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**Transparency - an essential requirement  
in medical device regulatory reform**

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## **Transparency - an essential requirement in medical device regulatory reform**

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**Summary:** Medical devices placed on the EU market include a large variety of products. Several devices, in particular high risk products that are invasive and implanted in a patient's body can pose substantial health problems to patients in case of malfunctioning, improper use and adverse effects. While direct-to-consumer advertising of medical devices is allowed under EU law, it is difficult for the public to have access to non-promotional, objective, reliable information on devices available on the internal market. In the context of the 2012 revision of the EU regulatory framework on medical devices, this paper reviews the EU rules relevant to access to information for the public. It highlights a number of concerns regarding transparency of regulatory procedures, and compares medical devices to prescription medicines in terms of EU rules on information to patients. Furthermore, the paper discusses whether recent experiences with defective implant recalls are likely to prompt a reaction at EU level that leads to better information and increased transparency.

**Keywords:** Medical devices, information to the public, transparency, EU law

**JF codes:** K32, I18

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## 1. Introduction

The medical devices industry is a rapidly growing, highly innovative and competitive sector that encompasses a large number of heterogeneous products used in health care<sup>1</sup>. The sector is characterized by emphasis on research and development, short product lifecycle, and rapid pace of innovation. The European medical technology industry captures more than 30% of global sales of medical technology, and nearly 8% of annual sales is reinvested each year in research and development<sup>2</sup>. In 2009, the medical devices sector filed more patent applications than any other sector in Europe<sup>3</sup>.

The overall aim of EU action in the field of medical devices is to promote innovation and competitiveness while ensuring public health and safety. EU involvement focuses mainly on guaranteeing the free movement of medical devices as goods in the internal market. The EU pursues this goal by preventing barriers that result from the adoption of diverging national rules and standards, as well as promoting mutual recognition and technical harmonization of products. Following the concept of the New Approach to technical harmonization and standardization<sup>4</sup>, legislative harmonization in this sector has been limited to essential requirements relating to the safety and performance of devices placed on the internal market. The technical specifications of products meeting these essential requirements are set forth in harmonized standards, and products manufactured in compliance with these standards are presumed to be in conformity with the requirements<sup>5</sup>. In addition, the EU promotes international convergence of national regulatory practices as a member of the International Medical Device Regulators' Forum (IMDRF)<sup>6</sup>.

A number of medical devices placed on the EU market – in particular, products that are invasive or implanted in a patient's body – can pose substantial and even life-threatening

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<sup>1</sup> According to World Bank, Espicom, EDMA and Eucomed calculations for 2009, the European medical technology industry is growing at more than 5% per year. Eucomed. 'Medical Technology – key facts and figures', at [http://www.eucomed.org/uploads/Modules/Publications/110930\\_medicaltechnology\\_keyfacts.pdf](http://www.eucomed.org/uploads/Modules/Publications/110930_medicaltechnology_keyfacts.pdf) (last accessed on 29 March 2012).

<sup>2</sup> According to Espicom and Eucomed calculations, idem footnote 1. See also the website of Eucomed: <http://www.eucomed.org/key-themes/innovation-research-smes>.

<sup>3</sup> European Patent Office, Statistics 2009. See also Eucomed. 'Medical Technology – key facts and figures', cited at footnote 1.

<sup>4</sup> 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 of 7 May 1985 on a new approach to technical harmonization and standards, *OJ C* 136, 4.6.1985.

<sup>5</sup> See for further details, part 2 of this paper (overview of regulation of medical devices in EU law).

<sup>6</sup> Efforts to promote international regulatory convergence and the role of the IMDRF are discussed further in part 2 of this paper (overview of regulation of medical devices in EU law).

risks to patients in case of malfunctioning, improper use and adverse effects. Given the increasing number and complexity of high risk devices, increased regulatory transparency and better access to information for the public have been demanded especially by physicians and other persons using them as part of a professional healthcare activity<sup>7</sup>. While direct-to-consumer advertising of medical devices is allowed under EU law, it is difficult for the public to have access to non-promotional, objective, reliable information on devices available on the internal market. Clinical data used by manufacturers to have their devices approved for the EU market and the scientific rationale for approval are currently treated as confidential and commercially sensitive information that is not open to the public<sup>8</sup>. Increasing access to comparative data would enable better co-operation between healthcare professionals and their patients in assessing a device against others available within the same category and choosing the most appropriate one. Demands for better information and transparency have intensified further to the growing number of safety notices and medical device recalls<sup>9</sup>. Access to regulatory data for the public has been called for as a means to enable informed treatment choice and enhance consumer protection<sup>10</sup>.

This paper focuses on access to information for the public and transparency on medical devices available on the EU market. First it provides an overview of the distinctive features of the medical device sector and the EU regulatory framework. It then reviews the EU rules relevant to information to the public on devices and highlights a number of issues concerning transparency of regulatory procedures and access to data. The paper compares medical devices to prescription medicines in terms of EU rules on access to information. Towards this end it reviews the efforts of the European Commission and Parliament to put in place harmonized rules on information provided by the pharmaceutical industry to consumers on prescription medicines. Against the background of EU institutions' harmonization efforts to promote access to high quality, non-promotional information on medicines, the paper discusses the feasibility of transposing similar harmonization to medical devices.

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<sup>7</sup> See for example, Fraser A.G., Daubert J.C., Van de Werf F., Estes M., Smith S.C., Krucoff M.W., Vardas P.E., Komajda M., 'Clinical evaluation of cardiovascular devices – principles, problems and proposals for European regulatory reform: Report of a policy conference of the European Society of Cardiology', *EUR Heart J* 2011, 32:1673-1686, p. 1684.

<sup>8</sup> See also Cohen, D. and Billingsley, M. 'Europeans are left to their own devices', *BMJ* 2011;342:d2748.

<sup>9</sup> Heneghan, C.,Thompson, M., Billingsley, M., Cohen, D. 'Medical-device recalls in the UK and the device-regulation process: retrospective review of safety notices and alerts', *BMJ Open* published online 15 May 2011, doi: 10.1136/bmjopen-2011-000155.

<sup>10</sup> See Cohen, D. and Billingsley, M., 2011, cited at footnote 8. See also Billingsley, M. 'Clinical data on high risk medical devices should be made publicly available', *BMJ* 2011;342:d4162; Cohen, D. 'Out of joint: The story of the ASR', *BMJ* 2011;342:d2905.

Furthermore, it discusses whether the recent experience with defective implant recalls (in particular, the incident that led to the investigation of the French manufacturer Poly Implant Prothèse (PIP) for the fraudulent use of non-medical grade silicone in breast implants – hereafter the PIP incident) is likely to prompt an answer at EU level that leads to better information and greater transparency.

