistently across the Member States, as it is directly binding everywhere at the same time.

A final observation when comparing the texts at first glance is that the Articles in the Medical Device Regulation are divided in several chapters, which have a title that often is similar to the titles of the articles in the Directive. This seems to imply that in the Medical Device Regulation the main themes and systems have remained the same, but that some clauses, specifications and details have been added in order to for example clarify or restrict certain procedures. In order to check whether this observation is correct, we have to have a more detailed look at the main similarities and differences between the Medical Device Directive and Medical Device Regulation. I will make a chapter wise comparison, and will discuss the relevant Annexes along with the subsequent chapters.

4.3.1 Chapter I: Scope and definitions

Chapter I deals with the scope of the legislation concerning medical devices, and the definitions of the most important concepts related to devices.

In the description of the scope is stated to which devices the legislation applies, but also which categories of products are excluded from the legislation. If we compare the scope of Directive 2007/47/EC with the proposed Medical Device Regulation, we see a lot of similarities. Both regulations apply to medical devices and their accessories, and explicitly exclude *in vitro* diagnostic medical devices, medicinal products (covered by Directive 2001/83/EC), human blood, blood products, etc., cosmetic products, transplants, tissues or cells of animal origin, and transplants, tissues or cells of human origin. The proposed regulation however does not exclude active implantable devices anymore, since they are no longer covered by a separate directive, but included in the proposed Regulation. The proposed Regulation nevertheless does explicitly exclude now advanced therapy medicinal products (ATMPs), [291] products that contain or consist of viable biological substances or organisms,[292] and food.[293]

Also with respect to borderline products, there are quite a lot of similarities between the old and new regulatory framework. That is, the demarcation of a device administering a medicinal product, or of a device 'which incorporates, as an integral part, a substance which, if used separately, would be considered to be a medicinal product […], including a medicinal product derived from human blood or human plasma […], with action ancillary to that of the device,' is basically the same in both legislative texts. The only difference with respect to these kinds of products, is that the proposed Regulation explicitly adds that if the action of the medicinal substance is principal, not ancillary to that of the device, the product shall not

[291]Article 1 sub 2 (ba). NB. If I refer to legislative Articles in this subchapter, I refer to Articles of the 'tentatively agreed consolidated compromise text of the proposed Regulation on medical devices', unless specified otherwise.
[292] Article 1 sub 2 (f).
[293] Article 1 sub 2 (g).

be covered by the Medical Device Regulation. Although this phase is new, it could already be deduced from the 'old' definition of medical devices, which, as we will discuss later in this paragraph, is very similar to the new definition. In combination with the fact that both 'principal mode of action' nor 'ancillary mode of action' are still not defined in the proposed regulation, the phrase doesn't add much with respect to clarity of borderline cases. The biggest change with respect to borderline products lies in the fact that the proposed regulation also pays attention to the inclusion of devices which incorporate as an integral part *in vitro* diagnostic medical devices,[294] or devices which incorporate as an integral part 'tissues or cells of human origin or their derivatives with action ancillary to that of the device', i.e. ATMPs.[295]

The biggest change concerning the scope of the legislation is the fact that the proposed Regulation shall also apply to 'the groups of products without an intended medical purpose', which are analogous to devices with a medical purpose, in particular if they are based on a similar technology.[296] This products for example entail contact lenses, facial dermal fillers, and equipment for electromagnetic brain stimulation.[297] All the products which belong to this category are listed in a new Annex, Annex XV. These products must meet so-called 'common specifications'[298], which are new, to be adopted, technical specifications that the Commission can adopt where no harmonized standards exist, or where they are not sufficient.[299] They will officially be delved with in the discussion of Chapter II.

Regarding the definitions section of the first Chapter, we can observe a significant expansion. While the medical device directive merely consists of 14 definitions, the proposed regulation contains 71 definitions in total.[300] The 14 'old' definitions, however, are mostly still part of the new list, but have changed slightly sometimes. I will start making a comparison between the 'old' and 'new' definitions, and will then discuss the definitions that have been added to the new regulation.

[294] Article 1 sub 3.
[295] Article 1 sub 5a.
[296] Article 1 sub 1a.
[297] CROMSOURCE, Changes to EU Medical Device Legislation, p. 3.
[298] Amongst others Article 7, MDR.
[299] CROMSOURCE, Changes to EU Medical Device Legislation, p. 3; Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 4.
[300] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 4.

First, of course, the definition of 'medical device'[301]. Table 1 respectively shows the 'old' and 'new' definition:

Table 1: Comparison between the definition of 'medical device' in Directive 2007/47/EC and the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

Directive 2007/47/EC	*Proposed Medical Device Regulation*
'medical device'[302] means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used *specifically for diagnostic and/or therapeutic* purposes and *necessary for its proper application*, intended by the manufacturer to be used for human beings for the purpose of:	'medical device'[303] means any instrument, apparatus, appliance, software, implant, *reagent*, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the *specific medical* purposes of:
— diagnosis, prevention, monitoring, treatment or alleviation of disease,	– diagnosis, prevention, monitoring, *prediction*, *prognosis*, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or *handicap*,	– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or *disability*,
— investigation, replacement or modification of the anatomy or of a physiological process,	– investigation, replacement or modification of the anatomy or of a physiological or *pathological* process or *state,*
— control of conception,	– *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations*,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.	and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. Products specifically intended for the *cleaning, disinfection or sterilization of medical devices* and devices for the purpose of control or support of conception shall be considered medical devices.

If we compare the definitions in Table 1, we observe that they are basically the same, except for some different phrasing of the purposes. The biggest difference between the definitions then, is given by the last sentence of the 'new' definition, in which products specifically intended for the cleaning, disinfection and sterilization of medical devices are considered to be medical devices themselves. In the MDD, products used for cleaning, disinfection or sterilization were accessories to medical devices and hence

[301] Article 2, sub 1 (1).
[302] Article 1 sub 2 (a) of Directive 2007/47/EC.
[303] Article 2, sub 1 (1).

accessories to cleaning, disinfection or sterilization products were not within the remit of the directive, as accessories to accessories are not in the scope of the legislation. However, if cleaning, disinfection or sterilization products now become medical devices, their accessories (according to the description of the scope of the legislation) will be covered by the Regulation as well.[304] The scope of the Regulation thus has been extended by the updated definition of medical devices.

The definition of 'accessory' or 'accessory to a medical device'[305] has also been changed slightly:

Table 2: Comparison between the definition of 'accessory (to a medical device)' in Directive 2007/47/EC and the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

Directive 2007/47/EC	*Proposed Medical Device Regulation*
'accessory'[306] means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;	'accessory to a medical device'[307] means an article which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the device(s) to be used in accordance with its/their intended purpose(s) *or to specifically and directly assist the medical functionality* of the medical device(s) in view of its/their intended purpose(s);

The comparison between the definitions shows that in the proposed MDR the definition of 'accessory (to a medical device)' is expanded to 'specifically and directly assist' and not merely 'enable' (a medical device). Consequently, the kinds of products that could be classified as accessories to medical devices have been extended.

Also the term 'intended purpose'[308] has been slightly changed:

Table 3: Comparison between the definition of 'intended purpose' in Directive 2007/47/EC and the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

Directive 2007/47/EC	*Proposed Medical Device Regulation*
'intended purpose'[309] means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials;	'intended purpose'[310] means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and *as specified by the manufacturer in the clinical evaluation*;

[304] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 4.
[305] Article 2, sub 1 (2).
[306] Article 1 sub 2 (b), Directive 2007/47/EC.
[307] Article 2, sub 1 (2).
[308] Article 2, sub 1 (10).
[309] Article 1 sub 2 (g), Directive 2007/47/EC.
[310] Article 2, sub 1 (10).

As we can see in Table 3, the new definition of 'intended purpose' explicitly refers to what manufacturers specify about the device in the clinical evaluation, which consequently seems to play a bigger role than before.

Related to this, two new terms have been added to the proposed Regulation, which focus on providing information about the device:

- 'Instructions for use'[311] means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;
- 'Unique Device Identification'[312] ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;

In addition, several definitions have been added to the proposed Medical Device Regulation, which deal with performance aspects of medical devices.

First, 'performance' itself:

-'Performance'[313] means the ability of a device to achieve its intended purpose as claimed by the manufacturer;

-'Risk'[314] means the combination of the probability of occurrence of harm and the severity of that harm;

-'Benefit-risk determination'[315] means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer.

With respect to definitions about clinical evaluation and clinical investigations, which obviously are related to the performance of the device, some definitions have been changed, and some definitions have been added in the proposed Regulation.

The proposed Medical Device Regulation makes a distinction between 'clinical evaluation' and 'clinical investigation' and provides a definition for both processes:

-'Clinical evaluation'[316] means a systematic and planned process to continuously generate, collect, analyze and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;
-'Clinical investigation'[317] means any systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a device;

[311] Article 2, sub 1 (12).
[312] Article 2, sub 1 (13).
[313] Article 2, sub 1 (15a).
[314] Article 2, sub 1 (15d).
[315] Article 2 sub 1 (15e).
[316] Article 2 sub 1 (32).
[317] Article 2 sub 1 (33).

Interestingly, the term 'safety' is not at all defined in the proposed Regulation. Also, it should be noted that the definition of clinical investigation does not explicitly include assessing/verifying clinical benefit. Furthermore, it should be noted that in the case of clinical evaluations, no evaluation of the device on human subjects is needed.

In order to properly perform clinical investigations, a clinical investigation plan needs to be formulated, which is defined as follows:

'Clinical investigation plan'[318] means a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organization and conduct of a clinical investigation;

The goal of a clinical evaluation or investigation is to generate data, which can be used to make an assessment of the device. Such data is called 'clinical data'[319], and was already defined in the medical devices directive, as we can see in Table 4.

Table 4: Comparison between the definition of 'clinical data' in Directive 2007/47/EC and the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

Directive 2007/47/EC	*Proposed Medical Device Regulation*
'clinical data'[320] means the safety and/or performance information that is generated from the use of a device. Clinical data are sourced from: —clinical investigation(s) of the device concerned; or —clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or — published and/or *unpublished* reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated;	'clinical data'[321] means the information concerning the safety or performance that is generated from the use of a device and that are sourced from the following: – clinical investigation(s) of the device concerned, – clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, – reports *published in peer reviewed scientific literature* on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated, – other clinical data coming from the *post-market surveillance system, in particular the post-market clinical follow-up;*

The comparison between the definitions of 'clinical data' shows that the requirements with respect to data from reports have become stricter: information from unpublished reports is no longer considered to be clinical data, nor information published in non-peer reviewed literature. On the other hand, an extra option for generating clinical data has been added to the definition: data from post-market surveillance is considered to be clinical data.

[318] Article 2 sub 1 (35).
[319] Article 2, sub 1 (36).
[320] Article 1 sub 2 (k), Directive 2007/47/EC.
[321] Article 2, sub 1 (36).

In addition, the proposed Regulation on medical devices defines a few other terms related to clinical evaluation and clinical investigations of devices:

-'Clinical evidence'[322] means the clinical data and clinical evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;

-'Clinical performance'[323] means the ability of a device to achieve its intended purpose as claimed by the manufacturer, including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer;

NB. It might be interesting to compare this definition with the definition of 'performance', as is done in Table 5:

Table 5: Comparison between the definition of 'performance' and 'clinical performance' in the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

'Performance', Article 2 sub 1 (15a)	*'Clinical performance', Article 2 sub 1 (37c)*
means the ability of a device to achieve its intended purpose as claimed by the manufacturer;	means the ability of a device to achieve its intended purpose as claimed by the manufacturer, *including any direct or indirect medical effects on humans as well as the clinical benefit on patients resulting from the technical or functional, including diagnostic characteristics of a device, when used as intended by the manufacturer*;

So, the term 'clinical performance' is more strict, in the sense that it includes the clinical effect of the device, while 'performance' merely focuses on the requirements on how the device should perform. However, as both terms are defined in the definitions section, both can be expected to be used in the remainder of the legislation. Consequently, we need to look careful which term is used in what context.

'Clinical benefit'[324] then, is defined as follows:

'The positive impact of a device on the health of an individual, to be specified as meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis or a positive impact on patient management or public health.'

Finally, in the context of clinical evaluation and clinical investigation, it is interesting to note that the MDR seems to pay more attention to ethical aspects, as the terms 'informed consent'[325] and 'ethics committee'[326] are defined as well. As the definitions are very similar to common definitions of these terms, I don't cite them here.

[322] Article 2 sub 1 (37b).
[323] Article 2 sub 1 (37c).
[324] Article 2 sub 1 (37d).
[325] Article 2 sub 1 (37k).
[326] Article 2 sub 1 (37l).

With respect to economic operators and users, several definitions have been added in the proposed MDR. The most important economic operator though, the manufacturer, was already defined in the MDD, as shown in Table 6:

Table 6: Comparison between the definition of 'manufacturer' in Directive 2007/47/EC and the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

Directive 2007/47/EC	*Proposed Medical Device Regulation*
'manufacturer'[327] means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or *on his behalf by a third party*. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name.	'manufacturer'[328] means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.

The biggest change with respect to the definition of manufacturer, then, is the fact that it is not explicitly stated anymore whether someone is still considered to be the manufacturer of a product, if the production is carried out by a third party, on his behalf.

Also the authorized representative (AR) was already defined in directive 2007/47/EC:

Table 7: Comparison between the definition of 'manufacturer' in Directive 2007/47/EC and the proposed Regulation for medical devices. Underlined text in italics shows the differences between the definitions.

Directive 2007/47/EC	*Proposed Medical Device Regulation*
'authorized representative'[329] means any natural or legal person established in the Community who, *explicitly designated* by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive;	'authorized representative'[330] means any natural or legal person established within the Union who has received and accepted a *written mandate* from a manufacturer, *located outside the European Union*, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;

[327] Article 1 sub 2 (f), Directive 2007/47/EC.
[328] Article 2 sub 1 (19).
[329] Article 1 sub 2 (j), Directive 2007/47/EC.
[330] Article 2 sub 1 (20).

As Table 7 shows, are both definitions quite similar. The biggest difference is the fact that the new definition explicitly states that the manufacturer should be located outside the European Union.

Several related terms have been defined in the proposed Regulation for medical devices, Articles 2 sub 1 (16)-(27), such as 'importer'[331], 'distributor'[332], and 'user'[333].

Also the term 'reprocessing', fiercely debated during the parliamentary discussions of the reviewed regulation (see previous subchapter), is defined. The definition is as follows:

'Reprocessing'[334] means the process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilization and related procedures, as well as testing and restoration of the technical and functional safety of the used device.

Finally, several terms have been defined with respect to concepts related to post-market surveillance, vigilance and market surveillance, Articles 2 sub 1 (40a)-(47). Obviously, 'post-market surveillance'[335] and 'market surveillance'[336] have been defined, but also 'recall'[337] and 'serious incident'[338]. Remarkably, 'vigilance' is not defined in the first Chapter of the proposed Medical Device Regulation, though you would expect it in the context of related terms.

Having defined the most important terms, policy and legal issues will be discussed. This is done in the remaining chapters.

4.3.2 Chapter II: Making available and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement

The second chapter of the proposed Medical Device Regulation deals with market entrance of medical devices and the responsibilities of the respective economic operators concerning lawful market entrance.

In comparison with the current MDD, the system of market entrance has not changed much in the proposed Regulation. Medical devices must meet the requirements set out in Annex I, which are no longer called essential requirements, but 'General Safety and Performance requirements'.[339] Annex I states the general requirements that devices need to comply with, if this Regulation applies to them. Annex I resembles Annex I of the current MDD, which, as said, deals with 'Essential requirements'. The first chapter is basically the same, except for an important insertion in the first section: 'taking into account the generally acknowledged state of the art.' Although it is not clear who will decide, and on what standards, what the generally acknowledged state of art is, one might expect that current (international)

[331] Article 2 sub 1 (21).
[332] Article 2 sub 1 (22).
[333] Article 2 sub 1 (25).
[334] Article 2 sub 1 (27).
[335] Article 2 sub 1 (40a).
[336] Article 2 sub 1 (40b).
[337] Article 2 sub 1 (41).
[338] Article 2 sub 1 (44).
[339] Article 4 sub 2.

standards and published (scientific) literature will be used.[340] Another difference is that the phrase 'reduction of risk as far as possible' is now explicitly explained as reducing 'without adversely affecting the risk benefit ratio'[341]. Finally, added to the requirements is that the manufacturer is obliged to implement a risk management system.[342] The second chapter lists the requirements regarding design and manufacturing of devices, with particular attention to devices such as those incorporating a medicinal product, incorporating materials of biological origin, and active implantable devices. Although much requirements have been adopted from the current directive, the number of requirements and the level of detail has increased. For example, a paragraph[343] has been added on protection against the risks posed by medical devices intended for use by lay persons.

In addition, compliance with relevant harmonized standards, published in the Official Journal of the European Union, presumes compliance to the requirements of Annex I, as was already regulated by the MDD,[344] and is retained in the proposed Regulation.[345] New to the Regulation are the Common specifications (CS), already mentioned in Chapter I, which the Commission may adopt 'where no harmonized standards exist or where relevant harmonized standards are not sufficient, or where there is a need to address public health concerns,'[346] with which manufacturers should comply unless duly justified otherwise.[347] The influence of the European institutions, especially the Commission, on the internal market of medical devices, in principle thus has been increased.

Is subsequently demonstrated that a device fulfills all the requirements of the proposed MDR, a declaration of conformity shall be drawn up,[348] and the device will get the CE marking of conformity.[349] Afterwards devices are allowed to move freely within the internal market,[350] a procedure which is retained from the current MDD.

Added in comparison with the MDD is the description of and the demarcation between the responsibilities of various economic operators in the supply chain of medical devices. While Directive 2007/47/EC merely distinguishes two economic operators (and doesn't use the term '(economic) operator'), i.e. the manufacturer and the authorized representative, the proposed Regulation distinguishes between the manufacturer, the authorized representative, the distributor and the importer. In the Regulation, basically all economic operators will get more and new responsibilities.

The manufacturer, for example, is obliged to create and implement quite some documentation, plans and procedures, such as technical documentation, a quality management and post-market surveillance

[340] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 5.
[341] Annex I Chapter I, 1aa.
[342] Annex I Chapter I, 1a.
[343] Annex I Chapter II, 18.
[344] Article 5 sub 1, Directive 2007/47/EC.
[345] Article 6 sub 1.
[346] Article 7 sub 1.
[347] Article 7 sub 3.
[348] Article 17.
[349] Article 18.
[350] Article 22.

system, and to conduct a clinical evaluation.[351] Manufacturers are also, upon request from a Competent Authority, obliged to provide Competent Authorities with 'all the information and documentation necessary to demonstrate the conformity of the device',[352] on penalty of taking 'all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it',[353] if the manufacturer fails to cooperate with the Competent Authority or the information and documentation provided is incomplete or incorrect. At the same time, the Competent Authorities are allowed to share that information with potentially injured patients and users, if they want to claim compensation for potential damage done by the device in question.[354] This might obviously provide more information to the public, but might also make manufacturers more prudent providing information, even though they could be punished for not being complete.

Also with respect to authorized representatives (AR) responsibilities will change. The biggest difference is that the authorized representative is made jointly and severally liable for defective devices.[355] As a consequence, the Emergo Group (a medical device consultant) expects that 'non-European manufacturers will face higher costs and more complex processes to enter the European market, compared to their European counterparts.'[356] Also, they expect that the liability clause might put pressure on the willingness to share information with the Authorities,[357] similarly to the presumed reluctance manufacturers will show. In addition, many ARs are expected to cease activity due to the new measures.[358] Consequently, many manufacturers may need to change of authorized representative, which actually is provided for in a new article.[359]

The obligations of importers and distributors are laid out as well,[360] but there are no penalty clauses, nor indications who would be liable in case they are not compliant to their responsibilities.[361]

Lastly, three new articles are introduced in this chapter, which might have significant impact on the medical devices industry. First, the obligation for manufacturers to have a highly educated and experienced person responsible for regulatory compliance available.[362] Although 'having available' might not seem to indicate that the person concerned must be an employee of the organization, but can also be a consultant or other external resource, [363] the fact that is stated that small enterprises and authorized representatives merely shall have a person for regulatory compliance 'permanently and continuously at their disposal'[364] does imply that in the first case, this person should be an employee of the organization.

[351] Article 8.
[352] Article 8 sub 9.
[353] Article 8 sub 9.
[354] Article 8 sub 9.
[355] Article 9 sub 4a.
[356] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 5.
[357] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 5.
[358] BSI, How to prepare for and implement the upcoming MDR, p. 4.
[359] Article 10.
[360] Respectively Article 11 and 12.
[361] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 5.
[362] Article 13.
[363] BSI, How to prepare for and implement the upcoming MDR, p. 4.
[364] Article 13 sub 1a and sub 4.

Second, the much-debated reprocessing of single-use devices is discussed in Article 15. The proposed outcome is that this may only take place if it is permitted by national law, and under strict conditions.[365] For example, full product liability is placed on the reprocessor (except when reprocessed within health institutions[366]),[367] while the name of the original manufacturer shall no longer appear on the label.[368]

Finally, a new article requires that patients with an implanted device will be provided by the manufacturer with an implant card, [369] which is likely to increase the traceability of the device.

4.3.3 Chapter III: Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices

Chapter III continues on the issue of traceability and transparency. This chapter, of which basically all articles are new in comparison with Directive 2007/47/EC, describes the conditions to ensure that it will be possible to identify economic operators to whom medical devices are supplied, or from whom devices are purchased.[370] In order for the traceability to be successful, distributors and importers are obliged to work together with manufacturers and authorized representatives.[371] In addition, to provide for the traceability of devices from manufacturer to the end-user, devices should have a unique identification number.[372] The Unique Device Identification (UDI) system is described in Annex V, Part C, and the relevant UDI carrier must be included on all medical device labels, other than custom-made and investigational devices.[373] The UDI system will also be used for reporting serious incidents and taking fast and effective measures in case of safety problems.[374] To this end, the UDI database is to be integrated in the European databank on medical devices (EUDAMED).[375]

EUDAMED is a system of several electronic databases, connected with each other, about medical device related aspects, such as UDIs, economic operators, outcomes of clinical investigations, and data on vigilance and post-market surveillance. A 'summary of safety and clinical performance' of Class III devices and of implants of lower classification, will also be part of the data.[376] As this summary amongst other things must include the intended purpose of the device, indications and contra-indications, reference to standards and common specifications, a summary of clinical evaluations and a suggested profile and training of users,[377] and should be written such that it is clear to the intended user,[378] generating the

[365] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 5.
[366] Article 15 sub 1a.
[367] Article 15 sub 1.
[368] Article 15 sub 5.
[369] Article 16.
[370] CROMSOURCE, Changes to EU Medical Device Legislation, p. 4.
[371] Article 23 sub 1.
[372] Article 24.
[373] Article 24 sub 4.
[374] Article 24 sub 4a; CROMSOURCE, Changes to EU Medical Device Legislation, p. 4.
[375] Article 24b.
[376] Article 26 sub 1.
[377] Article 26 sub 1a; BSI, How to prepare for and implement the upcoming MDR, p. 7.
[378] Article 26 sub 1.

summary is expected to be a major effort for manufacturers.[379] After creating the summary, notified bodies will assess the document and upload it to EUDAMED.[380] The European Commission will be responsible for setting up and managing these databases, but the users will be responsible for the content, in the sense that they thus should upload information directly into EUDAMED.[381] The databases then, will be accessible for economic operators, notified bodies, Competent Authorities and the European Commission. For the first time, major parts of the databases will also be accessible to healthcare professionals, patients and the general public.[382]

4.3.4 Chapter IV: Notified bodies

The fourth chapter of the proposed Medical Devices Regulation deals with the position, responsibilities and supervision of notified bodies. As several legal experts contend, the position of notified bodies (NBs) changes considerably in comparison with the MDD;[383] 'from an industry partner into a police-like extension of the Competent Authorities' market surveillance apparatus.'[384]

In the new regulation, all notified bodies, also the currently existing ones, need to be accredited by the national Competent Authority (CA) in the Member State where they are based. The applicable Competent Authority will consequently review a request to designation and create a preliminary assessment report, which they will submit to the Medical Device Coordination Group ('MDCG').[385] After receiving the report, the Commission, in conjunction with the MDCG, will assign a joint assessment team, consisting of at least three experts, who will review the application documentation.[386] The national Competent Authority, together with the joint assessment team will conduct an on-site assessment of the applicant notified body, including sites in other Member States, or outside the Union.[387] Afterwards, the national authority draws up its final assessment report, in response to which the joint assessment team and the MDCG will provide a final opinion.[388] The Competent Authority is consequently required to 'duly take [this advice] into consideration' in its decision on the designation of the notified body.[389] What this phrase exactly implies, and how it works out in practice, remains to be seen. The new process shows however, that although on legal grounds, the formal designation and assessment of notifying bodies is left to Member States, it is likely that in practice quite a lot of influence is transferred from Competent Authorities to the Commission and its advisory teams. This is especially so, since the process can merely be finished when the required advices have been provided. In the Regulation, there are strict timelines given for the whole process, but there seem to be no consequences for the Competent Authorities or for the MDCG if they are not met.[390]

[379] BSI, How to prepare for and implement the upcoming MDR, p. 7
[380] Article 26 sub 1.
[381] Article 25; Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 8.
[382] Article 25a sub 6; Article 27.
[383] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 8; BSI, How to prepare for and implement the upcoming MDR, p. 10.
[384] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 8.
[385] Article 32 sub 1 and 2.
[386] Article 32 sub 3 and 4.
[387] Article 32 sub 4.
[388] Article 32 sub 4 and 6.
[389] Article 32 sub 6.
[390] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 8.

The criteria on which the assessment of (potential) notified bodies will be based, are formulated in Chapter IV and Annex VI. It is for example required that notified bodies make a public list of standard fees for their conformity assessment activities,[391] and have highly qualified personnel, with relevant experience, employed by the body itself, and thus not subcontracted.[392] Subcontracting of product related reviews is allowed, but under strict conditions.[393] When applying notified bodies pass the assessment and are designated to be a notified body, the monitoring of the body doesn't stop. That is, at least once a year, the national authority responsible for notified bodies shall re-assess whether each notified body, and when appropriate, the subsidiaries and subcontractors under its responsibility, still satisfy the requirements and fulfil their obligations set out in Annex VI.[394] In addition, three years after notification of a notified body, and again every fourth year thereafter, a complete re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VI, shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described before, i.e. the application procedure.[395] Due to this frequent controls, it might be that several notified bodies will cease, or have to cease activity in the future, due to which manufacturers may need to change notified body.[396] All notified bodies not willing to cease activity thus face a severe challenge: to gain and retain highly qualified staff with the required expertise. As the competition will be intense, it is easy to foresee a shortage in the availability of qualified personnel, which may lead to significant delays in conformity assessments and potentially higher costs for manufacturers.[397]

4.3.5 Chapter V: Classification and conformity assessment

Chapter V deals with two subjects: the classification of devices and the procedures for conformity assessment.

With respect to the classification of devices, not much changes with respect to the current MDD. Similar to the current MDD, devices will be divided into classes I, IIa, IIb and III, taking into account the purpose intended by the manufacturer and inherent risks.[398] Classification shall be carried out in accordance with the classification criteria set out in Annex VII (Annex IX of Directive 2007/47/EC).[399] Annex VII contains some changes and additions with respect to classification rules in comparison with the current Annex; to be more specific, the current Annex has 18 classification rules, while the proposed Annex consists of 23 rules (though there are some numbering issues). I summarize the main differences here.

Several kinds of devices are new class III designations:

[391] Article 40a.
[392] Article 29; Annex VI Chapter 3: Resource requirements.
[393] Article 30; Annex VI Chapter 3 Paragraph 3.4.
[394] Article 35 sub 3.
[395] Article 35 sub 4.
[396] BSI, How to prepare for and implement the upcoming MDR, p. 10.
[397] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 8.
[398] Article 41 sub 1.
[399] Article 41 sub 1.

- 'All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body';[400]
- 'Active implantable devices or their accessories'[401];
- Breast implants or surgical meshes, total and partial joint replacements, and implantable devices that come into contact with the spinal column[402];
- 'All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices'[403].

Also, some new classification rules have been added to the proposed Regulation:

- A new subrule for classification of software.[404] Software can be in all risk classes, depending on the effect it might have on the health of the patient.
- Rule 19 classifies devices with nanomaterials, depending on their potential for internal exposure (e.g.. high or medium exposure is Class III);[405]
- Rule 21 places devices composed of substances that are absorbed by or locally dispersed in the human body in different risk classes (ranging from class IIa to class III), based on their level of exposure to the human body;[406]
- Finally, Rule 23 places active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device in Class III (e.g. closed loop systems or automated external defibrillators).[407]

Before devices are allowed to be placed on the market, manufacturers (and third parties, if required) shall undertake an assessment of the conformity of that device, the procedures of which are related to the risk classification of the device,[408] which is also the case in the current MDD. The conformity assessment procedures are set out in Annex VIII to Annex XI. In comparison with Directive 2007/47/EC, the amount of routes to conformity assessment has been reduced,[409] and might consequently have become clearer. Furthermore, the option to choose Full Quality Assurance (Annex VIII) as a module for conformity assessment, is in the proposed Regulation also possible for Class IIa devices (NB. in the MDD, a similar module, i.e. the full quality assurance, is merely an option for Class III and Class IIb devices). No matter the route to conformity assessment chosen for devices of Class IIa, IIb and III, each procedure contains mandatory assessment of Quality Management Systems of the manufacturer by a notified body, chosen by the manufacturer (similar to the current MDD).

[400] Annex VII, Classification Rule 3.
[401] Annex VII, Classification Rule 8.
[402] Annex VII, Classification Rule 8.
[403] Annex VII, Classification Rule 9.
[404] Annex VII, Subrule 10a.
[405] Annex VII, Special Rule 19.
[406] Annex VII, Special Rule 21.
[407] Annex VII, Special Rule 23.
[408] Article 42 sub 1.
[409] Article 42 sub 2, sub 3, and sub 4.

Annex VIII on 'Conformity assessment based on a quality management system and assessment of the technical documentation' includes conditions on surveillance, which are added in comparison with the current MDD. In this respect, section 4.3 of this Annex states that notified bodies shall, at least once every 12 months, carry out audits and assessments to make sure that the manufacturer applies the approved quality management system and post-market surveillance plan. In addition, notified bodies should perform unannounced on-site inspections of the manufacturer (the option of which was already available in Directive 2007/47/EC, but has become obligatory now) and (if applicable) of the manufacturer's suppliers or subcontractors at least once every five years.[410] During this audits, an adequate sample from the production or manufacturing process shall be tested.[411] Notified bodies are also encouraged to test samples from the market.[412] In the case of class III devices, the surveillance assessment shall include a test of coherence between quantities of parts and finished products as well.[413]

Additionally, Annex VIII describes the clinical evaluation consultation procedure, which should be followed when performing a conformity assessment of implantable class III devices and active class IIb devices intended to administer medicinal products.[414] According to this procedure, the notified body prepares a clinical evaluation assessment report based on its review of clinical evidence supplied by the manufacturer and transmits this report, together with the relevant documentation of the manufacturer to the Commission. The Commission then, submits the documents to an expert panel, who may, but is not obliged to, give a scientific opinion within a specified period. Where an opinion is delivered, the notified body should give due consideration to the views expressed when continuing with the conformity assessment procedure.[415]

With respect to devices of class III and IIb, the legislator has also foreseen in a new scrutiny mechanism of conformity assessments.[416] This mechanism requires that a notified body shall notify the Competent Authorities of certificates it has granted to devices, the conformity assessment of which has been performed.[417] Such notification shall include the summary of safety and clinical performance, the assessment report by the notified body, the instructions for use, and, where applicable, the scientific opinion of the expert panels.[418] A Competent Authority and, where applicable, the Commission may, based on reasonable concerns, apply further appropriate procedures,[419] and the MDCG may request scientific advice from expert panels.[420]

The conformity assessment procedure of Class I devices becomes slightly more demanding in the proposed Regulation. Like in the current MDD, Class I devices can be certified by manufacturers themselves, without involvement of a third party.[421] The manufacturer however must set up a quality management system, draw up the technical documentation set out in Annex II, and sign the Declaration

[410] Annex VIII Section 4.4.
[411] Annex VIII Section 4.4.
[412] Annex VIII Section 4.4.
[413] Annex VIII Section 4.5.
[414] Article 43a and Annex VIII Section 6.0.
[415] Annex VIII Section 6.0; CROMSOURCE, Changes to EU Medical Device Legislation, p. 5.
[416] Article 44.
[417] Article 44 sub 1.
[418] Article 44 sub 1.
[419] Article 44 sub 1aa.
[420] Article 44 sub 1a.
[421] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 9.

of Conformity, as described in Annex III.[422] The technical documentation described in Annex II, a new requirement compared to the current MDD, should include amongst others demonstration of conformity with the general safety and performance requirements, a risk/benefit analysis, and results of the clinical evaluation.[423] Consequently, also with respect to lower risk devices, attention will be paid to clinical aspects.

