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SPENDING OF MEDICAL DEVICES IN SLOVAKIA
SPOTREBA ZDRAVOTNÍCKYCH POMÔCOK NA SLOVENSKU

Original research article

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Abstract Medical devices (MD), together with pharmacotherapy are supportive treatment of many acute and chronic diseases. MD as a part of medical technologies lead to more effective treatment, faster patient recovery and a reduced risk of complications. Many MD are reimbursed from public health insurance funds entirely; for others, particularly advanced functional types of MD, there must be patient participation on price or they can buy them according own decision (direct sale). The target of this study is to analyze the data from paid databases of National Center for Health Information (NCHI) that collects the outputs of provided healthcare. The most recent data were from 1.1.2013 to 30.9.2013. According to NCHI, apart from community pharmacies, there are 226 registered establishments that sold MD until 30.9.2013. Their specialization included dispensing MD (n=163), dispensing orthopaedic devices (n=48) and dispensing audioprosthetic devices (n=15). In the observed period, **average monthly spending** on MD were 10.1 million packages and 14 million €. Average monthly spending on **reimbursed MD** were 8.8 million packages and 12.9 million €. The groups with the largest shares were MD for incontinence and urinary retention, 7.7 million packages (86.9%) and 3.9 million € (30.7%); plasters and bandaging materials, 0.5 million packages (6.0%) and 1.3 million € (10.1%); MD for ostomies, 0.4 million packages (4.5%) and 1 million € (8.0%); and the MD for diabetics group, 0.1 million packages (1.4%) and 1.6 million € (12.8%). **Direct sales of MD** per month on average reached 1.3 million packages and 1.1 million €. The groups with largest shares were MD for incontinence and urinary retention, 629,660 packages (50.3%) and 291,919 € (26.2%); plasters and bandaging materials, 388,111 packages (31.0%) and 227,119 € (20.4%); and MD for diabetics, 56,014 packages (4.5%) and 81,721 € (7.3%).

Slovak abstract Zdravotnícke pomôcky spolu s farmakoterapiou sú podpornou liečbou mnohých akútnych a chronických ochorení. Zdravotnícke pomôcky ako súčasť "zdravotníckych technológií" vedú k efektívnejšej liečbe, rýchlejšiemu zotaveniu pacientov a zníženiu rizika komplikácií. Veľa zdravotníckych pomôcok je hradených z prostriedkov verejného zdravotného poistenia plne, pri iných, najmä pokročilých funkčných typoch zdravotníckych pomôcok sa musí pacient spolupodieľať na úhrade, alebo si ich môžete kúpiť podľa vlastného rozhodnutia. Cieľom práce bolo analyzovať dáta z platenej databázy Národného centra zdravotníckych informácií (NCZI), ktoré zhromažďuje výstupy o poskytovanej zdravotnej starostlivosti. Aktuálne údaje boli od 1.1. - 30.9. 2013. Podľa údajov NCZI, je k 30.9.2014 okrem verejných lekární 226 registrovaných prevádzkarní, ktoré zabezpečujú zdravotnícke pomôcky. Sú to výdajne zdravotníckych pomôcok (n = 163), výdajne ortopedickoprotetických zdravotníckych pomôcok (n = 48) a výdajne audioprotetických zdravotníckych pomôcok (n = 15). V sledovanom období priemerná mesačná spotreba zdravotníckych pomôcok bola 10,1 mil balení a 14 mil €. Priemerná mesačná spotreba zdravotníckych pomôcok uhrádzaných z prostriedkov verejného zdravotného poistenia bola 8,8 mil balení a 12,9 mil €. Najväčší podiel mali skupiny zdravotnícke pomôcky pre inkontinenciu, retenciu moču 7,7 míl balení (86,9%) a 3,9 milióna € (30,7%), obväzový materiál, náplasti a zdravotnícke pomôcky na aplikáciu liečiva 0,5 míl balení (6,0%) a 1,3 mil € (10,1%), zdravotnícke pomôcky pre stomikov 0,4 mil balení (4,5%) a 1 mil € (8,0%) a zdravotnícke pomôcky pre diabetikov 0,1 mil balení (1,4%) a 1,6 mil € (12,8%). Priamy predaj zdravotníckych pomôcok pacientom / zákazníkom priemerne mesačne dosiahol 1,3 mil balení a 1,1 mil €. Najväčší podiel mali skupiny zdravotnícke pomôcky pre inkontinenciu, retenciu moču 629 660 balení (50,3%) a 291 919 € (26,2%), obväzový materiál, náplasti a zdravotnícke pomôcky na aplikáciu liečiva 388 111balení (31,0%) a 227 119 € (20,4%) a zdravotnícke pomôcky pre diabetikov 56 014 balení (4,5%) a 81 721 € (7,3%).