## **2. Features of the medical device sector in the EU**

A medical device is defined in EU law as “any instrument, apparatus, appliance, software, material or other article, intended to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease, an injury or a handicap, for the investigation, replacement or modification of the anatomy or of a physiological process, or for the control of conception”<sup>11</sup>. This encompasses a large variety of products, from simple and low-risk products like gloves, gowns, stethoscopes to invasive or implantable devices such as pacemakers, hip prostheses, coronary stents and complex machines like magnetic resonance imaging systems and dialysis machines.

The medical device sector has a number of distinctive features that differ considerably from the characteristics of the medicinal products sector (pharmaceuticals). Such features include rapid pace of innovation and change in the device industry, heterogeneity of products placed on the market, and fragmentation of the sector with a large number of small firms and a few multi-national companies. The medical technology industry is largely built on small and medium sized enterprises. According to the estimates published by Eucomed, about 80% of the 22,500 medical technology companies in Europe employ fewer than 250 people, and about 9,000 companies employ ten people or less<sup>12</sup>. The number of different product groups currently on the market is over 10,000 and the number of different products reaches 500,000<sup>13</sup>. This includes single-use products meant for individual patients and procedural, multiple-use products used as part of medical procedures. The sector of single-use products is particularly characterized by rapid innovation, large variety of products, short investment

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<sup>11</sup> As defined in the EU medical device Directives: Directive 90/385/EEC concerning active implantable medical devices, Directive 93/42/EEC concerning medical devices and Directive 98/79/EC concerning in vitro diagnostic medical devices (see footnotes 17, 18 and 19 for full citation).

<sup>12</sup> According to World Bank, Espicom, EDMA and Eucomed calculations for 2009. Eucomed. Medical Technology – key facts and figures. <http://www.eucomed.org/facts-figures> (last accessed on 29 March 2012).

<sup>13</sup> See also European Commission. Commission staff working document: impact assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. SWD(2012) 30 final, Brussels, 1.3.2012, ANNEX 9, p. 53.

recovery period and very short product lifecycles with superseding improved versions usually arriving within 18 to 24 months of introduction<sup>14</sup>. The rapid pace of change in this sector makes it difficult for regulators to keep up with the developments.

Another significant difference between the medical device sector and the pharmaceutical sector concerns pricing and mechanisms of inclusion of products in the health benefit package provided by national health systems and covered from public funds. As shown by the European Commission, only 15% of devices undergo a listing and pricing process similar to that applied to pharmaceuticals in order to be covered from public funds<sup>15</sup>. Such devices are supplied directly to patients. The significant majority (about 80%) of devices placed on the market in the EU is procured through the health system (via public tenders) and covered as part of the service/intervention provided by the healthcare professional. The remaining 5% of devices are sold over the counter and the costs are covered by patients out-of-pocket; such products are not subject to price and reimbursement regulations. According to the medical device industry, the share of over the counter products is expected to increase as more and more devices are excluded from public coverage and paid for out-of-pocket by patients<sup>16</sup>.

## **2.1. Overview of regulation of medical devices in EU law**

The core EU legal framework on medical devices was created in the 1990s by adopting three main directives: Directive 90/385/EEC concerning active implantable medical devices<sup>17</sup>, Directive 93/42/EEC concerning medical devices,<sup>18</sup> and Directive 98/79/EC concerning in vitro diagnostic medical devices<sup>19</sup>. These directives aim at balancing the efforts to promote the internal market for medical devices with the protection of public health and patient safety. They have been supplemented later on by amending and implementing legislation; the latest directive was adopted in 2007<sup>20</sup>. The wide range of products and product types in this sector

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<sup>14</sup> Eucomed website: <http://www.eucomed.org/key-themes/innovation-research-smes> (last accessed on 29 March 2012).

<sup>15</sup> Idem footnote 13, pp. 56-57.

<sup>16</sup> Idem footnote 13, page 55.

<sup>17</sup> 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 , 20/07/1990, P. 0017 – 0036.

<sup>18</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, commonly known as the Medical Device Directive, *O J L* 169/1 of 1993-07-12.

<sup>19</sup> 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 , 07/12/1998, P. 0001 – 0037.

<sup>20</sup> 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, p. 21, 21.9.2007.

make it difficult to adopt product-specific norms or standards. Consequently, legislative harmonization has been limited to essential requirements relating to the safety and performance of devices, according to the New Approach concept<sup>21</sup>.

The EU regulatory framework has been complemented by several guidance documents that are legally non-binding and reflect the consensus of major stakeholders regarding the interpretation of the directives. Such guidelines include the European Commission Guidance documents providing explanations to the directives (such as the Blue Guide<sup>22</sup>), the MEDDEV guidelines and consensus statements published by the Medical Device Expert Group (MDEG), and the NB-MED Guidance documents issued by the Notified Bodies<sup>23</sup>. 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<sup>24</sup>.

In addition, the EU is one of the five founding members of the Global Harmonization Task Force (GHTF) that adopted and disseminated non-binding guidance documents related to this sector<sup>25</sup>. Bringing together representatives of national regulatory authorities and the industry, the GHTF was created in 1992 as a voluntary task group promoting international convergence in regulatory requirements and approaches related to medical devices. In 2012 the GHTF was replaced by the International Medical Device Regulators' Forum (IMDRF)<sup>26</sup>, a regulator-led harmonization and collaboration group. The IMDRF has been created with the goal to speed up international regulatory convergence. Regulatory authorities from the EU are represented in this forum together with members from Australia, Brazil, Canada, Japan, and the USA<sup>27</sup>. While the IMDRF continues to rely on input and advice from the industry, it has broadened the range of stakeholders that can provide input to its work by involving

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<sup>21</sup> European Commission. Guide to the implementation of directives based on the New Approach and the Global Approach, see footnote 4.

<sup>22</sup> European Commission. Guide to the implementation of directives based on the New Approach and the Global Approach, see footnote 4.

<sup>23</sup> The interpretative documents, guidelines and consensus statements concerning medical devices can be accessed at the website of the European Commission, Directorate-General for Health and Consumers: [http://ec.europa.eu/health/medical-devices/index\\_en.htm](http://ec.europa.eu/health/medical-devices/index_en.htm) (last accessed on 23 October 2011).

<sup>24</sup> Eucomed Medical Technology. *Code of Ethical Business Practice – Eucomed Guidelines on Interactions with Healthcare Professionals*, Brussels, Eucomed, 2008.

<sup>25</sup> See the website of the GHTF: <http://www.ghrf.org/> (last accessed on 24 October 2011).

<sup>26</sup> See the terms of reference of the IMDRF: <http://www.imdrf.org/pdf/imdrf-tor.pdf> (last accessed on 29 March 2012).

<sup>27</sup> China, India and Russia have been invited to participate but have not confirmed membership by 1 March 2012 (see the IMDRF terms of reference cited at footnote 26).



healthcare professionals, the academia, consumer and patient groups in information sharing and scientific exchange<sup>28</sup>.