4.3.6 Chapter VI: Clinical evaluation and clinical investigations

The clinical aspects of medical devices are more thoroughly delved with in Chapter VI, the chapter that deals with clinical evaluation and clinical investigations of devices. As becomes clear from paragraph 4.3.5, the proposed MDR puts more weight on results of clinical evaluations, as this is required for the technical documentation of medical devices of all risk classes. In that sense, one could say that the roles of clinical evaluation and clinical investigation become more prominent in the proposed Medical Devices Regulation. If we however compare the proposed Regulation with the current MDD, we observe that most of the requirements have become more explicit or more detailed, but that the texts do not differ significantly.

Both legislative texts for example require clinical evaluations in order to demonstrate compliance with the relevant essential requirements on safety and performance.[424] In both legislative texts, clinical evaluation can be done by studying relevant scientific literature and/or[425] a critical evaluation of the results of all (relevant) clinical investigations.[426] New to the MDR is that 'a consideration of currently available alternative treatment options for that purpose,'[427] is also part of a clinical evaluation. In both legislative texts, it is also (still) possible to demonstrate conformity merely based on non-clinical, or pre-clinical data, if duly justified, the criteria for which seem not very strict.[428] It should be noted however, that this exclusion is no longer possible for class III and implantable devices. For these devices, as is actually already the case in the current MDD, clinical investigations shall be performed, unless it is duly justified to rely on existing clinical data.[429] The proposed MDR explicates in what cases such a justification is valid: for example, if the device has been designed by modifications of an equivalent device already marketed by the same manufacturer, the notified body has confirmed that it is only a modification, and the manufacturer has full access to the technical documentation of the older device, also if the older device is not manufactured by him, then equivalence is justified. [430] Another justification for not performing a clinical investigation is if implantable and class III devices are currently already on the market and comply with current requirements for clinical data and future common specifications.[431] With respect to implantable and class III devices, it becomes possible in the proposed MDR for manufacturers to consult

[422] Article 42 sub 5.
[423] Annex II.
[424] Article 49 sub 1 versus Annex X Chapter 1, 1.1, Directive 2007/47/EC.
[425] It depends on how one interprets the enumeration, whether all options mentioned should be performed, or whether one is allowed to choose between them. In comparison with the current Directive, in which explicitly is stated that one should allowed to choose between options, the first interpretation (i.e. that all options should be performed) is more likely.
[426] Article 49 sub 2 versus Annex X Chapter 1 1.1.1 and 1.1.2, Directive 2007/47/EC.
[427] Article 49 sub 2 (d).
[428] Article 49 sub 3 versus Annex X Chapter 1 1.1d, Directive 2007/47/EC.
[429] Article 49 sub 2a versus Annex X Chapter 1 1.1a, Directive 2007/47/EC.
[430] Article 49 sub 2a and sub 2aa.
[431] Article 49 sub 2ab.

an expert panel prior to the clinical evaluation.[432] This consultation can be done on a voluntary basis, but the manufacturer is obliged to give due consideration to the views expressed by the expert panel.[433] Another (new) obligation for manufacturers of class III and implantable devices, is that manufacturers should summarize the main safety and performance aspects of the device and the outcome of the clinical evaluation in a document that should be publicly available.[434] Consequently, it will need to be provided in laypersons' terms.[435]

With respect to clinical investigations, a third objective is added in the proposed Medical Devices Regulation. In addition to verifying the performance of the devices, and determining any undesirable side-effects, establishing and verifying the clinical benefits of a device is a purpose of clinical investigations.[436] New to the proposed MDR is the requirement that sponsors of clinical investigations need to apply for the clinical investigation, by submitting relevant data and documentation, such as a clinical investigation plan, to the electronic EUDAMED database, after which it is assessed by the Member State.[437] Annexes XIII and XIV on clinical evaluation and clinical investigations respectively, describe what documentation is required and what information should be in there, for example methodology. One of the general requirements regarding clinical investigations, already mentioned in the current MDD, is that clinical investigations must be carried out in accordance with recognized ethical principles.[438] Also, both legislative texts require that an ethics committee, in accordance with the law of the Member State concerned, has issued a favorable opinion on the clinical investigation, after performing an ethical review of the clinical investigation plan.[439] In comparison with the current MDD though, the proposed MDR pays much more attention to what it seems to understand with ethical principles that have to be respected. The Regulation for example adds the clause that '[c]linical investigations shall be designed and conducted in a way that the rights, safety, dignity and well-being of the subjects participating in a clinical investigation are protected and prevail over all other interests.'[440] In addition, special attention is paid to, and special conditions are formulated concerning informed consent,[441] and clinical investigations on incapacitated subjects,[442] on minors,[443] on pregnant or breastfeeding women,[444] and in emergency situations.[445]

After the Member State concerned has authorized the clinical investigation (no timelines are set on this), the proposed Regulation provides the sponsor and the investigator with the responsibility to ensure that the clinical investigation is conducted in accordance with the approved investigation plan.[446] Interestingly, it is the sponsor himself who, according to the proposed MDR, should monitor the conduct of the clinical investigation. Also the extent and the nature of the monitoring should be determined by him. Member

[432] Article 49 sub 1a.
[433] Article 49 sub 1a.
[434] Preamble (39).
[435] BSI, How to prepare for and implement the upcoming MDR, p. 14.
[436] Article 50 sub 1 versus Annex X Chapter 2, 2.1, Directive 2007/47/EC.
[437] Articles 51 and 51a.
[438] Annex XIV Chapter I Section 1 versus Annex X Chapter 2, 2.2, Directive 2007/47/EC.
[439] Article 50 sub 3 versus Article 15 sub 2 and 3, Directive 2007/47/EC.
[440] Article 50 sub 3.
[441] Article 50aa.
[442] Article 50c.
[443] Article 50ca.
[444] Article 50cb.
[445] Article 50cd.
[446] Article 51e sub 1.

States, on the other hand, are provided with corrective measures by the proposed MDR, which they are allowed to use if they have grounds to believe that the requirements concerning clinical investigations are no longer met.[447] Before taking such measures, like requiring modification or temporary halting the clinical investigation, though, the Member State shall first ask the sponsor for his/her opinion.[448] All in all, penalties are either absent, or not likely to be applied very often.

4.3.7 Chapter VII: Post-market surveillance, vigilance and market surveillance

In the case of post-market surveillance and vigilance by manufacturers, discussed in Chapter VII, not much measures seem to be in place either, if manufacturers do not comply with all the requirements laid upon them in this chapter. In comparison with the current MDD however, which merely states that '[t]he clinical evaluation and its documentation must be actively updated with data obtained from the post-market surveillance. […] Where post-market clinical follow-up as part of the post-market surveillance plan for the device is not deemed necessary, this must be duly justified and documented,'[449] the proposed MDR provides much more, and detailed criteria on post-market surveillance. Annex IIa of the proposed Regulation describes the technical documentation on post-market surveillance. This consists of the post-market surveillance plan, the post-market clinical follow-up plan and the periodic safety report. According to the Regulation, this whole post-market surveillance system 'shall be suitable to actively and systematically gather, record and analyze relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.'[450] The focus of post-market surveillance thus seems to be shifted to a continuous evaluation and improvement loop.[451] The periodic safety report steers manufacturers into this loop by requiring that manufacturers of class IIb and class III devices shall update the report at least annually,[452] and that manufacturers of class IIa devices shall update the report when necessary and at least every two years.[453] This may provide quite some work for the manufacturers, as this report must evaluate the benefit risk determination, the main findings of the Post Market Clinical Follow-up report, and the volume of sales of devices and an estimate of the population that use the device.[454] Manufacturers of implantable or class III devices must upload their periodic reports to the EUDAMED database, for evaluation by the notified body involved in the conformity assessment.[455] Afterwards, the reports and evaluations will be electronically available to the Competent Authorities.[456]

With respect to vigilance, manufacturers are required to report serious incidents (or Field Safety Corrective Actions (FSCA)) to the EUDAMED database within 15 days,[457] in case of death or unanticipated

[447] Article 56.
[448] Article 56 sub 0b.
[449] Annex X Chapter 1, 1.1d, Directive 2007/47/EC.
[450] Article 60a sub 3.
[451] BSI, How to prepare for and implement the upcoming MDR, p. 16.
[452] Article 60c sub 1.
[453] Article 60c sub 1.
[454] Article 60c sub 1.
[455] Article 60c sub 2.
[456] Article 60c sub 2.
[457] Article 61 sub 1b.

serious health deterioration the maximum is 10 days;[458] in case of a serious public health threat this timeframe is limited to two days.[459] Also, manufacturers are required to perform necessary analyses, such as a risk assessment, of the incident and the field safety corrective actions, and shall provide a final report to the Competent Authority, in order to be submitted to EUDAMED.[460] The EU database will be used to share these vigilance reports with the following parties: the Member State where the incident occurred, Member State(s) where the FSCA is undertaken, and the Member State in which the manufacturer (or its Authorized Representative) is based.[461] Also, the proposed Regulation requires that '[t]he manufacturer shall ensure that information about the field safety corrective action taken, is brought without delay to the attention of users of the device in question,'[462] and that the Commission shall ensure that healthcare professionals and the public have 'appropriate levels of access to EUDAMED concerning vigilance data.'[463] Although the level of access is rather vague, providing information to the public is explicitly paid attention to in the Regulation. And not only attention is paid to allowing the public to be informed, but also to getting information from the public itself. That is, the Regulation requires Member States to take appropriate measures to encourage and enable healthcare professionals, users and patients to report to their Competent Authorities suspected serious incidents.[464] Both manufacturers and the public shall thus take part in vigilance activities.

Competent Authorities and notified bodies shall also take part in vigilance activities, but in that case it is called 'market surveillance'. Market surveillance, which is already provided for in the current MDD, does entail that '[t]he Competent Authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples.'[465] For this activity, the Regulation requires Competent Authorities to allocate a sufficient number of competent human and material resources.[466] If an evaluation shows that a device presents an unacceptable risk to the health or safety of patients or other users, or shows other non-compliance,[467] the relevant economic operators are required to take all appropriate corrective actions to bring the device into compliance with the requirements.[468] When the relevant economic operator(s) does not take adequate corrective actions, the Competent Authorities shall take all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it.[469] So, penalties by surveillance authorities can be seen as an *ultimum remedium*: they are merely taken if the relevant economic operator is not willing to take the required corrective actions.

[458] Article 61 sub 1d.
[459] Article 61 sub 1c.
[460] Article 63.
[461] Article 66a.
[462] Article 63 sub 5.
[463] Article 66a sub 3.
[464] Article 61 sub 3.
[465] Article 67.
[466] Article 67 sub 1a.
[467] Article 73.
[468] Article 70.
[469] Article 70 sub 4.

4.3.8 Chapter VIII: Cooperation between Member States, Medical Device Coordination Group, Expert laboratories, Expert panels and device registers

The main differences between Directive 2007/47/EC and the proposed Regulation with respect to Chapter VIII, concern the establishment of a Medical Device Coordination Group (MDCG) and the possibility to appoint expert panels. The members of the MDCG shall represent a Member State and shall be chosen for their competence and experience in the field of medical devices.[470] The MDCG is empowered with significant responsibilities: it will amongst others provide advice, contribute to the development of devices standards and Common Specifications, and will assist the Competent Authorities in their vigilance and market surveillance activities.[471] Although the MDCG is not bestowed with formal powers, the broad spectrum of tasks the MDCG is expected to perform, from creating standards and specifications, to interpreting them and monitoring their application, concerns a legal consultancy firm on medical devices to such extent, that they think this might be in conflict with the *Trias Politica* on which the European law making is based.[472]

Another task of the MDCG, together with the Commission, is to appoint expert panels for scientific, technical, and clinical opinion and advice, and to assess clinical evaluations in the relevant medical field.[473] Manufacturers and notified bodies may be subject to pay fees for the advice provided by expert panels.[474] Members of the expert panels however, like members of the MDCG, should perform their tasks with impartiality and objectivity, which means they should neither seek nor take instructions form notified bodies or manufacturers.[475] Also, they obviously should not have financial interests in the medical devices industry which could affect their impartiality. In order to monitor this, members of the MDCG and expert panels shall declare any direct and indirect interests they may have in the medical device industry, which will be made publicly available.[476]

4.3.9 Chapter IX: Confidentiality, data protection, funding, penalties

Chapter IX deals with miscellaneous issues, of which confidentiality, levy of fees and penalties are the most relevant for this thesis.

With respect to confidentiality, the article in the proposed Regulation has changed quite a bit from the current article in the MDD. Where the MDD wants Member States to ensure that 'all the parties involved in the application of this Directive are bound to observe confidentiality with regard to all information obtained in carrying out their tasks,'[477] the proposed Regulation requires all parties involved in the application of this Regulation to respect the confidentiality of information and data obtained in carrying out their tasks in order to protect a) personal data, b) commercially confidential information and trade secrets, or c) the effective implementation of the Medical Devices Regulation, in particular for the purpose

[470] Article 78.
[471] Article 80.
[472] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), endnote 18.
[473] Article 81a sub 5a and 6.
[474] Article 81a sub 9.
[475] Article 81a sub 3.
[476] Article 82.
[477] Article 20 sub 1, Directive 2007/47/EC.

of inspections, investigations or audits.[478] In the proposed Regulation, confidentiality thus needs to be protected as long as it serves particular goals. Interestingly, these goals might be in conflict, since a disclaimer is added to goal b), that commercially confidential information might be disclosed if it is in the public interest. Since the results of inspections, investigations or audits might be of public interest,[479] it is unclear whether they should be kept confidential in such a case.

With respect to levy of fees (a new article in the MDR) Member States have the possibility to levy fees for the activities set out in the Regulation.[480] The level of the fees must be transparent and on the basis of cost recovery, and shall be publicly available on request.[481] This does however imply that every Member State is allowed to set their own level of fees, and that differences between the levels of fees among Member States are allowed to occur/remain.

With respect to penalties, a new, but very general article is formulated, stating that '[t]he Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive.'[482] The article however does not state to whom the penalties are allowed to be applied, nor what the penalties are allowed to entail. Neither does the Regulation define penalties for Member States if they transgress their powers, violate their obligations, or turn out to be negligent performing their duties.[483] Some more detail might thus be needed in this Article.

4.3.10 Chapter X: Final provisions

Finally, the last chapter of the proposed MDR, deals with final provisions on for example the transitional period between the formal publication of the new Regulation on medical devices, i.e. the date of 'entry into force', and the date of application. It is stated that the Regulation shall apply three years after entry into force.[484] Until the date of entry into force, notified bodies may issue certificates compliant to the current MDD, that at the latest become void four years after application of the MDR.[485] On the other hand, notified bodies which are designated compliant with the new Regulation, may issue certificates in accordance with the new Regulation before its date of application, also for devices that are currently on the market and need to be recertified.[486] Under all circumstances, manufacturers will need to invest resources in developing a transition plan for their devices currently on the market, since all such medical devices will need to be (re)certified under the new rules, as no grandfathering has been foreseen in the new Regulation. This implies that none of the devices on the European market is allowed to remain on the market under the current rules, and all devices must eventually be transitioned into the new system.[487] This also means quite a lot of extra work for (presumably less) notified bodies, which might

[478] Article 84 sub 1.
[479] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 11.
[480] Article 86.
[481] Article 86 sub 2.
[482] Article 87.
[483] Emergo, Understanding Europe's New Medical Devices Regulation (MDR), p. 11.
[484] Article 97 sub 2.
[485] Article 94 sub 2.
[486] Article 94 sub 4.
[487] BSI, How to prepare for and implement the upcoming MDR, p. 18.

either lead to delays in conformity assessment procedures, and consequently compliant devices that lose access to the European market/innovative devices entering the market later than wished for by the patients, or less stringent conformity assessments than required by the new Regulation. Neither of these options are very appealing.

4.4 Policy analysis

Having examined the parliamentary debates and the differences between Directive 2007/47/EC and the proposed Regulation on Medical Devices, we should be able to evaluate the extent to which the ethical notions, identified in paragraph 4.1, have been taken into account in the new Regulation. The order of notions discussed in this policy analysis, will be same as in that paragraph. So first, patient safety will be discussed (paragraph 4.4.1), second, reliable and responsible clinical research of medical devices (paragraph 4.4.2), third, transparency and informed decision-making (paragraph 4.4.3), and, finally, legal certainty and patients' trust (paragraph 4.4.4).

4.4.1 Patient safety

With respect to the current Directive, several factors were identified that influenced patient safety to not be ensured. In paragraph 4.1.1, we discussed that patients were at risk of potential harm, due to the fact that clinical efficacy of medical devices was not required to be tested, that there was no clear definition of patient safety, that the capacities of notified bodies varied significantly, that post-market surveillance of medical devices was limited, and finally, that devices, intended for single-use, were re-used without any guarantee of being cleaned properly. Since, according to the parliamentary debates, patient safety was of utmost importance to all the political groups in the European Parliament, one might expect the notion of patient safety to have been much taken into account in the proposed Regulation. If we however compare the current Directive with the proposed Regulation, we observe that some safety aspects have been taken into account, while other aspects have not been touched upon at all.

First of all, the CE-system of market entrance, which did not guarantee clinical efficacy. In the proposed Medical Device Regulation, the system of market entrance is not changed (although there has been quite some criticism on the system[488]). That is, devices must merely be shown to conform to the general safety and performance requirements, before they are allowed on the market. A clinical evaluation shall be part of the conformity assessment,[489] as is however already the case with the current Directive.[490] Although the requirements for clinical evaluations have been intensified (rather than either evaluating relevant scientific literature or the results of all clinical investigations made, it seems that in the proposed Regulation, both options should be evaluated, as well as any alternative treatment options), clinical efficacy is not necessarily tested for. In case of Class III and implantable devices, clinical investigations shall be part of the conformity assessment, as is the case under the current Directive. New to the Regulation is that one of the goals of clinical investigations is the determination of clinical benefit. This

[488] See for example: van Est et al., 2017.
[489] Article 4 sub 3.
[490] Annex I, Chapter I sub 6a, Directive 2007/47/EC.

new concept is stated to be 'the positive impact of a device on the health of an individual,'[491] and can consequently be considered a suitable alternative to clinical efficacy. Yet, it is not required that clinical benefit is determined during clinical investigations, as just verifying the intended performance of a device, is a goal of clinical investigations as well.[492] In addition, the Regulation does not prescribe how clinical benefit should be determined. Consequently, it is not likely that clinical benefit will frequently be determined. So, it could be concluded that the CE-mark will still not guarantee that the medical device will work in patients, or that it does not cause harm to patients in other ways. Thus, the proposed Regulation cannot be said to take into account the notion that sound clinical evidence is needed before devices are put on the market, and subsequently, patient safety is still at stake.

Second, although many definitions have been added to the proposed MDR, the concept of 'patient safety' remains undefined. So, also this aspect of patient safety is not taken into account at all in the proposed Regulation.

Third, the position of notified bodies. As discussed in paragraph 4.3.4, under the new Regulation, the oversight of notified bodies will increase significantly. Due to the fact that all notified bodies need to be accredited (again), and will be audited each 3-4 years, it is to be expected that the notified bodies that pass the tests, will be more adherent to the Competent Authority of the Member States in which they are based. In that sense, notified bodies are expected to be less a friend of industry (although they remain to be private companies). Reasoned from the notion that patient safety should be ensured, this can be considered a welcome development, as more adherence to Competent Authorities will imply more stringent conformity assessments by notified bodies, and consequently a higher chance of harmful devices being detected at an early stage. The latter obviously increases patient safety. So, this aspect of patient safety can be considered to be taken into account.

Adherence to the Competent Authority of a certain Member State, does however not imply an equal level of capacities among the Member States, as some Competent Authorities might be more stringent than others. In combination with the fact that manufacturers are still allowed to choose any notified body among Europe, patient safety might still be hampered by 'forum shopping'. It should be noted however, that even though differences in fees are still possible, it is expected they will be flattened out, as a list of standard fees for conformity assessment shall be made public by a notified body. Also, it is worth to mention that even though differences between Member States might remain, the involvement of the European Commission in assigning a joint assessment team, implies that the European Union believes some centralized oversight is necessary, and will be provided for. Nevertheless, the involvement is limited, as the advice provided by the joint assessment team should merely be duly taken into consideration. Although it is unclear what this exactly implies in practice, for sure it means that Member States have a final say in the designation of notified bodies. Consequently, the notion of equal capacities of notified bodies can thus be considered to be partially taken into account.

[491] Article 2 sub 1 (37d).
[492] Article 50 sub 1 (a).

Some legal experts worry that due to the increased oversight of notified bodies they will cease activity, which might cause delays in conformity assessments. From the notion of increasing patient safety, notified bodies ceasing activity is not necessarily bad, as it might imply that the more stringent notified bodies will remain, which is likely to increase patient safety. However, delay in conformity assessment, due to shortage of personnel, might also imply that some safe, effective devices will reach patients later than could have been the case. They might thus be harmed by the unavailability of devices, which implies that lack of (timely) innovation is not desirable either. So, although notified bodies ceasing activity could be a sign of the notion of patient safety being taken into account, it is still recommended that a discussion on the right balance between patient safety and timely innovation will be performed.

Fourth, the themes of post-market surveillance and vigilance. As described in paragraph 4.3.7, in comparison with the current Directive, in the proposed Regulation much more requirements have been formulated with respect to vigilance and surveillance activities. Manufacturers have to provide more data on the functioning of devices while on the market, and the controlling bodies have to perform more surveillance activities. As chances are subsequently higher that harmful devices will be detected, the notion that post-market surveillance should be increased can consequently be considered to be taken into account. It should be noted though, that data on clinical benefit/clinical efficacy are not necessary to be acquired during post-market clinical follow-up, and evaluation methods are not specified in the Regulation. In this sense, clinical efficacy of devices is still not tested for, which implies that devices might cause unnecessary harm to patients. Another point of criticism is that it remains to be seen whether the requirements will be followed by the parties involved. Not much penalty clauses have been provided for in the proposed Regulation, and if they are, they can be seen as an *ultimum remedium*. This might be problematic with respect to patient safety, as the penalty clauses may turn out to be paper tigers, which do not urge manufacturers or notified bodies to be law-abiding. All in all, the notion that post-market surveillance should be increased in order for patient safety to be ensured, can be considered to be partially taken into account.

Fifth, the reprocessing of devices intended for single-use. In the proposed Regulation, reprocessing is no longer unregulated. The proposed Regulation states that reprocessing may only take place if it is permitted by national law, and under the conditions specified. These conditions entail that reprocessors are considered to be manufacturer of the reprocessed device, and should comply with the obligations incumbent on manufacturers laid down in the Regulation. So, for example, the devices have to comply with the general safety and performance requirements, and a new CE mark has to be attached. For reprocessing within health institutions, less strict conditions might apply. From the notion that unregulated re-use of single-use devices might be harmful for patients, the fact that reprocessing is no longer unregulated, but that conditions have been provided for, such that reprocessed devices need to have certain safety levels that might decrease harm to the patient, can be considered as the notion being mostly taken into account. Nevertheless, the more single-use devices are disposed of, the lower the risk of infection, and the higher patient safety. From this perspective, banning reprocessing of single-use devices (and encouraging the use of single-use devices rather than reusables) would be the safest for patients. Yet, such a measure would most likely increase healthcare costs, which might lead to less products available, or less interventions performed, and thus –indirectly- to patients being harmed. In

that sense, it might be that reprocessing of single-use devices under strict conditions might be the right balance between decreased risk of infection and dysfunctionality, and increased healthcare costs. In order to assess this balance, it is recommended that the benefits and risks of the new requirements are strictly monitored the upcoming years.

Finally, two measures have been proposed in the Regulation, which show that the notion of patient safety has been taken into account: first, the inclusion of groups of products without intended medical purpose in the scope of the Regulation, and second, the obligation for manufacturers to have a person responsible for regulatory compliance available. The first measure is likely to increase safety with respect to these products, as the requirements on medical products are generally stricter than the requirements on other products that need to have a CE-mark. The second measure is likely to increase patient safety, as this person, that is supposed to be independent, will monitor manufacturing practice daily. It is however unclear to whom this person should report, and what measures will be taken if the person responsible turns out to cover up malpractices. As this is unclear, this aspect of patient safety can merely be considered to be partially taken into account, and patient safety might be hampered.

4.4.2 Responsible and reliable clinical research of medical devices

In addition to aspects related to the notion of patient safety, several aspects were identified that should be taken into account with respect to reliable clinical research on medical devices (paragraph 4.1.2). These aspects entail methodological and practical challenges of clinical trials, the lack of requirements regarding clinical evaluations/investigations, the blurring of research and clinical practice, and the limited review by ethics committees. The comparison of the current Directive with the proposed Regulation concerning these aspects unfortunately shows that most of them have not been touched upon.

For example, both the ethical and methodological objections to randomized clinical trials, and the request to deal with the complete system surrounding medical devices, including the learning curve, are not mentioned in the proposed Regulation. Actually, clinical trials for medical devices are not discussed at all. So, while it is required for implantable and class III devices to perform clinical investigations, the Regulation does not require those to be clinical trials, although recommended by the experts in the field.[493]

Yet, in comparison with the current Directive, the requirements on clinical investigations have been intensified. As discussed, the determination of clinical benefit is one of the endpoints of clinical investigations. Annex XIV on clinical investigations requires that the 'endpoints shall be determined and assessed using scientifically valid methodologies'[494]. Although the Regulation does not specify what scientific methodologies are required, and although investigations need not be clinical trials, the Regulation requires the Clinical Investigation Plan to contain the 'design of the clinical investigation with justification of its scientific robustness and validity'[495]. Also, it requires '[d]etails of measures to be taken to minimize bias (e.g. randomization) and management of potential confounding factors'[496].

[493] Vinck et al., p. 14.
[494] Annex XIV Part I 2.4a.
[495] Annex XIV Part II 3.6.
[496] Annex XIV Part II 3.6.3a.

Subsequently, Member States should assess the clinical investigation design, also with respect to the reliability of the data to be generated. Even though there are no instructions on how the reliability of the data should be assessed, and there are no penalty clauses on Member States too lightly assessing the design (which might cause variation among Member States), the fact that the design should be assessed implies that the reliability of clinical investigations has received more attention. Consequently, this aspect of reliable and responsible clinical research can be considered to be at least partially slightly taken into account.

Stricter requirements are also formulated with respect to the use of equivalence. Although the use of equivalence is still possible, and although the decision on equivalence is still left to manufacturers and notified bodies, the stricter requirements should ensure that more clinical investigations are performed. The requirements on equivalence seem to be reasonable (the device should merely be a modification of an already existing device, and the manufacturer should have full access to applicable technical documentation), although little modifications could have severe effects. It is also worrisome that no clinical investigations have to be performed if the devices have been lawfully placed on the market in accordance with Directive 2007/47/EC, as we have concluded that the requirements on clinical data in Directive 2007/47/EC are not sufficient to ensure patient safety. This clause does not encourage new clinical investigations to be performed, and consequently the issue regarding lack of proper clinical data may pertain. It thus remains to be seen how less frequent the equivalence clause will be used, and how much more clinical investigations will be performed under the proposed Regulation. It is therefore doubtful whether this aspect of clinical research has been taken into account.

In those cases in which no sufficient clinical evidence has been generated before the device is allowed on the market, clinical research on medical devices tends to blur with clinical practice. This issue, and the strict legal distinction that commonly is made between both concepts, has not been addressed in the proposed Regulation. Consequently, there might be less oversight of 'research' in clinical practice, than would be the case if the research was performed pre-market. A welcome development in this regard though, is the proposed increase of post-market surveillance. As it however remains to be seen how much post-market surveillance will actually be performed in practice, this potentially increased surveillance cannot be sufficiently relied on to consider the blurring of research and clinical practice to be taken into account in the new Regulation.

As the blurring of clinical research and clinical practice has not been taken into account, this implies that the lack of review of clinical practice by ethics committees has not been discussed either. This is the case indeed. Both the problems of limited review by ethics committees and the specific knowledge that might be required, but is usually not available, have not been touched upon in the proposed Regulation. We thus have to conclude that the notions regarding ethical review are not taken into account at all, and that the new Regulation is thus unchanged in this regard.

4.4.3 Transparency and informed decision-making

While not much has been changed with respect to reliable clinical research, this fortunately is not the case with respect to the notion of transparency. In paragraph 4.1.3, we identified that there was quite a deficiency in transparency on performance of medical devices, due to the emphasis on confidentiality of information, and the lack of rules on providing information to central databases, and on accessibility of

the information to the public. Consequently, it is not possible for healthcare providers to properly fulfill their duty to inform their patients, and for patients to make an informed decision on their treatment.

In the proposed Regulation on Medical Devices, the focus has shifted away from confidentiality. Although confidentiality is still protected, protection is merely allowed when it serves certain goals. As discussed in paragraph 4.3.9, these goals might be in conflict, if for example commercially confidential information is in the public interest. Although it is not clear whether information will be disclosed in such cases, and who will decide on disclosure, the movement towards more disclosure of information shows that this aspect of transparency has been taken into account in the new Regulation.

With respect to requirements on providing information to central databases, and accessibility of those databases to the public, much is changed in the proposed Regulation, as well. In accordance with the Declaration of Helsinki, clinical investigations should be registered in EUDAMED, as well as the clinical investigation plan, and the outcomes. In addition, devices of all classes, except for custom-made devices, should be registered in EUDAMED, and the information should be kept updated by the manufacturer. Furthermore, information on certificates issued, and vigilance, post-market surveillance, and market surveillance should be uploaded to the database. Finally, also the new UDI system is to be integrated with the EUDAMED database. So, quite a lot of information is to be uploaded to the central database, which clearly shows that this aspect of transparency has been taken into account in the new Regulation, especially in comparison with the current Directive. In practice however, it remains to be seen to what extent information will really be uploaded, as not all information in the database will be assessed by notified bodies or Competent Authorities. While information on clinical investigations should be assessed by Member States, this is for example not the case with registration of devices. In addition, the accuracy of the data is usually not evaluated by public bodies. Consequently, the information in EUDAMED might in practice not be as complete and accurate as required for in the proposed Regulation.

The accessibility of the EUDAMED database has been changed significantly, though. For the first time, major parts of the database will be open to the public. This entails amongst others the information described above, but also the summaries of, for example, safety and clinical performance of Class III devices,[497] and a summary of the review of Member State market surveillance plans.[498] As those summaries should be written such, that it is 'clear to the intended user and, if relevant, to the patient,'[499] writing them might provide some extra work for manufacturers and controlling bodies. Therefore, it remains to be seen whether these summaries will always be written in accordance with all the requirements. But if we assume most of them will, it seems to imply that the aspect regarding patients' access to information has been mostly taken into account. As Fouretier and Bertram contend: 'Enabling access for the public and health care professionals to EUDAMED will finally respond to the current lack of verified information and will empower medical device users.'[500] It also enables healthcare providers to fulfill their duty of properly informing their patients, and patients to make well-informed decisions. Whether the aspect of providing information to the public is taken into account in practice, remains to be seen, though. This is not only because the information available might not be fully accurate, complete, or understandable for the intended audience, but also because healthcare providers and patients might not

[497] Article 26.
[498] Article 67 sub 2.
[499] Article 26 sub 1.
[500] Fouretier & Bertram, p. 357.

use the database as frequently as hoped for, due to for example lack of time, or lack of user-friendliness. In such cases, informed decision-making might still be hampered, so it is recommendable to monitor the (public) usage of the EUDAMED database accurately.