Keywords *medical devices, spending of medical devices, reimbursed medical devices, direct sale of medical devices, groups of medical devices, effective treatment, cost savings*

Kľúčové slová: *zdravotnícke pomôcky, spotreba zdravotníckych pomôcok, hradené zdravotnícke pomôcky, priamy predaj zdravotníckych pomôcok, skupiny zdravotníckych pomôcok, efektívnosť liečby, úspora nákladov*

INTRODUCTION

MD are products intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease likely to affect the structure or any function of the body of humans or other animals (Food and Drug Administration [FDA], 2014). MD work only if they are used correctly. Their effectiveness depends on the skills and experience of the physician using them, the quality of the hospital, and many other factors. The devices are by and large mechanical in nature and have

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an inert effect on the human body. There are more than 500,000 different types of MD produced globally. MD range from simple and everyday consumer products such as spectacles, dentures and sticking-plasters to incontinence and ostomy care products, syringes and bandages, hip implants, MRI and X-ray equipment, and pacemakers. The technologies concerned also extend far beyond those of pharmaceutical science to include materials science, bioengineering, engineering, electronics, software, information and communication technology, nuclear, aerospace, plastics technology, surface technology and many more, which are applied across all areas of clinical practice and homecare. Driven by technology, device improvements are typically available to users and patients within 18–24 months of previous iterations (Eucomed, 2014).

Over the past 2000 years, the materials used in MD have ranged from stone, wood, metal, ceramics, and most recently plastics. MD also have evolved in sophistication and complexity over time. With the formalization of the scientific method in the seventeenth century, such devices became more prevalent. Many MD were manufactured by doctors or small companies and sold directly to the public **with no government standards or oversight**. With the explosion of medical technology in the early twentieth century, several intermediaries evolved between the medical device industry and the public. In 1879, Dr. E. R. Squibb, in an address to the Medical Society of the State of New York, proposed the enactment of a national statute to regulate food and drugs. In 1906, the Food and Drug Act was signed into law. At that time, devices that were harmful to human safety and health proliferated the market, but regulation of MD by the Bureau of Chemistry (the precursor to the FDA) was limited to challenging commercial products only after they had been released into the market. The devices in the marketplace that were defective, adulterated, or misbranded were seized and the device manufacturers were prosecuted in the court of law, but only *after* the products were sold in the market and caused harm to the end users. Thus, there was a strong need for regulating the devices *before* they entered the marketplace (Sastri, 2014).

Currently, in keeping with its mandate to provide the least burdensome means of product regulation, the US FDA's Center for Devices and Radiological Health uses many different standards to facilitate the review of premarket submissions of MD. The benefits of using standards in this manner include providing a set of common requirements and test protocols to the device manufacturer, thus reducing the manufacturer's need to "reinvent the wheel" for each new bench test to ensure safety and effectiveness of the device. With the current trend toward international harmonization of standards, tests performed in accordance with an international standard may be acceptable to several countries. However, there are instances in which FDA does not agree with certain provisions in a standard (Ho *et al*., 2005).

In the European union the European Medicine Agency (EMA) Committee for Advanced Therapies (CAT) - Notified Body (NB) Collaboration Group, facilitates the implementation of the aspects of Regulation (EC) No. 1394/2007 when Advanced Therapy Medicinal Products (ATMP) are combined with Medical Devices (MD). The Mandate, objectives and the tasks of the EMA/CAT-NB Collaboration Group include the overview, coordination and the need for any update of any **process and guidance for consultation of a notified body** for medical devices during an assessment undertaken by the CAT of a combined ATMP/MD; at the request of the CAT, coordinate of the development of **guidance on the standard information** to be exchanged relating to the assessment of the NB for the CAT's assessment of a combined ATMP/MD; the coordination of the development of a **process and guidance relating to postauthorisation activities** for combined ATMPs/MD relating to variations/modifications to the combination and pharmacovigilance-vigilance legal provisions (EMA, 2014).