### ***Risk-based classification of devices***

An explicit purpose of the medical device Directives is to guarantee the free movement of medical devices as goods in the internal market. National rules on the safety and performance of devices have been harmonized since the 1990s. The Directives set out the essential requirements regarding design and construction to ensure the protection of health and safety of patients and healthcare professionals. They establish the conformity assessment procedures for the different classes of devices. Devices that are in conformity with the provisions of the Directives get a CE marking, which enables them to move freely within the internal market and to be put into service in accordance with their intended purpose. As a general rule, Member States are not allowed to create any obstacles to the placing on the market or the putting into service on their territory of devices that bear the CE marking.

The Directives classify medical devices according to risk. The lowest risk devices are assigned to Class I, the medium risk devices fall into Class IIa and Class IIb. The highest risk devices such as a number of surgically invasive and implantable products, as well as products that include as an integral part, a human blood derivative or a medicinal product are assigned to Class III<sup>29</sup>. The process of marketing approval and the levels of testing and evidence required differ according to this classification. Devices in Class I can be approved on the basis of the manufacturer's self-declaration of conformity with the essential requirements set forth in the Directives. Class II and III devices must pass a conformity assessment procedure before they are placed on the EU market<sup>30</sup>. For this, the manufacturer must prove that the device seeking approval satisfies the essential requirements of safety and performance stipulated in the Directives. Performance requirements focus on the mechanism of action; the basic principle is that the device must carry out the functions that it is intended to perform as specified by the manufacturer<sup>31</sup>. Class III devices must also undergo human clinical investigations as a condition for approval; however, randomized clinical trials are not mandatory.

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<sup>28</sup> Statement from the GHTF chair: Update on Future Directions of GHTF, 28 March 2011.

<sup>29</sup> See *ANNEX IX* of the Medical Device Directive 93/42/EEC on the classification criteria.

<sup>30</sup> See the directives on medical devices (Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC).

<sup>31</sup> As stated in *ANNEX I* on essential requirements of the Medical Device Directive 93/42/EEC, "devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions [...] as specified by the manufacturer" (Directive 93/42/EEC, General requirements, paragraph 3).

It is noteworthy that the essential requirements stipulated in the medical device Directives do not require proof of clinical (therapeutic) effectiveness. Instead, they focus on safety and performance. 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. Furthermore, if an equivalent device exists already on the internal market, then the new device can be approved on the basis of equivalence and marketed without having to prove that the clinical effectiveness is of a similar level<sup>32</sup>.

### ***Responsibilities of national authorities and Notified Bodies***

Member States are responsible for implementing the EU medical device Directives in national rules. Member States designate so-called Notified Bodies for carrying out one or more of the EU conformity assessment procedures described in the annexes of the Directives. National authorities inform the European Commission about the Notified Bodies that they select and designate. Notified Bodies take the decisions on the approval of medical devices and their placement on the EU market. They are also responsible for suspending or withdrawing the conformity certificates when they find that a manufacturer no longer satisfies the essential requirements set forth in the Directives. Designation of a Notified Body may be restricted to certain types of devices and/or conformity assessment procedures. A manufacturer intending to place a medical device on the EU market can choose any Notified Body in the EU, designated under the appropriate Directive for the respective conformity procedure. The European Commission publishes and updates regularly the list of bodies notified under each of the three Directives together with their identification numbers and the tasks for which they have been notified<sup>33</sup>.

Most Notified Bodies are privately owned and run commercial organizations<sup>34</sup>. The medical device Directives set forth the criteria to be met for their designation by national authorities. These criteria are meant to ensure the impartiality, professional integrity, competence and

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<sup>32</sup> See also Fraser A.G. et al, 2011, p. 1674, cited at footnote 7.

<sup>33</sup> In May 2012, there were 63 bodies notified to operate in EU countries under the Medical Device Directive 93/42/EEC; there were 19 bodies notified under the Active Implantable Medical Devices Directive 90/385/EEC and 23 under the In vitro Diagnostic Medical Devices Directive 98/79/EC. The list of the bodies is available at the website of the European Commission, Directorate General for Enterprise and Industry: <http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main> (last accessed on 20 May 2012).

<sup>34</sup> See also Cohen, D. and Billingsley, M., 2011, cited at footnote 8. See also Billingsley, M. 'Clinical data on high risk medical devices should be made publicly available', *BMJ* 2011;342:d4162.

expertise of the bodies. National authorities are responsible for monitoring and periodically auditing Notified Bodies, and for withdrawing their status if they no longer meet the criteria. Notified Bodies are obliged to observe professional secrecy with regard to all information gained in the course of their duties (notwithstanding their obligations to inform the competent authorities of the Member States in which they operate)<sup>35</sup>. Confidentiality is extended to product claims and clinical data submitted by manufacturers as well as the conformity assessment. Such data are not available for the general public<sup>36</sup>.

A European Databank on Medical Devices (Eudamed) has been created with the aim to promote information exchange between national authorities and the European Commission. A major goal of the databank is to improve market surveillance by ensuring that all authorities record and have access to certain regulatory data, in particular vigilance and clinical investigation data. Eudamed contains data on registration of manufacturers, authorized representatives and devices<sup>37</sup>, certificates issued, modified, supplemented, suspended, withdrawn or refused according to the EU conformity procedures, clinical investigations and post-marketing surveillance<sup>38</sup>. Since 1 May 2011, Member States have been obliged to report to Eudamed the above mentioned regulatory data<sup>39</sup>. They have also been obliged to enter by 30 April 2012 all the data existing on products notified before May 2011. The database is currently only accessible to national and EU authorities; it is not open to the public<sup>40</sup>. The 2012 recast of the EU regulatory framework envisages opening up some parts of Eudamed to the general public, although it is not yet clear what type of data would this concern.

### ***Recast of the medical device Directives***

The European Commission initiated in 2008 a fundamental revision of the three medical device Directives. As stated by the Commission, the overall aim of the recast is to consolidate and simplify the regulatory framework, promote its uniform implementation across Member

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<sup>35</sup> See ANNEX XI of the Medical Device Directive 93/42/EEC on criteria to be met for the designation of Notified Bodies.

<sup>36</sup> See also Heneghan, C. et al, 2011, cited at footnote 9.

<sup>37</sup> Excluding data related to custom-made devices (see Article 14a of the Medical Device Directive 93/42/EEC).

<sup>38</sup> See Article 14a of the Medical Device Directive 93/42/EEC.

<sup>39</sup> Commission Decision 2010/227/EU on the European Databank on Medical Devices (Eudamed), OJ L102/45 of 23 April 2010.