4.4.4 Legal certainty and patients' trust

Public access to information might also help to restore patients' trust in the healthcare system, as patients may consequently know whether a device poses a risk to health and safety.[501] While patients' trust might thus be restored due to public access to information, this unfortunately is not the case with other factors we identified (paragraph 4.1.4) to endanger patients' trust, such as legal uncertainty, the misleading CE-mark, and controversies broadly covered in the media.

As discussed, legal uncertainty arises due to the case-by-case classification of borderline products, which might be problematic because of the big regulatory differences between pharmaceuticals and medical devices. In the proposed Regulation, the differences between the regulatory framework of pharmaceuticals and medical devices remain to be big, as for example the systems of pre-market approval still differ significantly. Also the classification of borderline products has not changed much: classification is still binary and mutually exclusive,[502] which means that a medical product either has to be classified as a pharmaceutical, or as a medical device. Although it is explicitly added to the proposed Regulation that '[i]n deciding whether a product falls under Directive 2001/83/EC or under this Regulation, particular account shall be taken of the principal mode of action of the product,'[503] the Regulation does not define what is meant by the 'principal mode of action'. Moreover, the decision whether or not a product falls within the scope of the Medical Device Regulation, is still the responsibility of the Member States on a case-by-case basis.[504] Added to the Regulation though, is the phrase that '[i]n order to ensure consistent qualification across all Member States, particularly with regard to borderline cases, the Commission may, on its own initiative or at a duly substantiated request of a Member State, having consulted the MDCG, decide on a case-by-case basis whether or not a product or groups of products fall within the scope of this Regulation.'[505] So, although the decision on borderline products is still the responsibility of Member States on a case-by-case basis, the Commission may interfere, which could increase legal certainty in these kind of cases, as decisions of the Commission apply directly in all Member States. In practice however, it remains to be seen how often the Commission will use this possibility to interfere. So, the notion that borderline products should be properly classified in order to increase legal certainty, can, at most, be considered to be slightly taken into account.

As the interference of the Commission theoretically thus seems to increase legal certainty, in general we could argue that the legal certainty of medical devices is likely to be increased, due to the fact that the Directive on medical devices has been changed into a Regulation on medical devices, and the fact that Regulations are directly binding throughout all Member States, while Directives are not.[506] So, overall we could say that the notion of legal certainty might have partially been taken into account in the new

[501] Fouretier & Bertram, p. 357.
[502] Hancher & Foldes, p. 5.
[503] Article 1 sub 2 (b).
[504] Preamble (8).
[505] Preamble (8).
[506] See for example Paragraph 2.4.3, and Altenstetter, 2013, p. 450.

Regulation. Consequently, the trust of the patient in the medical devices sector might partially increase as well. However, patients' trust is also affected by other aspects, such as the misleading CE-mark and the recent controversies that have been broadly covered by the media. With respect to the meaning of the CE mark, not much seems to change under the new Regulation: the CE mark still merely entails that products conform to general safety and performance requirements, and this commonly does not imply clinical efficacy or any clinical benefit, as one might expect. So, the CE mark could be considered to still be misleading for patients and users, and consequently as still diminishing patients' trust.

With respect to controversies with medical devices, it obviously is hard to predict whether new controversies might arise in the future. However, as the notion of patient safety, and especially of clinical benefit has not been extensively taken into account in the new Regulation, future controversies cannot be ruled out. For sure, when controversies are discovered, they will be broadly covered in the media, and the effectiveness of the new Regulation might be questioned. New controversies would consequently harm (rebuild) patients' trust. For all parties involved, but especially for the patients, it is therefore important that the relevant ethical notions are taken into account and that future controversies are prevented from happening.

4.4.5 Summary & Discussion

To summarize, to what extent have the ethical notions on medical device legislation (as identified in paragraph 4.1) been taken into account in the new Regulation on medical devices, according to our policy analysis?

Concerning the notion of patient safety, we have seen that some aspects have at least partially been taken into account (i.e. equal capacities of notified bodies, and increased post-market surveillance), but that other important aspects, such as the provision of sound clinical evidence, cannot be considered to be taken into account. Overall, we could conclude that the notion of patient safety has been partially taken into account in the proposed Regulation. Although this might be considered a welcome development – assuming that more patient safety is believed to be better-, it is worthwhile to note that according to the Members of Parliament, patient safety was generally accepted to be of utmost importance. In that regard, one might expect the notion of patient safety to have been taken much more into account than is actually the case. Consequently, it is of interest to investigate the reasons why the notion of patient safety is taken into account to a lesser extent than one might expect, based on the parliamentary debates. Which other stakeholders have been involved at what stages of the legislative process and how have they influenced the final version of the new Regulation?

Obviously though, completely ensuring patient safety is not conceivable either, as individuals might respond differently to a device considered safe, and innovation would be hampered significantly. It seems fair to assume that the medical device industry might have a different view on a proper balance between patient safety and innovation, than for example patients have. Therefore, it is also recommendable to have an ethical debate on the right balance between patient safety and innovation, so as to arrive at a broadly supported criterion that this Regulation on medical devices (and future versions) can be judged upon.

Concerning the notion of responsible and reliable clinical research, we can conclude that the different aspects have hardly been taken into account in the proposed Regulation. In that regard, it might be of

interest for further research to investigate to what extent the pharmaceutical and medical device legislative framework remain different, given the new Regulation on medical devices, especially with respect to the requirements on clinical investigations.

Concerning the notions of transparency and informed-decision making, we can conclude that basically all aspects have been taken into account. In practice however, it remains to be seen whether all the paperwork required will be generated, and whether the available information will be used frequently, to make informed decisions. It is therefore recommendable to accurately monitor the usage of the databases by patients, physicians, and the general public.

Concerning the notions of legal certainty and patients' trust, we can conclude that the aspects regarding legal certainty can, at most, be considered to be slightly taken into account. The aspects of patients' trust related to the notion of legal certainty, consequently can be considered to be slightly taken into account, as well. The other aspects of patients' trust, however, cannot be considered to be taken into account. In the case of patients' trust (and obviously also of patient safety) it is of particular importance that future controversies are prevented from happening. So, if it is discovered that, in practice, the new Regulation does not (sufficiently) sort the effects desired, it is recommendable to investigate what are the most important causes of the undesired outcomes. If these would turn out to be (partially) related to the ethical notions currently not taken into account or partly taken into account, it is advisable that these notions be taken into account in future versions of the Regulation on medical devices, preferably before any new controversies have happened. This approach may help to restore patients' trust, while ensuring more medical devices to be safe for patients.

5 Conclusion

In this thesis, we have investigated to what extent ethical notions on medical device legislation have been taken into account in the new Regulation on medical devices. It was identified that several ethical notions on medical device legislation were addressed by experts in the literature. These notions were that 1) patient safety should be ensured, that 2) clinical research should be responsible and reliable, that 3) transparency of data should be encouraged to enable informed decision-making, and that 4) legal certainty should be increased to restore patients' trust. For each of the notions, several aspects were determined, of which the literature suggested that they should be taken into account in the new Regulation on medical devices.

During the legislative process of the new Medical Device Regulation, discussions were held in, amongst others, the European Parliament. An analysis of the parliamentary debates showed that the main themes of the debates were patient safety, rapid innovation of medical devices and the competitiveness of the European medical devices sector –and the potential conflict with patient safety-, patients' trust, distrust in industry, and transparency & traceability. The theme of legal certainty is merely addressed by some political groups. If we compare these themes with the ethical notions addressed in literature, quite some overlap can be observed. Most the main ethical notions have thus been addressed during the debates, except for the challenges with respect to clinical research.

Consequently, one might expect most of the main ethical notions to have been taken into account in the new Regulation on medical devices. A comparison between the legislative texts of the Medical Device Directive and the proposed Medical Device Regulation, however, shows that not all notions have been taken into account, and that some notions have been taken into account only partially. The notion of patient safety, for example, can be concluded to have been partially taken into account, as some aspects were paid attention to, while other aspects were not touched upon at all. The notion of responsible and reliable clinical research can be concluded to not have been taken into account, since most of the aspects have not been touched upon in the proposed Regulation. The notions of transparency and informed decision-making, on the other hand, can be concluded to have been taken into account, as basically all aspects have been paid attention to in the proposed Regulation. Finally, the notions of legal certainty and patients' trust can be concluded to have, at most, been slightly taken into account, while the aspects of patients' trust not related to legal certainty cannot be concluded to have been taken into account. So, there is a large variation in the extent to which the ethical notions on medical device legislation have been taken into account in the new Regulation on medical devices.

Based on these results, it is recommended to investigate the reasons why some of the ethical notions, in particular patient safety, have not been taken into account to the extent that could be expected from the parliamentary debates. For example, which other stakeholders have been involved at which stages of the legislative process and how have they influenced the final version of the new Regulation?

It is acknowledged that completely ensuring patient safety is not conceivable, as innovation would be hampered significantly. Therefore, it is also recommended to have an ethical debate on the right balance between patient safety and innovation, so as to arrive at a criterion that this and future versions of the Regulations on medical devices can be judged upon.

In addition, an investigation and debate is recommended on the extent to which the pharmaceutical and medical device legislative framework remain different, given the new Regulation on medical devices, and to what extent the legislative frameworks should be similar (i.e. to what extent pharmaceuticals and medical devices should both be considered biomedical products).

Furthermore, it is recommended that the practice of the new Regulation be monitored, in order to determine whether the ethical notions that have been taken into account, indeed have the desired effect. If it is discovered that, in practice, the new Regulation does not (sufficiently) sort the effects desired, it is recommended to investigate what are the most important causes of the undesired outcomes. If these would turn out to be (amongst others) related to the ethical notions currently not taken into account or partially taken into account, it is advisable that these notions be taken into account in future versions of the Regulation on medical devices, preferably before any new controversies have happened. This approach may help to restore patients' trust, while ensuring more medical devices to be safe for patients.

As the main motivation for writing this thesis lay in the surprise about the currently un(der)demanding European legal framework for medical devices, that potentially creates unsafe and harmful circumstances for patients, it is hoped that this work will provide a valuable source of information for politicians, policy makers and other actors involved in future regulation of medical devices, in particular with respect to the ethical notions that should be taken into account.

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Appendices

A) Transcripts of debates in ENVI committee and Plenary

Legend:

Ethical issue/Discourse

Nodal point (the central signs, around which the other signs are organized and derive their meaning and which exclude other possible meanings)

Linguistic feature

Comparison with Commission/earlier version MDD

Spoken in English (which is not presumed to be the native language of the speaker, based on the country he/she is representing)

Rapporteur: Dagmar Roth-Behrendt (Germany, S&D)

Shadow-rapporteurs:

Mairead McGuinness (Ireland, EPP (Christen-Democrats))

Holger Krahmer (Germany, ALDE)

Michèle Rivasi (France, Group of the Greens)

Marina Yannakoudakis (United Kingdom, European Conservatives and Reformists Group (ECR))

Alda Sousa (Portugal, Confederal Group of the European United Left)

A.1 Debate 20/03/2013 in ENVI Committee

http://www.europarl.europa.eu/ep-live/en/committees/video?event=20130320-0900-COMMITTEE-ENVI#managehelp

(English transcription)

Introduction President (Matthias Groote, S&D, German)

President: So, we now move on to point four on our agenda: medical devices. I know that there are a large number of colleagues, who would like the floor. I would like to give the rapporteur the floor for five minutes and then after that, we need to move down to two minutes for speaking time, because many many colleagues want the floor and we have only got half an hour (?) for this and we want to hear from the Commission as well and others, so that we have a good debate. So, let me give mrs Roth-Behrendt the floor straight away and then I am going to open the list for those who would like to speak and then I will close it. So, Dagmar, you will have the floor.

03:43, 20 March

Dagmar Roth-Behrendt (German, S&D, speaking English)

Thank you very much, Matthias. So the German (?) I do my preparations in English, I work on that dossier in English, due as well to my colleague Nicolas (?), who prefers to work in French or in English. So that, and my, that is, well my text is, will be as well in English this morning, and (ehm) normally if I not (?) to do that in the committee. Matthias, allow me please, and colleagues allow me just to be very stringent with, in five minutes. And I want you to know that the whole legislation on medical devices on my part, not the in-vitro, where Peter Liese will come step in a little bit later, I first have to say: we all know it is an important legislation, I believe the Commission text is a good starting point but we would want to im, perhaps, improve it a little bit. I believe at the time when the Commission did drafted (?) it, perhaps some of the parts we are aware now, perhaps have not been so clear and I hope that bits of my proposals for changes will be accepted. Not only by the majority in the house, but as well by the Commission.

Having said that, I believe that the whole structure of the text is not logic. I follow now the structure of the Commission text, to make it easier for you, to understand the different chapters, but then, at the end, I will tell you as well how I believe this care (?) text should be structured.

Let's first/us start with what is (?) chapter two which is reprocessing of single-use devices. We have the problem that we have, for the time being, a definition for single-use, but we have as well, at the same time, a reprocessing of single-use, which is per se an illogical, ununderstandable situation, because if you define something as a single-use, you would anticipate that it is a single-use, means, one-use, for one patient, during one treatment. We have a reprocessing nevertheless, sometimes in high-quality,

sometimes, I exaggerate a little bit, in the kitchen of a hospital, on which standards ever. So, we have to look at the whole system of single-use and multiple use. I want to have a definition of single use, which is a better definition than that in the Commission's text; everything else what is not single-use will then be multiple use. The Commission foresees for everything which is reprocessed, a manufacturer situation for the reprocessor and the liability for the reprocessor as well, I agree with that. Nevertheless, we have to be clear amongst us how a single use, does single-use mean always only single-use and is it realistic? Is it realistic when we have an image building camera for a heart check, which costs 1000 euro, which where the check of the patient takes an hour; we all know that in 90% of those cases, even if it's a single-use product, it will be reprocessed. So, we have to deal with that in a way that we guarantee that there is no danger for patients of a hospital infection or any other disease and there I want to invite the Commission as well to come forward with ideas which are better than the text which it is now.

We then just have to look how do we bring a product on the market? What is necessary for that? The Commission starts with that, I believe it is wrong, but in, they have in Chapter four and in annex six the notified bodies. There, I will clearly only on the notified bodies, not deciding yet at that stage, whatever task they will have; they will, I will look at the fee situation, we cannot allow that we have a competition in between the European Union and in the same Member States, concerning the amount of fees that one notified body, hence (?) the other notified body concerning the fees, and the quality of the delivery, so we want to have a transparent fee system in the European Union. The Commission foresees something in the text which I believe has to be more stringent and more obligatory for the Member States.

Concerning staff, at the moment there is not clear obligation for a notified body, whatever they do, at the moment for all four classes of medical devices, class I, IIa, IIb and III, they do not have to guarantee to have in-house expertise, neither on physicians or medical doctors or on pharmacologists. I believe that that is wrong. We need to make sure that they have to provide in-house expertise. Whoever wants to notify a medical device has to have in-house expertise. I do not mind, as it is foreseen, that notified bodies can as well look for expertise from outside; there I think that we have to look better on the contracts they have. That the contracts to whoever they give a task for expertise has to be transparent, has to be notified properly (?) with a national authority and has to have the best quality of expertise and then coming the in-house expertise has to be available to check if the quality which comes from outside is good, yes or no. We then have on concerning the staff and the subcontracting, have to be very clear that that guarantees the best evaluation.

On Chapter 5 one and annex 7 in the text as it stands, is the classification. At the moment, we have four classes, I, IIa and IIb and III. I do not necessarily mind that we keep that. What I disagree with are certain articles that the Commission introduces, especially on changing certain medical devices from class II to III, especially the articles 19, 20 and 21, I look at, I believe 21…

Is five minutes already over? One last sentence, system of approval of medicines, that's the most important (bit?). Matthias, honestly, it is a big piece of legislation and five minutes is quite quite…

The system of approval of medical devices. I think that we, for the highest risk class, we need a conformity assessment, which is like a centralized pre-market authorization. I want to have a centralized pre-market authorization for the highest class. Then we do not need a scrutiny mechanism, because the

Commission in the text at the moment has not foreseen a market authorization, but has a very complicated scrutiny mechanism which comes afterwards, because they honestly themselves do not believe that the notification is good, so article 44 can be deleted, but we have a pre-market authorization.

On clinical investigations we need to be better, and finally, I make a summary, Nicolas ehhh, we are too short in time, finally, I will have a different order; I will start with a classification, I will then come to the centralized pre-market authorization in my text, well then come to reprocessing of single-use devices and standards for reprocessing, have to ensure that notified bodies under point 4 have the best scientific expertise in-house and a limited number out-house and ensure that there are enough clinical evidence and data for more clinical data clinical trials available.

Oef, But that was the fastest I could do, Matthias, honestly. And I skipped half of the information necessary.

[zucht van verlichting en verontwaardiging]

10:59, 20 March

President: Thank you very much for that five minute introduction from the rapporteur. We now have the shadow rapporteurs. Now I know that this is a major piece of legislation, but given that we have rearranged the agenda, we now have 45 minutes less. We are going to get into difficulties.

Now, Mrs McGuinness is the first speaker.

11:29, 20 March

Mairead McGuinness (Ireland, EPP(Christen Democrats)) : Thank you, chairman, and my sympathies and thanks to our rapporteur, because this is very complex and in a way it is unfair to ask someone to condense very technical and very important legislation into five minutes. And what one of your key points, I do think we need to allow you to expand on in your response if you will, and I start with that, this idea of a system of approval, pre-market authorization. I know that you are very keen on this proposal. I remain to be convinced, but I would like to hear how this would work, because I am not convinced that we need to altogether scrap the idea of very strong post-market surveillance, which is what you are suggesting, I think, but I would like that the chairman would give you time to elaborate on what I believe is a key part of your departure from the Commission's proposal for class III medical devices.

On the other issues, I think your points on reprocessing and single-use, this is, you know, a conflict of English, let alone (?) of procedure and device, so we need to have some clarification on that. Essentially, what we are trying to achieve, with very limited resources, and I think resource constraint is a factor in this redrafting of legislation, because Member States have the responsibility, but many of the Competent Authorities do not have the competence in my view, and the expertise to do all this scrutiny and therefore we have two key points:

One is let's look at the Competent Authorities and also the notifying bodies, because these are key components of consumer safety and industry security as well. So we need to strengthen our notifying bodies; they need to be expert in the areas that they are certifying and I suppose that there is a question for us to address, Chairman, in so far as 'Does Europe have the expertise sufficiently to do all this scrutiny?' And there is a responsibility for industry and notifying bodies to make sure that we have the experts in place.

It is a regulation and I think that is an improvement beyond a directive. I think that is crucial. I believe that there is a willingness on all parties to improve and that's very important and there is a timeframe which will possibly be four to five years before this comes into effect.

And I think that there are two key points that we have to deal with, and I run over time, first is to restore consumer and patient safety and confidence in the system, and to secure the industry's ability to innovate, and put products on the marketplace. So, on the point, if the rapporteur would elaborate on her key issue of concern, and perhaps the Commission could respond also, but this is important and it does need the time, chairman. Thank you.

14:24, 20 March

President: Thank you. Now, we have [names] Schnellhardt, Liese, Sousa, Rosbach… Those are all on the list. Holger Krahmer, please.

14:55, 20 March

Holger Krahmer (Germany, ALDE): Well, I don't want to repeat what has previously been said; it is almost impossible to deal with this very complicated piece of legislation in five Dagmar-minutes as you might say, someone pressed the fast-forward button, I think, and you have to listen then very carefully if you want to get the content. Now, at the end of the day what we are talking about is regulating the question of who, in authorization process for a medical product, who will be communicating with who, and who will be taking the decision. It is very very complicated and it is impossible to really get to the nutsballs(?) in two minutes. So let me just concentrate on the most important priorities, as far as I am concerned. I can support almost everything the rapporteur said, on definitions, for example, I think it is essential to make sure that we avoid a competition of notified bodies, to make sure that people don't just look at where things are cheapest and where the requirements are lowest. So, the Commission proposal there is a good way to achieve that. Now, every centralization decision we take, is one we should think twice about, because we have experience here. In the United States, for example, there is a centralized authorization process, which didn't stop the problems with hip implants. And so it is not just the case that centralizing authorizations will automatically lead to more product safety. So we need to ask ourselves the question as to how we can increase the quality of notified bodies. We also need to look at the question of whether all notified bodies should all do everything, or whether some should be allowed to specialize, for example, Class III medical products might need special requirements and we need to look into what is being implanted and used in the human body. So, I don't think what we are

talking about here is people putting their stamp on company documents. I think that's a bit old-fashioned, that approach. I think for the Class III products in particular, that we need to have real-life tests. And in car-glass approval, for example, you have that sort of system, and some products are not allowed on the market. Some cars are not allowed on the market, unless you have crash-tests. And I think we need the same sort of thing for medical products, too. And, you know, a plaster needs to be dealt with in a different way, a sticking plaster dealt with in a different way than a pacemaker. So, we need to remember that there are special requirements for certain products and I think, by way of conclusion, that pre-market authorization is not necessarily helpful. I think that we need to remember market supervision. There are certain products, where, even if you have pre-market authorization, you need to be able to react extremely quickly. So we can avoid a future hip-implant problem.

18:22, 20 March

President: Mrs Auken will now be speaking on behalf of mrs Rivasi.

Margrete Auken (Denmark, Group of the Greens, speaking English): Michèle Rivasi, who is our shadow, is not here, so I will just have a few remarks on her behalf. On my own, and I guess on her too, I will first of all thank our rapporteur. I have, we are in, as far as I could hear, we are in agreeance on almost everything and let me then just stress a few, not additional, but part of this here, which is important for us, that we and I quote from Michèle Rivasi, 'what is important for us, is on class III medical devices, which I don't have to define further, we want a pre-marketing authorization in order to avoid new she mentions a French scandal, the PIP'; I could mention some Danish scandals and we have our local stories on hips and so on. And on clinical investigation we want transparency, no secrets, that is one of the best guaranties. If we have smooth authorization procedures, we can prevent, you know, real bad handling, if we guarantee full transparency. Then it is, will be more safe that the control is in place. And public accessibility of course, to the data, not only to the summaries and always tell industry that if they are able to make a fair summary, they are also able to have, then they have the date. Because they cannot make a fair summary if they don't have the data. So that means it is not complicated to give access to the data, if they have done a proper work on the summary.

And then we also want, as mentioned, toxicological studies on implantable devices in order to avoid, what I now prefer to call hormone disrupters, because it is only the experts who know what endocrine disrupters are, so to make the public oblisation (?), I think we should swift into another good English word and much more common, hormone disrupters, yeah that's my ??. So that we have this in the CMA's controlled in this is substances. Yes. Thank you, mister chair.

21:02, 20 March

President: Thank you, Margrete Augen. Next is Anna Rosbach, she is replacing mrs Yannakoudakis.

21:15, 20 March

Anna Rosbach (Denmark, Europe of freedom and democracy Group /European Conservatives and Reformists Group (ECR)): Thank you very much. I am going to speak Danish, as I have the opportunity to do that.

Now, the Commission has come along with this proposal at the right time. Because, as other people have already said, there has been a whole range of scandals with breast and hip implants. And that means that the people have lost trust in this sort of thing, and we need to be seen to restore trust. And that's why we think, in our group, that the directive really needs to be approved and safety needs to be right into the center. We need to learn the lesson of the past and improve our monitoring and controls. And we need to make sure that we are inspecting, and keeping tests (?) on things without needing to be asked. And the notified bodies, this is also a very important point in the directive, because products with high levels of risk, need to be properly approved. Look at what is happening in Germany and elsewhere, there is a difference between an implant on the one hand and a pacemaker, for example. So, safety is top of the list.

And when it comes to re-use or recycling, we think that it is very important that liability and responsibility are clearly defined. And that's rather missing from the Commission proposal right now. It really ought to be possible to see how often things are re-used. And there needs to be transparency, and openness, so that there is proper traceability possible for these medical products. One way or another, you need to be able to trace any mistakes.

23:25, 20 March

President: Thank you. Mrs. Estrela is next.

23:30, 20 March

Edite Estrela (Portugal, Socialist Group in the European Parliament): Thank you very much, chairman. First of all, I would like to thank Dagmar for all of the work she has done; it is an excellent job of work. And it has been a very interesting debate; we have had various public hearings, which have also been very fruitful.

I am going to speak as the social and employment committee rapporteur, and I would like to talk about the user issues and medical devices are used in hospitals. And health workers, but there are other areas where this is used, for example in prisons. So, there are persons who are at risk through ill people and users they are health sick self the workers who use these type of devices, and also assistants, for example, laundry and cleaning personnel. Health and safety are issues which are mentioned throughout the proposal as fundamental objective, so which need to be reached. Now, I tried to link medical devices and the quality and safety thereof to having safer workplaces. So, that needs to link in to European legislation in effect on occupational health and safety. And that also has to link in on the framework on preventing injuries in hospitals, to avoid for example hospital infection spreading.

Now, the main aim of the report is for these devices to make sure that workplaces are as safe as possible.

25:50, 20 March

President: Thank you very much. Peter Liese is next.

25:55, 20 March

Peter Liese (German, EPP (Christen Democrats)): Thank you very much. I too would like to thank Dagmar Roth-Behrendt. This is indeed a very complicated topic and to present it, or present the outlines even in seven minutes was quite something. Now, I am the rapporteur on in vitro diagnostics and Dagmar Roth-Behrendt's report on medical products overlaps great deal with that and I would like to thank her for the talks we have already had.

Many of her ideas, I think, are very useful. Turning around the order of the chapters to make sure safety is priority number one and that the quality of the nominated authorities is improved as well is very important. I would like to thank mrs McGuinness, the shadow rapporteur from the EPP, who has said that we are not yet convinced, I am not sure we will be convinced that we really pre-market authorization, by way of state authorized bodies is really the right way forward. Now, mrs Roth-Behrendt talked about Class III, which is a very small sector, but it could be that products from Class IIa and b might be moved over to Class III as well, and then things become a bit more difficult. The question is: "will that work in the future?" Now, perhaps I could just add to what previous colleagues have already said. Now, in the pharmaceutical sector, we have a state-authorization system and that didn't stop scandals from taking place either. We talked about contraceptives, amongst other products, and these are scandals which, despite the fact we have state-authorization, were still possible, were not prevented. And so, I think that we should stick with the Commission's overall structure of the text and I, as rapporteur for the in-vitro diagnostics product, will say that in the future we should remember that the problem can apply after authorization. An authorizing body can also have the world pulled over their eyes and so I think, as H. Krahmer said, we need real-life tests. After the notification takes place, after authorization. We need to make sure that there are proper checks; not just the document being checked, but the product itself needs to be checked physically in the whole chain of its use. And that's an essential point that the Commission is proposing and we need to emphasize that.

28:34, 20 March

President: Thank you, Peter Liese. And now, Alda Sousa has the floor.

28:39, 20 March

Alda Sousa (Portugal, Confederal Group of the European United Left): Thank you very much. I would also like to take this opportunity, to congratulate Dagmar for an excellent job of work. This is something that has allowed us to participate in the way we did on the aid (?) and also today. Just a few comments on the issue.

First of all, the issue of safety, safety of persons who are ill. That is of capital importance. And this is not something that runs counter to innovation, but what we do need is legislation that on the one side will guarantee safety, and on the other hand, as mr Peter Liese has just said, should also allow for proper controls. We need to make sure that the conditions for health and safety, after authorization are being complied with. This has to happen also in the post-market phase; it is extremely important. I also feel that there are certain aspects in the Commission's proposal, for example those elements that have to do with the classification system, that could be reviewed. I think they could actually be made more consistent.

Also, it is very important to provide information to the public at large. People need information on the available medical devices, and this is something that really links into the issue of transparency, which is very important for this reason: the public needs to have access to information and this is of course of the most importance to health workers. Health workers need to be able to have the information to assess the devices in order to make recommendations on the use of medical devices. But a review of current literature is not enough. I think we need to have a full overview of the medical devices. We need to see which medical devices have been withdrawn from the market, which are still on the market, which ones function well, which ones do not. But I think we will need to continue, that's.

31:40, 20 March

President: Well, perhaps you weren't there when I mentioned this, but we have limited the speaking time to two minutes. Horst Schnellhardt, please.

31:46, 20 March

Horst Schnellhardt (Germany, EPP (Christen-democrats)): Thank you very much. Well, I am pleased that Dagmar is dealing with this; we are guaranteed that it is going to be a very good report and things are going to be delved with properly; it is a very complicated procedure and it is clear to see. But I would also like to support Peter Liese, who said that for certain products the product itself needs to be checked, without notification, without prior notification, that's an important point. Now, there is one point I would like to go into and that is the recycling of products. I have the feeling after many conversations I have had that there is not a lot of good order here. The manufacturers of medical products say that these products should only be used once, although it can be used several times. Because they of course want to increase their turn-over. Now, hospitals do carry out recycling and I think that here we should try to get a bit more good order in the processes that are used. And perhaps we ought to say that there are certain bodies who are allowed to carry out these kind of recycling. It should not necessarily be the end-user, because there are financial pressures which come into play here. So, I think we should tempt to set out a number of, a few rules here for good order.

Now, moving on to the question of fees. Now, I had the experience with food hygiene. We had similar wording here. But then countries got into problems, even in countries, even in one country, you had different levels of fees, between two places a hundred kilometers apart. So, we need to make sure that we are able to have access to what the Commission is planning here, if they are going to use delegated

acts. So, we need to make sure we don't end up with a chaotic situation with different levels of fees, as we dealt with with food hygiene.

34:00, 20 March

President: Thank you, mrs Parvanova is next.

34:05, 20 March

Antonyia Parvanova (Bulgaria, ALDE, speaking English): Thank you very much, President. I would like also to thank Dagmar for this presentation. This will be a difficult dossier and I should say that the leading on issue should be the safety issue. And we have to do the utmost to guarantee and to improve the proposals. I am very much in favour of the classification, and giving the fact that there are medical devices which are from, starting from tests, which may have a significant, as Peter Liese said (?), impact, based on how reliable they are and how much trust is based on them and what are the further medical implications for the patient. And coming to medical devices, like pacemakers, or those which are like insoles (?) etcetera. That is way I would support amendments which will improve the classification procedure and also, probably it is good to think for the D class, for those which might be dangerous for the patients and for their safety, to have pre, to have something like clinical trials or pre-test. This is absolutely necessary, and there have been number of tests of cases reported in which there are defective medical devices. There is no first of all traceability, but this defective medical devices, especially those which are for inter/intra corporal use, may cause further complications of the medical diagnosis, or may cause side-effects. And that is why it is necessary this cases to be reported and further actions to be taken. As to the case with the PIP it was a fraud. It was not something that was a problem of safety, but because of the fraud.

And then, also, I would like to point out that for the software, it might be necessary to consider whether the software should be covered by this proposal, and finally, as regards to the single-use or double-use; there is the tendency in the companies to put a lots of plugs and switches etcetera as single-use, or part of the device which is unreplaceable, which makes actually a lots of spendings on the national health insurance, without necessarily being important for the patient's safety, but making it unique, so that the medical devices are not replaceable or compatible. This probably also needs to be considered and switch and plugs etcetera not to be made unique, or irreversible. Thank you.

36:55, 20 March

President: Thank you, mr Cabrnoch.

37:04, 20 March

Milan Cabrnoch (Czech, ECR): Thank you very much, Chair. I think that I can support a lot of what has been said. This is a complex directive. It is very technical, and I think that it is vital to cooperate with experts who have experience in this field. I would also underline the safety issues, because this is one of the pivotal questions. Let me just add three more comments.