MD and the materials they are composed of need to be assessed for their safety within the context of a risk management process. Safety issues related to toxicity can be evaluated using the ISO 10993 series of international standards for biological evaluation of MD. It provides an approach that combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests, thus enabling a full evaluation to be made of the biological responses to each medical device, relevant to its safety in use. Various test methods, both *in vitro* and *in vivo* are used for this evaluation. *In vitro* cytotoxicity tests for genotoxicity, interaction with blood, and irritation. *In vivo* tests for irritation and sensitization, hemocompatibility, genotoxicity, implantation and systemic toxicity (De Jong *et al*., 2012).

Plastics are one of the most used materials for MD production. Plastics used in medical device applications must meet stringent performance requirements through production, packaging, shipping, end use, and disposal. Many devices and device kits are sterilized before they are shipped for use. During manufacturing and during end use, they also come in contact with various chemicals, solvents, bodily fluids, skin, organs, and tissues. The materials used in such devices must be resistant to the sterilization methods, chemicals, and fluids that they encounter; be compatible with bodily fluids, skin, and tissues, and still maintain their safety, effectiveness, and functionality (Sastri, 2014).

Strict safety regulation also applies to active implantable MD that are brought to the market, specifically the European Union and the United States of America. Proving that they are safe to use and indeed work as specified involves an extensive series of tests and trials, including bench testing, animal studies and human clinical trials. When the device finally reaches the market, its manufacturer still has obligations to maintain feedback from the market environment (Inmann and Spensley, 2013).

Non-clinical functional studies are often needed to evaluate performance as well as safety of a medical device under conditions of use. The appropriate animal model mimicking the

intended clinical use is selected. The definition of the objectives of the study based on the product characteristics, the use of appropriate evaluation tools, the definition of appropriate control groups and time-periods must be clearly selected and defined. Finally, strategies to incorporate requirements of other safety standards in the design of combined functional studies are involved as well (Clermont, 2012).

Medical device systems have become increasingly complex, interconnected, and interoperating. A major challenge is how to ensure and improve the safety, security, and reliability of MD. An efficient human reliability analysis and assessment for MD is essential for improving the quality of medical treatment and preventing an accident (Lin *et al*., 2014). It can be done by using both qualitative and quantitative methods to analyze human reliability for MD.

After placing MD on the market, the manufacturer runs post-market medical product safety surveillance. It is a complex task requiring standardized data collection, prompt adverse event reporting mechanisms and appropriate methodologies to identify low-frequency safety threats and risk communication. The Data Extraction and Longitudinal Trend Analysis (DELTA) network study of the medical device safety surveillance fulfils this role (Vidi *et al*., 2011).

Adverse event reporting after medical device implantation is essential to understand the safety and performance of a device. Standardization of reporting attains great importance when comparing different devices and for the ongoing surveillance of a marketed device. There are governmental guidelines and regulations for reporting adverse events that occur during a clinical trial as well as those that occur after a device has been introduced into the marketplace. These regulations are country specific, but several multinational non-governmental organizations have taken the lead to achieve a level of international conformity and standardization (Ouriel *et al*., 2013).

Description of medical device market and spending in Slovakia

Slovakia is a small consumer of MD compared to USA where medical-device market is the world's largest with over $100 billion in sales in 2011 (Kampfrath, 2013). In 2005, Slovakia consumed €90 million worth of MD, which accounts for about 0.3% of the total EU consumption. (Emergo Group, 2014).

According to Business Monitor in 2013, the Slovak medical-device market was estimated at US$545.0 million, or US$100 per capita. This market size is comparable to Hungary, while per capita expenditure is similar to Estonia. The 2008–2013 compound annual growth rate (CAGR) was estimated at 2.1%, but the market is expected to expand at a CAGR of 3.9% over the 2013–2018 period, reaching US$659.9 million, or US$121 per capita by 2018. Around 88% of the medical device market is supplied by imports. Slovakia imported MD valued at US$482.1 million in 2013; this represented an increase of 7.6% over 2012 and a 2008–2013 CAGR of 1.5%. Imports grew every year between 2004 and 2013, except for 2009. Slovakia exported MD worth US$221.5 million in 2013, representing a decrease of 7.7% compared to 2012 and a 2008–2013 CAGR of −2.4%. The trade deficit increased from US$208.0 million in 2012 to US$260.5 million in 2013, due to import growth. Slovakia has an established medical device manufacturing sector, although domestic companies struggle to compete with Western manufacturers with regard to product quality or innovation. Areas of specialty include X-ray and dental products. Domestic medical device production is estimated to be in excess of US$300 million. The Slovakian medical device market is expected to grow by a CAGR of 3.9% over the 2013–2018 period, as the economy grows and health spending remains at a high level. Slovakia is heavily reliant on imported MD despite the presence of an established medical-device industry. Health spending is high for the region, in per capita terms and as a percentage of GDP. If the government is successful in creating a single health insurer, the amount of funding within the health system should increase (Business Monitor, 2014).