<sup>40</sup> See also the information provided on website of the European Commission on Eudamed: <http://ec.europa.eu/consumers/sectors/medical-devices/market-surveillance-vigilance/eudamed/> (last accessed on 20 January 2012).

States and fill in the regulatory gaps that have emerged with regard to a number of new technologies<sup>41</sup>. A specific goal is ensuring convergence of the EU regulatory framework to the global regulatory model of the GHTF as a means to promote competitiveness of the European industry on the global market.

The Commission launched two public consultations, one in 2008 concerning the revision of the legal framework for medical devices<sup>42</sup> and a second one in 2010 on technical aspects of the revision of Directive 98/79/EC regarding in vitro diagnostic medical devices<sup>43</sup>. In June 2011, the Council of the European Union adopted its conclusions on innovation in the medical device sector in which it invited the Commission to consider a number of improvements in the legislative framework in the course of the recast process<sup>44</sup>. In particular, it invited the Commission to ensure transparency around the collection of clinical data from pre-marketing studies and post-marketing surveillance, enhance the oversight of Notified Bodies by national authorities and improve the harmonized criteria for their designation. It also emphasized the need to address the regulatory gaps concerning the borderline cases between devices and other products (such as pharmaceuticals), to clarify the definition of medical devices and the classification criteria.

The Commission published its latest recast roadmap in November 2011. The roadmap envisaged the adoption of two proposed Regulations (one concerning medical devices to repeal Directives 90/385/EEC and 93/42/EEC and another one concerning in vitro diagnostic medical devices to repeal Directive 98/79/EC), and a Communication regarding innovation in medical devices<sup>45</sup>. Initially expected for the second quarter of 2012, the proposals were delayed as a result of the PIP incident that prompted the Commission to take into account the

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<sup>41</sup> See the website of the European Commission's Directorate General for Health and Consumers: [http://ec.europa.eu/health/medical-devices/documents/revision/index\\_en.htm](http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm).

<sup>42</sup> See the summary of responses published by the European Commission: European Commission. Recast of the Medical Devices Directives: Summary of Responses to the Public Consultation. ENTR/F/3/D(2008) 39582, Brussels, 5 December 2008. Available at: [http://ec.europa.eu/health/medical-devices/files/recast\\_docs\\_2008/responses/responses\\_public\\_consultation\\_recast\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/recast_docs_2008/responses/responses_public_consultation_recast_en.pdf). (last accessed on 24 October 2011).

<sup>43</sup> See the summary of responses published by the European Commission: European Commission. Revision of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices: Summary of Responses to the Public Consultation. Brussels, 23 February 2011. Available at: [http://ec.europa.eu/health/medical-devices/files/recast\\_docs\\_2008/ivd\\_pc\\_outcome\\_en.pdf](http://ec.europa.eu/health/medical-devices/files/recast_docs_2008/ivd_pc_outcome_en.pdf). (last accessed on 24 October 2011).

<sup>44</sup> Council of the European Union. Council conclusions on innovation in the medical device sector, *OJ C* 202/7-9 of 8 July 2011.

<sup>45</sup> See the Roadmap 2012 published on the website of the European Commission: [http://ec.europa.eu/governance/impact/planned\\_ia/docs/2008\\_sanco\\_081\\_proposal\\_medical\\_devices\\_en.pdf](http://ec.europa.eu/governance/impact/planned_ia/docs/2008_sanco_081_proposal_medical_devices_en.pdf)

‘stress-test’ of the proposals against the regulatory shortcomings revealed by the PIP case<sup>46</sup>. The draft Regulations and the impact assessment documents are expected for the autumn of 2012, to be sent then to the European Parliament for first reading and the Council.

The PIP incident has prompted the European Commission and Parliament to call for action to prevent a recurrence of similar events. In February 2011, the Commission called for the immediate co-operation of Member States to strengthen post-market surveillance, provide better safety guarantees and restore patient confidence<sup>47</sup>. In particular, it urged action to empower patients and encourage healthcare professionals to report adverse events, and enhance the traceability and long-term monitoring of devices in terms of safety and performance. The proposed Regulations are envisaged to introduce a central registration system for devices and relevant economic operators in Eudamed and open up parts of this database to the public (although it is not clear yet which parts)<sup>48</sup>.

In a resolution adopted in June 2012, the European Parliament called for more stringent surveillance, safety controls and placing on the market requirements<sup>49</sup>. MEPs argued that the current regulatory system was malfunctioning both at European and national levels in terms of information sharing, notification of adverse effects and ensuring traceability of materials used for medical devices. They emphasized that patients needed to be better informed about the quality of implanted devices and the potential risks. They called on Member States to improve their efforts to raise awareness of the risks attached to cosmetic surgery, and to better regulate the advertising of cosmetic surgery in order to allow for appropriate risk assessment on behalf of patients. MEPs recognized the need to provide retrospective information to patients who have already received implants. They also called for measures designed to facilitate and actively encourage individual patients, patient groups and healthcare professionals to report adverse effects to the authorities as a means to improve the vigilance system. MEPs stressed the need for a system of collective redress for patients to

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<sup>46</sup> European Commission. Press release: Medical devices: European Commission calls for immediate actions - tighten controls, increase surveillance, restore confidence, Brussels, 9 February 2012, <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/12/119&format=HTML&aged=0&language=EN&guiLanguage=en> (last accessed on 31 May 2012).

<sup>47</sup> European Commission press release, cited at footnote 46.

<sup>48</sup> The publicly accessible database would form the basis for the EU Unique Device Identification (UDI) systems. Hoekstra-van den Bosch, S. ‘Revision of the Medical Device Directives: Wat staat ons te wachten?’, RAPS meeting presentation, Eindhoven, 30 March 2012.

<sup>49</sup> European Parliament resolution of 14 June 2012 on defective silicone gel breast implants made by French company PIP (2012/2621(RSP)), Strasbourg, 14 June 2012.

obtain compensation. They called for the introduction of implant recipient's passports (stating the implant's specific characteristics and its potential adverse effects), and interconnected implant registers across Member States. Furthermore, Parliament asked for a single European database that brings together information about medical devices placed on the EU market, registration of economic operations, vigilance and market surveillance, clinical investigations, Notified Bodies and EC certificates granted. It asked for increased transparency on the functioning and tasks of Notified Bodies and establishment of an EU-wide qualification management system for them. It called on the Commission to put in place a pre-market authorization system for certain devices, especially those belonging to higher risk categories (Class IIb and III). The resolution adopted by Parliament puts pressure on the Commission to address the issues of transparency and information as part of the revision of the regulatory framework. It remains to be seen to what extent the final text of the proposed Regulations adopted by the Commission will follow the Parliament resolution.