First, we should always have the subsidiarity in mind. Is it really effective to regulate this issue at the European level? We should also take into account specificities of individual Member States, which can be cultural and historical and so on. And we shouldn't change some very good method in some Member States. Then I have also questions regarding delegating powers to the Commissions. I think we should be really very cautious and this applies also to the other proposal on in-vitro diagnostic medical devices, because there are a lot of powers that are supposed to be delegated to the Commission. And let me also stress the importance of experience and of, we should also discuss these questions with practitioners, with people who have experience. And some practitioners are not sure whether state-bodies are ready to implement this new direction. I am afraid that in some cases the access to medical care…

39:04, 20 March

President: Rebecca Taylor, last but not least.

39:06, 20 March

Rebecca Taylor (United Kingdom, ALDE): Thank you, President, it's a brief point. I think that in relation to the discussion about pre-market approval or post-marketing surveillance, I think we need to consider whether the benefits gained in patient safety are enough to warrant the extra administration. And also, would we need to create a new agency, and would that be realistic, especially at time when actually we have been cutting, you know, reforming the staff regulations in the institutions. And I also would add a sort of note here, that the US regulatory approach classifies devices into three categories. The third category has three (?) which requires pre-market approval. But some devices which did not fitted into class three, the classic example being the metal-on-metal hip device, hip replacements, have turned out to present significant risks to patients. And I think the problem, that we need to, and is (?) why the post-market surveillance is really important, is that the risks associated with devices may not be identified and so they have been used for a number of years, so you have got enough clinical evidence and actual data on patient use. So, I think pre-market approval should be treated with some caution. Thank you.

40:20, 20 March

President: Thank you. The Commission. Head of unit, Sabine Lecrenier. You have the floor.

40:37, 20 March

Commission of health (Sabine Lecrenier, Belgian, speaking English): Yes, thank you very much, Chairman. Good morning, ladies and gentlemen, and good morning to mrs Roth-Behrendt. I would like to apologize for mrs Sabinas, who is indisposed, she is actually at an international forum and therefore cannot be here with you for this first exchange of views.

First of all, I would just like to recall the three guiding objectives that we used to draw up this proposal. The three objectives were to strengthen protection of health and safety, the well-functioning of the

internal market, and the support for innovation and competitiveness of the sector, which is an experiencing great changes. So, that was basically the underlying thesis for the document.

I would draw this distinction between questions that have to do with pre-market and post-market matters and then I would like to deal with the issue of transparency very specifically. Now, there are some points that have been mentioned on various occasions and that is the issue of reprocessing or reusing medical devices. In the text on medical devices, we have a definition of single-use devices. Now, of course, there seems to be contradiction in terms when you have the reprocessing of single-use devices, but basically this has to do with the manufacturer's intent. So, the manufacturer has put the device on the market with the intention of using it a single time. And so that basically has to do with the characteristic of the device. It may be dangerous to re-use it, or, perhaps, it may be because the manufacturer has not conducted the necessary studies to know how many times, and under which conditions a product may be re-used. Now, in the definitions, we also have a definition of critical devices, i.e. where there are surgical, invasive surgical procedures necessary. These are devices which in principal are excluded from reprocessing. And of course, so we base this on an independent scientific body's assessment, we have taken up the notion of the reprocessor, and that is linked in to the manufacturer, because he may change the initial objective of the manufacturer, so those who proceed to reprocessing are linked to the manufacturer and they should line up with all of the conditions enforced by the manufacturer. There is a specific clause which allows for an opt-out and therefore a ban on reprocessing or the marketing of reprocessed devices on their territory. So, we have implemented the scientific advice that we were given by the European Committee, and we have a system which allows for reprocessing, but under safe conditions.

And then a second point which was raised was that the notifying bodies. This is one of the weak points and we know that. So we point in the current system and so we have strengthened the organizations on various levels. So, we have strengthened the requirements are put on bodies which designate those bodies. Those are national authorities. We have an annex, which is dedicated to the criteria for these notifying bodies; they have to be impartial, independent, competent, and they have to have the right staff and procedures. And then those bodies can be subjected to joint (?) audits by Member State and Commission authorities and then the work of these bodies will be subjected in certain cases to controlled procedures. This is the scrutiny mechanism.

So, we feel that we have considerably strengthened the text and the controls and criteria that these bodies have to comply with. And of course we can go even further, but we believe that these bodies will work in an equivalent way and ensure a very high level of quality and independence. On fees, there is an article that will empower the Member States.

President: please conclude, all our colleagues are trying to keep it to the speaking time, please conclude.

Commission: And then the final point on classification rules. We have reviewed the rules and we have taken experiences into consideration and we have looked at international developments in this area as well. There is a rule that has to do with inhaled or ingested products, products that are introduced vaginally or anally, that is in the text, linking that with public health issues, because we feel that these problems do pose safety problems.

President: Thank you, that comes to an end. Greatshaw, director general who is new, perhaps it would have been good for him to appear to the European Parliament. We are legislators, we are not an

international conference, that shows the priorities of the Commission. So, the Committee chair extends greetings. The rapporteur.

47:31, 20 March

Dagmar Roth-Behrendt(German, S&D, speaking English): Thank you very much, mr President. I want to come, to get back to some of what the colleagues and shadow rapporteur said, and first I want to underline one thing, because mr Cabrnoch referred to that we should have expertise. I hope that you are listening to me at the moment. Mr Cabrnoch? No you are not listening? I am referring to you. Good.

It is naturally evident that everybody who is rapporteur, takes things serious and will have best expertise available. And I am sure you are aware that the Parliament organized one workshop, which took place three weeks ago, which was attended by roughly 180 experts and quite a huge amount of members and their assistants. And that I, my political group, organized a workshop yesterday, which was attended as well by roughly more than hundred people and member shadow rapporteurs and assistants and has been web streamed yesterday, visited by 700 people, all experts. So, you can be sure, no worry, that we take into account what doctors and experts say.

Having said that, I want to come immediately to some of the remarks from colleagues. Exactly, the committee of European doctors, as many others, insist on a prior authorization procedure for class III, for the high class products. I have to say that very clearly; the doctors, not only consumer organizations, but doctors all over the place, as specialists, as orthopedics, cardiologists and others, were always very clear, in the hearing and everywhere, they insist on a centralized procedure on class III products. Having said that, we are speaking about roughly 2% only of the whole market of medical devices. 2% and only novel products, so which comes no long (?) on the market, which would affect roughly 500 till 600 devices per year in class III, which is 2%. Having said that, yes, the Commission transferred with article 21 some products into class III. But I am very sorry, Sabine, it is ridiculous what you do there. And I am normally not as harsh, you know me, but there, I have to say, you were not aware, my suspicion is, you were not aware what you were doing there. Because that you take artificial ears, eardrops, and others into class III now from class II, that is simply not appropriate. And we agree, naturally, that if it is something is a pharmaceutical, it should not be in the medical device, but if something is not in the pharmaceutical world and cannot be a pharmaceutical, because it does not fulfill the demands and it doesn't have a physiological effect, like some laxatives, some other products, then we have to find another solution for that. But clearly, it is not the right thing to say that some biologicals, which only change the pH value in parts of the body, are class III. Together with a high-risk product! You must have seen that, that that is some, that that must be wrong. I will abolish your article 21, if you have concern that there are products in there which are pharmaceuticals, we open them the role (?) for the pharmaceutical line. But that is not the right way to approve. And then my amount of points. Because that was Peter Liese referring to quite rightly. He said take article 21 of the Commission. By a sudden we have a huge amount of products in class III. But honestly, that, we don't take artificial ear liquids, which has the same pH value than the liquid in my eye, which only helps my eye not to be dry, that is not a medical device in the future, class III. At the moment they are forced to be medical devices, because they don't have a physiological effect.

Coming to some of the bits Mairead McGuinness, and I am grateful for you to attend all the workshops and all the hearings, because I am very happy always when I see people and colleagues who follow it in the web stream, and so, because I, it gives me the feeling that we all have the same amount of

information there as well. I hear what you say on the pre-market authorization and how should it work. And isn't is better to have a strong post-market surveillance as well, like the Commission foresees it. Yes, we do have the real test, real-life test, as Holger Krahmer and others said that. Because when we speak implants, we will never have enough clinical data, and never enough clinical trial, so you will always have to follow in the real-life. But the real-life means in the patient! So, let's be honest, we partly use patients as guinea pigs. We have to accept that in some areas, but we need at the same time to have a balance with more clinical data. The real-life test only to look at, let's say, the implant outside of the body, again and again, that won't help us, because you wouldn't see anything else than at the beginning. So, we will have to do that. But again I have to say, we need for certain parts a better pre-market authorizational access procedure. You said, and others said, not all Competent Authorities have the competence of scrutiny, or the competence at all, and yes, you are right, and all of you are right. Some Member States drive back their financing of their Competent Authorities and their national authorities. That is a wrong way to go, because they as well have the national authorization procedure for pharmaceuticals. So, what happens in some of the Member States, like UK for example, like the Netherlands, like as well in Germany, is the wrong way to go. We have to say that. And it is not the way that they refinance themselves via EMA, as an act of desperance, because they are totally desperate. That's not the right thing to do and we have to, we have to look at it.

Again I have to say, the coming into force is foreseen for three years, so we are speaking about something which comes into effect out three years after we have decided on it. On the notified bodies, all of you referred to that. What I believe we all are clear about is if a notified body, about whatever class decides, we would want and demand in-house expertise. We cannot allow a notified body to decide on any medical product without medical expertise in-house. And to think that it is enough to outsource that and to get the reports back, but not having the in-house expertise even to check if that report is valuable yes or no, for sure is not the right approach. You perhaps will not have twenty physicians, medical doctors and pharmacologists in every notified bodies, in all of the eighty notified bodies of the European Union, but you will have at least have to have enough to be able to scrutinize what they get in as in-house expertise and there we have to be very clear. And yes, I agree with Holgar Krahmer and many others there, we should, we should not allow a competition between notified bodies, and yes, I would agree and would prefer if we would have clusters of excellence, and centers of excellence. That we would say: certain medical devices can only go to a national authority in the Netherlands, or in Poland, or in Estonia, because there is the center of excellence. But that is not foreseen, neither in the legislation, nor in the idea of the notified bodies.

One colleague said, ow, it is subsidiarity. No, it is not subsidiarity. We are speaking about products which are in the whole European market. And no, there is no cultural specialty in the Member State, because whatever is possibly a medical device, in Czech-Republic can be sold as well in Germany. And if there was a specialty only for the Czech-Republic, nevertheless the producer is allowed to sell it everywhere else. So we have to have the same safety standards that we have to be absolutely clear.

Concerning some bits what Margrete Augen and other said, yes, we need more transparency on clinical data and we need more clinical data. For that we probably need more clinical trials, and we have to strengthen the procedure; from the first second on, we have to have the registration and then we continue. At the moment it is a leave way for producers just to go for clinical trials and clinical data and then perhaps take their demand for the product back again.

And yes, we need controls and we need as well unannounced controls; all that is good. But it doesn't help us if we do not have the best expertise everywhere. Then Peter Liese referred again as well to the question: Is pre-market authorization the hail and solution for everything? No, it is not! But Peter Liese referred as well, and other do, to the national, to pharmaceuticals. And he referred that we have as well scandals after authorization procedure. But that was always a national authorization. Whatever you touch, if it was hormones, if it was Mediata, it was always a national procedure. So, it is more as an argument for me, that we will have a centralized procedure, honestly, I am afraid, I have to say. And yes, I agree with the real-life test, as well mrs Sousa, Alda Sousa said and others. Concerning what, and this is my last sentence Matthias, concerning, concerning, but we still have quite, we only use an hour now for more than half of that bit up till now, concerning the question of reprocessing and single and multiple use, that will be absolutely difficult to solve in a, in an appropriate way. Because it is like squaring a circle: from the logic, a single-use product is only used once, for one patient. That's what it is supposed to be. That is not the reality. So, we have to see what we want. Do we want to stick to a single-use as one patient, one product? And do we believe it is true and do we stand to that as well? Do we stand and say: yes, that can work for that inside of the heart, check of a heart patient who has to do that every two years, which costs thousand euro and which takes an hour, is then thrown away. Will we, do we believe that that is our reality? And the reality is it will not take place, whatever we do. We will make all hospitals illegal, I do not mind to do that, but the question is: Is that the right approach? If that is not the right approach, we have to see as well how to define single-use. Then people come and say: if you strengthen the single-use definition and then the producer fills in a piece of plastic to make sure it is not reprocessable. So we should be process, reprocessing and allowing to reprocess everything, which would mean we would not have any characterization and classification between single-use…. Uh?

President: Thank you for the last sentence…

Roth-Behrendt: Yeah. That last bit of the last sentence, Matthias, was that we need to decide amongst us, what do we really want? I want to have proper reprocessing, and I want to have proper standards of reprocessing, but the reprocessor has to be treated as a manufacturer, he has to be liable, but at the same time, we have to define, and we have to give that obligation to the producer, to define if there was something a single-use. You producer defined it single-use, why do you do that and what does it mean really? Does it mean it is not reprocessable? And we don't allow producers to qualify it single-use, only because they want to get rid of the liability in any other case. That is something where we have to work at and I don't have a solution for the perfect wording yet.

59:21, 20 March

President: Thank you for your last 150 sentences. Well, I know it is important to that sort of legislation. Mrs McGuinness, mention of order.

59:35, 20 March

McGuinness (EPP): I would ask the Commission to clarify, for my understanding, on unannounced checks. I understand that that exists currently in the directive, but has never been applied. What guarantees will we have if we revise this legislation and include this, that it will actually happen?

President: Commission, briefly please. One minute to answer the question, otherwise we are overrunning.

1:00:05, 20 March

Commission: Thank you, Chairman. This point is one clearly high-lighted in the PIP affair. PIP. Because the current legislation allows the notified body to make unannounced checks, but since this is not an obligation, in practice these checks very rarely take place. In the proposal we make it mandatory that these checks be conducted by the notified bodies at manufacturers without any warning. So, that would be regular checks, which are announced, because the manufacturer has to prepare documentation. But alongside that, there will also be unannounced checks, which will be conducted in businesses and during those checks, product samples may be removed for testing purposes.

1:01:13, 20 March

President: Thank you, well, that concludes the debate. A workshop was held on the 26th of February, organized by our policy department. A rarely seen great success; all participants were involved. It was very useful and interesting. The slightly negative note is, perhaps there weren't quite as many people as you would want, but the third of May is the deadline for amendments and the amendments will be dealt with on the 29th of May in the committee and the plans are that the 10th of June we will see the vote in the committee and plenary some stage thereafter. Thank you, one and all, for that brief debate. And we move on to the next agenda item, which is Peter Liese's report, and this report concerns in-vitro diagnostic medical devices. Please give us an introduction, mr Liese.

A.2 Debate 24/04/2013 in ENVI Committee

http://www.europarl.europa.eu/ep-live/en/committees/video?event=20130424-0900-COMMITTEE-ENVI

(English transcription)

Introduction President

02:44, 24 April

President: So we move straight on to point four, the medical devices report, Dagmar Roth-Behrendt's report, and we have set aside plenty of time for this, which we will probably need, of course. And then, following on from that, we have Peter Liese's text; his report on in-vitro diagnostic medical devices. And I think we should try and work and take those together, if there are no objections. So, perhaps I could hand the floor straight away to the rapporteur.

03:15, 24 April

Dagmar Roth-Behrendt (German, S&D, talking in English): Yes, thank you very much, mr Chairman. Now, if you would allow, and I do ask for the understanding of the colleagues and the interpreters, I am actually going to do this in English, because my colleague, Nikolas, and myself, have been working on the text in English.

As you know and as the shadows know, because we had already one shadow meeting, I do welcome the Commission proposal, because it is overdue (?) that we have a revision over this already twenty year old framework, and I believe it is a good starting point. Perhaps in the in-vitro part, perhaps even a better starting point than in my case for the medical devices. I believe that there are changes needed, and there should be changes introduced in the text. And I have to say in the beginning, before I go into the detail of some of the changes, more than innovation for the sake of innovation, which is not a sake in itself. I want to have quick access for patients, but I also want patient safety. And I have to underline, yes I do want quick access to the patients, because some of the companies mislead not only citizens, but as well members of Parliament by pretending that my proposal would prolong the market-access, which is a lie. I want to have quick access, but patient safety we all agree and I hope as well companies would agree and the industry would agree, is as important as that. And I want as well that medical devices, which will be placed on the EU market, have been sufficiently tried in real-life, and have proven to bring benefits to patients, and means real benefits to patients. And that should happen before the devices are sold as a true, so-called true innovation.

So, having said that as an introduction, I would propose some major changes, and I want to come to those changes, which are the main important part for me, just to be sure that I use my time sufficiently,

which you allow me to have, mr President. Let me perhaps start with the scope and the classification of devices, I, where I have tabled amendments 5, and 22 and 140. I want to ensure that there was no general exclusion of biologicals, I deleted the root 21, because there are devices, devices touched and tackled which are probably only devices which are like salt-solutions and others, and, and therefore the scope I believe we should just look at that.

Coming to the main point of the market authorization, amendment 67 and 79. At the moment, we have a simple notification system. I clearly believe that we have to make a distinction between devices and their different classes, and that we have to look differently on the access to the market. In all ways differently: on the safety before, on the trials before, on the clinical data before, the access to the market, and on the capacity, the competence of the body allowing access to the market. Having said that, I propose a system with a, in certain areas, with a centralized procedure and a decentralized procedure for for products. On the limited scope only class III devices, and all devices which are implantable also, I look at those. So we would at certain parts look at class IIb and class III, so products on a high-risk products or products implanted. I have proposed in 41a, article 41a new, centralized procedure at the medical agency in London, limited to some very innovative implantable devices, or innovative devices incorporating or administering medical substance, means combined with a medical substance. And I have proposed a decentralized procedure for the other non-innovative devices with the highest potential risks. So we would have a three, a three ways system: the normal notification system for everything like plasters and easy things. We would have a system of a decentralized and a centralized system. And that is an offer for myself, mr President and colleagues, but I truly believe that we have to change the system as it is now. If you are prepared to follow my line, or if we find in a compromise a different line, we have to make a distinction on the access to the market as we have it now. And when I come to the competences of notified body in a second, I will go into depth with that.

Now the the, some now would pretend that there are delays with my ideas. I have to say, there are very tight delays with the approval of medical devices at the moment. For my my proposal foresees, for the centralized procedure, less than nine months to bring something on the market. Perhaps, to give you an idea of the timing today, coming back to those lies put into public in a very, in a very provoking form, that poor patients would have to wait three years, which is irresponsible from certain medical companies or from certain roof organizations, I have to say, that belongs to that kind of lobbying which I really detest, because it is a absolute un.., commercial, badly done and misleading lobbying. To give you an idea about of the current time to market, under the current legislation: according to the Commission impact assessment and what the companies and notified bodies gave back to the Commission, the actual system at the moment takes between 2,5 and 4 months on average for class III. The new Commission proposal adds to that system, as it is at the moment, additional three months. With the scrutinizing procedure and others. So, we would end up roughly between 7 and 8 months. My proposal foresees on the market authorization, my proposal foresees, for the decentralized procedure, 7,5 months maximum and for the centralized procedure 9 months maximum. So, we are speaking about the same time for the decentralized procedure, and two months more, perhaps, maximum, for the centralized procedure. And you would agree, colleagues, that everybody who pretends something else is a liar. I have to say that as well, or somebody who is too stupid to read and to understand, which I hope companies are not when they cope with patients, because we hope they are responsible enough.

Having said that on the market access, the next part is, who is allowed to to speak about and to deal with market access. And we come to the notified bodies, the amendments 43 to 66 and 126 to 139,

Whatever we agree later on the market access of medical devices, we have to make sure that we have competence in those bodies working on the market access. That is an essential! You would not allow your bakery to make a, to make a notification of a hip! Neither would you want someone who is, who is responsible for the safety of your car to look for an implantable device. You would not want that! You would expect that somebody who is able to do that, has medical, in-house, experience. So, in my amendments, I ask for the notified bodies, that they have permanently, in-house competent personnel, and a more transparent and expertise in the clinical field. And at the same time, what they do at the moment notified bodies, they subcontract. But nobody knows where they subcontract to. And I say therefore we have to ensure that subcontracting occurs only in a limited amount of cases, and the lists with the subcontractors have to be published. And disclosed. So we want to know naturally whether a notified body is responsible. Have they done it alone or have they had a subcontractor and who was the subcontractor? Again, I say it as well that a notifying body applying another Member State, must be, it must be insured it is registered and informs (?) the national authority in its Member State. And, I want to ensure that fees charged by national authorities for national activities are comparable across Member States, now made public. At the moment, you can notify an implantable hip for thousand euro in the European Union, in a half day, and you can pay 50.000 euro and have nine months. You have all that spectrum. And you would agree with me that that is not what we can expect and accept! That that is not acceptable! And that is the reality. I do not invent that; I have proof for that and most of you know it as well, because there have been examples published as well. So that is my way to upgrading the quality of notified bodies, because they will play an important role in my system, my proposed system, in every system. And we have to make sure that the notified body, responsible for a medical device, has the right medical competence and pharmacological competence at the same time.

Finally, the last big part is the question of labelling of devices as single-use or reusable and then the reprocessing of devices. At the moment, we have single-use and multiple use. Single-use means a device is used in one patient, in one treatment, nothing, nothing else. But we know as well that that's, that those single-use products are very often expensive, and therefore re-used. We do not have a clear, strict demand on how they are reprocessed, if they are reprocessable, is it done correctly, who is doing it? The Commission kept, for me non-logical class of medical devices for single-use, and the Commission as well has no proper standards on the reprocessing. I have introduced some provisions. I introduced provisions to ensure that only devices labelled as reusable, can be reprocessed. To ensure that devices are all labelled as reusable as a rule, and, by derogation manufacturers still have the possibility to label them as single-use, if they really provide justification, based on sufficient scientific evidence, why that device is not re-usable. And to ensure the possibility for reprocessors, companies, or hospitals very often, it must be challengeable. Somebody must be able to challenge that definition of the manufacturer, the single-use label, and must be able to provide evidence, 'yes, I am able to reprocess a single-use device safely,' to make that system complete. And with that, I want to ensure that single-use is really only used when it is non-reprocessable, and everything else has to be reprocessed, and at the same time we have standards, best practice standards, for reprocessing. Those are, those are the main points.

I have then on clinical investigation important parts on amendments 25 to 29, 84 to 96 to make sure that performance also encompasses efficacy and benefit to the patient, becau, which is not included at the moment, as well as I take, ensure the approval of a the clinical investigation by an independent ethics committee, there I take those parts which I have tabled and others have tabled as well for the clinical trials.

On the vigilance and market entrance surveillance, amendments 97 and 102, I want to make sure that reporting to the electronic system includes date and place of incidence, and where available as well data and information on the patient and user, health care professional. That is that the health care professionals want us, because they say the failure of a medical device can be the failure of a medical device, but as well, it can, it could be as well a failure of the health care professional and therefore we need as well all those data included. Mr President, I now have been going through that very quickly, I know I have nevertheless spoken too long. You have recognized that I changed the order of the text significantly, in the amendments 110 to 119, which I had to do to make it coherent with my ideas. And I am very happy now to to to listen to colleagues and to the shadow rapporteurs.

16:08, 24 April

President: Yes, thank you very much. Thank you very much, mrs Roth-Behrendt. So, let's start now with the shadow rapporteur, Mairead McGuinness.

16:20, 24 April

Mairead McGuinness (Ireland, EPP(Christen Democrats)): Thank you, Chairman and thanks for our rapporteur for the clear outlining of her position. Could I, before I comment on some of the amendments, refer us back to February of last year, when the Commissioner, the then Commissioner outlined an action plan for medical devices. And I would like the Commission to update us, because we now are a year with that plan, it put in place by Competent Authorities and Member States. Do we have any results of what has happened on the ground in Member States? For example, Member States were asked to verify the designation of notified bodies, to ensure that they were designating all of the assessment of devices and technologies, corresponding to their expertise. Do we have any indication as to what is happening on the ground? On unannounced inspections? Do we know if this has happened in the last year? How many? And what have been the outcomes? The improving the function of the vigilance system, was it called-for, including the information on the adverse effects? So, I think the Commission might help us legislate better, if we knew what has actually happened in the last twelve months in this sector. I understand that there have been developments, but I would like to know what they are, and what the Commission has done to monitor –we hope- improvements in the system, because, I think we are all working here on the same objectives, to improve patient safety, to put innovative and novel medical devices on the market, and that they are safe for patients. So, there is no disagreement here in terms of objectives, but we may differ on the path we take to achieve those objectives.

So let me come now, Chairman, to some of the ideas which the rapporteur has put forward. The last time I was quite cautious, I said that I remained to be convinced about central authorization. And I am afraid that I have read very carefully, and I understand what the rapporteur is coming from on this, and I am not sure that the amendments will give us a better situation than we currently have. My view is, that if we strengthen, in equal measure, the notified bodies and the Competent Authorities, we should get a better result for the patients, and secondly for the industry. And I think that we need to focus particularly on what the Competent Authorities should do, and are not doing. And we should focus on

the expertise that Competent Authorities have, and indeed at the moment perhaps do not have. And I think that is a key part of how regulation of this industry can be improved. On the notifying bodies, I am a little concerned that the idea of having in-house experts is always better than having experts from outside. And I say that, because sometimes you need a movement of expertise, so that people are always upskilled, rather than having a flat level of expertise. So, I think that's not something that might work for the results we are trying to achieve. And we need to be careful on that particular issue; we certainly need experts in notified bodies! But we need to be cautious of just having experts that don't upskill, that would not be good.

On the issue of fees, I mean there are two levels of fees here: there are the fees charged by the notifying bodies to the industry, and then we need to look at how the Competent Authorities bill or charge fees for the work that they do. And again, it would be regrettable if there were shopping around for the lowest price, but on the other hand, we need to be careful that we don't have a situation where prices sky-rocked. So, again, on this issue, I think we need to be very cautious as to how we move, but certainly it needs to be addressed in this particular point.

When we come back to the authorization process, which I think is a key part of our rapporteur's proposal, in my view it complicates the system without giving us absolute clarity that it gives us a better system. And therefore I would suggest that in my amendments, I would be looking at strengthening the Commission proposal, so that we get the results that we all are hoping to achieve. And that involves, in my view, post-market surveillance has to be greatly strengthened, the role and operation of the notified bodies needs to be absolutely strengthened, and the Competent Authorities need to do now, what they are currently not doing. In the current legislation they are not implementing it, so if we are to add more, we need to make sure that they are now implementing what is currently on the table and that is why the Commission needs to tell us what is happening on that.

I move to the issue of single-use. I think we need to be very careful on this and I did read, with great detail, the rapporteur's proposal. And I am looking at this as a patient: if a manufacturer labels a product as single-use, and I am in the hospital bed, and I see the hospital rinsing it or deciding to re-use it, I think I am a bit concerned about that. So, the idea of everything is re-usable until you can prove otherwise, on the face of it makes sense, but on the other hand, I think we need to be careful how that might be implementable, both for the manufacturer and indeed what its impacts might for the health care system. We know it is happening. But I wonder are patients and patient groups fully aware and have they concerns around that? So, again, I think we would be proposing some other ideas around that particular issue.

On the order of the text, perhaps that is not as great an issue and there are some areas, where we can absolutely see agreement. So I summarize, chairman, by saying, because I see you with the gaffer (?) in your hand, we are on the same objectives, we have some differences on how we might achieve them, and perhaps, when we listen to comments of other colleagues, we may see some scope for compromise between us all. Thank you.

22:48, 24 April

President: Thank you very much. Holger Krahmer is the next speaker.

22:55, 24 April

Holger Krahmer (Germany, ALDE): Yes, thank you very much, Mr Chairman. I think that the rapporteur has done an excellent job. She has submitted an excellent draft report to us, which provides us with a very good working basis and we will be working in the right direction. I am quite sure that we are going to come up with compromise agreements on the most important points. I can agree with the previous speaker, I can follow most of the important proposals, I obviously only have three minutes, so I am going to be, it is going to be hard for me to go into all the details, especially in such a complex file. But I will to address one or two points.

When it comes to classification of products, there are one or two rules in the Commission's proposal, which I think are not clear enough and perhaps would create legal uncertainty in implementing this. So, rule 21, the rapporteur is deleting that, I can agree and as well 19, which refers to nanomaterials in risk-classification, but without any further differentiation, sort of dealing with them all as the same kind of thing. So, I think that would pose problems, there is the issue of costma (?) and burden, but I think I can support the proposals. I think if we want to increase requirements for the notified bodies, I agree with that. And in the report there are specific measurements, specific measures being proposed, which state that the notified bodies need the requisite expertise, when it comes to notifying certain devices. And I think it should be one of our main aims to have that stronger supervision and vigilance, surveillance on the market, of devices that are already on the market, so that we can have better information about adverse effects. Obviously, we are going to have to gather far more data, and set-up databases, well in the Member States, make sure we get this information and data from the Member States.

Mrs Roth-Behrendt knows that I am no friend of some of the ideas that she has in her report on centralized authorization. And I think I can agree with mrs McGuinness on this point. I think it is useful to make sure that we think these things are from the back forwards, if you will. What is going to guarantee greater patient safety at the end of the day? There is a Boston Consulting Group, or there are certain consulting groups, who have carried out recent studies, looking at devices which have been withdrawn. They compared the situation in the US and in Europe. In the US they have a centralized authorization system and the results of the study show that between the two markets, i.e. the American market and the European market, there is no difference. There are no significant differences when it comes to the frequency of medical devices, so and no more devices are withdrawn in Europe than in the US. And so, I think we have to give some critical thought to this particular issue, there I would imagine it should be possible to have some kind of compromise agreement, when it comes to the role of the medical device coordination group, that the Commission is suggesting in their proposal. We have to think about what kind of powers that group would have. But when it comes to the coordination group, I don't think they should have any powers when it comes to devices themselves; they should draft opinions, provide advice, but I think it would be perhaps, the group itself would be the right address, and I am coming to a close, would be the right address, the right body to take a look at powers relating to surveillance and authorization from notified bodies. We want to have expertise, greater expertise in the notified bodies. Obviously not every notified body should be able to do absolutely everything, especially in the case of these kind of devices.

In my final point, this whole debate about single-use or not. I think that I can agree with the rapporteur that when she says that it is illogical if you have provisions for the re-use of single-use devices. Single-use is single-use and they should not be reused or recycled or regenerated. But I think in practice, it

would not really be feasible or work, that, just to say that, and if you take a look at my own Member State, the information from Germany is that there are problems with regenerated, recycled products than with single-use products. So, I think we are going to have to give some careful thought to the kind of rules we draft here. Obviously, it is quite clear that we can't recycle, regenerate single-use devices, although it does sometimes happen in practice, and it is probably difficult to avoid. What is important, is to make sure that we have more stringent controls of those who do recycle such devices. But I think we are on the right path, we should be able to work towards compromises. I know there are certain controversial points, this sort of partial centralized authorization procedure, but I am quite sure we will be able to overcome all of that and come with good compromises. Thank you.

28:10, 24 April

President: Yes, thank you very much, mr Krahmer. Well, we will take the time you ran over from your speaking time on light-commercial vehicles. The next speaker, please.

28:24, 24 April

Michèle Rivasi (France, Group of the Greens): Yes, thank you very much, Chairman. I would also like to thank the rapporteur. Mrs Roth-Behrendt has proposed an improvement of the system, but at the same time conserving the deadlines for, which is important for placing devices on the market. I think transparency and information are important, control surveillance and governance.

First of all, if I could say something about transparency. One point I would like to make to the rapporteur is that we really ought (?) to take transparency a little further in the case of clinical trials. When it comes to transmitting data about clinical trials, then there is a directive on clinical trials, we have got regulation 10/94 that is applied. I think that we have to look at the interest of public health and obviously take careful stock of the results, the effects of the clinical trials.

