

UNIVERSITY OF LJUBLJANA  
FACULTY OF ECONOMICS

DIPLOMA THESIS

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DIPLOMA THESIS  
**CORPORATE SOCIAL RESPONSIBILITY AND  
PHARMACEUTICAL INDUSTRY**

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## **STATEMENT**

I, Brina Brate, student of the Faculty of Economics, state that I am the author of this diploma thesis, whose mentor was Dr. Marko Jaklič, and that I do permit this paper to be published on the faculty's web pages.

In Ljubljana, 15<sup>th</sup> of February 2012

Signature: \_\_\_\_\_

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## **INTRODUCTION**

Today there is a growing demand for Corporate Social Responsibility (CSR) being incorporated in businesses and practiced worldwide. Companies should realize that a commitment to CSR is an important part of business and therefore should have the same attention as any other business activity in the company. CSR is a concept that connects the company to its stakeholders, usually employees, managers, shareholders, non-governmental organizations or any others who are affected directly or indirectly by the company's actions.

Like any other major business sector, the pharmaceutical industry is under immense pressure regarding the way it operates. Since there is a growing interest by the media and the public in the type of healthcare service being practiced, pharmaceutical companies cannot avoid being talked about in the discussions of such issues. The corporations undertake the task of curing and preventing the world's diseases. However, due to the capitalist nature of many developed societies, pharmaceutical corporations are often driven by profit. This is sometimes perceived as immoral, since these companies should work in the best interest of healthcare and patients and not for their shareholders and managers. Therefore pharmaceutical companies and the entire pharmaceutical industry have to focus on CSR as one of their main strategies. A commitment to corporate social responsibility is in the industry's interest in order to prove its credibility and to encourage greater understanding of its work.

The purpose of my thesis is to present the corporate social responsibility of the pharmaceutical industry and whether the industry is committed to CSR activities, acting ethically and following one of its main purposes of helping people worldwide.

The diploma thesis is divided into three parts. In the first part a theoretical concept of CSR is presented. It consists of a definition of the concept, followed by its history as showing the way the concept had evolved in the past. Furthermore, a theoretical framework of CSR is presented for better understanding. The first section concludes with a chapter on business ethics. The second part is addressing the pharmaceutical industry and its connection to CSR. Here main issues of the industry are presented as ways of engaging in CSR. Intellectual property rights, price controls and access to medicine are the most important issues that are addressed and explained. The difference in price control of the United States and the European Union are presented, followed by a concept of access to medicine in the developing world and drug donations, concluded with suggestions for better access to medicine. The third, and the last part of the diploma thesis outlines possibilities for a sustainable path and the future of CSR in the pharmaceutical industry. I finish the thesis with my findings and some concluding thoughts.

## **1. CORPORATE SOCIAL RESPONSIBILITY**

The Corporate Social Responsibility (CSR) concept is gaining in importance and becoming a crucial part of everyday business. Businesses today are expected not to limit their activities only on profit realisation but also to understand that they have a bigger role in society and therefore should act responsibly towards all of their stakeholders and the environment

In the first part of my thesis I will explain the meaning of CSR and give a historical background. Then I will focus my attention on the theoretical framework of CSR. For better understanding, I will conclude with a part about business ethics.

### **1.1 DEFINITION OF CORPORATE SOCIAL RESPONSIBILITY**

A lot of businesses accepted and implemented the concept of CSR during the last three decades, but only limited consensus has emerged about what CSR really means (Carroll & Buchholtz, 2000, p.27). To agree on one definition would be really difficult because each one has a different viewpoint and in some way tries to explain the connection between a business and its environment. For a number of sources, a key element of CSR is its voluntary nature. In other words CSR points to business activities that are not mandated by law.

Therefore there are still a lot of different definitions of CSR in today's literature. According to Post, Lawrence and Weber (2002, p.58) CSR means that businesses should be held accountable for any of its actions that affect people, their communities, and their environment. Harm to people and society should be acknowledged and corrected as such. It may require a company to let go of some of its profits if its social impact seriously hurts its stakeholders and that those funds used for positive social impact.