### **3. Information to the public on medical devices: challenges of under-regulation**

As discussed earlier in this paper, increased transparency on regulation of medical devices has been demanded to help patients and their physicians know what a device has been approved to do, use it safely and appropriately, and assess its benefits against the possible health problems created by adverse effects and malfunctions<sup>50</sup>. Given the increasing number of recalled devices and the expected increase in the level of scrutiny, precautions and liability concerns, better communication of the risk of the recall has been asked for in order to allow for a better risk assessment and evidence-based decisions on device replacement by patients and doctors<sup>51</sup>. Publicly available and comparable data on clinical effects, safety, performance and the benefit-risk balance of medical devices would enable healthcare professionals to assist patients in making better informed treatment choices. As discussed above, the PIP incident has prompted the European Parliament to put pressure on the European Commission and the Member States to ensure increased transparency and better information. Indeed, there are a number of concerns in the current regulatory framework related to access to information for the public, transparency of regulatory practices and patient empowerment.

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<sup>50</sup> See for example, Billingsley, M. 'Clinical data on high risk medical devices should be made publicly available', *BMJ* 2011;342:d4162; Cohen, D. 'Out of joint: The story of the ASR', *BMJ* 2011;342:d2905; Freemantle, N. 'Commentary: Evaluating and regulating device therapy', *BMJ* 2011;342:d2839; James, S., Daubert, J-C., Van de Werf, F. 'Commentary: Use of registries to investigate the past and develop the future', *BMJ* 2001;342:d2826; Fraser A.G. et al, 2011, p. 1684, cited at footnote 7.

<sup>51</sup> Heneghan, C. et al, 2011, cited at footnote 9.

### 3.1. Access to information on medical devices under EU law

The EU medical device Directives do not say much about quality standards for information to consumers and the communication channels that might be used by the industry. They focus only on the type of information that must be provided by the manufacturer as part of the device packaging, label and leaflet<sup>52</sup>. The basic principle is that the manufacturer is obliged to include in the packaging of a device all information that is needed for its safe and proper use. This includes a clear indication of the intended purpose as well as instructions for appropriate use and reuse, risks and undesirable side-effects, warnings or precautions to take<sup>53</sup>. Furthermore, the packaging must include information that enables the identification of the manufacturer (name, trade name and contact details), the date of manufacture, the time limit for safe use, the date of issue or latest revision of the instructions for use, as well as any special conditions for use<sup>54</sup>. Manufacturers are also obliged to inform users about any residual risks due to shortcomings of protection measures taken on risks that cannot be eliminated. Apart from the rules concerning device packaging, leaflet and label, the Directives do not regulate information to the public on medical devices and include no harmonized standards for information content and presentation.

Instead of information to consumers, the Directives emphasize confidentiality. Staff members of Notified Bodies are obliged to ensure professional secrecy with regard to all information gained in the course of their duties (except *vis-à-vis* the competent administrative authorities of the Member State in which their activities are carried out)<sup>55</sup>. Confidentiality extends to data resulting from clinical investigations of medical devices<sup>56</sup> as well as claims submitted by manufacturers to Notified Bodies, assessment reports, and evaluation of the device by Notified Bodies. Clinical data are gained from investigations conducted under normal conditions of use of a device, to determine its safety, performance and effects on patients.

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<sup>52</sup> See for example, *ANNEX I* of the Medical Device Directive 93/42/EEC on essential requirements, paragraph 13 on information supplied by the manufacturer.

<sup>53</sup> Instructions for use must include information allowing medical professionals to brief the patient on any contra-indications and precautions to be taken, as well as the degree of accuracy of devices with a measuring function. Notably, the Directive on Active Implantable Medical Devices 90/385/EEC includes also an obligation for the manufacturer to ensure that instructions presented by means of a visual system are understandable to users and patients (see *ANNEX I*, paragraph 13 of this Directive).

<sup>54</sup> I.e., single use, custom-made use, use for clinical investigations only, special storage or handling conditions, details on the nature of the emitted radiation if applicable, etc.

<sup>55</sup> See *ANNEX XI* of the Medical Device Directive 93/42/EEC on criteria to be met for the designation of Notified Bodies.

<sup>56</sup> See *ANNEX X* on clinical evaluation of the Medical Device Directive 93/42/EEC. Notably, the Directive on Active Implantable Devices 90/385/EEC states that “all data must remain confidential unless it is deemed essential that they be divulged.” It does not specify, however, in what circumstances the divulgence of such data might be required (see *ANNEX 7* of this Directive).

They provide information on undesirable side-effects and are necessary for determining the benefit-risk balance<sup>57</sup>. Nevertheless, such data are treated as commercially sensitive information. Clinical data used to approve high risk medical devices are very difficult to access by patients and physicians treating them.

EU law imposes no quality standards and safeguards on consumer information provided by the medical device industry. At the same time, it does not prohibit the industry to advertise its products to the public. It allows for direct-to-consumer promotion of devices placed on the market as long as the device is advertised for its intended purpose (as indicated on the labeling, the instructions for use and/or in promotional materials)<sup>58</sup>. Products that are not (yet) placed on the market can be nevertheless shown at trade fairs, exhibitions and demonstrations if it is clearly indicated that they cannot be marketed or put into service before obtaining a CE marking<sup>59</sup>. This includes devices that are still in the stocks of the manufacturer, offered in a catalogue or by means of electronic commerce that have not been transferred yet to the distribution stage and/or have not been granted release for free circulation in the EU by customs<sup>60</sup>. Advertising of products that are already placed on the market is only prohibited if it is for off-label use<sup>61</sup> or misleading. Directive 2006/114/EC stipulating general rules on misleading and comparative advertising applies directly to medical devices in the absence of specific rules in the medical device Directives<sup>62</sup>. As defined in Article 8, advertising is

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<sup>57</sup> Clinical data are sourced from clinical investigations of the device concerned, clinical investigations or other scientific studies of a similar device with demonstrated equivalence, or published and/or unpublished reports on other clinical experience of either the device concerned or an equivalent device. See Article 1(k) of the Directive on Active Implantable Devices 90/385/EEC.

<sup>58</sup> See Article 1(2)(g) of the Medical Device Directive 93/42/EEC. A medical device is placed on the market in the EU when it is supplied for the first time for distribution, consumption or use on the EU market. A device must have been transferred from the stage of manufacture to the distribution chain in order to be considered as placed on the market. See Article 1(2)(h) of Directives 90/385/EEC and 93/42/EEC, respectively, and Article 1(2)(i) of Directive 98/79/EC. See also Article 2(2) of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93. See also European Commission, Interpretative document of the Commission's services: Placing on the market of medical devices. SANCO/B/2/PBE/pdw Ares(2010) 332016. Brussels, 16 November 2010, pp. 3-5.

<sup>59</sup> See Article 4(3) of the Medical Device Directive 93/42/EEC and Article 4(3) of the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

<sup>60</sup> Such products are not considered to be placed on the EU market. See European Commission. Guide to the implementation of directives based on the New Approach and the Global Approach (The Blue Guide), Luxembourg: Office for Official Publications of the European Communities, 2000, p. 18.