Then we are going to be talking about the notified bodies for certification. They have to transmit the data, not only the results. And if they are to control and monitor the notified bodies, then obviously, and this is in the light of the studies that have been carried out, and have access to that information. And very often, there isn't access to that information. And when it comes to control inspection, how are we going to control all these notified bodies? So there are those who say: well, it is up to the Member States. But I am always somewhat afraid of a conflict of interest between the Member State and the authorization body in the Member State itself. I have discussed these issues with inspectors and I have been told that if some kind of alert or prior warning in a Member State, then obviously one has to go to the notified body to investigate. Not only where the approval authorization is been given, but also in the Member State where the alert has been announced. And then of course, the, when we are talking about control and supervision, you need information from the health personnel, from the users. And there has to be more information provided about EUDAMED, because we are talking about surveillance, about medical devices, but very often we see that patients don't provide information about side-effects or adverse effects about these devices.

Coming onto governance, well governance poses a major problem. The experts group, which is going to be set-up compared to the 27 mem, the expert group of 27 Member States into 28 Member States, this is a bit of, kind of a floating body. But if you look at the FDA, that level, they are responsible for pharmaceutical products, medicinal products, but also devices as well. And mrs Roth-Behrendt is saying that there should be authorization for placing on the market, and we have to focus specifically on class III, category 3, i.e. (?) innovative products, devices. But what is innovative? I think any implantable device, and active therapeutical device which is in direct contact with the circulatory system, nervous system, or the heart, and then implantable invasive devices, which used for aesthetic purposes, we should not forget those either, because we have seen the scandal in France on breast implants. So there is that aspect that we have to consider as well. So, we have to attach this to the EMA, that would provide us with a centralized structure… ow, I lost my thread. Yes, a centralized, but then also there are this medical devices which straggle different categories. But I think this only really concerns category 3, class III, more specifically. So, that is something we have to have a clearer definition of, i.e./aye (?) innovative. So, the centralized, well yes. You have got I, II, IIa… Well that could be decentralized, when it comes to the authorization, but if you implant a medical device into the body and there is no authorization for placing this on the market under that class, then I think that is taking an enormous risk. And chemical products, and anything that is NCMR (Non-Conforming Material Report?), endocrine disrupter, carcinogenic, mutagenic, we have to add those as well, because we have to rule those out. They should not be in a medical device. Thank you.

32:58, 24 April

President: And then, to represent mrs Udakis, mr Cabrnoch.

33:11, 24 April

Milan Cabrnoch (Czech, ECR): Thank you, mr Chairman and dear colleagues. First of all, I would like to apologize on behalf of my colleague, she is unable to attend this morning and I will speak on her behalf this morning.

We are looking at this text together with the IVD medical devices text. But there are significant differences, here.

Now of course, this regulation gives us a wider scope of measures that can be used than a directive. But the thing we should be focusing on is treatment and patient safety. On the other hand, we also need to look at healthcare systems and how they are being made accessible to patients.

Moreover, access to medical devices should not hamper access to medical care for patients. And we have to make sure this is not going to lead to non-effective, or inefficient structure. There are a number of mechanisms in place. We have the conformity assessment, for example, that is been issued by notified bodies.

I think looking at everything at the same point in time could be counterproductive. If we double check, or if we want to double check, and are going to double check all the information provided, we will be able to achieve an added value.

On mobile institutions, for example when we look at devices used to measure patient's blood pressure, this could be linked, for example this could be connected to a telephone. So is this really a medical device or not? And the same holds true for software. Is software an essential part of a medical device, or not?

I have been working as a pediatrician for nine years in intensive care, and on these single-use medical devices. Well, let's have a look at what things look like in practice: I think it would be inappropriate to leave everything to the manufacturer, and to leave it up to the manufacturer to decide what medical devices should be single-use or should be understood to be single-use or not. Personally speaking, I think it would be better to look at reprocessing. I have experienced this on regular basis, where tubes for example were being washed or cleaned by the nurse, but at the time that was the only possibility we had.

37:35, 24 April

Alda Sousa (Portugal, Confederal Group of the European United Left): Thanks, mr Chairman. First of all, let me compliment Dagmar Roth-Behrendt for her tremendous job on this issue. It's very complicated, very tricky, but it's an area where we indeed need to revise the existing legislation. And Dagmar, I think, has come up with something that improves the initial Commission proposal in a logical and sensible way. I think that, when we have the debate possibilities, we will be able to deal in more detail into some of the aspects. I also like to say how pleased I am that we have got the pre-marketing authorization aspect addressed here, too. Clinical research and clinical tests, which could be used to provide data as to the usefulness and safety of medical equipment as well as of course moral and ethical aspects too. And ethical, moral opinions that's significant as well.

The notifying bodies is a very complicated issue too. I think that, when it comes to high-risk equipment, or experimental or innovative equipment, it's important that a more centralized body carry out authorization procedures. This has to of course be linked with Member States and the bodies that are already established for the certification of medical equipment. It's important, I think, where there are some products, endocrine disrupters, for example. We have just had a report on endocrine disrupters in the Parliament. And it is important that for things like that, we are very careful when it comes to legislating on such dangerous products. And there would (?) be a red line when it comes to the use of such products in medical devices.

Finally, I would like to say a few words about single-use or re-use of equipment. Generally speaking, I agree with the criteria put forward by mrs Roth-Behrendt. But I think one or two aspects are still slightly problematic. Obviously, the patients won't see it in the labels on the products, but the medical professionals will. And I think that we have to be a bit concerned, when we are legislating for the European Union area to make sure that single-use products are single-use for everybody and that they wouldn't be send to other parts of the world, third countries and be re-used there. But I think we already laid the foundation for some very good work here, thank to mrs Roth-Behrendt and I am sure that we come up with a good final result. Thank you, mr Chairman.

41:43, 24 April

President: Thank you. We will now take comments from colleagues. And that means we will have to shorten the speaking time to two minutes, because otherwise we will be running out of time, because we will also have to discuss Peter Liese's report and listen to the Commission. Next up is Zofija Mazej Kukovic.

42:10, 24 April

Zofija Mazej Kukovic (Slovenia, EPP (Christian Democrats), speaking in English): Thank you, President. And thank you to our rapporteur, because we really need a better system for medical devices. And from my experience, the first problem by medical devices is transparency. Transparency and very different approach in different Member States. And because of that, I think that we have to build also here some kind of internal market, because we are talking by other topics about internal market, but, I am sure that by medical devices it could be a big, a big challenge. And then of course the access to the market. By centralized authorization, my question is: reasonable, reasonable time for the whole process. Because it is always the question of time. It is always the question of when the patient could, could have this medical devices. And, the second question is: where, where could be such of number of expert? And the last the question of real implementation, on a real time, we could say. So, my feeling is that we need some improvements. We need some sticking point, also. Some European sticking point. But it's, it is still a question of such of centralized authorization, for me. Thank you.

44:14, 24 April

President: Thank you very much. Next: mrs Parvanova.

44:22, 24 April

Antonyia Parvanova (Bulgaria, ALDE, speaking English): Thank you very much. I would like also to congratulate the rapporteur, because all her considerations are focused on the patient safety and I welcome very much such approach. Directly on the very sensitive matter on the pre, on the centralized pre-market assessment. First of all, probably, to avoid flooding of the centralized procedure with lots of products, it might be necessary to specify class 3+ criteria and to exclude some of the class III devices which might not be necessary to put on the centralized procedure.

Then, a concern I have is that most of the notified bodies do not have in-house qualified staff and the competences, nor the qualifications to evaluate the clinical data is required in the new Commission proposal. And they have, they don't have sufficient expertise to check the quality, especially of the clinical evaluations they could potentially commission to external subcontractors, as suggested by some stakeholders. The example of United States FDA has been many times mentioned, and I should say that there is big list of devices, which have not been allowed and approved by the FDA, but at the same time, later on, they have been withdrawn from the European market, because of serious problems. And also it is important to mention that FDA has a mandate to protect and promote public health, while the

notified bodies do not have such a mandate, and even the Commission is proposing to set-up medical devices coordination groups, that, their opinion is not binding and that is why it could not improve patient safety. And the central approval should cover also limited number of devices, but probably class III, implants and devices incorporated substances, considered to be medicinal product. As I said, probably plus some criteria will help.

As regard to the single-use. Probably, it will be necessary to have a specified labelling, because labelled as a single-use creates some confusions and I would suggest that one day we regulate this by a separate piece of legislation. Anyway, we should not compromise with the safety, and also the liability may cause…

46:52, 24 April

President: Thank you very much, Corinne Lepage.

46:57, 24 April

Corinne Lepage (France, ALDE): Thank you, mr Chairman. And thank you to the rapporteur for this report. This discussion is taking place at a point in time where in France we have Jean-Claude Marsse (?), the founder of that company. Now, when it comes to the PIP breast implants, the FDA actually refused at the accreditation in 2000, because it was not in line with their standards. In 2005, they arrived in the UK, in 2007 in France. Now, looking at the text as proposed, would it be possible to avoid this, a similar case? We are looking at making stakeholders responsible. But, mr Chairman, and dear colleagues, as we have seen, if we don't have effective controls and no sanctions in place, will this legislation, the best possible letters (?) for text in the world cannot do all that much. We have to keep the market competitive, but we will also have to make sure patients are safe and the system can be trusted. The breast implant case has also shown a number of market surveillance issues. And here the text isn't going far enough. Manufacturers have to be inspected in a neutral way, both on their methodology and on quality.

Once a product is being notified and marketed over the internet, check-ups must be carried out. PIP should be a warning system. Looking at the Telegraph and the British medical journals' reports, they provide us with important information. Looking at mr Krahmer's suggest, I do not agree with his proposal. I think this would lead us down a very dangerous path.

49:26, 24 April

President: Peter Liese is next.

49:29, 24 April

Peter Liese (German, EPP (Christen Democrats)): Thank you, mr Chairman. I would like to thank mrs Roth-Behrendt for her work. But I would also like to thank Mac McGuinness, who has made a number of

comments on behalf of the EPP, which I can agree with. We have to protect patients, and I think we agree on a number of things, and I am sure mrs Roth-Behrendt's anti (?) will come up with a number of similar suggestions, looking at both our reports. Her proposal to change the order of the text makes a lot of sense, and I will try and adopt a similar strategy.

I think we also need to do more about notified bodies, whether we are going to use the current wording or maybe a different wording, we have to see, but we should be more specific on this in this text.

Single-use as a rule, should we be introducing that? And the wording on nanoparticles that mr Krahmer has mentioned. I am slightly more critical when it comes to this. I do share the position of Mad McGuinness and many other colleagues, that we shouldn't have a centralized system. Innovation, in this case, is happening faster on European markets than on other markets, say for example the US. And we have scandals not just for medical devices, but also for medical products looking at current contraception scandals, for example. But I don't think we can get the EMA involved to the extent that mrs Dagmar Roth-Behrendt is planning for. We need a longer transition period, longer than three years and I therefore am not convinced this is the right way forward. Thank you.

51:42, 24 April

President: Mr. Schnellhardt.

51:47, 24 April

Horst Schnellhardt (Germany, EPP (Christen-democrats)): Thank you, chairman. Ladies and gentlemen, our rapporteur has presented us with a good report as per usual. I would like to focus on a number of points; when it comes to the order of chapters, well, okay, we can do this or not. I don't think this is going to benefit the text all that much, but in our last discussion I already mentioned the following: in practice, manufacturers only want single-use. For example, when they manufacture some of these devices, they do that with the single-use in mind. And we need to find a system here. I don't know what that system should look like, personally speaking, I am in favor of reprocessing, but of course, it's a very different methodology. And there are standards that can be used in order to reprocess these devices. Should we leave that up to hospitals, or medical institutions, or should there be a specific institutions in charge of this? Perhaps that would be a better solution. But not leaving it up to the manufacturer. To this, on this system change, I am slightly more skeptical. I don't know if this will be a good step forward. Perhaps we should have a separate accreditation or approval procedure for specific medical devices instead.

And when it comes to the fees, I think what we have in the text at the moment can be a supported. Now, for control, I think we should be stricter. And we should have more flexibility, so you have unannounced inspection visits, for example. And then, we have to make sure that in all Member States this flexibility should be in place, and I think that will prevent scandals. So, these unannounced inspection visits, I think are very important. And setting up a body that actually controls the controlling authorities, perhaps that would be a step forward as well.

54:33, 24 April

President: Thank you very much, that brings me to the end of the speakers' list. I welcome mrs ?new who is joining us this morning. Mrs Lecrenier was your substitute last time, but I would like to welcome you here today, so you have the floor.

54:59, 24 April

Commission (speaking English): Thank you very much, mr Chairman. Thank you honorable members, for today's opportunity to hear your views. Vital for the European Commission. I want to, since this is my first time here, just to clarify, that I come with a very clear mandate from by political boss. That, yes indeed, this is a proposal that we revamp, exactly because patient safety was in our head. So, there I think we all agree and I am grateful that this has been the theme under which all the proposals have been made. So, it is with this in mind that we have made our proposal, and with the lessons learned, not least from the scandal on the PIP, that is the elephant in the room always, and I am grateful that in fact the question has been asked on where we are with the action plan that the Commission has proposed last year. But I will leave that, chairman if you allow me, this information for the end, if I have time, otherwise I am sure you will allow me the extra time that may be necessary; I am happy to inform you about that.

On the topics raised. Of course, the market authorization is the issue, and, all the work that we have done in our proposal was with one issue in mind: how to increase and strengthen patient safety through the process? I think we have discussed already before in this House, with the opportunity of the rapporteur, who we are grateful to have organized very useful workshops, what the philosophy of our proposal has been. And I think there our impact assessment was also clear, in that what we propose, was also aimed at increasing patient safety, and that the system of a centralized pre-market authorization would not necessarily increase that aspect and that is clear in the Commission's impact assessment, and I think I don't need to repeat what is in there. So, it is about patient safety, it is not just about the competitiveness of the sector, which is equally important of course, but I think that there we depart largely form the philosophy. We understand the thinking of the rapporteur, we are very sensitive to the issues raised, but I think we can work on other aspects of the proposal, to increase the safety aspects, because there again the scrutiny that we have introduced, was exactly aimed at that. And if it works well, it should bear the desired results for everybody who aims for more patient safety.

When it comes to the reprocessing issue, we understand the concerns that are raised and in fact a lot of the ideas that are raised, they are very logic. But, as some members also said, it is also about the feasibility. If we are going to go for specific labelling, if we are going to go for single-use or intendancy use (?), all these ideas merit attention. But again, we should make sure that the solution is feasible and implementable.

On rule 21, I think there we are happy to provide further clarifications. Our aim is not to go for products that present no risks. Here again, we are talking about products that are in specific categories, very well-defined, where we need to make sure we increased the safety and that is why they are classified in that way.

On clinical investigations, again this House has had a lot of discussions of that on the parallel negotiations on clinical trials, the Commission is happy to reinforce that, we take into account the point on ethics committee, but obviously there will need to be an alignment with what is going on in the clinical trials proposal.

When it comes to the notified bodies. Yes, we must make sure the right people are in charge, and we take the point of the need for transparency. That is correct and when it comes to fees, we also understand the points made, on the need to provide more information. The same for vigilance and market surveillance. Again for us this is key for the implementation of the legislation and again there I think, we can consider as acceptable a lot of the points that have been made. They are going to the sense of our proposal and would be happy to adjust and increase the elements of the information that needs to be provided in that respect.

On the order of the chapters, I think that this is up to this committee to decide if it is more logic to follow another way. And again, I don't think this would go against the core of the proposal, so again, we welcome any improvement that can be made on how logic this text reads.

Now, when it comes to what has happened since last year, as you know, and I think that also answers some of the questions that have been raised here today. When we had the PIP scandal, because this was a scandal, it was a, it was a fraud, it was pure fraud, we did a stress test to see whether the proposals that we have tabled, would have, in fact, addressed the problem. Would we have saved the situation had we applied this legislation already back then? And that stress test was positive. And I think there we need to be reassured and it was already in the announcement of the Commission when we revent (?) the legislation that we have taken into account, what happened with the PIP and our hope is that there will not be another PIP once this legislation is in place.

Moreover, since last year, we have taken all this tests necessary that we have promised; there have been joined audits already by the Commission's food and veterinary office that has been added actually, that has added to its mandate the possibility to audit nationally. We have done already four countries and I think there are more that will come very soon. When it comes to strengthening the criteria for notified bodies, to be made by, to be verified by notified bodies and the criteria to be made for the designation of notified bodies, we have prepared a letter with measures and I think we should be the couple of months or so ready to announce them. In fact, so that I respect the time, we are preparing currently a document that should be ready hopefully by this summer. That outlines everything we have done to respect the action plan. So this action plan has not been forgotten; it is work that we carry out parallel with the work we do on the proposals. We would be happy to come and even present it to you, if you think that is necessary, we should be ready, but our assessment is that 60 to 70 percent of that action plan has already been delivered. And I am happy to answer any other questions.

01:01:43, 24 April

President: Thank you. So, Dagmar Roth-Behrendt, over to you, then.

01:01:48, 24 April

Dagmar Roth-Behrendt (German, S&D, talking in English): I can't react naturally to everything has been said. Let me please group to some of the main points. Perhaps access to the market. Because that was as well what my colleague mrs Mazej (?) and others put forward. I want to underline one thing again. I want to underline the timing. The actual timing at the moment, from the impact assessment from the Commission, takes up till four months for a product on the market. The Commission with a new proposal, they propose, add another three months, so we end up to have seven months for the time being coming on the market. My proposal, with clear dates, so it is countable, it is not invented, foresees, for the centralized procedure, for those which would be in in in the national authorities, would foresee around seven months and for the de (?) centralized, for the national procedure, decentralized procedure seven months, and for the centralized procedure nine months. So, we are speaking actually about the same times, to be very clear. There is no delay in access to the market. So, to be very clear again about that. So whoever pretends that it takes three years is simply not saying the truth, and should not mislead neither patient organizations or patients nor us. Everybody who is from the Social Security Company or social security organization or everybody else, knows that. So, that is really bad quality lobbying from that roof organization, I have to say.

Then coming to the question of centralized or decentralized. A lot of you have addressed that. Antonia has addressed it, nearly everybody. We have to make very clear that we speak, in my project, where I addressed naturally everything which is implanted, as miss Rivasi referred to, or all class III products. We speak about 20% of all products. That is a very small amount. 20% of everything is on the mark, of what is on the market. That we have to be really aware. I think it was Peter Liese who referred to perhaps a possible class III plus, and to just, to have a difference there. I don't mind to look how we can define it, but I believe personally, for everything which is implanted, and which stays in the body, and for everything which is connected with an active ingredient, with a pharmacological substance, that has to undergo a very similar procedure than a pharmaceutical. It is connected with your body, imagine that. It should deliver a pharmaceutical where you have to be safe that it does that. If it is heparin whose (?) in the blood to protect against thrombosis, or if it is insulin or whatever, you have to be sure that that devices functions properly. And there it is the distinction we have to make. If we have a centralized procedure, or a decentralized procedure, with a national authority, with EMA, or if we have an upgraded, different procedure, that is not my main point. My main point is that we have to differentiate between a plaster, and an injection needle, and a hip implant or an insulin pump or an insulin implant. That is something else and every, the simplest person in the world would understand that. That the procedure we have now, is wrong. Is deeply wrong.

Having said that, when we look at the notified bodies, yes, I agree, we have to upgrade them. I don't mind how we do that. But if we do not insist in in-house expertise, we always, always rely on their subcontractors. How do you want to know that they are good? You do not have any control on that. The national authorities have control on the notified bodies, but they do not on the subcontractors. That is a clear possibility for failure. That is a recipe for disaster. What, where do we know this subcontractors have their knowledge from? How would you, how would you dare to notify something where you do not have either a physician, a medical doctor, a pharmacologist in there? How could you imagine that somebody authorizes, or prepares the authorization for a product which stays in the body, who has no idea of the medical function of it, and what the body, how the body could react. That is not acceptable. And it is not acceptable that a notified body is nothing else but an umbrella and then gives it to

whatever a variety of people. And I must say, colleagues, I am a little surprised, how much many of you referred to controls and post-market surveillance. Yes, that is important. But who is doing the post-market surveillance? And who is doing the post-market control? That is done by the national authorities! By the state! And who is paying for that? We all are paying for that! We are paying for something, which should not be necessary, if the market access is done properly. You have much less problems with control, if you have an access to the market which is perfectly done. And that is the place where we really have to refer to.

On the question of single-use and multiple-use. I personally do not care how we deal with it. But at the moment, it is, we know that the product is labelled single-use, and it is reprocessed an uncountable amount of times. That that is not correct. And the naivest person should understand as well. Mr Cabrnoch was nice enough to say it has been washed by the nurses. Yes! That is, we have no idea how products are reprocessed. Nobody has that! Everybody who pretends that you have an idea about how an endoscopic instrument with a little camera used for an endoscopic research of your stomach, which is supposed to be used only on one patient on one treatment, which is not. But you, miss Class (?), me, nobody has an idea if that product is reused. You don't know it. And how often is this re-used. And you can only pray to whoever that the reprocessing has been done properly, because the infection otherwise you get, and you will never be able to prove where you got that infection from, you don't know if you survive it or how you can treat it. Why do we look for so many hospital infections? Why do we look urgently for new antibiotics, which are not misused in the meantime? And colleagues, we cannot let that opportunity go now. How we..? For me, I am a very simple person. If something is single-use, for me I understand it is single-use. And some colleagues said, we should not leave it to the manufacturer. Okay, fine, but who should then define it? The poor Commission? Us? The manufacturer is the one to say and to prove why it is single-use, why it is not reprocessable. Now, I am not naïve, I know that that is still a way of printing money, and I am sorry, I should not be so direct, and I know that that is a possibility for a manufacturer to pretend that it is single-use. That is why I open it up and why I say: whoever is able to prove that it is reprocessable, every hospital, every reprocessing company, can do so. And then, it is not single-use from that day onwards. Then it is not allowed to be labelled single-use anymore. Again, we can naturally say: we don't label anything, but it does not, there is no value in it. You have to understand. If at the moment it is labelled single-use and it is not single-use, it is re-used. Where is the value? There is no value. And we need a system, which system ever, if you find a better system, I am happy to take that, but we need to know what is not allowed to be reprocessed, and no means never, and what is reprocessable and then we need best standards for reprocessing. That is, and I have to apologize, those are only very little bits I could come back and yes, mrs Mazej is totally right, transparency is a key part in it. I want just to say one bit to mrs Lepage and others who referred, miss Rivasi naturally as well, on the PIP scandal. We can always have scandals. Criminal energy, because that was criminal, criminal energy can always occur. You will, even If you have thousands of inspectors, those people from the, whatever people from the food and vet office qualifies them to make audits on medical devices, I have no idea, but that is something the Commission will explain at another stage to us. But what we have to make sure is that we pre-market surveillance, and the clinical trials are so good, and it is so clear that we close loopholes as well and then, again, post-market authorization yes, post-market surveillance, yes, but please, who pays for it? I do not want that the state and the Member States and the tax payers pay for something where, what is on the responsibility of the producer.

1:10:56, 24 April

President: Thank you. This brings us to close. The deadline for amendments is the 13th of May. We will discuss these proposals here on the 29th of May, and there is going to be a vote in the ENVI committee on the 10th of July. And then in September, we will discuss the report in plenary. This brings us to the next item on our agenda, or the second part of this agenda-item, which is Peter Liese's report.

A.3 Debate 29/05/2013 in ENVI Committee

http://www.europarl.europa.eu/ep-live/en/committees/video?event=20130529-0900-COMMITTEE-ENVI

(English transcription)

Introduction President

04:30, 29 May

President: Brings us to the next item on the agenda: medical devices. Mrs Roth-Behrendt is the rapporteur and she is responsible for that and that's why she has got us so many papers with her, all the various amendments and so on. But the next one is 6, the Liese report. We have got a bit of additional time, so we can take the two points together.

04:56, 29 May

Dagmar Roth-Behrendt (German, S&D, talking in English): That is not really my fault that you have so much paper around you, because my amendments are very small and modest 145 amendments, which is not too much, but we face 760 amendments from colleagues on that report, which shows how important it is. We just had a shadow meeting from eight o'clock onwards up till now, and I very much appreciate that all the shadow rapporteurs were there, it is not necessarily the best time of the day to do that, so that was even the better. That means that they will now… more or less two are there, Alda is there already, Mairead is there; but the rest will, I guess will make their way from the other part of the building over here then.

What I want you to, to, where I want to refer to quickly only is that we do have three very contentious items which I mentioned last time, and that is featured as well by the amount of the amendments. And those areas, that is, the question of the market access of a medical device. You know that I have foreseen in my text a centralized and decentralized market authorization procedure. That is in line with some of my colleagues, who support that, others do not. We now have to see what compromise can we find, as well together with the Commission, to make sure that patient safety is the highest impact and that only medical devices get on the market which are safe and which are prudently looked at. You know that on medical devices not only clinical data are more difficult to get, but as well the traceability and long-term studies are more difficult, because the device very often is implanted, so we have to be there very prudent. We look at, and I looked at that as well, to make a distinction in medical devices which are, let's say innovative, or which are in class III. Some of my colleagues even include class IIb. These are devices which stay in the body, which are implanted, or devices which are connected with an active ingredient, which dispends a pharmaceutical, or devices for example which are not implanted, but

are perhaps injecting or giving dispensing as well, outside from the body, a a active ingredient. So, we will have to look at that, mr President, and I hope that we find a compromise. I am not sure at the moment, because we have everything, from even sharpening my line, in different political groups, and we have everything from keeping the system as it is at the moment. But I am optimistic that we at least make a very hard try to get an agreement, as well together with the Commission there on that part. And we plan to do that in a very short timetable. We agreed today that on a technical level all the colleagues working on that will meet very soon at the end of this week, beginning of next week perhaps even, so that there might even be the possibility for next shadow meeting on next Wednesday.

Mr President, the other two items where I want to refer to is reprocessing, there we have as well 25 amendments, on pages 50 till 63, which is a significant problem as well. The Commission has foreseen that everything which is reprocessed, the reprocessor is treated as a manufacturer and takes over the liability, that does not leave room, that does not explain why still we have single-use products which are labelled as single-use, but where everybody obviously sees, in fact it is totally normal, that they are reprocessed. There we have to make a distinction. Is single-use really single-use, and if not, why is it labelled then single-use? In my amendments, as I told you already last time, I tried to strengthen that, and tried to bring a little bit of clarity into that jungle, by increasing the obligation for the manufacturer to define why it is single-use, and at the same time not allowing single-use as long as it is not proven that it is safely possible, and then that has to be done and authorized by the standing committee in the Commission and then the producer/manufacturer is not allowed to label it single-use any longer. We have different parts and different amendments from not only the, one shadow, but as well many amendments from others as well, going into all directions, for like defining it intended single-use, some of them which I do not, really do not understand. Some strengthening as well, as well the applications for example for hospitals and others. So, we have, we have everything there possible; setting up a list for devices unsuitable for reprocessing from one colleague, so that is where we will focus as well on specially.

And, and then, finally, we have the whole area of the notified bodies. There as well we have several amendments from amendment 481 till amendment 533, on page 18 till 49 on your books, they are all shadow rapporteurs' tabled amendments, and only shadow rapporteurs tabled amendments on that. There as well, we have different, different attitudes. We, we agree today, and I think that is at least the line we can, we can find a common line, that notified bodies should be looked at a little bit, with a little bit more caution. Not necessarily my approach all over the place, but I still believe that naturally the the quality of the notified body, or the conditions for being a notified body will differ significantly with the task we give them. If they are still allowed to notify all classes, that makes a totally different obligation on them, as if they would only notify class I and IIa. So, we have still to be a little flexible in finding compromises there, which I am deeply convinced we could. My ideal world still would be that if there is no centralized or decentralized authorization, which I hope we get, but if we do not get it, and if we do not all agree on it, we really would have to strengthen the quality of notified bodies, and I insist that whoever is a notified body has to have in-house staff. It means in-house physical doctor, medical doctor, in-house pharmacologist, in-house medical engineers. And I do not allow the current (?) situation that you could continue to outsource to a totally unclear situation of different sources of wisdom. So, if we want to restrict the possibility of outsourcing the notification process, or the knowledge for that, and at the same time, if it is still possible to out-source, and we still allow it, it has to be very clear what the outsourced body has on competence. So, that has to be more transparent, as we, as I tabled it as well.

And some of the amendments are close to that. The scrutiny mechanism is important for many of us. Many of my colleagues tabled amendments on the scrutiny mechanism as well, as well on notified bodies.

That is now, mr President, only is reflecting situation of, of three bigger parts, but the most contentious parts. On the reprocessing, on the access to the market, scrutiny mechanism and the market authorization and the notified bodies. I hope, I deeply hope that we can find compromises, needs compromises amongst all of us. I am prepared to do that, in good faith, but I have to say at the same time, we have an obligation to improve patient safety, we have an obligation which not only medical doctors oblige us to, but as well patient organizations expect us to and that gives at least on the question of the evaluation, the amount of clinical data necessary, the amount of clinical trials on that necessary, the the mechanism of the market access, of what quality ever that is, there the room for compromises is limited, so we we have to see that we go good together. I know, and I discussed it with the Commission as well, that if we would change the Commission proposal on the market access in some way, we could have the Commission on our side. Perhaps not as far as I was prepared to go, but perhaps on a compromise level, which I am would be happy to hear from the Commission as well, if you could tell us, you could imagine, in some part a different market access procedure for, for class III, or perhaps even class IIb medical devices.

Mr President, that is a very strange situation that you don't call me off, so I, I am very grateful for your generosity, and I now want to listen as well to the Commission and to my colleagues, please. Thank you very much.

15:15, 29 May

President: Well, that is not the first time that that will happen. We will have to take that risk and we have caught up a little bit with the next report. So we will be able to carry on talking about that, but we do need to take care that we stick within the time parameters, so that we could have enough (?) time for the Liese report. Starting with the shadow rapporteur, and I would like to ask you to stick to four minutes, if possible. Miss McGuinness has the floor, please.

15:53, 29 May

Mairead McGuinness (Ireland, EPP(Christen Democrats)): Thank you chairman. We have had a breakfast meeting without breakfast. Which was a very productive meeting, so I would like to thank the rapporteur for that. Can I say I had breakfast on the way to this meeting, so I am well-fed, thank you. I won't repeat the key points; our rapporteur has done that for us. And there are a few points that I would like to pick-up from her comments. One is that in good faith. We are working in good faith, all of the people involved in this dossier. We have increased patient safety at the core of our work, and we are aware of the pressures in terms of wanting to have new products on the marketplace as well. So there is room for compromise, in some areas it would be difficult, perhaps impossible and the committee will have to decide. And I think the strategy we have agreed this morning at the breakfast meeting, is the most effective one, where we will deal in detail at a technical level with many of the issues and then at a political level with those which are extremely complex. But certainly, stepping up the quality of our

notified bodies, the staffing of these bodies, the scrutiny, all of these things will be absolutely vital and I have a real concern too about post-market surveillance and the issue of incidents being reported and whether we should have a difference between serious or just incidents, these are technical issues which we will work on and I too would like to hear the response from the Commission on the points raised by our rapporteur. There you are, extra time for you, Chairman. Thank you.

17:27, 29 May

President: Thank you very much. That's great. ?? Holger Krahmer.

17:37, 29 May

Holger Krahmer (Germany, ALDE): Thank you very much, indeed for giving us a whole four minutes. That is unusual. Taking a look at the amendments, I think there are two main points in this issue, which give rise to the possibility of compromise amendments. We have to look at how to appoint the designated notified bodies and how to monitor them. I think we can find some common ground for compromise here. We do have to watch out that we don't get backed (?) down in all details here, details which we will be unable to solve in the committee meeting. If you look at some of the examples you brought up, say in-house experts, some of the suggestions you made were (?) be possible, but if we have a specialized notified body, that deals with cardiac issues, for example, they will always be able to have an in-house expert. But perhaps there would be a, some of this in-house experts may be somewhat disappointed that they are spending the whole time doing a very specific task, and they may lose some of their expertise in other areas. So, it may not be realistic, although it sounds like a very good idea. We may also be able to agree with you on issues related to how we deal with products which are already on the market, with a surveillance and follow-up. How can we get better information about necessary cases? I think we can reach a compromise on this and I think we could agree that we need more and more vigorous controls, especially for the producers. That is really the point where abuse, or criminal activity can be detected. Now, they should not have centralized or decentralized market authorization procedure; that is not so clear. We have to try and find arguments for or against this.