In Slovakia, MD are sold in community pharmacy, branch of community pharmacy, dispenser of MD, dispenser of orthopaedic devices and dispenser of audioprosthetic devices. MD are reimbursed from public health insurance funds entirely; for others, particularly advanced functional types of MD, there must be patient participation on price or he or she can buy them according to their own decision (known as direct sale). MD are grouped into several groups according to the purposes intended such as MD for incontinence, ostomies, diabetics, for compression therapy, for eye disorder, bandaging material, physiotherapy equipment, MD for patients with mobility problems, individually prepared MD, breast prosthesis, orthopaedic MD and others.

AIMS AND OBJECTIVES

The target of this study is to analyse the data from paid database of National Center for Healh Information (NCHI) in Slovakia that collects the outputs of provided healthcare. Data were focused on MD in the time span from 1.1.2013 to 30.9.2013.

METHODOLOGY AND RESEARCH METHODS

The methodology conducted relies on monitoring, calculation and assessment of data related to spending on MD. The most recent data about spending on MD were evaluated according quality (groups of MD) and quantity characteristics (packages and value) from the point of reimbursed MD by health insurance funds and direct sales realized by patients in cash. We used basic statistical method of evaluation to present average monthly spending of MD. This type of assessment is very rare. That confirms our scientific literature research made before evaluation. There is little evidence to indicate assessment of MD both in Slovakia and the world.

RESULTS

According to NCHI, apart from community pharmacies and branches of community pharmacy, there were 226 registered establishments that sold MD until 30.9.2013. Their specialization were dispenser of MD (n=163), dispenser of orthopaedic devices (n=48) and dispenser of audioprosthetic devices (n=15). In the observed period, **average monthly spending** on MD was 10.1 million packages and 14 million €. Average monthly spending on **reimbursed MD** amounted to 8.8 million packages and 12.9 million €. The groups with the highest shares were MD for incontinence and urinary retention 7.7 million packages per month (86.9%) and 3.9 million € per month (30.7%), followed by plasters and bandaging materials 0.5 million packages per month (6.0%) and 1.3 million € per month (10.1%), MD for ostomies 0.4 million packages per month (4.5%) and 1 million € per month (8.0%), and MD for diabetics 0.1 million packages per month (1.4%) and 1.6 million € per month (12.8%). Rest of the results are present in the Table 1.

Average monthly spending on MD through **direct sales** reached 1.3 million packages and 1.1 million €. The groups with the highest shares were MD for incontinence and urinary retention 629,660 packages per month (50.3%) and 291,919 € per month (26.2%), followed by plasters and bandaging materials 388,111 packages per month (31.0%) and 227,119 € per month (20.4%) and MD for diabetics 56,014 packages per month (4.5%) and 81,721 € per month (7.3%). The high-spending group also included "other MD", 135,396 packages per month (10.8%) and 327,668 € per month (29.4%). Rest of the results are present in the Table 2.

DISCUSSION

Spending on MD can be influenced by many factors. One of them is high quality, well-designed MD are necessary to provide safe and effective clinical care for patients as well as to ensure the health and safety of professional and lay device users. Capturing the requirements of users and incorporating these into design is an essential component. The field of **ergonomics** has an opportunity to assist not only with this area, but also to encourage a more general consideration of the user during medical device development (Martin *et al*., 2008). Otherwise, spending on MD can be influenced when they are reused. MD such as surgical instruments and endoscopes are multiuse devices designed to be used on multiple patients over a prolonged period of time. Devices designated by manufacturers as single-use devices are intended to be used on a single patient for one procedure. Many single-use devices, including needles and syringes used for injection, are truly intended for single use. However, complex single-use devices that are frequently used in surgical, endoscopic, and intravascular procedures are often **reused for economic reasons**. In resource-limited settings throughout the developing world, reuse of single-use devices is especially common because of cost constraints. Reprocessing of single-use devices is often problematic because of lack of standardized procedures, and adverse events related to device contamination or damage do occur. Such events can potentially offset any cost savings gained through reuse (Shuman *et al*., 2012).