We can also look at CSR from the viewpoint of a four-part definition by Archie B. Carroll (Carroll & Buchholtz, 2000). Social responsibility of a business combines the economic, legal, ethical and philanthropic expectations placed on organizations at a given point in time. This definition tries to place economic and legal expectations in perspective by relating those to ethical responsibilities and voluntary (philanthropic) responsibilities.

World Business Council for Sustainable Development (WBCSD, 2002) defines CSR as: " [...] the commitment of business to contribute to sustainable economic development, working with employees, their families, the local community and society at large to improve their quality of life."

Commission of the European communities (2001, p.6) has made a general definition of CSR in trying to promote this concept in Europe. They issued a Green paper in which they define CSR as a concept whereby companies integrate social and environmental concerns in their business operations and in their interaction with their stakeholders on a voluntary basis.

European Commission (2011, p.6) presented a new definition and a new strategy for CSR in Brussels in October 2011. It states that CSR is a responsibility of enterprises for their impact on society and therefore should have a process to integrate social, environmental, ethical, human rights and consumer concerns into their operations and core strategies in close collaboration with their stakeholders. Their aim should be maximising the creation of shared value for their owners, stakeholders and society by indentifying, preventing and mitigating their impacts.

There are a lot of historical views that differ from the ones stated above and I will focus my attention on them in the next chapter.

## **1.2 HISTORY OF CORPORATE SOCIAL RESPONSIBILITY**

We can trace the concept of CSR far into the past. It had different names and connotations to it but basically every author in some way described it as the need for corporate responsibility towards society, today generally excepted as CSR.

Formal writing on social responsibility began in the 20th century, especially in the past 50 years. The concept mostly developed in the Unites States, where most of the literature was accumulated. The first major book entitled “Social Responsibilities of a Businessman” was written by Howard R. Bowen in 1953 and it represented the origin of the modern debate on this subject (Carroll, 1999, p.268). For Bowen social responsibility refers to the obligations of businessmen to pursue policies, to make decisions and to follow lines of action which are desirable in terms of the objectives and values of our society.

The CSR literature significantly expanded during the 1960s and focused on the question of what CSR really means (Carroll, 1999, p.271). In 1960, William C. Frederick asserted that CSR implies a public posture toward society’s economic and human resources and also willingness to see that those resources be used for broad social ends and not just for interests of private persons and firms. Another important author Keith Davis argued that some decisions made by businessmen, had in mind their social responsibility. He set his definition of social responsibility by arguing that it refers to businessmen's decisions and actions taken for reasons beyond the firm's direct economic or technical interest. Davis later came back to the concept and stated that social responsibility broadens a person’s view to the total social system. In 1963, another prominent author Joseph McGuire presented a definition in which obligations of a corporation extend beyond just economic and legal.

Milton Friedman had an opposing view to McGuire in his article: The Social Responsibility of Business is to Increase its Profits (Moura-Leite & Padgett, 2011, p.530). His definition of CSR is very conservative and was quite groundbreaking by the end of 1960. Friedman (1970) believes: " [...] there is only one social responsibility of business - to use its resources and engage in activities designed to increase its profits so long as it



stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud."

According to Heald in the 1970s business practices that might be categorized as social responsibility embraced topics like philanthropy, customer relations, employee improvements and stockholder relations (Carroll, 1999, p. 273). In 1973, Keith Davis reinforced his 1967 work with the Iron Law of Responsibility, which states that whenever power and responsibility become substantially out of balance, forces are generated to bring them into closer balance. Power cannot be viewed in isolation from responsibility, and this relationship is a foundation of CSR. Those who do not use power in a manner which society considers responsible will tend to lose it because other groups will eventually step in to assume those responsibilities (Davis, 1973; in Carroll 1999, p.273). One important definition is also Archie B. Carroll's four-part definition of CSR (Moura-Leite & Padgett, 2011, p.531). He believes that the social responsibility of business encompasses the economic, legal, ethical and discretionary expectations that society has of organizations at a given point in time.