Now, any issues related to medical devices, these aren't necessarily improved by having a centralized procedure. If we are talking about having a producer, who is involved in criminal activity, we are unable to improve this situation if we are just to say: well, for class III products these should be controlled on a centralized level, this will always give rise to a problem. Perhaps the notified body can be more effective here, compared to a centralized authority, because the notified body would actually be closer to the ground and I don't think centralization here would solve any problems. We need to try and strengthen the system, and improve quality. It is very often the case that many problems related to medical devices are not automatically (?) traced back to the producers, we do have to be careful to see that there are some problems with the usage of the devices, often the doctors themselves, and very often, it is the patient, who is not familiar with how the device should be used.

We have been on to single-use devices, we do have to be careful with this discussion, it is a tricky one, we don't think it is one we are going to resolve today. We have to be sure that somebody who produces a product, which is then re-used, and then reprocessed, should always bear responsibility for what they

are doing. If someone produces a product, they must have a responsibility for the proper usage of this product, whether or not it can be re-used. And this goes for the producer and the reprocessor. We must ensure that the reprocessors are accountable, one they provide a product which should then used by a hospital, which then uses it as instructed. We have to make sure there is the surveillance and control mechanisms in place. So the question of whether single-use is written on the product or not, at the end of the day, I don't think, I think this is a question which can't be resolved here today. But on the centralized issues I think and on the notified bodies, here we can find a compromise.

23:00, 29 May

President: Thank you very much.

23:04, 29 May

Michèle Rivasi (France, Group of the Greens): Thank you, Chair. I wanted to clarify a number of things. I have just been to Marseille, and that is where this whole PIP trial took place. When we had an resolution on that, and we also worked to mimic (?) our concerns in this directive. 7500 women were there and they experienced this problem with these breast implants, that were manufactured with industrial silicon. And this happened under the existing system. So, I think we need to look at this very closely. These breast implants were certified, by a certifying body in Germany. They carried out checks, and they didn't see anything. They didn't detect anything during these checks. This means that having certifying bodies, does not guarantee patient safety.

Secondly, when the Food and Drug Administration in the US was asked for a certification by, for these PIP breast implants, well they came to carry out checks and they stayed for a week and they said: no, we will not give any market access authorization to these breast implants. So, that means that when we have this FDA, when somebody asks them for a market access authorization, and they say no. But there was a problem afterwards. They sent this to the national agency in France, they sent their information, and they did not react on the FDA alert. So, I mean this is why we are saying that we need to strengthen checks, but these certifying bodies, with all the experts that may be available to them... I mean, how are we going to make sure that they detect anything, knowing that all their funding comes from manufacturers! We need a public body to exercise oversight! We need a public body with checks, because these controlling bodies of course they carried out checks, on the ground, in Marseille, but they did not detect anything. But, if they had looked at the accounting of this whole manufacturer in Marseille, they could have seen that the ingredients they used, did not actually correspond to those declared. They could just have seen it from that side. What we need, is to stop fraud. But there is still fraud. We have just seen another case, another implant using a European Community label. And the hospitals adjusted it to the device and they used it for patients, because they saw this European Community label. So it is the producers, the manufacturers who carry out fraud, and the certifying bodies are not a guarantee against fraud. So, I feel that for all implants, anything that we are going to insert into body, we need a market access authorization. And then of course there are certain devices that are high-risk, and who is going to pay when something goes wrong? Not the manufacturers. No! It is the taxpayer. So, we need market access authorizations, and we need clinical trials before anything is

authorized. And people say, well/all well, this will waste the manufacturer's time, but what are two, three months compared to the harm to patients that are to receive a fraudulent implant? I think that if, I mean people think that if we have a different process, then the manufacturers will stop committing fraud. No! There is fraud every day. We can't just have certifying bodies, when all their financing comes from the manufacturers. So, we have a real problem here. A market problem, a problem for patient safety. You know, and I was with the victims in Marseille. And all the victims are asking for market access authorizations. I mean, maybe we need to do this at the level of the European medicinal agency, at the EMA, just like you have the FDA in the US. We need something, we need to reject the system, we need more guarantees for patient safety, that is what we need, my true concern.

28:24, 29 May

President: Next speaker is Marina Yannakoudakis.

28:28, 29 May

Marina Yannakoudakis (United Kingdom, European Conservatives and Reformists Group (ECR)): Thank you, chairman. Yes, we have an obligation to patient safety. We also have an obligation to have a system that is going to work, that is not over bureaucratic and will not stop getting people the care they need. Now, we have got, I think in terms of thousands of amendments for this and we are looking at now, in our shadows' meeting, there will be compromises. The interesting thing is where we find compromises and where we need to cross red lines for each political group. It is a very technical dossier as has been said, so I think we are well versed to deal with the technical side first, and then fight out the political battles amongst ourselves. For myself, there are the usual areas of concern: notified bodies, centralized system, pre-market authorization, and one-use device. I am not going through them again, to save time. But when we talk about fraud, and some of the problems we have envisioned are with fraud, we need to have systems in place, that have traceability, so we know where these devices are coming from. There has to be responsibility and there has to be a finding or, that is proportional to the, to the fraud that has taken place. So, we have still got a long way to go, I think we will have to come up to some compromise there, and hopefully we will protect patients' safety and keep devices working for everyone.

30:08, 29 May

President: Thank you very much. Next speaker is Alda Sousa.

30:17, 29 May

Alda Sousa (Portugal, Confederal Group of the European United Left): Thank you, Chair. I think that Dagmar has already given us a very good outline of the situation after the first shadow rapporteurs' meeting this morning. I would like to bring a couple of the points, which have actually already been mentioned, but I would like to underline them. I don't think we could ever say that, regardless of any legislation which may be introduced, that fraud will continue. Well, that is true on the one hand, but it is

not entirely true. It is clear that with this legislation, or other legislation, we are not trying to introduce a police state around surveillance and control, but as said, it doesn't mean we should just forget about having solid guarantees. It has been said by both Michèle Rivasi and Dagmar herself, that we need to stress the importance of certification and the granting of market authorization before these products are placed on the market. And clearly, I agree with Dagmar's proposal that medical devices of high-risk categories, and those which are deemed to be innovations, should have an authorization granted on a centralized level, or an EU level. Other categories of devices could be granted authorization on a national level. This would also meet some of the concerns raised by, mdm Rivasi. It is clear that all the experts who carry out this type of authorization, have to be completely independent. They cannot have an interest elsewhere, or be in the pay of other producing bodies. These organizations who are responsible for giving authorization, must, have to be completely independent, so that they don't end up being an easy pray for the pharmaceutical industry.

I also believe that monitoring and control after market access is granted is absolutely crucial. We need to ensure that both the notified bodies are of very high quality indeed, and we also need to try and produce or eliminate any mistakes made by these notified bodies. We have to bear in mind the needs of the patients and their health issues which are at stake, and try to introduce legislation in this area, which both takes into account what we are trying to achieve in terms of innovation, but this was never be at the cost of patient safety. Because, when things go badly, that is not the moment to try and introduce a solution, or try and resolve the problem. We need to deal with the problem upstream, and try and ensure that the guarantee is in the certificate an authorization files is of the highest possible quality, before devices are placed onto the market.

I think that our next few meetings will be very, well they are going to involve lots of hard work, but I do think it will be possible to get a good piece of legislation out of this.

33:59, 29 May

President: Thank you. Now moving on to other speakers on the list. Zofija Mazej Kukovic, Milan Cabrnoch, Anna Rosbach and Rebecca Taylor. Did I forget anyone there? Richard Zeba. That's, we can close the list there. Mazej Kukovic, please.

34:26, 29 May

Zofija Mazej Kukovic (Slovenia, EPP (Christian Democrats), speaking in English): Thank you, President. And thanks to our rapporteur and shadows rapporteur for a very difficult work, I have to say. I also put some of amendments and I supported some of them of my colleague McGuinness and Rosbach. I would like just, just a point out some crucial, some crucial point from mine amendments. The manufacturers should take special care when using nanoparticles, that can be released to the human body. And those devices should be subject to the most severe conformity assessment procedures and the same standards. The standards of quality, the standards of safety, standard of environment, but important is on the level, on the same standards. Later, later on, it is appropriate to set out clear, clearly the general obligation of the different economic operators, including importers and distributers. It is important to establish conditions enabling small and medium size enterprises with smart specialization to have easier

access to this market. Because it is always very difficult, special during this economic crisis, for small and medium enterprises to have normal access also here.

Furthermore, for high risk medical devices, in the interest of increased transparency, manufacturers should summarize the main safety and performance expert (?). Transparency of procedures should be ensured, where similar incidents have occurred, or failed safety corrective actions have to be carried out in more than in one Member States. EU directive use various definition of the terms placing on the market, and making available on the market. Devices should comply with the regulation immediately, they have place on the market, irrespective of whether for and end-user or for stock in storage.

At the end, a notified body shall be capable of carrying out all the task. The process shall be monitored to ensure that it is of the requisite quality. Thank you.

37:24, 29 May

President: Thank you. Next: Milan Cabrnoch.

37:33, 29 May

Milan Cabrnoch (Czech, European Conservatives and Reformists Group (ECR) / EPP (Christen-democrats)): Thank you, mister Chairman. I would like to make a notion/mention of a couple of topics that have not been mentioned here yet. And I would like to appreciate the work that has been done. We have had a very detailed and open discussion so far and thank you for that. We are talking of a regulation that is of a stable piece of legislation that should be predictable and that is why we should try to discuss and reduce the powers of the Commission to issue delegated acts in this matter. I welcome discussion aiming at the clarification of the position of the producer and the distributer. I can't see any sense in transferring powers of the producer of the, such as keeping the documentation up to date and etcetera. I believe also the language requirements for the documentation should be simplified, simplified where documentation is to serve administrative purposes, and is not targeting end-users or patients, and brings no substantial information to them.

As regards reprocessing, I am a very much influenced by my personal experience. We should have said out such rules as to provide for the biggest safety, patient safety possible, but at the same time not place obstacles in front of medical facilities and doctors. So, I believe that there should be a negative list of single-use devices. And the question whether a scalpel, a lancet packaged for, as a sterile single-use device. I mean, that should not prevent it from being sterilized and re-used again. This is a very wide topic. At the same time, I would like to say I am disturbed by the discussion concerning the checks and the compliance with rules. We would all wish that clear rules be established and that everybody should follow them, and that there would be a body supervising that. But I should not discuss here or talk here about the failure of the supervision systems, where somebody clearly is in breach of clear rules. And I don't believe that when we check the, when we change the system of financing, things would change. This would be like us saying that people steel, although it is prohibited, and police should make sure that people do not steel. And if people do steel, we can't say that the police doesn't work, can't we?

40:36, 29 May

Anna Rosbach (Denmark, Europe of freedom and democracy Group/European Conservatives and Reformists Group (ECR)): Yes, well, I am from a country that does produce quite a lot of single-use products, particularly plastic products. Tubes, for example and containers for liquids, for example. And when I talk to the manufacturers, and those using these products, well, the reply I receive is that single-use products have been designed for single-use. And therefore, it is a problem, when they are re-used, because in many cases, it is not possible to guarantee that they are properly cleaned. And therefore, I would prefer banning re-use of single-use products completely. And so I am very grateful for madam Lepage's proposal that we should ban such a re-use. There are things that could be reprocessed and re-used, but there are certain products, certain devices, which simply cannot be sterilized! It is not possible to guarantee that they are as safe to use as they were the first time round.

However, if it is not possible to introduce such a ban, then for me, what matters most, is of course patient safety. And patient information. Because I myself would preferably not want to be treated with re-used single-use devices or products. I would want to know. And I really think that patients are entitled to information and we are all patients! Everyone here in this room is a patient and we are entitled to know whether the devices or the products that's been used on us are safe or not. And therefore it is also very important that we know that the same rules apply, regardless of who is using this single-use device for treatment. Whether it is been used to by a private caregiver, or a public hospital, you should be entitled to the same safety and information.

And I would also like to support any proposals that go along the line of strengthening expertise within the notified body, and any certifying bodies. I think we do need more certification there, thank you very much for an excellent report, Dagmar.

And I do hope that we can come up with some good common amendments, some compromises, because otherwise, Lord knows what is going to happen during the vote. So, good luck. Thank you.

43:19, 29 May

President: Thank you very much. Peter Liese.

43:25, 29 May

Peter Liese (German, EPP (Christen Democrats)): Thank you very much, Chair. Thank you very much, Dagmar Roth-Behrendt, for your hard work here on the report, which I have drawn up as well on IVD medical devices, very closely linked to this report, so it is logical that most of the amendments to my report actually come from Dagmar Roth-Behrendt. We do have another point on the agenda to talk about this, but we have tried to harmonize the two reports as much as possible. I agree with Mac McGuinness, and other people who have spoken today, that we do have to be careful about introducing a centralized system. I said last time, and I do want to make it clear, that I have talked about this for many years, that I believe that if we have a completely new system, which is built up by the EMA, for surveillance of medical devices, well this is a Herculean task. We need experts on medical issues, financial experts, and I think that this alone would take far too much time. We have only got a

transposition period of three years foreseen in the Commission's proposal, and I don't think this will be possible. We need to improve the system and this should (?) be a lot quicker. And this is why I think we should stick with the current system, but improve it.

I believe that Dagmar Roth-Behrendt's amendments on qualification of people who are working in notified bodies are heading in the right direction. I could take about the way in which these are phrased, but the Commission's proposal isn't good enough here. It says (?) that businesses, even SMEs, who are active here, should have experts, and three years' experience in a specialized field and so on and so forth. But with notified bodies, it is, the specifications are fairly vague. So, this is why we have amendments move (?) for both reports, and I am sure we will be able to find compromise in this area.

Now, my final point on this report. I would like to point out there are three particular amendments tabled on my report and this report. There is a question of subsidiarity. In pharmaceutical legislation, clinical tests, Member States should be able to have the possibility to question a product from ethical reasons. It may be that some products are legal in certain Member States, but other products offered elsewhere, other products may be deemed not legal in certain countries. So we have a clauses allowing for this elsewhere and that should be introduced in this regulation as well.

47:06, 29 May

President: Thank you very much, Peter Liese. Rebecca Taylor, please.

47:12, 29 May

Rebecca Taylor (United Kingdom, ALDE): Thank you, Chair. Very briefly. I will save my substantial comments for the IVD discussion, but I just wanted to make the point that the files are very interconnected and some of the comments I will make on the IVD will apply to medical devices as well, particular relations to the authorization process, the governance of the system and the European databank. I hope the committee does not allow, and I don't think this will happen, the proposal is too separate too much because they do need to be kept in line.

So, very briefly on the medical devices proposal. On the main point of substance, the centralized procedure proposed by colleagues, the rapporteur Dagmar Roth-Behrendt and Margrete Augen, I am still of the belief that the advantages of a centralized procedure are not sufficient to merit its introduction and the establishment of such a system would be severely hampered by very real financial and organizational barriers. The European medicines agency has no expertise in medical devices. Nonetheless, I will be looking at all the amendments in further detail over the coming weeks. And as I said, I will save my substantial comments for the IVD discussion. Thank you.

48:32, 29 May

President: Thank you, and then Richard Seeber.

48:39, 29 May

Richard Seeber (Austria, EPP (Christen Democrats): Thank you, Chair. Well, I think we should try and use the good side of this, quick market access, presumably (?) given how many interpretations they are in different countries regarding this. So, regarding 508, all of these amendments, I think we should try and make sure we get the new article for 44a, whereby national bodies would be checked properly before they are able to give a market authorization, and then to make sure that products in group 3 particularly, were suitable for the community market. And this issue, because of all the SMEs involved here, is the central market access authorization procedure, and this is something were the scrutiny process is very important. And this is something the Commission has put forward. The fact that this takes a long time, ninety days for a product to get through and it is a problem for patients as well as SMEs, and in the long term there isn't much of a benefit from such a system, so I think that we should have a single criteria for all these different bodies and regularly check them across the board, and make sure that they are capable of giving a market authorization.

Another problem is that, as with the previous situation, there is no clear delineation of what should, for all in group 3, and has safety implications. Obviously we have criteria drawn up for the central body, for example, but I think it would be better here to go along with the system that I and colleagues have put forward, whereby competence is apportioned to different areas and that would be the best way of safeguarding patient safety.

50:59, 29 May

President: Thank you. I would like to call upon the Commission to take the floor. Mrs Lecrenier. No, not here? Sorry it had to be …

51:12, 29 May

Commission: If you don't mind, Chair. Sabine, is here, mrs Lecrenier. Thank you very much, Chairman, for giving me the floor and for giving the Commission the floor and thank you for this opportunity of today. It is a very enriching experience, because the amendments were very interesting, and then listening also the richness of, and the variation of the views, of the honorable members is for us a very good opportunity to work on the way forward. And we respect this exercise and the seriousness, and the sense of urgency which with the rapporteur, and your committee are taking this issue forward. And we want to help in the direction of resolving the outstanding issues. Having said that, we have noted that there is a very broad spectrum of opinions on the issue of authorization, and it makes this exercise very difficult. Still, from what we heart here today, I think one thing is for sure and one thing is common, that the fundamental objective is to ensure the highest level of safety for patients in Europe, and that we should all see how such safety, when it comes to medical devices that are placed in the market, is to the highest possible level. And where we can strengthen it, we should. And the Commission is very conscious of its duty in that direction. We are glad to hear that you will be working intensely this week at the technical level, and I would like to tell you that we stand ready to help in this discussions, as much as we can. I think that what we have noted, also from today's discussion, also by looking at the amendments is that the idea for a full pre-market authorization, is also not considered as meeting the

philosophy of the Commission's proposal and as you know, this was also identified in the impact assessment as a solution that would not add to the safety aspects for the authorization of medical devices. However, what we do see, as a point of convergence, is that strengthening the criteria for notified bodies, is definitely a direction we can work towards. And there the Commission, as I said, stands ready to help. This is our duty to safety, because safety is the priority issue, and it is also our duty learning from the lessons of the past, that many of the honorable members mentioned here. So, I hope that this is clear to answer to the rapporteur's specific question to the Commission.

On reprocessing, which seems to be the other very important issue, I would like to reassure you that the proposal of the Commission, that placed the reprocessor in the same position as the original manufacturer was exactly to take a strict approach and create a high level of responsibility to respect safety. But we understand that there may be a wish to improve this direction. There are issues, especially concerning, and I will be very precise here, hospitals, and I am very sensitive to the point that was made by honorable members: yes, we have a duty to our patients, who have no control whatsoever over this issue. So again, there we stand ready to work towards a constructive solution that will allow this committee to have also a constructive vote on the 10th of July.

In the same vein, and I will close with that to respect the time, Chair, on other amendments that are going in the direction of strengthening the monitoring of notified bodies, I think we can see the benefits and we can work again towards that direction, and the same stands for other very constructive amendments, such as the single UDI, that you need the device identification system for the amendments go really to a very positive direction. So, there are many elements where I think we can see benefits as positive, again, we are grateful for the urgency which with the Parliament is treating this file. You know it is a priority file for the Commission, we want to see this adopted in the current legislature, and we are very appreciative of your efforts in this direction. The efforts of the rapporteur in particular. So, we stand ready to help with this constructive exercise as much as we can. Thank you.

55:27, 29 May

President: Thank you, and the rapporteur has the floor finally.

55:34, 29 May

Dagmar Roth-Behrendt (German, S&D, talking in English): Thank you very much for everybody contributing to this debate. Because now we have all the amendments in front of us, the debate gets even a different level than we had in our debates before. I very much appreciated the comments of colleagues, some very supportive, some perhaps not yet as, as much on line with my approach as I would wish to, but that's the reason we need to make compromises. I simply want to make, to make some things very clear. We.. I do not want colleagues to fall into that trap which the producers of medical devices try to pretend. They try to pretend that any other system will prolong the market access longer, and patients do not get access. Like one roof organization of producers did in a very moving way, describing that poor lady not getting the urgently needed device. Colleagues, we just always want to speak about the real facts. The Commission proposal we are speaking about speaks, results in a procedure, and a market access which is roughly seven months. So, from the Commission procedure I

just always have to make sure I get the numbers right, we have seven months. The procedure I have foreseen, adds additional two months. Which is nothing, colleagues! Honestly nothing. When you see at the same time that those seven months from the Commission do not necessarily imply the direct market access, most Member States they have to go still, they have to start still the negotiations of the social securities, who have to, have to pay for the implants. And that is not always going in parallel, and sometimes that takes much longer. If you look for example on, on certain in the pharmaceutical areas, you would have always a faster and an easier negotiation process on pharmaceuticals which have a centralized authorization. Which is clearly evident, because the process is more transparent, everybody is involved in. So, so please do not fall into that trap when people lobby you that any new procedure takes products from the market and does make the European Union not competitive anymore. I can assure everybody in that room that yes, patient safety is a main topic for me, but yes, at the same time I see that companies producing medical devices, should do that in a competitive way, and in a way that they can be in the European Union as good on the market as they could.

Mr Krahmer said that there were no, no reasonable or sensible arguments, but only what one believes. And he then continued to speak about criminal, criminal energy. I have to say, very clearly, when as the Commission proposal came, I always made very clear that that Commission proposal has nothing to do with the PIP scandal. It was in the impact assessment and in the preparation procedure, long long before. And as we all might remember, we had from a former colleague, mrs Majori already a report asking the Commission urgently in an assessment procedure, to put forward a new legislative proposal. So, yes, there was the PIP scandal, but it had nothing to do with the Commission proposal. And if no criminal act ever would happen, I nevertheless would say that the state of are where we are, in at the, for this time in our life, with the specificness of our medical devices, the notification process as it stands is not state-of-the art anymore. We have, I would always have said that, and that has nothing to do, mr Krahmer, with what I believe. It just has something to do with what I can prove. And yes, perhaps not every notified body needs an in-house medical doctor, pharmacologist and medical engineer, every time, all the time. But for sure, we cannot continue to have notified bodies giving notifications without anything like that. On medical devices of class III, or class IIb, or even on class IIa, by simply outsourcing the whole knowledge they want to get. That is not the way we should deal with products. Or if you find it appropriate, we should deal with that with pharmaceuticals as well. Sorry? Yeah, I only want to react, mr Krahmer said without microphone that I am not fair, because I would create a black-and-white picture. That is the last, that is why I repeated it, because it is without microphone. I am, the last thing is that I want to be unfair, that is normally as well not my my attitude. I only reacted on on your, your remark where you said 'da gibt es keine sachliche Argumente, [there is no technical arguments, there is just belief], and I had to react on that, because I believe that I do have arguments, and it is not about what I believe.

As well, when we speak about patients taking responsibility of themselves for their implants. Yes, it is for sure true that the success of implant, of an implant as well can be connected with the lifestyle of a patient. But the patient for sure cannot take the responsibility of the product. If you show a patient three or four different hip implants, or knee implants, I have a colleague in my delegation, she is mid, at the end of the thirties, I guess, and she has a knee implant now. She is of the higher level of education and understanding. But if you would have shown her three or four different knee implants, she would not have known what to choose. She would rely on her doctor, naturally. And that is what we need to do as well. I believe that what what people said, as well mr Krahmer and others, that traceability is an

important point, that is true. We have to make sure that we have, that is what doctors ask us, that we have a traceability system for products, and of the place where the surgery took place, and of the person who did the surgery. Because that gives a picture. A product might be totally perfect, but the medical professional who did the surgery was not perfect. That would be what the orthopedist association and others asked us to do, and I understand that that is a good idea.

I am grateful to mr Cabrnoch and others, who said: yes, we have to look at reprocessing. He made some proposals on that in amendments, others did, Anna Rosbach did it, and others. I believe we will work on those lines and have to look what we can do there. Mairead McGuinness made very clear at the beginning that there were, that there was already now room for compromises where we are not too far away from each other, but other, in other areas we have to see if we find room room there. I believe we can. I would prefer not to go in, on major items into a controversial vote, but it has to be really a compromise. And I am grateful to the Commission signalizing that in some areas they could imagine as well, that we could cooperate there.

From my point of view, not only from the way of proceeding, I would like to proceed as fast as possible. If I have the support here, if we manage to have a very consensual vote here in the committee, I believe that, yes, we can, perhaps, get a mandate for our first reading, but if I would not, because it is a major item, I would not do that controversially, and would not want to have that in a vote with a small majority. I want to have that in in really in accordance with everybody here in that house, in the room, and then we could, I believe, could finish that procedure till the end of the year, latest perhaps the beginning of next year.

1:04:12, 29 May

President: Thank you very much, Dagmar Roth-Behrendt. On the 10th of July, we will vote on that report in the committee, and we have the plenary sitting in September for medical devices that what we are planning on. Thank you very much for the debate. Brings us to the linked report, Peter Liese in-vitro diagnostic medical devices. You have the floor.

1:04:45, 29 May

A.4 Debate 22/10/2013 in European Parliament

http://www.europarl.europa.eu/sides/getDoc.do?type=CRE&reference=20131022&secondRef=ITEM-004&language=EN&ring=A7-2013-0324

4. In vitro diagnostic medical devices- Medical devices

The President (Vice President Miguel Angel Martínez Martínez, Spain, S&P (Socialist Group))

The next item on our agenda is the joint debate on medical devices. We have a report from mr Liese on in vitro diagnostic medical devices, followed by mrs Roth-Behrendt on medical devices. I have been informed that mrs Roth-Behrendt is going to speak first and she has four minutes for her presentation. Dagmar.

22/10/2013

Dagmar Roth-Behrendt (German, S&D)

Thank you very much indeed, mister President. Well, if you would allow me, maybe we can just give my colleagues a few moments to leave the hemicycle.

-colleagues of previous agenda point leaving-

Second attempt. Colleagues, what are we discussing today when we talk about medical devices? Well basically we are talking about devices, products, which are supposed to guarantee safety for patients, help them in their suffering and their illness, and should also assist doctors, to be sure that they are using the best possible products when they want to assist their patients. And we are also discussing the competitivety of the European industry.

Now, are we actually going to achieve that with the legislation? What has happened to date? Well, to date/today, doctors have been telling us that hundreds of for example hip replacements were defective, they had to be taken out again. Huge expense for the health system, huge suffering for the patients and that means there is something very wrong. That is why we need a new system for medical devices, because the old system, the former system, is now so antiquated that it no longer meets modern day requirements.

We need a better system, and in that better system, we need basically the best bodies that can certify these products. They in turn have to have the best scientific backing. Is that a reason for European industry to react in panic, hysterically? I am convinced the answer is no. I feel that if it is true that European industry is innovative and produces good products, then, European industry should not be afraid of going to the best trained points in Member States and establishing (?) and going through a

procedure which will take four months. Four months is a drop in the ocean compared with the time it takes to develop a product or the lifespan of a product, when we are talking about years.

And if that is the case, if with this legislation in other words, we can ensure that we have good notifying bodies, good well-trained bodies, that we have good scientific support and thereby create greater safety, why the hysteria? Mister the Commissioner, maybe you could answer this question, you know, because, you know, patient safety, I wish that was a term which is as used as often in the Commission as competitiveness, but maybe the Commission can learn something about this and the Commissioner as well.

I am convinced that with this proposal we have before us from the employment committee, we can take a step in the right direction. It is great, European doctors are saying that we would have centralized authorization or need have centralized authorization for high-risk products; we haven't managed that, but I think that what we have before us, will take us a major step towards creating more patient security.

It is maybe not a milestone as such, but what this means as well is that if medical devices are used second time rounds they will have a high level of security. That is something we don't have now. We don't have unified standards within the European Union. Every doctor in the European Union can do pretty much what they want, with different conditions, different criteria, different terms. And we have no idea of how many of the infections which exist in hospitals can be attributed to these defective products.

So we need, we know, products which are one-use; constructed in such a way that they can no longer be purified, or, you know, somebody would have to do/create a miracle or maybe the manufacturer has not told the truth. We have to ensure that we have the best possible quality across the phase of the European Union, not just in a handful of states and that the manufacturers of these products are responsible and liable for them as well. This is something that we should have done years ago, and I really hope that our colleagues have enough respect for a patient's safety and doctors, that the vast majority will be able to support this. Thank you very much indeed.

President: Peter Liese now has the floor as the rapporteur.

22/10/2013

Peter Liese (German, EPP (Christen Democrats))

Thank you very much President, colleagues. Yes indeed, there are problems out there in the world of medical devices and that also applies to diagnostic devices. The Competent Authority in Germany, the Paul-Ehrlich-Institute, realized that there was a HIV test on the market for years with a CE mark which was giving a lot of false negative results compared to other tests, so quite often the test was saying that there was no virus, but in reality the patient was already infected with HIV, (with?) All of the consequences that arrive from that, if you have blood transfusions, or various other kinds of contact. So, the current legislation is not sufficient, it does not sufficiently protect patients and we need to make improvements here.

I am very pleased that we have got broad consent on many of these aspects. That we should have unannounced checks, and if we would have had that a few years ago, the PIP scandal would have been discovered much earlier and thousands of women would have been saved a lot of suffering.

Now, as the EPP group, we support the speeving/briefing? up of the so-called notified bodies for high-risk products. However, what we did not want was a state pre-authorization of products, what we did not want was central authorization by the EMA. That does not necessarily bring extra security, that applies to pharmaceutical products where we still have a long list of scandals. Various new forms of anti-baby pills etcetera. And we find huge new practical problems, there are big issues in ensuring that innovation is safe (?) for patients. So we need to act actively, but there are lot of people at the industry who also say that we don't want any extra security, and we don't want a European expert group to have a look at our products. Well, I did not accept those arguments either, I think we managed to get a good compromise, we have got good amendments from the EPP and other groups today, that I think we can use to further improve the proposal. So, I think that it is important that we want to abolish the 23 subgroups that currently exist to make the system much more transparent, to get a better overview. We have got a proposal for common technical standards and we are talking about reference laboratories; they have an important task here in assessing the high-risk products. So, I think that on the whole we can say we are making a huge step forward. A step forward to better patient safety, without endangering innovation in the industry.

There is one aspect that I want to bring up particularly, that the committee voted in favour of. In the area of DNA tests. DNA tests can have major effects on patient's life. There are illnesses which cannot be treated, but if they are not diagnosed at an early stage, for example when there are not symptoms; I mean you have Huntington's disease, which is a central nervous system disorder. It could take 50 years or so to develop, but there it could (?) lead to death and terrible consequences. But if you discover this at the age of eighteen on the basis of genetic information then you can act. So I think it is very important to act at an early stage. There is no cure to this; that can lead to psychological problems, it can cause problems with insurance companies, and in employment. So we need to ensure that we cannot have any all (?) person offering these tests over the internet. Rather we need to ensure that we have these tests offered in a proper medicinal environment with reliable products. Now, there are some amendments suggesting it could be other specialists rather than a doctor, but I am very glad to see that we have the important issue of informed consent getting through here. That is part of a chart of fundamental rights, so I am glad to see it should be respected here too.

Well ladies and gentlemen, I would like to thank everyone who has helped in getting these two reports through committee. I would like to thank Dagmar Roth-Behrendt as the rapporteur on medicinal products. I would like to thank the shadow rapporteurs from the other groups as well, I would like to thank the secretary and the Commission. But I would also like to thank the Council of Ministers. Unfortunately their seats are empty this morning. But the Council of Ministers got work to do now. Fourteen months after the Commission put forward this proposal, we haven't got a position from the Council on any single article, but we do need a rapid decision. That is

important for the private sector to take decisions; it is important for patient's safety as well. So, we need to ensure that this dossier gets through before the European elections! Thank you very much.

President: Thank you very much indeed, mister Liese.

On behalf of the Commission, Commissioner Mimica will have the floor.

22/10/2013

(**EN) Neven Mimica, Croatia,** *Member of the Commission***. –** Mr President, the two proposals on medical devices and in vitro diagnostics that we are debating today are of the highest importance for patient safety. Current legislation has shown shortcomings far beyond the PIP breast implant scandal. This was a case of fraud which, even with the toughest pre-market controls, could not have been prevented. But we need better clarity for innovative and borderline products. We need stricter requirements for notified bodies and for their oversight of manufacturers. Without changing the law, unannounced audits will not become obligatory. With such unannounced audits, even the PIPS scandals – though it was a case of fraud – would have been detected much earlier.