In many developing and transitional countries, reuse of cheap single-use devices (needles, syringes, surgical gloves) is common, leading to large numbers of unsafe interventions,

Table 1. Average monthly spending on reimbursed MD paid by health insurance funds in packages and value (€).

Group	Average monthly packages	%	Average reimbursed monthly value	%
Plasters, bandaging material	533,305	6.04	1,298,247	10.10
MD for incontinence, urinary retention	7,671,341	86.88	3,943,731	30.67
MD for diabetics	123,567	1.40	1,642,229	12.77
MD for ostomies	399,069	4.52	1,032,520	8.03
MD for compression therapy	10,276	0.12	196,534	1.53
Breast prosthesis	692	0.01	18,468	0.14
MD individually prepared	20,036	0.23	2,596,299	20.19
Orthopaedic MD	34,459	0.39	838,811	6.52
Physiotherapy equipment	20,885	0.24	381,438	2.97
MD for patients with mobility problems	1107	0.01	341,937	2.66
MD for ear disorder	3121	0.04	376,430	2.93
MD for eye disorder	6575	0.07	154,512	1.20
Other MD	10,803	0.12	872,879	6.79
Sum	8,830,303	100.00	12,859,304	100.00

MD: Medical devices.

Table 2. Average monthly spending on MD on direct sale realized by patients in cash in packages and value (€).

Group	Average monthly packages	%	Average monthly value	%
Plasters, bandaging material	388,111	30.98	227,119	20.37
MD for incontinence, urinary retention	629,660	50.26	291,919	26.18
MD for diabetics	56,014	4.47	81,721	7.33
MD for ostomies	887	0.07	2252	0.20
MD for compression therapy	4455	0.36	12,177	1.09
Breast prosthesis	200	0.02	2405	0.22
MD individually prepared	794	0.06	1434	0.13
Orthopaedic MD	6417	0.51	46,976	4.21
Physiotherapy equipment	6283	0.50	25,263	2.27
MD for patients with mobility problems	411	0.03	6387	0.57
MD for ear disorder	559	0.04	5683	0.51
MD for eye disorder	23,732	1.89	84,090	7.54
Other MD	135,396	10.81	327,668	29.38
Sum	1,252,919	100.00	1,115,093	100.00

MD: Medical devices.

specifically injections, and, as a consequence, infection with hepatitis B, C or HIV. There are various reasons for reuse: limited resources, insufficient knowledge of healthcare workers and the belief of patients that injection is more beneficial compared to oral medication. Reuse of cheap single-use devices should cease and both medical staff and the public should be informed about potential safety risks associated with injection. In developed countries, reuse of single-use items is less common, but may include expensive technical products. Reuse is regulated in many countries (e.g. US, Canada, some European countries) demanding ethical and legal considerations, high standards of reprocessing and training of staff, risk assessment, management and validation of reprocessing. **Well regulated reprocessing** can decrease the number of single-use devices reprocessed. In developing as well as developed countries, the decision to reprocess single-use devices should only be made after a careful consideration of the advantages and disadvantages (Popp *et al*., 2010).

The other factor that influences the spending on MD is their safety. The recent scandals involving the sale and manufacture of defective MD such as the PIP breast implants and the DePuy implants have resulted in the **long-awaited modernization of the Medical Device Directive**. Taking cognizance of the increasing integration of MD 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 patients' safety (Kierkegaard and Kierkegaard, 2013).

Analysis by Niederländer *et al*. on safety issues and monitoring implant MD found that there is **lack of surveillance of MD**. They detected and classified 101 implant registries and their distribution showed variation in Europe. For a lot of implant categories, none or very few registries could be identified. Some countries run more registries than others. There are a lot of differences in aim and structure among the registries. Niederländer reveals lack of transparency concerning number, aim, structure and quality of registries. This is crucial, as registries work as early warning systems for identifying and notifying patients at risk. (Niederländer *et al*., 2013).

