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Danger to public health: Medical devices, toxicity, virus and fraud

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ABSTRACT

The recent scandals involving the sale and manufacture of defective medical devices such as the PIP breast implants and the De Puy Implants have resulted in the long-awaited modernisation of the Medical Device Directive. Taking cognizance of the increasing integration of medical devices and technology, as well as the importance of electronic information, the proposed EU Regulation on Medical Devices promises greater European control on Notifying Bodies and more transparency to ensure patient's safety. This paper discusses the current directives and proposed legislation as well as the liabilities of manufacturers and software vendors for product failure.

1. Introduction

Protecting and promoting the health is a key priority of the European Union. The EU has always valued healthcare as a human right. The EU has been expanding its authority in the health sector as it attempts to regulate the healthcare sector, with member states determined to retain control. Healthcare policy and aspects of goods and services market such as medical devices fall under the ambit of the EU internal market principles and at the same time under the realm of member states' jurisdictions in healthcare.

The EU Commission has pushed for greater integration of the international market through the provision of cross-border healthcare services, ensuring free movement of products, people and services. Freedom of movement for goods, services and people has been a priority for the European Union. Although there have been attempts to harmonise the EU health policy, many member states are reluctant to yield their authority to Brussels citing, among others, the rampant lobbyism by interest groups to promote their agendas. The recent resignation of the EU Health Commissioner John Dalli highlights the tactics of lobbyists in derailing initiatives to promote safety and health. Despite the efforts to clean up, selling influence and personal connection are still rampant. The problem is that the EU Commission is still reliant on the expert advice of groups representing companies and organisations and has delegated important tasks to private companies without installing proper regulatory and oversight mechanisms. For example, European patients' groups, set up to represent the interests of the subjects of medical procedures in their dealings with healthcare systems, insurance firms and drug companies, are in many cases bankrolled by pharmaceutical firms,[1] which can afford to spend €40 million annually to lobby EU officials compared to the €3.4 million

[1] EU drugs agency working with patient groups bankrolled by big pharma. http://euobserver.com/news/29934.

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spent annually by public health NGOs.[2] But as long as the EU has a system that bends down to the whims of big money, Big Pharma, the top tier of the industry will continue to reap 77% percent on their lobbying investment. As the age of blockbuster drugs are fading, it is alleged that major pharmaceutical companies are increasingly resorting to fraud. According to a new report by Public Citizen (2012) settlements between pharmaceutical companies and state and federal governments over cases of Medicaid fraud are at an all-time high, with financial penalties for major drug companies on the rise.[3] The charges against major pharmaceutical companies accused of defrauding their Medicaid programs, include overcharging health programs, largely in the form of drug pricing fraud, as well as unlawful promotion of 'off-label' drugs (promoting drugs for unapproved uses). GlaxoSmithKline has been fined $3 billion rising from the company's illegal promotion of some of its products, its failure to report safety data and alleged false price reporting. But the fine is generally considered cost of doing business and is budgeted for in exchange for marketing blockbuster drugs. Big pharma has wielded almost limitless influence over medical research, education, and the media. "Retraction of scientific papers published in respectable, peer-reviewed academic journals is at an all-time high, and drug-related research is disproportionately represented among papers withdrawn due to fraud."[4] The EU has been accused of protecting the health of the single market, i.e. the industry, rather than the health of the community.

Member States shed some of the burden of blame. Member states have made significant cutbacks in public spending and putting a strain on the healthcare systems resulting in large ramifications for the ability of the states to provide quality of care. Moreover, there has been increasing reports of negligence by care givers not only in administering medicines and treatment, but also in handling sensitive personal data of patients. Health providers involved in data breaches merely get slapped on the wrist while the public is forced to suffer for their mistakes.

Another sector in the health industry which has recently risen to notoriety for fraud and corruption is the medical device industry. Medical Devices contribute significantly to enhance the quality of healthcare and economic outcomes for Europe. Medical devices in the 27 EU states plus Norway and Switzerland were worth 95 billion euros ($122 billion) in 2009 with a yearly growth of around 5–6 %.[5] Besides being an important and innovative industry, medical devices represent the bulk of medical technology. Technological progress in medical care has been the main driver of improvements in healthcare systems in order to prevent, diagnose and treat diseases, as well as enhance health status and the quality of life.

Over the last five years, the US FDA agency says it has received reports of 710 patient deaths linked to problems with the devices.[6] In the UK, the devices subject to recalls or warning have risen significantly.[7] In Europe, many patients are at risk because the current system of regulation on medical is inadequate and full of legal gaps. High-risk devices only have to establish safety and performance without providing appropriate clinical data and evidence of improvements in clinical outcomes, unlike in the US where the FDA requires clinical data. Device approvals are carried out by a private company before they can be allowed to display the Conformité Européenne (CE) mark. Many medical devices are being recalled but data related to recalls are not available to the public under the confidentiality provision in the Medical Device Directive.

Currently, there are proposals to amend the Directive. This article will explore the proposed EU revisions of the EU Directive on Medical Device and discuss the legal challenges posed by bugged and faulty medical devices.

2. EU laws

In the EU, the medical device manufacturers currently have to comply with one of the following Directives:

- Medical Devices Directive 93/42/EEC (MDD)
- Active Implantable Medical Device Directive 90/385/EEC (AIMDD)
- In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

These have been supplemented over time by six modifying and implementing directives, including the most recent technical revision – Directive 2007/47/EC.

No supranational EU regulatory body enjoys comprehensive regulatory authority over medical devices; instead, each member state enforces its own national law promulgated pursuant to the three directives through a National Competent Authority (NCA).

2.1. *Medical Devices Directive*

The Council Directive 93/42/EEC of 14 June 1993 concerning medical devices also known as the Medical Devices Directive (MDD) is one of a suite of three directives which together cover all medical equipment. The associated directives are the Active Implantable Medical Devices Directive (AIMDD) and the In Vitro Diagnostic Devices Directive (IVDD). The Medical Devices Directive was enacted to provide for a harmonised regulatory environment for all medical devices sold within the European Economic Area. This directive includes equipment intended by the manufacturer to be used to diagnose, prevent, monitor, treat, alleviate, compensate for and/or control a disease, injury, handicap, physiological process or

[2] Big Pharma spends over €40 million per year lobbying in the EU, dwarfing public health NGOs (2012) Corporate Europe Observatory. Available at http://corporateeurope.org/pressreleases/2012/big-pharma-spends-over-40-million-year-lobbying-eu-dwarfing-public-health-ngos.

[3] Sammy Almashat (2012) Pharmaceutical Industry Criminal and Civil Penalties: An Update. Public Citizen. Available at http://www.citizen.org/documents/20731.pdf.

[4] http://anh-europe.org/Big-Pharma-and-the-Watergate-moment.

[5] U bolsters medical device checks after implant scandal. (2012) Reuters. http://www.dw.de/eu-bolsters-medical-device-checks-after-implant-scandal/a-16266612-1.

[6] Barry Meier (2010) F.D.A. Steps Up Oversight of Infusion Pumps.

[7] C Heneghan, M. Thompson, M. Billingsley, D. Cohen. Medical-device recalls in the UK and the device-regulation process: retrospective review of safety notices and alerts. *BMJ*.