These are just a few examples of why the revision is needed – and it is needed urgently in order to fully restore the trust of patients, consumers and healthcare professionals in the regulatory system. For this reason, let me thank the rapporteurs, Ms Roth-Behrendt and Mr Liese, together with the shadow rapporteurs, for their determination, expertise and personal commitment towards advancing these two important files. I will not explain to you the details of the Commission's proposals again, as you are well aware of them. Instead, let me address two key elements which have been subject to particularly intensive discussions over the last couple of months, including in Parliament.

As regards the system for the approval of devices, the Commission's proposal was to maintain a system of self-certification by the manufacturer in the case of low risk – and of verification by notified bodies in the case of medium-risk – medical devices. In high-risk cases, the Commission has proposed allowing public authorities to have a second look at the assessment by the notified bodies in specific cases, for instance where the product is particularly innovative or where particular problems have occurred with the category of products. This was meant as an exceptional safeguard. In fact, our impact assessment assumed that something like 50 products would be scrutinized per year.

Different changes have been proposed in your committees. I have no problem accepting that the Commission proposal can be improved. It may not have considered sufficiently, for example, how to ensure the necessary technical and scientific expertise for the scrutiny, but overall I believe that the scrutiny procedure, as a form of exceptional safeguard, is the best compromise to ensure a high level of patient safety while avoiding too burdensome processes.

For the reprocessing of single-use medical devices, I strongly believe that we need European rules that fill the current regulatory gap. The Commission has proposed strict rules on reprocessing based on the

latest scientific evidence. It would allow the practice of reprocessing to develop further under clear and safe conditions, leading to potential savings for healthcare systems.

I have followed attentively the different ideas that have been put forward in Parliament on reprocessing, and I am, of course, open to carefully analyzing the amendments you will be voting on after this debate in order to see whether they would further improve patient protection. Apart from these issues, there are many other suggestions from Parliament which I am happy to consider favourably. You propose, for example, strengthening the provisions on ethics committees or on minors and incapacitated patients. I am open to these changes, as long as they remain in line with the provisions that are currently being negotiated in the context of the proposed regulation on clinical trials on pharmaceuticals. Similarly, there are a number of specific issues on the proposal concerning in vitro diagnostics which, in my view, are also valid and acceptable in principle. This concerns, for example, in-house exemption and counselling and informed consent in the field of genetic tests.

I am very interested now in hearing your views on these, as well as on other issues on which you think the Commission proposals need to be improved. I cannot give you a final position on all details, but I will commit myself to carefully analyzing all the amendments you adopt on both of these proposals. My guiding principle will be the aim of ensuring the highest level of patient and consumer safety, whilst making sure that innovation continues to flourish. I count on you to give a strong mandate to the rapporteurs, Ms Roth-Behrendt and Mr Liese, which will pave the way for successful negotiations, so that together we can deliver for citizens by concluding these important files within the current parliamentary term.

President: Thank you very much indeed. On behalf of the committee on employment, mrs Estrela the floor.

22/10/2013

Edite Estrela, Portugal, S&D

Thank you very much President, Commissioner, colleagues. Now in my role as (shadow)rapporteur for the employment committee, I would like to congratulate the rapporteurs, Dagmar Roth-Behrendt and Peter Liese for the excellent work they put in. I would like to thank them for very good cooperation with myself as well. Now, the employment committee, is mostly interested here in the issue of safety for health workers and users. We are talking about doctors and nurses of course, but there are other people exposed to medical devices, such as laboratory workers, alternative health institutions, cleaners, people who work in the laundry and all other people who work in hospitals. So, health institutions need to ensure that their staff had the right training to use medical devices correctly. We need to prevent problems with syringes, we need to ensure that new medical technologies can be used safely, and other surgical tools. Thank you very much.

President: Can I get the floor to the next speaker, on behalf of the committee of internal market and consumer protection this is Nora Berra.

22/10/2013

Nora Berra (Christian Democrats, France)

Thanks you so much President, Commissioner, on behalf of IMCO (?) I would like to welcome the initiative of the Commission to deal with medical devices, taking account of the changes in this sector. I would like to thank the work of the rapporteur and the shadow rapporteur. The text clarifies the obligations of the manufacturers, the vigilance, the surveillance of the products and traceability, linked to a European database, which will make it much easier for us to actually look at this in greater depth and coordinate the activities of the public authorities. We would no longer like to see the scandals of the former (?) situation, which has led to many protests across Europe. The ENVI committee has taken up a lot of the issues. But there are two issues which I think we need to look at more carefully. I think the practice related to the withdrawal (?) of devices, this should be in the hands of the individual Member States, and the high-risk devices we need to look at public collegial (?) monitoring. The commissioners looked at this on a case-by-case basis, but it is essential to get legal predictability on the part of the manufacturers. We must also make sure that we are not going to be strangling in ambitions. In one of the sectors, which is so important to the economy, I would also like to thank rapporteur Peter Liese on the auto diagnostic tests and the genetic tests, and the general support of patients, knowing that the results of these tests can have an important effect on the health of the patient.

President: Thank you, colleague. Can I now get the floor to the speaker on behalf of the group, on behalf of the PPE group, mrs McGuinness.

22/10/2013

(EN) Mairead McGuinness (Ireland, Group of European People's Party (Christen Democrats))

Mairead McGuinness, *on behalf of the PPE Group*. – Mr President, I would like to thank the rapporteur for the very detailed and collaborative work with the shadows. This piece of legislation affects every single citizen of Europe. I think that is an absolute fact – if not now, then certainly in the future. So it is absolutely crucial that we get it right.

I think what is of concern to us is that people did not understand how the system worked. Let us be absolutely clear: the industry works with notified bodies, and they certify the product. In theory, that should work very well, but examples have shown where it has failed us. So we are trying to improve on this position. It is a pity it takes a crisis to provoke action, but already there have been huge improvements in the system. I think it is worth stating for the record here in plenary that the Commission and the Member States have carried out joint audits of notified bodies. You have had eleven to date, and in two cases notified bodies have been asked temporarily to stop working. So when you check, you get results. That is what we are trying to do in reviewing the medical devices legislation.

I want to mention four key points: one is to strengthen special notified bodies. We are doing that, and I think it is very important with high-risk devices that only specialized notified bodies are able to certify

these products. Secondly, we have an additional layer of scrutiny in particular cases where products demand that additional scrutiny, and we have details in the text. But we also need much tighter post-market surveillance, so that when a problem is detected there is feedback of that information right through the system and there is a rapid reaction to it. I think that is crucial for the effective regulation of medical devices.

Commissioner, you mentioned the issue of the reprocessing of medical devices. This is very complex, and I think we need to stick closely to the Commission proposal. However, I think we need more careful consideration of this. Some Member States ban reprocessing, others allow it; some have standards, others do not. I would ask that you come back to us with a detailed proposal on that issue in the future.

President: On behalf of the socialists, can I get the floor to Gilles, my dear friend Gilles?

22/10/2013

Gilles Pargneaux (France, S&D)

President, Commissioner, Rapporteur, this directive aims at enhancing safety, stops some gaps, identify resistance tests and this revision I think partly responds to the concerns expressed under our parliamentary resolution on the breast implants back in July 2012. But it puts on the back burning/backbone (?) those issues relating to patient safety and public health and that is why I fully supported my colleague, Dagmar Roth-Behrendt, in striving to reorganize the text, ensure that patient security and safety lies at the very heart of the provision, particularly in terms of implants as well. Right from the beginning there, I was in favor of Dagmar's position, and in order to achieve a consensus, she had to water down her initial position and certain parts (which?) had to be left out completely. That is regrettable, because the compromise we have achieved is not enough. It puts forward a non-systematic control mechanism, which is not binding either. I would have preferred to have systematic, prior independent evaluation. Nonetheless though, this compromise is there, because it is the least bad solution and also there is this question of single-use devices. I personally am not in favour of re-use, because it can expose patients to health risks, and also there is no prove that they can be reusable, so Member States would like to have a derogation (?) which would allow them to prohibit this, I think would be a very good idea. Thank you very much.

President: Thank you, Gilles. About the liberals, I would like to give the floor to mrs Rebecca Taylor.

22/10/2013

(EN) Rebecca Taylor, (UK, Alliance of Liberals and Democrats for Europe (ALDE)) *on behalf of the ALDE Group*. – Mr President, I welcome Dr Liese's report on IVD devices, which is being voted on later today. I believe that the considerable efforts made by the rapporteur and shadows, both on this and on the Roth-Behrendt report on medical devices, have, I believe, resulted in legislation that will meet the needs of patients, healthcare professionals and device manufacturers.

In relation to high-risk devices, I am pleased that we have now reached a workable and more streamlined procedure than was adopted in committee. Authorizing high-risk IVD devices to a scientific committee of the Medical Device Coordination Group will lead to safer devices and greater transparency without being overly bureaucratic. I hope Parliament will adopt these provisions.

Unfortunately, there remain elements in the IVD text which are of concern for the Liberal Group. We cannot support amendments 72 or 271, which restrict genetic medicine unnecessarily. Genetic tests range from those informing you of an increased risk of diabetes through to tests diagnosing an incurable, life-threatening illness such as Huntington's disease. I believe the rapporteur has created a framework that responds to the problems stemming from genetic tests for life-threatening conditions but has applied this framework to all genetic tests, which risks damaging current routine medical practice.

Genetic testing is not just about diagnosing serious inherited disorders. In cancer, for example, genetic screening can ascertain sensitivity to treatments, thus producing test results that are risk based rather than deterministic. For these reasons, as well as the fact that the EU has no legal power to regulate national medical practice, we oppose those amendments and support instead amendments 255 and 256, which seek solutions to the problem identified by the rapporteur without damaging developments in the field of genetic medicine.

We also cannot accept amendments 42, 68 and 205, which could have a severe impact on public health – primarily sexual health – in Europe by making all high-risk devices, including HIV tests, prescription only. This threatens public health policies in France and the UK which seek to make HIV tests easily available to high-risk groups. Amendments 268 and 205 will do the same in various different ways. The ALDE Group would like to support this report, but the concerns I have outlined may prevent us from doing so.

President: Thank you so much, mrs Taylor. On behalf of the green group, 1,5 minute for mrs Auken.

22/10/2013

Margrete Auken (Green group, Denmark)

Thank you chair. I am the steel granny here. I have artificial knees, artificial hair (?) and an artificial hip and I am very much know that we need full control of the implants that are put into us. We need to make sure that they are safe and industries' position (?) is to proper control saying is too cumbersome, that's something that's quite out of place, considering what we are dealing with here. I think we have found a very good approach here, and I would very much like to thank Peter Liese and Dagmar Roth-Behrendt for their excellent work and cooperation. I think we have quite a good result. To Peter Liese I would like to say: I am happy that the ethics committees are emphasized so much and also happy that we have the requirement for qualified counselling for DNA tests. In answer to people who worry, whether this is sufficiently strict in approval procedures, I think if we have transparency in this, and transparency so that researchers can check the tests, that they can check the methods, and that they have access to all results, then I think we have a good chance, that in the end we will have a safe system.

We will have a safe system which also will encourage Member States to criminalize the industries that are not sufficiently safe, because we are dealing with the health of our population. So thank you for the work and if you also ensure transparency, then I am also sure.

President: Thank you so much, Margrete. Member of conservatives missing, so the floor to Mrs Sousa, on behalf of united left? (1minute).

22/10/2013

Alda Sousa (Portugal, United left)

Thank you very much, President. Now, what we are discussing today, and voting on tomorrow, are two files which are of great importance to all of Europe's citizens. Now, although there are some technical aspects here, this isn't simply a technical file. These are pieces of legislation which effect the security of our citizens. And they put the safety of our patients at the very center of our attention. We are not talking about consumers here; we are talking about the right of our citizens, to have information, and the maximum level of security, when they are either taking diagnostic tests or using medical devices.

So, I would like to thank the two rapporteurs for the excellent report that has been put in together. Now, we do need to consider the aspect of clinical practices in the negotiations that we are going to be entering into from this point onwards. We are going to have to ensure that there will be a guarantee on the high-risk devices; we need a guarantee that there is no difference between the approval(s) system that applies for citizens in Lithuania or in Portugal. I think it is very important that it should be the same across the board/border. Everyone deserves the same level of protection. Thank you.

President: Thank you so much. The last speaker; mr Clark.

22/10/2013

(EN) Derek Roland Clark, (UK, EFD (Europe of freedom and democracy) group)

Derek Roland Clark, *on behalf of the EFD Group.* – Mr President, I am against this report because I am a libertarian. I want to let the people decide what is best for them, and several UK organizations agree with me, especially on Amendment 40. The Commission document is a real dog's breakfast. It lists among the regulatory instruments everything from sticking plasters to X-ray machines, taking in elbow implants, lung implants, breast implants, even presumably the metal implant in my own left ankle, which is now all metal and pieces of plastic and I am perfectly okay.

The impact of this will, of course, be in over-the-counter sales, and here we have small and medium-sized enterprises at risk. You are going to drive up unemployment at a time when we already have over-unemployment; many young people out of work, when they could be working in shops selling this sort of thing. It will only produce more red tape, and the SMEs will then suffer. And who picks up the bill? Who picks up the pieces? Why, the big pharma. They will make hay while the sun shines, when all the

time everybody in the EU thinks it is all about them as individuals. It is not. It is all about the big companies.

President: Thank you mr Clark. This concludes this list of speakers and I now want to move on to give the floor to other speakers.

22/10/2013 (38:40).

Jolanta Emilia Hibner (Poland, EPP (Christen Democrats)

Thank you President, ladies and gentlemen. Today we are facing an important challenge that is about the new regulations on medical devices and IVD. What are the medical devices about? I would like to check what we are really trying to regulate. These are heart valves, implants, pacemakers and tests, such as DNA tests, HIV tests and so on. Where are the controversies in this house? Well there are none, because the patient is the key element of the process here. The patient is the most important element, so if we are discussing the fact that the producers need to have certain rights, because otherwise their products will not be able to be sold on the market, we are not trying to understand the people! The people who really need our help very often. And secondly, very often producers do (?) not want to buy insurance. When we are buying a car, we need insurance. And it is the same for producers of various medical devices. Today a company is producing medical devices and tomorrow it goes bankrupt. We need to make sure that all medical devices are of high quality, that they are available, that they are certified, and that they are efficient and infallible. That is the most important element, that they need to be infallible. Thank you very much.

Thank you, 1,5 minute please. Next speaker.

22/10/2013

Christel Schaldemose (Denmark, S&D)

Thank you, chair. Artificial hips that make people invalid instead of helping them, or breast implants that leak dangerous substances, or net put in the body causing pain. The list of scandals with medical devices is very long. Now we have proposed legislation which could help this sector, but will it help? The problem is that it will only partially alleviate the problems. With the proposal we have on the table now, we close some loopholes. Unfortunately, not all of them. We, social democrats, with Dagmar Roth-Behrendt at the head, have fought for central approval authority to prevent future scandals. But the right wing of this Parliament has considered industry more than patients. And the central authority is actually something both doctors and patients have requested. And it is a shame that we don't get this. But that being said, at least now, things will improve a bit for the patients. It will be a bit safer for them. We will get a bit more control and more unannounced visits in the production facilities. I think I will say the same as Dagmar: this is a step in the right direction. But unfortunately, it is not a milestone for the patients in the future. Thank you.

President: Thank you mrs Schaldemose. Mrs Auken has a question for you, are you prepared to take this question? Margrete, go ahead. 30 seconds.

22/10/2013

Margrete Auken (Denmark, Green group)

Thank you, Christel. I very much agree with you for quite a bit, but when we get full transparency, so that we make sure that the people who try to cheat us won't be able to hide, wouldn't you agree that then we have solved some of the dramatic parts of this problem and therefore we can afford to take the SMEs into account, because they cannot get away from my efficient control system?

President: Thank you. Do you want to reply to your colleague?

22/10/2013

Christel Schaldemose (Denmark, S&D)

Thank you, Margrete. Yes, transparency is important. And it is also a step in the right direction. But I do not believe that this will work efficiently well (?) around 80 notified bodies in Europe. It would have been better if competencies were all gathered in one place, because then we would be able to stay on top of things and prevent corruption, and ensure safer products for patients. But of course, yes, transparency is a step in the right direction.

President: Thank you, Christel. Two minutes for your presentation mr Krahmer. You have the floor.

22/10/2013

Holger Krahmer (Germany, ALDE)

Thank you, President. Patients in Europe, I think, are rightly expecting that if they need to use medical devices, they should be safe, you know. When you go to the hospital, have to be seen (?), you trust the doctor and you trust what is used there, meets safety requirements.

But in our debate, here, we are talking about a system where we want to regulate approval for such products. Now we have to ensure that what we do, can be implemented in practice. Now, what the committee I think, has decided upon this, probably could not be implemented. So many committees, groups with unclear competences, and I think at the end of the day we are going to extend the time needed for procedures to be approved, products to be approved, but we are not necessarily improving the safety of those devices. Now, really, I think we have a tiny tiny percentage of quality products

relating to the actual quality/quanty (?) standards with the products, which can be attributed to the manufacturers. I think, really, with the implementation of these devices in hospitals, it is a lot to do with how they are actually used.

And I don't know whether it is a good idea to have a debate here, which focusses on the black sheep in this; the people who have criminal intent. I mean there is just a tiny percentage of people on the market, because most other people want to market good products. They are in competition and that is why I believe that if we decided today that we wouldn't have this system change, we don't want it today, but we will talk about special notified bodies for approving these products, where we need to invest more there, and more on the market to avoid what happens with the breast implants for example, and we also have to recognize that in terms of the single-use products and their re-use you can't simply prohibit those. There is a lot of cost-pressure on the market of course and so I don't think a prohibition would actually work in practice. Thank you.

President: Thank you so much. I would like to give the floor to mrs Rivasi for a minute and a half.

22/10/2013

Michèle Rivasi (France, Greens/ALE)

Thank you so much, President. I think that over the last few years, there have been some serious problems, safety issues with these high-risk medical devices and particularly true for those devices which are the PIPs. But contrary to what mr Krahmer says, we have also realized that there was simply failure in the chain of responsibilities, the national authorities and the notifying bodies were negligent, intolerably negligent. And we had actually taken an initiative in June 2012 and the Green group had introduced a system for prior authorization for these particular devices, classified IIb came out onto the market. Now, it is a great shame this system was not taken on board by the Commission, because I think there is a paradox. Now we have authorizations on drugs, but on the high-risk medical devices, particularly implants, there is no particular authorization necessary. So, I don't understand why we have reached this system. We have now set up a system for special notification bodies, particularly for high-risk medical devices and then the work is supported by the authorities. This is a minimum, really. It has not, it should not be watered down. But we have actually achieved a competitive (?) clinical evaluation, compared to the existing treatments, whether it is the medical devices, or the drugs and then the clinical data on high-risk medical devices. This is essential. Especially before the devices come onto the market.

We have also asked for a ban on all kinds of carcinogens being used, so we really want this to be banned for the medical devices too.

President: Thank you, Michelle. (48:07) I now like to get the floor to mr Seeber, 1,5 minute.

22/10/2013

Richard Seeber (Germany, EPP (Christen Democrats))

Thank you very much, President. I would like to thank the rapporteurs and the shadows, because I feel that this report; the compromise that we have before us, is really deserving of our support. There may be a few details that we could change, but what we have agreed upon is that the patient security has to be the first priority here.

Okay, the different groups have slightly different positions, but I think that the compromise that we found is going to hold wardroom (?) practice, because I think that if we are going to have a system that doesn't have a central authority, then we will go through the advantages of a regional's system.

I think that people who believe that a central authority would avoid corruption is absolutely wrong; the central authorities have exactly the same failure rate as a regional authorities, on average. And medicine, medicinal products get onto the market 43 weeks earlier than the products in the USA, and I think now that is key for our patients and their health, because they faster these products are available, then the better it is for the patients. Of course, we need to ensure that there aren't any failings. We don't want unsatisfactory products to be implanted or anything like that. But we have the huge advantage of the European system, which is flexibility; we need to maintain that. And we need to continue to fine-tune our approach.

I mean jobs don't justify everything, but we have to remember it is a fact that this is an innovative sector; it's a market of hundreds of billions of euros where tens of thousands of people work there. Huge numbers of patents coming from the sector every year. Seven percent of all patents are for medical devices. So, if we are going to get advantage from all of this innovation, all these new patents, we need to have a good system. We need a proposal that goes against all centralizing tends.

President: Mr Perelló. (50:22)

22/10/2013

Andrés Perelló Rodriguez (Spain, S&D)

Thank you, President. This is the 21st century. Although [hoewel de bezuinigingen in de gezondheidszorg in sommige landen lijken] the situation in certain countries is a bit reminiscent of the 19th century. For example, the question of breast implants is a question of fraud and would been told that certain things have to change as a result. And that's why the work which has been put in by colleague Dagmar, I think, in such a complex issue which identifies the quality of medical devices and it makes it quite clear that supervision has to guarantee that we have transparency and we have traceability for each products. And that manufacturer controls are strict and this can be implemented without a prior warning. I think this is something that the Parliament could do in order to ensure that the health of patients, our first objective, is respected. You know, we people have implants which stay in their bodies for the rest of their life. And we can't have excuses, saying we are talking about transparency, and dragging things on etcetera. It is not possible to accept this. No. We are talking about the health of individuals, vis-à-vis

certain interest and that is why I would like to congratulate our colleague on the very complicated issue she has managed to worth (?) settle this conflict of interest on behalf of patients and their health. And that is what we should be doing in this Parliament. Thank you.

President: Thank you so much. I would like to congratulate the interpreters of the speech and the speed with which they are able to cope with that. The next speaker. (51:56)

22/10/2013

Milan Cabrnoch (Czech Republic, European Conservatives and Reformists Group (ECR))

Dear colleagues, I believe that the reports we are currently discussing, draft reports that is, in some points get into conflict with the principle of subsidiarity and I don't think that European law should decide which medical devices will be available on prescription, and which will be send over the countries, up to the Member States to decide on it. Because otherwise, this new legislation would make the system very expensive and it was also deteriorate the situation as far as innovations are concerned. Therefore, administrative regulations is something that we should be very cautious about. Preauthorization before medical devices are introduced in the market, this is also a too strict and harsh step. It will only increase burdensome administration and also we have heard many concerns on the part of our experts, because they are afraid that many aspects of specific care will no longer be available to the patients. We are interfering with the management of the healthcare, which is something that is not our responsibility. Thank you.

President: Thank you so much. I would like to get the floor to mrs Mazej Kukovic. (53:20)

22/10/2013

Zofija Mazej Kukovic (Slovenia, EPP (Christen Democrats))

I would like to support the compromises that have been put forward in the report. They make sense. And they give the report additional quality. We are limiting centralization, we are improving quality, we are improving patient security and patient's trust in the system is going to be improved.

We as politicians need to be aware of the importance of health. Health for everybody! Those who still have their health and those who have their health endangered. We need security in this area. And medicinal products are an element for social inclusion and dignity. Just imagine those women who lost their breast because of breast cancer and then need a silicon implant. Now, they are in a difficult situation and we need to ensure that these women could feel trust. We need specialized, small and medium sized companies to have access to the market. We also need to ensure that health insurance bodies, which are suffering under the prices, can continue to work. We also need to ensure that we have better transparency, because we need to get control of the costs of medicinal products and in-vitro diagnostic tools. I would like to thank the two rapporteurs.

President: Thank you, colleague. I now would like to give the floor to mrs Grossetête for a minute and a half. (55:03)

22/10/2013 (55:03)

Francoise Grossetête (France, EPP (Christen Democrats))

Thank you. Thank you so much. The scandals in the area of breast implants or hip implants has really made patients wonder about the medical situation. I think we need progress from industry, we need to look at innovation, but we have also been faced with frauds. Frauds, because of the system in the certification of medical devices and this is really a led (?) to these difficulties. And I think there have been some serious gaps and lacuna here. Now in order to give trust and confidence to the users and patients, we need to be very very strict on the criteria which we need to establish for the authorizing bodies. You cannot possibly authorize certain goods onto the market.

Of course, the whole procedure to put medical devices on the market is also very lengthy and cumbersome, but at the same time we need to make sure that there should be sanctions in the case of infringement, and what we also need to make sure is the re-use of medical devices, which are basically developed for single-use. I am entirely convinced that the single-use medical devices really will give us much more safety, particularly because the devices will have been sterilized or will give us more safety than the sterilized devices.

Lastly, I would also like to say that what we really do need, is a very strict vigilance. Just like we have vigilance for drugs, we need for medical devices.

President: Thank you very much indeed, Françoise. The last speaker in this round is Thomas Ulmer, who has one minute. (56:57)

22/10/2013 (56:57)

Thomas Ulmer (Germany, EPP (Christen Democrats))

President, ladies and gentlemen. Thank you very much indeed.

I am not going to stand up, because I still haven't decided to have a hip replacement. Maybe it is an irony of fate that we are discussing this issue right now, but we can see quite clearly the split here between industry and patient's rights. And it is not easy for us here to deal with this. You know, it is a typical thing in health quality, because the truth always lies somewhere between the two. And we shouldn't allow ourselves to be split, because, clearly, we are all responsible for patient's health. That's our ultimate aim as we deal with this. Now, what we need, are rapid, straightforward solutions, which are scientifically safe, not too complicated and which can be sustainable and which are workable.

All of these issues are of crucial importance and I think that we can live with the current compromise. Clearly, we are going to have to revise in a few years' time, to see how all this have worked and really, scandals cannot drive politics. We have to stand by and respect the majority of patients and honest industrial people. Thank you.

President: Thank you very much indeed. We now move on with the catch-the-eye procedure. And you know that I will cut off the microphone after one minute. One minute.

(58:32)

22/10/2013

Danuta Jazlowiecka (Poland, EPP (Christen Democrats))

Thank you so much, President. I think that adequate protection of our patients would form the basis of the health in the European Union. And this would require the following: first of all, accessibility to top-quality medical devices. That would guarantee top-quality, security and safety. We have to obviously protect small patients, minor patients, especially those who cannot agree themselves to test and the use of medical devices. Also, I think, clinical tests for medical devices are very important in this regard. There are many other aspects which are extremely important for our health and security. I am glad that we finally decided to tackle the subject and I really do hope that a responsible approach to the solutions proposed will enhance safety of our patients and medical devices. Thank you.

President: Thank you very much indeed. Mr Danellis now, for one minute. (59:40)

22/10/2013

Spyros Danellis (Greece, S&D)

Thank you, President. The recent scandals with breast implants from silicon as well as other implants, I think, have pointed out very clearly that European consumers are exposed to health risks. And that is why it is crucial that we very quickly take measures which will regulate the circulation of medical devices, with having common rules and also ensuring that we have safety on the market. The proposal, I think, stresses the differences which exist on the market to products related to free circulation, paid for by the patient's health.

We need to regulate better the manufacturers of these products with stricter rules for the approval of these products, and also about the use of these products. It has to made very clear to all those partners involved, the decision to implement common rules in Member States, -speaker has been cut off-

President: I am afraid you run out of time. Mr Petru Luhan has the floor.

22/10/2013

Petru Constantin Luhan (Romania, EPP (Christen Democrats))

Thank you, President. First, I believe this is a compromise report which is very necessary at this moment. Let me just draw your attention on several very important aspects. First, the approval procedures. Well, these are very difficult procedures; long, time-consuming and very unfavorable to new Member States. I think the Commission should do better here, should be able to find common standards for all Member States. Second, innovation. More precisely, there are huge differences in terms of innovation between various Member States. And the European Union should make sure that all patients, in all Member States, no matter how rich or how poor, have access to the same innovating equipment. And last but not least, we need to better train our personnel, medical personnel, to have an effective benchmarking. Again, the speaker was cut off.

President: Mrs Borzan, please. (1:02:04)

22/10/2013

Biljana Borzan (Croatia, S&D)

Thank you very much, indeed. Well, the current directive has only been in for us for a few decades, but nonetheless we made an awful lot of progress, whether we are talking about fillings in teeth, or pacemakers. Clearly, patients are those who have benefitted the most and that is why we have to encourage all inventions. But of course, that should never have repercussions in terms of patient's safety. Patients have to have the guarantees that the devices given to them are the best.

When a patient puts their life, their health in the hands of a doctor, the patient has to feel safe. And the doctor has to be able to trust the devices he is using. That is why we need a balanced directive, on the one hand, in order to encourage –the speaker has been cut off.

President: Mrs Prendergast has the floor.

22/10/2013

(EN) Phil Prendergast (Ireland, S&D). – Chairman, thank you very much. Like other speakers, I have listened to the entire debate here in the Chamber this morning. What I would say is that those people who have had defective products and implants put into their bodies, which require them to undergo constant care, constant hospital attendances, reassessments and re-evaluating their status and what the product was put in their body for and whether it is going to deteriorate and cause them undue hardship

– it is and it does. They worry about having these defective products in their bodies, and it is often very costly to have them corrected. I think any legislation that will improve the licensing of these products that are deemed fit for use should, never come under the aegis of cost. It should be fit for purpose, it should be safe and it should be for the best intentions of the patients. Thank you.

President: Thank you. Mrs Antigonè Papadopoulou is the finite (?) speaker. (1:04:29)

22/10/2013

Antigonè Papadopoulou (Greece, S&D)

Thank you, President. At the time of crisis of value I am wishing that humans are being exploited by humans. We have to combat fraudulent behavior, and we have to strengthen the quality control mechanisms we have, particularly for high-risk products. And they have to be applied on a unified basis across Europe. In-vitro products which are used and implants in patients have to be strictly tested in the course of their manufacturer as well as in practice, when they are used by the patients. We have to ensure, and I believe that this directive is moving in that direction, that these medical devices will not circulate on the market if they are defective – as has happened in the past. And we have to ensure that we can provide high-quality specifications, the correct procedures, protection, and accessible prices for everyone through-out the Member States of the European Union.

President: Thank you, Antigonè, and congratulations to the colleagues who respected the speaking time of one minute. Now, we have got to the end of the catch-of-the-eye procedure, so I would like to give the floor back to the Commissioner to react to the comments which have been named by our colleagues. Mr Neven Mimica, you have the floor. (1:05:57)

22/10/2013

(EN) Neven Mimica, Croatia, *Member of the Commission*. – Mr President, I have listened with great interest to today's lively and thorough debate, which has confirmed the convergent path of the Commission's and Parliament's views, proposals and positions on these two important files.

I would like to thank once again the rapporteurs, Mrs Roth-Behrendt and Mr Liese, not least for their drive and determination in the handling of these files over the past year. It is clear that compromise will be required on all sides in order to reach agreement on the two proposals within the term of the current legislature. I am convinced, however, that it is possible to find solutions to all the issues that need to be resolved. I reiterate my personal commitment towards bringing these important proposals to a successful conclusion.

Your strong mandate, which I have every reason to expect and welcome, would be a major contribution to paving the way to finally setting up these proposals. We shall all have to work on some pending issues in order to ensure a safe and efficient system for the pre-market assessment of medical devices.

I noted with appreciation that there is openness on both sides – I reiterate the Commission's openness – towards dealing further with reprocessing provisions, as well as with the scope, triggering/leading to a binding outcome and management of the scrutiny procedure. We all have to work on what is not an easy balance between patient safety and the industry's need – especially that of SMEs – to keep the existing innovative and competitive edge of European manufacturers. This balance would be easier to strike if our point of departure and arrival were to/would remain one of no compromise on patient safety.

I am even thinking ahead to future procedures, once we can/could be sure that the proposed regulation works and that the notification body – particularly the special notification body – fully meets the regulation's requirements. At that point/moment in the review process we could think about shifting the focus of the scrutiny from pre-market, product-based scrutiny to post-market, procedure-based scrutiny in terms of clinical and vigilance data that would actually enable and facilitate the work of the special notification body.

So there is work to be done, even further after we all agree on the new set-up of this regulation. I remain confident that we can succeed in concluding these files by spring 2014 and without undue delay. It is an ambitious but achievable goal if it is supported from all sides. Therefore, I very much appreciate that the Lithuanian Presidency is equally committed to starting interinstitutional negotiations by the end of this year. We have a duty to patients and consumers to deliver under the current legislature. I have every confidence that we can succeed in this endeavour. Thank you.