The next factor influencing the spending on MD has been described in an analysis carried out in a hospital by Cruiz. He revealed problems in users' training (errors in operating procedures), intrinsic **failures in MD**, and badly scheduled maintenance policies. Clustering techniques uncovered the main causes of failures. With the evidence obtained, corrective actions were taken. The service request average dropped dramatically from 6.4 to 0.4 during the analyzed period (Cruiz, 2013).

During the 1990s, economic evaluation of costly new pharmaceuticals and **MD** became increasingly widespread and systematic throughout the developed world. However, **serious concerns remain about the validity and relevance of this economic evidence, and about the transparency and accountability of its use in public sector reimbursement decisions**. Cookson and Hutton summarize current concerns in Europe, based on interviews with European health economists from industry, universities, research institutes and consulting firms. They identify five challenges for European policymakers and conclude that there is considerable scope for improving decision-making without damaging incentives to innovate. The challenges are **full publication of the economic evidence**

used in reimbursement decisions; the redesign of licensing laws to improve the relevance of economic data available at product launch; harmonization of economic evaluation methodologies; development of methodologies for evaluation of health inequality impacts; and negotiation of price–performance deals to facilitate the use of economic evidence in post-launch pricing review decisions, as information is gathered from studies of product performance in routine use (Cookson and Hutton, 2003).

MD are a component of healthcare technology (Waller, 2014). The role of medical technology in healthcare costs has long been a source of debate. It has been widely asserted that healthcare technology can be cost increasing due to price and volume effects both for medical technologies themselves and related services (See Fuchs, 1996). Other findings have suggested that **returns on spending on medical technologies can far exceed their costs**, particularly when long-term benefits are measured in terms of productivity and reduced disability (Cutler and McClellan, 2001). Yet, surprisingly, very little analysis has been conducted on the direct costs to the health system of MD themselves. A review of the literature for MD-related studies did not find a single, empirical study on systemic spending on all types of MD (INhealth, 2006).

A large share of financial resources in the Slovak healthcare system are absorbed by pharmaceutical spending (28% in 2008), which is 2-times higher than the OECD average. In contrast, spending on MD is 3%, which is lower compared to the EU, OECD averages and USA (6%) (Danahoe and King, 2012). Having achieved the goal of decreased spending on pharmaceuticals, an appropriate portion of the resulting savings must consequently be reinvested into supporting new modern medical technologies, which would lead to **more effective treatment, faster patient recovery and a reduced risk of complications. Reducing pharmaceutical consumption, investing into modern medical technologies, and focusing on the care pathway will help the Slovak healthcare system achieve both financial stability and sustainability** (Mičieta, 2012).

CONCLUSIONS

When an aging population creates an increased financial demand on the healthcare system, Slovakia must further focus on efficiency and sustainability. Medical technologies (including MD) represent the best approach because improvements in medical technologies are not a driver of cost. Medical technologies represent a small portion of overall spending and offer limited potential cost savings in procurement. In the context of the above, the pharmacists play an important role. Providing MD brings benefits not only for the patients, but also for the pharmacists. Such character of the provision of pharmaceutical care bring community pharmacies additional revenue and enable them to retain in a sufficient network of healthcare providers among which community pharmacies belong.