<sup>61</sup> Article 17(3) of the Medical Device Directive 93/42/EEC.

<sup>62</sup> Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising. *OJ L 376/21-27*, 27 December 2006. In determining whether advertising is misleading one should take into account all its features including the characteristics of the goods or services, the price and conditions of their supply and provision, as well as the nature, attributes and rights of the advertiser. Member States are allowed to retain or adopt provisions that ensure more extensive protection for traders and competitors against misleading advertising.



misleading if it deceives in any way (in its wording or presentation, actually or potentially) the persons to whom it is addressed or whom it reaches and is therefore likely to affect their economic behavior or injure a competitor. EU law allows for comparative advertising of medical devices directly to consumers. Comparative advertising is defined as ‘any advertising which explicitly or by implication identifies a competitor or goods or services offered by a competitor’<sup>63</sup>. Apart from the general rules, regulation of consumer-directed advertising of devices is left to the Member States and industry self-regulation. In case of comparative advertising, Member States are not allowed to retain or adopt provisions that ensure more extensive protection than the one ensured by Directive 2006/114/EC (as far as the comparison is concerned).

While EU law allows for direct-to-consumer advertising of medical devices, it does not address the issue of public access to non-promotional, objective data and information. This is a clear contradiction. At present, it is very difficult for the public to access to post-marketing surveillance data including information on device malfunction and/or deterioration which might lead to death or serious health damage. Currently there is no publicly available list of medical devices approved for the EU market. Regulatory data recorded, stored, evaluated by Member States and exchanged between national and European authorities via the Eudamed are not open to the public – including physicians responsible for treating and advising patients. The importance of empowering patients and healthcare professionals to report adverse effects and pooling expertise in analyzing such incidents has been emphasized by the European Commission and Parliament following the recent implant recall incidents. Yet, unavailability of data for the public makes it very difficult for patients, physicians and independent researchers to assess the health impact of such devices. In particular, the absence of a registry of high risk devices in use makes it very difficult if not impossible to determine the size and impact of harm caused by recalled devices<sup>64</sup>. Given the difficulties in access to data, it is very hard for physicians to fulfill their role as intermediary agents responsible for helping patients make informed treatment decisions.

### **3.2. Empowering patients to make informed treatment choices: developments concerning prescription-only medicines**

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<sup>63</sup> See Article 4 of Directive 2006/114/EC cited at footnote 62.

<sup>64</sup> Heneghan, C. et al, 2011, cited at footnote 9.

As discussed above, regulation of access to information for the public on medical devices is largely left to the national legislations of EU Member States and to self-regulation by the industry. Rules and practices differ across EU countries. Despite the existing cross-country differences in regulatory practices, information to the public on medical devices has not received much attention so far on the EU regulatory agenda. At the same time, cross-country differences in regulatory practices have been used by the European Commission as the main justification for proposing harmonized rules on information to the public on prescription-only medicines<sup>65</sup>. The following section will compare prescription medicines to medical devices when it comes to EU rules on consumer information. Table 1 in the ANNEX to this paper illustrates the differences between the two sectors in terms of the type of information that the industry *must* and *may* make available to the public. It also shows the differences concerning the existence of harmonized standards on the quality of information, communication channels, monitoring mechanisms and sanctions for non-compliance.

Information provision and direct-to-consumer communication on pharmaceutical products is currently regulated in Directive 2001/83/EC<sup>66</sup>, the so-called Community code relating to medicinal products for human use. The European Commission launched in 2008 a proposal to reform the regulatory framework in the form of an amendment to Directive 2001/83/EC. Revised in 2011 and once again in 2012 to incorporate the amendments of the European Parliament, the latest version of the Commission proposal is currently under review by Parliament and the Council<sup>67</sup>. The proposal includes rules on dissemination of (non-promotional) information on prescription medicines by the industry to the public and intends to clarify the boundary between advertising and information. The proposed harmonization aims at empowering patients to make informed treatment choices by ensuring better access to high quality, objective, non-promotional information on prescription medicines while maintaining the ban on direct-to-consumer advertising. It establishes:

- Harmonized rules on the type of information that the industry *must* and *may* make available to the public;

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<sup>65</sup> European Commission. Amended proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards information to the general public on medicinal products for human use subject to medical prescription. COM(2012) 48 final, Brussels, 10.2.2012; European Commission. Amended proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 as regards information to the general public on medicinal products for human use subject to medical prescription. COM(2012) 49 final, Brussels, 10 February 2012.

<sup>66</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as amended. *OJ L* – 311, 28 November 2004, p. 67-128.

<sup>67</sup> See footnote 65 for the citation of the Commission proposal.

- The permitted communication channels. The main communication channel envisaged is the internet where search by users is possible but unsolicited materials such as pop-ups are prohibited. The proposal restricts the channels to be used by the industry to internet websites, written answers to specific requests received from consumers and printed materials made available upon request or through healthcare professionals. It bans the use of TV, web-TV, radio, printed media and active distribution of any unsolicited materials to consumers;
- Quality standards for information content and presentation;
- Monitoring mechanisms and sanctions with specific rules for the internet<sup>68</sup>.

The proposal stresses the so-called “pull, not push” principle by obliging the industry to make information available for consumers actively searching for it but prohibiting the distribution of unsolicited materials. It emphasizes patient empowerment, the right of the public to access information and the importance of safeguarding consumers from materials meant to persuade them.

In case of prescription-only medicines, the European Commission justified extended harmonization arguing that this was necessary because the differences in regulatory practices had led to unequal access to information for consumers, legal uncertainty for the industry with cross-border activities, and impediments to the free movement of pharmaceutical goods. These arguments are also relevant to medical devices. Moreover, unlike prescription-only medicines, medical devices can be advertised directly to the public under EU law, which makes quality standards for direct-to-consumer communication even more important.

While information on prescription medicines has been high on the EU legislative agenda during recent years, information on medical devices has not received a similar attention until the recent PIP incident. As opposed to prescription medicines, there have been no efforts to put in place harmonized quality standards and monitoring rules applied to information to consumers on medical devices. Instead, confidentiality rules related to regulatory data - including clinical data - prevent healthcare professionals, patients and independent researchers from accessing such data and assessing the claims of manufacturers, the benefits and risks of devices and the harm caused by recalled devices. In the absence of publicly

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<sup>68</sup> The proposal envisages an obligation for pharmaceutical companies to register their internet sites with national competent authorities before making them available to the public. The Member State where the site is registered would be responsible for checking the information at the time of registration, monitoring subsequent information and adopting sanctions for non-compliance.

available data manufacturers advertising their products are able to interpret and edit their claims, and it is very difficult for consumers, users and independent researchers to double-check them. The level of consumer protection in EU law is thus lower in case of medical devices than in case of prescription medicines. Following the PIP incident, the European Parliament has called for increased transparency and better information as a means to ensure better patient protection. The Commission's recast proposal will reveal whether this will be actually reflected in the draft Regulations.