President: Thank you very much indeed, Commissioner. And in case to complete the debate, I am now going to give the floor to the two rapporteurs, with excellent work. Starting with mrs Roth-Berhendt. She has two minutes. (1:10:13)

22/10/2013

Dagmar Roth-Behrendt (Germany, rapporteur, S&D)

Thank you, President. Well, if listened carefully to today's debate, I think all colleagues have spoken in favour of more safety for patients and they have all said that we need to improve the system. So, I do hope that all of you will be voting in favour of/for the compromise amendments from the health committee. Because there are other amendments which I think are going to be watering down the system.

If I have been listening to those of you who industry, who said that industry needs to be competitive. Well, that is not really what is at stake here. Of course we want competitive industry, but of course we want goods and products that are safe and when people say: well, the whole authorization procedure needs to be simple, I do feel that products that have been developed for many many years and if you need a procedure which takes four months, surely that is not a long period of time. And it is a system very similar to what we do in the case of drugs. Now, this afternoon, we will have a vote and we need to decide on a whole series of other issues related to this subject.

People who talked about the re-use that could be dangerous, and I agree with you there. But other people say, well this is a bit far removed from reality. If you ban the re-use of single-use products, for why is a particular medical device used as a single-use, and then you authorize re-use. Well surely, if somebody has recognized a single-use well then it is single-use. Surely, if it is classified in a different way, then it wouldn't be single-use. So, I think that we should not authorize re-use of single-use.

And I agree with the Commission, the Council, the Presidency is now represented and I understand that money is more interesting than medical devices, I clearly understand this. But I am glad to see that the Presidency/President is here today. But within the committee, you can't interage (?) Member States to accept this. Well, we are still going to have a problem over the coming five years, so it is up to you, Presidents, Council, and I hope that the ministers will make an effort to make sure that we get a little speed behind this particular report. So that we can start up a trialogue with the Council and Commission, thank you.

President: Thank you, Dagmar. Congratulations on your excellent work. Mr Liese now has the floor to conclude this debate. (1:13:03)

Peter Liese (Germany, rapporteur, Christen Democrats)

Thank you very much, President. I would like to thank our colleagues through (?) the broad support that I have received and I think on the key points we all agree. But there are two points that I wanted to bring up again.

Some of the speakers mentioned the issue of informed consent on genetic tests. Now there is a suggestion that we are preventing certain medical practices in certain Member States. Well we have worked very carefully here. We have talked long lengths about this about this wording and I do think it is practicable.

What Rebecca Taylor mentioned, which is that if you have the issue of targeted treatments of cancer and things like that, we have taken that into account. I think that is all covered by the wording. So, we need to ensure that these products get onto the market, but they are also secure. Now there should be no advice. Well I think that that should be covered by that wording.

Then on ethics committees, well if we do adopt this proposal this afternoon, then of course there will be the requirement for the green light from an ethics committee. If you read the text carefully on clinical tests that is, then you get the same (at the?) out at the end of the day. So, I think it is very clear where the Parliament stands on these issues. Thank you very much.

President: Thank you, mister Liese, and also congratulations to you for work which has been recognized both by the Commission and all of the colleagues who have taken the floor.

So, the joint debate is now closed, and the vote will take place today at 11:30, when we vote this morning. Well, the Presidency has seen documentation on this and this, well, really a huge amount on

the next item, which I think reflects the importance of this issue and the work which has been put into it. The next item on the agenda it the report by mrs Hornmeier etc.

22/10/2013

Pavel Poc (Czech, S&D) WRITING

Europe's citizens expect that medical devices that are used in their countries, are safe. Their confidence has been undermined but a series of scandals - breast implants with industrial silicone, hip replacement, from which patients are released into the body of cobalt and chromium ions, and other cases clearly pointed to the fact that the current legislation is not able to ensure the safety of medical devices. It was the European Parliament which, in response to these events, adopted on 14 June 2012 a resolution calling on the Commission to draw up a legal framework that guarantees the safety of medical technology. The proposal we are now on the table, but it seems that some in a year and some months have forgotten what we actually brought to him, and he constantly tries to weaken. The rapporteur has done its utmost to reach a compromise and the proposal clearly increases patient safety in the EU. It could however do more if there was strong pressure from some stakeholders that the proposal was "balanced". This means in practice, as suggested by some MPs that it should find a solution that would suit both patients and entire sectors of production, distribution and sale of medical devices. In my view, however, the safety of patients in the first place and their confidence strengthened as a compromise, but clear rules that effectively prevent similar scandals.

A.4.1 Oral explanations of vote 22/10/2013 in European Parliament

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+CRE+20131022+ITEM-009-04+DOC+XML+V0//EN&language=EN

22/10/2013, oral expl. vote

Paolo Bartolozzi (Italian EPP (Christen Democrats))

Paolo Bartolozzi, you have the floor. Colleagues, thank you madam President. Today we have voted on the draft regulation on medical devices; a very important subject. And the proposal on in vitro devices does suggest that we examine the legislative reference context, to reinforce it, and to reinsure that we no longer have divergences between the Member States. There have been various health scandals as was recalled, and as such that was very important in terms of patient safety. Today, we therefore voted in favor for this text, which has, as its primary goal, the defense of European patient's health, but also a better definition of post-operative guarantees. And better definitions and requirements on manufacturers. At the same time, a great attention needs to be paid to the medical devices sector, in order to guarantee fair competition, which is very important in terms of jobs, considering the situation, whilst protecting the health of patients. I hope we continue down this line, and in net phase.

22/10/2013, oral expl. vote

Anna Rosbach, (ECR, Denmark).-

Thank you very much indeed, President. I would like to talk on both reports at once. I voted in favor of putting patient safety as the top priority and this is why we would like to have higher demands when it comes to the approval of medicinal equipment. I think it is very important that clear traceability of implanted products is indispensable. This is why I also supported better consultation when it comes to genetic tests. Now, I voted against the industries' right to re-use initial equipment. Well, I simply cannot grasp those colleagues who have thought to get these re-use of products which were designed to be used only once! And in my view, I think that this is taking risks with the confidence and the health of ill people. Thank you.

22/10/2013, oral expl. vote

English, Marian Harkin (ALDE, Irish). - Madam President, this report on medical devices is a balanced one which, like the in vitro report, puts patient safety first. Recent events such as the PIP scandal and the issue of certain hip replacements causing damage to bones are clear indications that we needed to review our legislation. One of the issues which was very clear was that all the different notified bodies in the different Member States were not operating at the same high level and that such gaps in regulatory controls had to be dealt with – and they were – in this proposal.

We now have a new medical devices coordination group and the new assessment committee for medical devices. Together they will ensure that there are no gaps in the very necessary regulatory controls. The report is proportionate, and we recognize that the PIP scandal was fraud. I think we have ensured an effective streamlined authorisation process which gives certainty to manufacturers and puts patient safety first.

Like Mr Higgins, I represent a country where there are 26 000 jobs in the medical devices sector – in Athlone, Sligo, Galway and elsewhere. Today we have helped to ensure the continuation of those jobs while at the same time putting patient safety first.

22/10/2013

Roberta Angelilli (Italian, EPP (Christen Democrats)), oral expl. vote

Thank you, madame President. How can we forget that defective implants that were posed (?) in 2000 of people. It is extremely serious that such an event as this is to happen. Health is a fundamental right, and as such should be an absolute priority. That is why I agree that we do need to reinsure that we have more stringent controls on medical devices. We need to improve their quality and safety, so patients can regain trust. That can only happen if we have a clear, safe reinforced legal framework. Guarantees, protection for patients, traceability and specific requirements on manufacturers. All of this while supporting innovation and competitiveness in a sector which in Europe employs half a million people and has a turnover of more than a hundred billion euros per year. We must be careful though, not to introduce extra red tape, particularly when it comes to SMEs.

22/10/2013, oral expl. vote

English, Diane Dodds (NI, Democratic Unionist Party (No group), United Kingdom). - Madam President, the health and wellbeing of our constituents are a top priority for all of us as legislators, and I welcome much of what is in this report before Parliament today. Confidence in all aspects of health care, especially in the safety of medical devices and of medical procedures, is paramount to both healthcare professionals and patients.

As technology evolves and further innovation brings yet more progress in the field of medicine, we ought to ensure that such innovation does not come at the expense of patients' safety. Information is also vital, and I believe that for many patients there is a vacuum of information – whether relating to benefits or risks – regarding the medical devices which are becoming more prevalent in treatment. That is a situation that must be addressed, and I believe this report can go some way to doing this.

22/10/2013, oral expl. vote

English, Seán Kelly (Irish, EPP (Christen Democrats)) - Madam President, like my colleagues Ms Harkin and Mr Higgins, I too give my general approval to these recommendations – both this report and the previous one. Certainly it is right that we should try to eliminate the duplication of research and studies,

and that we should eliminate inconsistencies across the European Union and help to complete the internal market. Many of the proposals go a long way to ensuring that this happens.

However, I am pleased that we have got a mandate to continue discussions with the Council, and I would hope that some of the concerns that industry has will be taken on board there. I met some representatives from my country of industries that account for EUR 7 billion in exports and employ 26 000 employees. They feel that, if it is implemented as it stands, it could lead to a three-year delay in approval for new products. This would not be good for Europe and not good for Ireland, and it certainly does not make more sense. I hope this can be addressed.

A.5 Press conference 02/04/2014 in European Parliament

http://www.europarl.europa.eu/ep-live/el/other-events/video?event=20140402-1500-SPECIAL-UNKN

(English transcription)

2 April, 2014

Chairman: Good afternoon, to everybody. Thank you for being here and thank you to those who are listening to us over the internet. There is going to be a vote at 6 pm on the medical devices regulation, so that is the final vote in plenary. I am going to hand over to the rapporteur.

00:40, 2 April, 2014

Dagmar Roth-Behrendt (Germany, rapporteur, S&D): ?? for starting late. I have to be in the plenary and you have other commitments as well. I was considering if I wanted to do a press conference at all, but I think I should share my frustration with you. That was the reason I finally said 'yes' to uhm… our frustration, some of our frustration, because more, not only me in that room worked hard. We are voting tonight in a simple vote, finally, on a legislative final resolution on a report which we have adopted in plenary in, with many amendments, already in October last year, 22nd of October 2013. The Christen Democratic group in the environment committee wanted not only the vote in committee, but as well in plenary to have a mandate for starting negotiations with the Council. I have to say they are not always coherent: now with the report of mr Liese on emission trading scheme there they want only the mandate in committee. Nevertheless, so we had to go to plenary, so we made that finally, only after the summer break, in October. From October onwards, we would have been able to negotiate with the Council. I was prepared to do so. We presented to the plenary already last year a vast part of amendments, representing compromises to deal, how to deal with medical devices. From the content wise, even that a lot of people think there was, the reason for making a revision of the legislation was the PIP scandal, the breast implant scandal in France, it was not really the reason, but it was a coincidence, because the old legislation from the beginning of the nineties was really necessary to be revisited. And the European Parliament had decided in, that already in some resolutions, so when we were looking at the piece of legislation we had a vast area of different topics.

One topic was how to allow a medical device to come onto the market. And we are speaking about, with medical devices, on everything. It's, it can be a simple syringe, it can be a little mirror that the dentist uses, it can be a blood pressure instrument, it can be a microprocessor implanted into the brain to fight Parkinson's disease, it is naturally as well, every implant like an implantable hip or a new knee joint or whatever. It is always as well naturally every stent which is put during the heart surgery. So there are many different parts of medical devices. We looked at the different bits and we saw and we tried and the whole, the main drive for us was on one hand to ensure patient safety, and on the other hand to make sure that the European industry is good and competitive. When we looked at the whole range of products and patient safety, we looked as well how do those products come onto the market? We recognized, that there was no real authorization scheme, but there was a simple certification in the

Member States. And the Member States decide who is allowed to give those certification signs, the CE sign. For that purpose they designate so-called notified bodies. When we started with the work on that piece of legislation, there were roughly 78 notified bodies overall in the European Union. In my own Member State, in Germany, there were 18. And those notified bodies do not have to fulfill a huge amount of conditions. Clearly they do not need to have medical competence. So, the check of the documentation of medical devices, implanted into the body for example, has been taken place at many of those notified bodies, not at all, I have to say friends wise (?), via the paper form. Engineer knowledge on how something works. That the engineer knowledge on how something works cannot always be sufficient, we recognized on metal-on-metal hip implants, where the engineers simply did not know how the joint finally afterwards works in the body. So, when we looked at that, we saw it also. That is the first problem.

The second problem is what happens to medical devices when they are, by definition, supposed to be only for single-use. Or for multiple use. So we now looked at all those bits. The original approach from my side was to say: high risk medical devices, to be implanted into the body, and to stay in the body, or to applicate an active ingredient, a substance, a pharmaceutical. Those should go, undergo a prior authorization process. I recognized very soon, even that I believe that is necessary for patient safety, and even that I believe that it is possible for those high-risk devices, as it is for pharmaceuticals normal, that that will be the future in some years, but it is now not foreseen with the majority of the house. It would not have been supported by the Member States, not by my own, not by others. It would not have been supported by the Commission, neither by the majority of the House. So, I tried to find the compromise. We tried to find a compromise by saying: then we distinct those high-risk medical devices and say: okay, at least if we stick to the system of notified bodies, those notified bodies dealing with those high-risk implants or devices which apply as active ingredient, a pharmaceutical, those have to go only to a special notified body, which could prove that they have the necessary medical knowledge, to understand what they certify there. We voted that, roughly like that, not exactly like that, in the plenary and we voted as well kind of a new system for reprocessing.

We wanted, again from the beginning, that we said if a producer explains or declares that it is a device for single-use, it can only, the definition of single-use is use once, with one patient. Not with the same patient twice or three times, once, one use, one patient. And I said, if a producer says that that is the only possibility because that device is not reprocessable, the producer has to prove that, has to explain why it is only a single-use and why is it not reprocessable. And then, it would have meant that single-use would have been single-use as long as not somebody is coming and saying: we have a safe way of reprocessing and that would have had to be certified by the Commission then. We lost that part in the plenary vote, and we as well lost clear provisions on labelling, because the PPE did not support us on that. There was an opt-out for Member States to ban reprocessing. So, Member States could decide that they ban reprocessing, like France for example wants to do that. France did a good way, I hope many Member States would do that, because that will give a clear drive at some stage, just to deal with the problem differently. And there was inscous (?) altogether a slightly weaker text in the report now on the functioning of the system.

Altogether, the compromises I made, I only made to have a legislation in place as soon as possible. Otherwise, I would not have made those compromises. Only for losing it or not for having anything, it is pretty easy. Then I would not have done that. But we face a situation here where the European industry pretends that that report would stop their innovation capacity, which is a ridiculous argument. Because

when you speak about high-risk products, you normally speak about products which are produced or developed in a time-frame of some years. You do not produce, and develop, and invent a processor to implant into the brain in half a year. So to speak then, about perhaps two or three months of a certification process, is nothing in the development time! But the industry, the European industry, not for me understandable, had the approach to keep the status-quo if possible. So they were similar to the tobacco industry with two lines: no legislation at all, but if a legislation, as late and as weak as possible. And obviously, they were successful up till now, because as late as possible we are now. We will have a vote tonight and that means we now close our first-reading procedure. That means that we now have to wait for a common position of the Council, whenever that comes, the normal second reading then in the Parliament starts. If that will finish then in a year or a year and a half, I have no clue. Clearly, I will not do it, because I am not a candidate for the next European election, whoever then will deal with it, I hope will do it responsibly. I have had two presidencies during that time, the Lithuanian and the Greek presidency, trying to bring that forward. I have to say that I understand naturally that every presidency has its priorities, I understand that the Lithuanian presidency had different priorities, I am very grateful to the Greek presidency and to the two colleagues who are present from the Greek permrep, and the permanent representation here. I know that they tried to do the impossible. Because it is, it was as badly prepared as you got it. It was nearly impossible, we had blockage from the Member States to do it. I am grateful to you and to your minister, if you could could transmit that message as well to him, that I really appreciate the effort, but it was not successful. So, I hope at least, whoever is continuing to work at the working group with the Italian presidency then, would be supported there as well. So, there we are. And if you find me sounding frustrated on that last vote on a report of mine after 25 years at the Plenary, I am frustrated.

11:25, 2 April, 2014

Chairman: Thank you very much. Are there any questions at all? Yes, go ahead sir.

Rory Watson, British medical journal. Is there anything that you do appreciate in the report, which will be queeding now to your successor?

Roth-Behrendt: If the report would be that I could not look into the mirror in the morning, I would not have supported it. It is, the report is still better than what we have now. To make a distinction in notified bodies, to increase the quality, I think it's a good thing. It's really good. And that we put the finger on the problem of of reprocessing is important as well. We tried to find out, and you come from the UK, so you perhaps are more successful than I, I tried to find out why at the NIHS, how many of those thousands and thousands and thousands of hospital infections and infections with resistant bacteria, with many people dying on that, is caused by non-properly reprocessed devices. And the simple answer was that they told me: we do not know. Well, that is an interesting answer, I have to say. So, if we put a finger on that, and if then Member States like France, are really starting to ban reprocessing, that will start to have a drive. And that we now force the notified bodies to get a better quality, that is an advantage as well. And I have to say, that is perhaps not the right place to praise you then, the British medical journal. The work some of you did from the medical journal, by showing up and decouvrer how work takes place in that notified body bunch of people in some areas and that you can more or less invent nearly everything and you get somebody to notify and to certify it, and somebody to do it between 300 euro and 10.000 euro. That is thanks to you as well and that was an important part. But neither your example which I always again use, was helping us. The industry was simply too pressurizing members, and as it is

a difficult topic, and as you need some time to understand it, to tell people: ow, that report will stop employment, or that report will close us down here, is emotionally too easy to understand and that is why members were not that responsible towards patients as they should. I would wish that many members from the PPE and from the liberals as well, especially the shadow rapporteurs, have to justify themselves on those were all roll-call votes they have taken last year in October.

14:14, 2 April, 2014

Chairman: Thank you, are there any other questions? Sophie.

Sophie Petigant, Europolitics. I have two questions. The first one: Do you think that the text, like it should be voted, would prevent new scandals, like the PIP scandal? And my second question is about your contact with the Council. How far are they? Have you been, have you discussed with the Greek, and how is it evolving? According to you is it in the right direction or is it too weak?

14:59, 2 April, 2014

Roth-Behrendt: So, perhaps I start with the last. Yeah, I myself, and as well as my colleague, Nikolas Palaye, who is sitting next to me, who was doing the main work on the report, let's say, honestly, more than I, let's say I am the loud speaker, and sometimes the idea giver, but vast parts, and a vast part of the work changing, changing roots and ways let's say three times to only to reach a majority has been done by him. So, he was in even closer contact with the Greek presidency. On working level with mr Florinus and his colleagues and with the, I with the minister as well in addition. And yes, it goes to the right direction. Now, finally it goes. You see that something moves, is kind of a revolution after during the Lithuanian presidency, with all respect, I had their regular contact as well, but I, and I have to say the Lithuanian health minister is a really engaged person, I very much appreciate him, but the way I.. it was clearly not their priority and the way they dealt with those robust Member States in the working group was really not efficient enough. And then I have to say, if you have Member States like Germany, who simply want to block it, or delay it, or do not work enough on it, or think that the German model can be haling the rest of the world, then that is not the best way to deal with it, I have to say. So, the German, the Germans could have been playing a much more active role, as the British could have been! And the French, who only, let's say at the very last, late stage thought they could be perhaps supportive. So, if I would have the support from larger Member States in the working group, who push on the speed a little bit, we could be much further.

So, but I am grateful, I am really grateful I did, normally I do not mention representatives from Member States because I find the Council normally is a bunch of people one have to hit the second, you always hit the right one, but that case I have to say, mr Florinus is sitting there with his colleague, is quite a different example, and I am really grateful to you, Dimitri.

The first part, first I have to say, because you know my work, and I have dealing with health policy and food policy many many years. I took the BSE committee, so I have quite a record. If somebody wants to be criminal, somebody can always be criminal. That led no legislation in the world will stop people to develop criminal activity. The only thing is we can try to do is, for those who do not do that, to have a clear, good framework and safety, and for the others, who want to cheat, and to fraud, and to do whatever, all the range between, between industrial jail, horse meat, all the vast way of cheating, there we need to have a good control system. One of the most important bits are inspections. Here I have to

say as well: we have in the report that there have to be unannounced inspections, the problem is simply the amount of controllers and inspectors Member States are willing to pay for. And are there, there are no European inspectors in that vast range that we could say: okay, we have a coverage there. But again, here I have to say, to have in the legislation the possibility of an unannounced inspection, standing in the morning in front of the door and saying: 'Good morning, could you please open the door' and then you are in five minutes later, that is quite extraordinary. I want to have that already since BSE time. Since BSE time I want that already with every part of the food chain and consumer goods chain that you can take the allowance to produce continuously again, immediately away, if somebody doesn't let you in. So you have to work as well on the sanctions as well, but that at least is a step forward.

18:49, 2 April, 2014

Chairman: Thank you, any other questions?

Doesn't seem to be the case. So, the vote will take place after six o'clock. There are some votes before, so it could be 6, 6.30. But I would just like to finish by thanking you all. Thank you very much. See you soon.

B) Correlation table of Articles and Annexes of Directive 2007/47/EC and in the tentatively agreed consolidated compromise text of the proposed Regulation on medical devices

NB. The correlation of the Articles is copied from Annex XVI of the proposed Medical Device Regulation, the correlation of the Annexes is made by the author.

Directive 2007/47/EC	Proposed Medical Device Regulation
Article 1(1)	Article 1(1)
Article 1(2)	Article 2(1)
Article 1(3) 1st subparagraph	Article 1(5) 1st subparagraph
Article 1(3) 2nd subparagraph	Article 1(5) 2nd subparagraph
Article 1(4) and (4a)	Article 1(4) 1st subparagraph
Article 1(5)	Article 1(2)
Article 1(6)	-
Article 1(7)	Article 1(6)
Article 1(8)	Article 1(7)
Article 2	Article 4(1)
Article 3 1st subparagraph	Article 4(2)
Article 3 2nd subparagraph	-
Article 4(1)	Article 22
Article 4(2)	Article 19(1) and (2)
Article 4(3)	Article 19(3)
Article 4(4)	Article 8(7)
Article 4(5) 1st subparagraph	Article 18(6)
Article 4(5) 2nd subparagraph	-
Article 5(1)	Article 6(1)
Article 5(2)	Article 6(2)
Article 5(3), Article 6	-
Article 7(1)	Article 88
Article 8	Articles 69 to 72
Article 9	Article 41
Article 10(1)	Number (43) and (44) of Article 2(1), Article 61(1), Article 63(1)
Article 10(2)	Article 61(3) and Article 63(1)
Article 10(3)	Article 63(2) and (4)
Article 10(4)	Article 66
Article 11(1)	Article 42(2)
Article 11(2)	Article 42(4)
Article 11(3)	Article 42(3)
Article 11(4)	-
Article 11(5)	Article 42(5)
Article 11 (6)	Article 42(7)

Article 11(7)	-
Article 11(8)	Article 9(3)
Article 11(9)	Article 43(1)
Article 11(10)	Article 43(3)
Article 11(11)	Article 45(2)
Article 11(12)	Article 42(8)
Article 11(13)	Article 47(1)
Article 11(14)	-
Article 12	Article 20
Article 12a	Article 15
Article 13(1) point (a)	Article 41(3)
Article 13(1) point (b)	Article 41(4) point (a)
Article 13(1) point (c)	-
Article 13(1) point (d)	Article 3(1)
Article 14	Article 25
Article 14a	Article 27
Article 14b	Article 74
Article 15	Articles 50 to 60
Article 16(1)	Articles 33 and 34
Article 16(2)	Article 29
Article 16(3)	Article 36(2)
Article 16(4)	-
Article 16(5)	Article 45(4)
Article 16(6)	Article 45(3)
Article 16(7)	Articles 31(2) and 35(1)
Article 17	Article 18
Article 18	Article 73
Article 19	Article 75
Article 20	Article 84
Article 20a	Article 77
Article 21	-
Article 22	-
Article 23	-
Annex I	Annex I
Annex II	Annex VIII
Annex III	Annex IX
Annex IV	Annex X
Annex V	Annex X
Annex VI	Annex X
Annex VII	Annex III
Annex VIII	Annex XI
Annex IX	Annex VII
Annex X	Annex XIII and Annex XIV
Annex XI	Annex VI
Annex XII	Annex IV

C) Completely new Articles and Annexes in the tentatively agreed consolidated compromise text of the proposed Regulation on medical devices compared to Directive 2007/47/EC

NB. Completely new article means that none of the paragraphs of an article in the proposed Medical Devices Regulation overlaps with an article in the current Medical Devices Directive.

In Chapter II; Making available and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement:

Article 5: Distance sales

Article 5a: Claims

Article 7: Common Specifications

Article 10: Change of authorized representative

Article 11: General obligations of importers

Article 12: General obligations of distributors

Article 13: Person responsible for regulatory compliance

Article 14: Cases in which obligations of manufactures apply to importers, distributors or other persons

Article 16: Implant card and information to be supplied to the patient with an implanted device

Article 21: Parts and components

In Chapter III; Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European databank on medical devices:

Article 23: Identification within the supply chain

Article 23a: Medical devices nomenclature

Article 24: Unique Device Identification system

Article 24a: Electronic system of UDI ('UDI database')

Article 24b: Process of registration of device

Article 25a: Process for registration of manufacturers, authorized representatives and importers, single registration number

Article 26: Summary of safety and clinical performance

Article 27a: Functionality of the European database portal and the Electronic system on UDI

In Chapter IV; Notified bodies:

Article 28: National authorities responsible for notified bodies for medical devices

Article 30: Subsidiaries and subcontracting

Article 32: Assessment of the application

Article 32a: Nomination of experts for joint assessment of applications for notification

Article 32b: Language requirements

Article 35a: Review of notified body assessment of technical documentation and clinical evaluation

Article 37: Challenge to the competence of notified bodies

Article 38: Peer review and exchange of experience between national authorities responsible for notified bodies

Article 39: Coordination of notified bodies

Article 40a: List of standard fees

In Chapter V; Classification and conformity assessment:

Article 43a: Clinical evaluation consultation procedure for certain class III and class IIb devices

Article 44: Mechanism for scrutiny of conformity assessments of certain class III and class IIb devices

Article 45a: Electronic system on notified bodies and on certificates

Article 46: Voluntary change of notified body

Article 48: Certificate of free sale

In Chapter VI; Clinical evaluation and clinical investigations:

Article 49: Clinical evaluation

In Chapter VII; Post-market surveillance, vigilance and market surveillance:

Article 60a: Post-market surveillance system of the manufacturer

Article 60b: Post-market surveillance plan

Article 60ba: Post-market surveillance report

Article 60c: Periodic safety update report

Article 61a: Trend reporting

No Article 64 and 65 in tentatively agreed consolidated compromise text of the proposed Regulation on medical devices

Article 65a: Analysis of vigilance data

Article 66: Implementing acts

Article 66a: Electronic system on vigilance and on post-market surveillance

Article 67: Market surveillance activities

Article 75b: Electronic system on market surveillance

In Chapter VIII; Cooperation between Member States, Medical Device Coordination Group, Expert laboratories, Expert panels and device registers:

Article 76: Competent Authorities

Article 78: Medical Device Coordination Group

Article 79: Support by the Commission

Article 80: Tasks of the MDCG

Article 81a: Provision of scientific, technical and clinical opinion and advice

Article 82: Conflict of interests

Article 83: Device registers

In Chapter IX; Confidentiality, data protection, funding, penalties:

Article 85: Data protection

Article 86: Levy of fees

Article 86a: Funding of notified body designation and monitoring activities

Article 87: Penalties

In Chapter X; Final provisions:

Article 89: Exercise of delegation

Article 90a: Separate delegated acts for different delegated powers

Article 91: Amendments to Directive 2001/83/EEC

Article 92: Amendments to Regulation (EC) No 178/2002

Article 93: Amendments to Regulation (EC) No 1223/2009

Article 94: Transitional procedures

Article 95: Evaluation

Article 96: Repeal

Article 97: Entry into force and date of application

Annex IIa: Technical documentation on post-market surveillance

Annex V: Information to be submitted with the registration of devices and economic operators in accordance with Article 25a and core data elements to be provided to the UDI data base together with the device identifier in accordance with Article 24a and the European Unique Device Identification System

Annex XV: List of groups of products without an intended medical purpose referred to in Article 1(1a)

Annex XVI: Correlation table

D) Comparison of Conformity Assessment Procedures between Directive 2007/47/EC and the Proposed Medical Device Regulation

<table>
<tr><th></th><th colspan="3">Directive 2007/47/EC</th><th colspan="2">Proposed Medical Device Regulation</th></tr>
<tr><td rowspan="4">Class III:</td><td colspan="3">a) Annex II (full quality assurance)</td><td colspan="2">a) Annex VIII (quality management system assurance & assessment of technical documentation)</td></tr>
<tr><td colspan="3">b) Annex III (type examination)</td><td colspan="2">b) Annex IX (type examination) + Annex X (product conformity assessment):</td></tr>
<tr><td colspan="2">+ Annex IV (EC Verification)</td><td>+ Annex V (production quality assurance)</td><td>Part A (production quality assurance)</td><td>Part B (product verification)</td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td rowspan="4">Class IIb:</td><td colspan="3">a) Annex II (full quality assurance),

but <u>not</u> point 4 (Examination of design of product)</td><td colspan="2">a) Annex VIII (quality management system assurance & assessment of technical documentation),
<u>except</u> for Chapter II (assessment of technical documentation)</td></tr>
<tr><td colspan="3">b) Annex III (type examination)</td><td colspan="2">b) Annex IX (type examination) + Annex X (product conformity assessment):</td></tr>
<tr><td>+ Annex IV (EC verification)</td><td>+ Annex V (production quality assurance)</td><td>+ Annex VI (product quality assurance)</td><td>Part A (production quality assurance)</td><td>Part B (product verification)</td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td rowspan="4">Class IIa:</td><td colspan="3">a) Annex VII (EC declaration of conformity)</td><td colspan="2">a) Annex VIII (quality management system assurance & assessment of technical documentation),
<u>except</u> for Chapter II (assessment of technical documentation),
<u>with</u> assessment of the technical documentation of at least one representative device for each category of devices.</td></tr>
<tr><td>+ Annex IV (EC Verification)</td><td>+ Annex V (production quality assurance)</td><td>+ Annex VI (product quality assurance)</td><td colspan="2"></td></tr>
<tr><td colspan="3">b) Annex II (full quality assurance), but <u>not</u> point 4 (Examination of design of product), i.e. equivalent to option a) of Class IIb.</td><td colspan="2">b) Annex II (technical documentation) + Annex X (product conformity assessment):</td></tr>
<tr><td colspan="3"></td><td colspan="2"></td></tr>
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<tr><td></td><td></td><td>Part A: Section 7 (production quality assurance)</td><td>Part B: Section 8 (product verification)</td></tr>
<tr><td>Class I:</td><td>Annex VII (EC declaration of conformity)
+ Draw up EC declaration of conformity by manufacturer</td><td colspan="2">Annex II (technical documentation)
+ EC declaration of conformity (Article 17)</td></tr>
<tr><td rowspan="4">Custom-made devices:</td><td rowspan="4">Annex VIII (Statement concerning devices for special purposes)
+ Draw up statement from Annex VIII by manufacturer</td><td colspan="2">Annex XI (Procedure for custom-made devices)
+ Draw up statement from Annex XI: Section 1 by manufacturer</td></tr>
<tr><td colspan="2">NB. Custom-made devices, of Class III, which are implantable:</td></tr>
<tr><td colspan="2">a) Annex VIII (quality management system assurance & assessment of technical documentation): Chapter I</td></tr>
<tr><td colspan="2">b) Annex X (product conformity assessment): Part A (production quality assurance)</td></tr>
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