REFERENCES

[1] Business Monitor. Slovakia Medical Devices Report. 2014, 157. Available at: http://store.businessmonitor.com/slovakia-medical-devices-report.html. Retrieved on August 14, 2014.
[2] Clermont G. Non-clinical functional evaluation of medical devices: general recommendations and examples for soft tissue implants. Biocompatibility and Performance of Medical Devices, 2012, 345-361.
[3] Cruz AM. Evaluating record history of medical devices using association discovery and clustering techniques. Expert Systems with Applications, 40(13), 2013, 5292-5305.
[4] Cookson R, Hutton J. Regulating the economic evaluation of pharmaceuticals and medical devices: a European perspective. Health Policy, 63(2), 2003, 167-178.
[5] Cutler DM, McClellan M. "Is Technological Change Worth It?" Health Affairs 20(5), 2001, 11 – 29.
[6] Danahoe G, King G. Estimates of Medical Device Spending in the United States. 2012, July, 16.
[7] De Jong WH, Carraway JW, Geertsma RE. *In vivo* and *in vitro* testing for the biological safety evaluation of biomaterials and medical devices. Biocompatibility and Performance of Medical Devices, 2012, 120-158.
[8] Emergo Group. SLOVAKIA - Medical Device Industry and Demographic Data. Available at: http://www.emergogroup.com/resources/market-slovakia. Retrieved on August 13, 2014.
[9] Eucomed. Medical devices and pharmaceuticals: Two different worlds in one health setting. Available at: http://www.eucomed.org/key-themes/medical-devices-directives/devices-pharmaceuticals. Retrieved on August 10, 2014.
[10] FDA. Is the product a medical device? 2014. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm. Retrieved on August 15, 2014.
[11] EMA. EMA/CAT and Medical Devices Notified Body (EMA/CAT-NB) Collaboration Group. Mandate, objective, rules of proceduce. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/contacts/CAT/people_listing_000086.jsp&mid=WC0b01ac058029021c. Retrieved on August 20, 2014.
[12] InHealth. Assessing the Impact of Medical Technology Innovations on Human Capital; Phase I Final Report (Part A): State-of-the-Science Literature Reviews", Prepared for the Institute for Medical Technology Innovation. Available at: http://www.inhealth.org/MediaCenter/Duke_Final_Report_A___State_of_the_Science_Literature_Reviews.pdf . Retrieved on January 31, 2006.

[13] Inmann A, Spensley J. Developing active implantable medical devices in a regulated environment. Implantable Sensor Systems for Medical Applications, 2013, 299-327.
[14] Kampfrath T, Cotton SW. The new collaborative path in medical device development: The medical device innovation consortium. Clinical Biochemistry, 46(15), 2013, 1320-1322.
[15] Martin JL, Norris BJ, Murphy E, Crowe JA. Medical device development: The challenge for ergonomics. Applied Ergonomics, 39(3), 2008, 271-283.
[16] Kierkegaard S, Kierkegaard P. Danger to public health: Medical devices, toxicity, virus and fraud. Computer Law & Security Review, 29(1), 2013, 13-27.
[17] Lin QL, Wang DJ, Lin WG, Liu HC. Human reliability assessment for medical devices based on failure mode and effects analysis and fuzzy linguistic theory. Safety Science, 62 (2), 2014, 248-256.
[18] Ho C, Jensen D, Lacy F, Muni N, Reilly S, Mallis E. Use of standards in the review of medical devices. Journal of Electrocardiology, 38(4), Supplement, 2005, 171-174.
[19] Mičieta V. AmCham Connection. 10(4), 2012, 3.
[20] Niederländer C, Wahlster P, Kriza C, Kolominsky-Rabas P. Registries of implantable medical devices in Europe. Health Policy, 113(1–2), 2013, 20-37.
[21] Ouriel K, Fowl RJ, Davies MG, Forbes TL, Gambhir RPS, Morales JP, Ricci MA. Reporting standards for adverse events after medical device use in the peripheral vascular system. Journal of Vascular Surgery, 58(3), 2013, 776-786.
[22] Popp W, Rasslan O, Unahalekhaka A, Brenner P, Fischnaller E, Fathy M, Goldman C, Gillespie E. What is the use? An international look at reuse of single-use medical devices. International Journal of Hygiene and Environmental Health, 213(4), 2010, 302-307.
[23] Sastri VR. Plastics in Medical Devices Regulations for Medical Devices and Application to Plastics Suppliers: History and Overview. (Second Edition), 2014, 336.
[24] See Fuchs VR. "Economics, Values and Health Care Reform,"The American Economic Review, 86(1), 1996, 1 – 25.
[25] Shuman EK, Chenoweth CE. Reuse of Medical Devices: Implications for Infection Control. Infectious Disease Clinics of North America, 26(1), 2012, 165-172.
[26] Vidi VD, Matheny ME, Donnelly S, Resnic FS. An evaluation of a distributed medical device safety surveillance system: The DELTA network study. Contemporary Clinical Trials, 32(3), 2011, 309-317.
[27] Emergo Group. SLOVAKIA - Medical Device Industry and Demographic Data. Available at:
[28] Wallner PE, Sandler HM. US Food and Drug Administration medical device review and approval; Myths, misconceptions, realities, and potential policy changes. Practical Radiation Oncology, In Press, Corrected Proof.

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