### **3.3. Combination products: at the borderline of diverging regulatory frameworks**

The previous paragraphs have highlighted the difference between EU regulation of prescription-only medicines and medical devices when it comes to information provision to the public. This difference leads to particular challenges in case of the so-called combination products. Combination products are therapeutic and diagnostic products that incorporate medical devices, medicinal products (pharmaceuticals) and/or biological products. Examples for combination products include prefilled syringes, metered dose inhalers, catheters with antimicrobial coating, orthopedic implants with growth factors, etc. Some combination products integrate a diagnostic device (often an in vitro diagnostic device) with a pharmaceutical product. Combined advanced therapy medicinal products (combined ATMP<sup>69</sup>) constitute a specific form of combination products that integrate medical devices or implantable medical devices with a cells or tissue component. To qualify as a combined ATMP the cellular or tissue part must contain viable cells or tissues, and the non-viable cell or tissue component must be liable to act upon the human body with action that is primary to that of the device<sup>70</sup>.

Development of increasingly sophisticated combination products has made it more difficult to distinguish between medical devices and medicines. Combination products raise regulatory challenges under EU law because they include components that would normally be governed by different instruments and different types of regulatory authorities. In EU law a product is regulated as either a medicine or a medical device. Medicines are defined in and governed by

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<sup>69</sup> As defined in Article 2(1)(a) of Regulation (EC) No 1394/2007, an “advance therapy medicinal product” is a medicinal product for human use that is either a gene therapy product or a somatic cell therapy product or a tissue engineered product. For the definition of combined advance therapy medicinal products see Article 2(1)(d) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004, *OJ L* 324/121, pp. 121-137.

<sup>70</sup> See Article 2(1)(d) of Regulation (EC) No 1394/2007, cited at footnote 69.

Directive 2001/83/EC<sup>71</sup>. Medical devices are currently defined in and governed by the three medical device Directives discussed earlier in this paper. The latter exclude medicines from their scope and stipulate that the distinction between medicines and medical devices is made on the basis of the principal mode of action. If the principal mode of action in or on the human body is achieved by pharmacological, immunological or metabolic means then it is medicine; otherwise, it is a medical device. Where a product contains viable cells or tissues, the pharmacological, immunological or metabolic action of those cells or tissues shall be considered as the principal mode of action<sup>72</sup> and the product is a medicine governed by Directive 2001/83/EC. Where a device and a medicine form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall likewise be governed by Directive 2001/83/EC<sup>73</sup>. In cases of doubt the definition of a medicine prevails over the definition of any other product to ensure a higher level of protection for consumers<sup>74</sup>.

Distinction of devices from medicines remains a disputed question because the term 'pharmaceutical, immunological or metabolic action' awaits further clarification. The European Court of Justice has emphasized the importance of the metabolic action in case of medicines and ruled that a product must 'significantly affect the metabolism and strictly modify the way in which it functions' in order to be considered as a medicine in the meaning of Directive 2001/83/EC<sup>75</sup>. The ECJ has been confronted in 2011 with a preliminary ruling reference on the definition of the term 'pharmacological action' as a demarcation between medical devices and medicinal products<sup>76</sup>. In this case the ECJ has also been asked whether recourse can be made to the European Commission's guidance document on medical devices to define this term<sup>77</sup>. The ruling is expected to be issued later in 2012 and will hopefully

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<sup>71</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use, as amended, cited at footnote 66.

<sup>72</sup> See Article 2(2) of Regulation (EC) No 1394/2007, cited at footnote 69.

<sup>73</sup> See Article 1(3) of the Medical Device Directive 98/79/EC. Moreover, ANNEX 1 of this Directive sets forth that, where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified according to Directive 2001/83/EC. The latter Directive does not include specific provisions on combination products.

<sup>74</sup> See Article 2(2) of Directive 2001/83/EC, cited at footnote 66.

<sup>75</sup> Case C-140/07 *Hecht-Pharma* [2009] ECR I-00041, paragraph 41; Case C-27/08 *BIOS Naturprodukte* [2009] ECR I-03785, paragraph 21.

<sup>76</sup> Case C-308/11, Reference for a preliminary ruling from the Oberlandesgericht Frankfurt am Main (Germany), lodged on 20 June 2011 - *Chemische Fabrik Kreussler & Co. GmbH v John O. Butler GmbH*.

<sup>77</sup> European Commission. Medical devices: Guidance document. Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human

provide further clarifications on the distinction of devices from medicinal products and the status of the Commission's related guidance documents.

As discussed earlier in this paper, the EU regulates information to consumers by the industry on medicines but it does not address this issue when it comes to medical devices (see also Table 1 in the ANNEX to this paper). There are also significant differences between the two sectors when it comes to EU rules on advertising. The EU does not prohibit the advertising of medical devices to the public and it leaves advertising regulation largely to Member States and to industry codes of conduct. However, when it comes to medicines, the EU imposes an absolute ban on advertising of prescription-only medicines to the public and it regulates advertising of medicines sold over-the-counter.

Directive 2001/83/EC regulates advertising of prescription medicines and over-the-counter medicines. It sets forth in Article 86(1) that advertising of medicines includes “*any form of door-to-door information, canvassing activity, or inducement designed to promote the prescription, supply, sale or consumption of medicinal products*”. The case law of the European Court of Justice clarified further the rules on advertising<sup>78</sup>. The Court ruled in *Gintec International Import-Export GmbH v Verband Sozialer Wettbewerb eV*<sup>79</sup> that Article 86(1) brought about complete harmonization in the field of advertising of medicines. Accordingly, Member States cannot diverge from this prohibition in any way in their implementing legislation. Moreover, third party statements – for example, statements by patient groups with a therapeutic interest, or by journalists – might constitute advertising if the purpose of the statement is promotional. Such statements are prohibited in case of prescription medicines even if the third party acts on his/her own initiative and has no commercial or industrial interest (as follows from the ECJ ruling in the *Damgaard* case<sup>80</sup>). The decisive factor in drawing the borderline between advertising and information provision is *the purpose of the message*, not the identity of the messenger. If the message is designed to

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blood derivative. The guidance document states that pharmaceutical action is “understood as an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent”. The German court referring the question to the ECJ asked also whether this definition required an interaction between the substance in question and cellular constituents of the user, or it was sufficient if the substance interacted with a cellular constituent that was not part of the human body.

<sup>78</sup> For a detailed discussion of the case law see Hancher, L. and Földes, M. E. ‘Push or Pull? – Information to patients and European law’, in *European Journal of Consumer Law EJCL/REDC*, 2011, 4:749-776.

<sup>79</sup> European Court of Justice, Case C-374/05 *Gintec International Import-Export GmbH v Verband Sozialer Wettbewerb eV*. ECR [2007], ECR I-09517.

<sup>80</sup> European Court of Justice, Case C-421/07 *Damgaard* [2009], ECR I-02629.

promote prescription, supply, sale or consumption of medicines then it amounts to advertising (see also the *MSD Sharp v. Merckle* decision<sup>81</sup>). Internet-based information provision for consumers is not considered to be advertising if it is based on the “pull” principle, i.e. it requires active search by users. However, unsolicited materials “pushed” on internet users such as pop-ups amount to advertising. Furthermore, information materials must consist solely of the faithful reproduction of the packaging and a literal reproduction of the Summary of Product Characteristics in order to exempt from the advertising ban (case *MSD Sharp v. Merckle*<sup>82</sup>).

The growing number and complexity of combination products imposes particular regulatory challenges because such products can fall under completely different rules when it comes to information and advertising (depending on whether they are regarded as medicines or as medical devices). If a combination product is categorized as a medical device then EU rules allow for its advertising to consumers, and impose no standards on information provision – even if the product incorporates also a medicine. If however, the product is regarded as a medicine then the EU rules on medicine advertising and information apply to it.

#### **4. Final remarks**

As opposed to prescription-only medicines where ongoing efforts by European institutions aim at putting in place harmonized rules on patient information, no similar efforts are present in case of medical devices. Despite the emphasis on empowering patients to participate in choices concerning their treatment, information on medical devices has not received much attention so far on the EU agenda. Regulation of information to the public is largely left to Member States and the industry codes of conduct, and rules and practices differ across countries. Inequalities in access and legal uncertainties caused by cross-country differences have prompted harmonization efforts in case of prescription medicines, but not in case of devices. Currently, the level of consumer protection in EU law is higher in case of prescription medicines compared to medical devices.

There is a legal void when it comes to access to information on medical devices. Yet, filling in that void is not at all simple. A mere transposition of pharmaceutical rules to devices

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<sup>81</sup> European Court of Justice, Case C-316/09 *MSD Sharp & Dohme GmbH v Merckle GmbH* [2011], judgment of 5 May 2011.

<sup>82</sup> European Court of Justice, Case C-316/09 *MSD Sharp & Dohme GmbH v Merckle GmbH* [2011], judgment of 5 May 2011, paragraph 43.

would be very difficult in the light of very different standpoints concerning what to regulate and how to regulate. As discussed before, there are a number of differences between the pharmaceutical market and the medical device market when it comes to their nature, structure and regulation. In particular, information to patients and advertising are regulated differently under EU law. The idea to integrate medical devices in the system set up for pharmaceuticals has been brought up and rejected before, latest during the debate around adopting a new EU Directive on transparency of pharmaceutical price regulation and inclusion in the scope of public health systems<sup>83</sup>. As argued by the European Commission in the impact assessment document accompanying this proposed Directive, inclusion of medical devices in the pricing and reimbursement system designed for medicines turned out to be unfeasible<sup>84</sup>. The legal and technical complexities of such an extension and the reluctance of the medical device industry to change the status quo convinced the Commission to discard the idea<sup>85</sup>. In the light of this outcome it is questionable whether an attempt to transpose pharmaceutical rules to devices could be carried out in the field of patient information.

Ensuring greater transparency and information for the public on medical devices remains an issue yet to be solved. This is particularly important in case of high risk, invasive and/or implantable products that can pose substantial health risks to patients, as illustrated also by the recent device recall cases. There is a clear connection between the risk level of a device and the potential harm for the patient that could result from its improper use, malfunctioning and adverse effects. The higher the risks of a device, the more important it is to ensure that patients and their doctors are aware of the potential risks and are equipped to make an informed treatment choice. Devices in the high risk categories necessitate stronger safeguards for consumer protection. This includes access to objective and high quality information of a non-promotional character. Even if we assume that doctors act as agents for consumers in case of high risk devices, patients should still be able to access information including

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<sup>83</sup> European Commission. Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. COM(2012) 84 final, Brussels, 1 March 2012.

<sup>84</sup> European Commission. Commission staff working document: impact assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems. SWD(2012) 30 final, Brussels, 1 March 2012.

<sup>85</sup> The idea of extension was dropped by the Commission even in case of medical devices subject to pricing and listing procedures similar to those applied to pharmaceuticals (see the impact assessment document cited at footnote 84).



potential harmful effects and the benefit-risk balance – just as in case of prescription medicines.

Further to the PIP incident, the European Commission and Parliament has emphasized the importance of empowering patients and their doctors to be aware of risks, report adverse effect cases, and play a greater role in long-term monitoring of devices in terms of safety and performance. The proposal of the Commission for the draft medical device Regulations is expected for the fall of 2012 and it remains to be seen whether it will move forward the objectives of patient and user empowerment by addressing the issue of access to information for the public. It is not possible to empower patients to take informed decisions and contribute to the improvement of the vigilance system without ensuring better access to data and increasing transparency on regulatory practices. Better access to information is also a logical complement to permission for direct-to-consumer advertising. It remains to be seen whether the efforts of the Commission and Parliament to improve surveillance and restore confidence will result in a renewed dialogue leading to better information and more transparency.

## ANNEX

**Table 1. Comparing EU rules on information to the public on prescription medicines and medical devices**

<b>Information by the industry to the public</b>	<b>Prescription medicines</b>	<b>Medical devices</b>
Type of information - obligatory	Directive 2001/83/EC: <ul style="list-style-type: none"> <li>• Summary of Product Characteristics</li> <li>• Labelling</li> <li>• Package leaflets</li> </ul> Revised Commission proposal (2012): <ul style="list-style-type: none"> <li>• Publicly accessible version of assessment reports</li> </ul>	Medical Device Directives: <ul style="list-style-type: none"> <li>• Packaging</li> <li>• Labeling</li> <li>• Package leaflets</li> </ul>
Type of information - permitted	Revised Commission proposal (2012): <ul style="list-style-type: none"> <li>• Environmental impact</li> <li>• Prices</li> <li>• Pack changes</li> <li>• Instructions for use completed with technical images illustrating use</li> <li>• Pharmaceutical, pre-clinical &amp; clinical trials</li> <li>• Summary of frequent Q&amp;A</li> <li>• Other information as approved by authorities</li> </ul>	Not harmonized
Harmonized standards	Revised Commission proposal (2012) - harmonized rules on: <ul style="list-style-type: none"> <li>• Quality standards for information content and presentation</li> <li>• Communication channels</li> <li>• Monitoring and sanctions</li> </ul>	Not harmonized

Table 1.