Great contribution to CSR came from the Committee for Economic Development (CED) in the 1971 publication *Social Responsibilities of Business Corporations* (CED, 1971; Carroll 1999, p.273). They observed that business functions and its basic purpose are to serve constructively the needs of society, which is to the satisfaction of society. It articulated a three concentric circles definition of social responsibility. The inner circle encompassing basic economic responsibilities, the intermediate one adding an awareness of changing social values and priorities, and the outer circle outlined that a business should be broadly involved in actively improving the environment. It was a decade during which business managers used traditional management functions to deal with CSR, the majority of them following the enlightened self-interest (Carroll 2008; in Moura-Leite & Padgett, 2011, p.532). In the 1970s many authors focused on the content of CSR that did not conflict with the fundamental interests of business.

In the 1980's CSR concept broke into new and more alternative definitions (Carroll, 1999, p.284). New themes were introduced such as corporate social responsiveness, public policy, business ethics, stakeholder theory and many more. Models from before were altered and authors tried to discover the "truth" of CSR. Thomas M. Jones made an important contribution in the 1980's. He drew an analogy with the political process, assessing that the appropriate process of CSR should be fair, where all interests of the stakeholders are heard. He focused mainly on the decision-making process, rather than on principles of CSR. In the following years another two authors made new theories. L.E. Preston and J.E. Post proposed that companies have to consider the consequences of their actions, but are not obliged to solve all the problems of society. Instead, they are required to target areas related to their activities and interests. The authors approached CSR in terms of primary and secondary involvement of the company with society. The primary involvement is to understand the behaviour, and transactions that go directly from the

property and the inside operations of the company, whereas the secondary involvement relates to the impacts and effects generated by the primary. Probably the most important author of the 1980's is R. Edward Freeman, who introduced the stakeholder theory in his book *Strategic Management: A Stakeholder Approach* in 1984 (Moura-Leite & Padgett, 2011, p.532). He recognized the growing importance of ethics and proposed the concept of stakeholder management as an integrating force to address CSR.

During the 1990s the CSR concept was being noticed worldwide. Many authors, mentioned before revisited the CSR concept at that time and themes, such as corporate social performance (CSP), stakeholder theory, business ethics theory, and corporate citizenship were highlighted (Moura-Leite & Padgett, 2011, p.536). In this millennium CSR became an important issue for many companies, since these changes made social and environmental sustainability an important source of legitimacy of companies, to the point where they also hold social responsibilities as well as legal responsibilities.

There are still things to be done in the future. More and more companies will adapt to CSR policies and modernize them to make them more affective and socially responsible, as has been the case during the last few decades. Different authors may still be revising and alternating existing definitions of CSR.

### **1.3 THEORETICAL FRAMEWORK FOR CORPORATE SOCIAL RESPONSIBILITY**

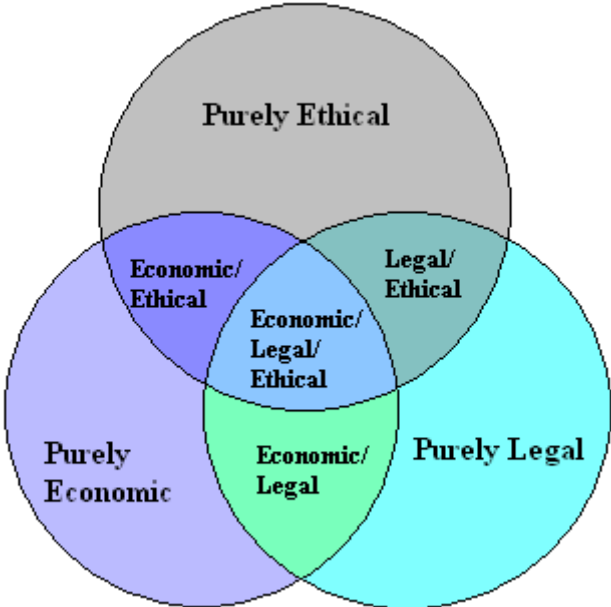
Each of the previously mentioned definitions of CSR has value but there is one that is a great starting point for understanding CSR and is one of the most famous in literature. It's called Carroll's pyramid of CSR (Carroll, 1991, p.40). Carroll focuses on economic, legal, ethical and philanthropic responsibilities. All of these four categories are envisioned as a pyramid, so there is a hierarchy of these components from economic at the base followed by legal, ethical and philanthropic at the top.

There are some limitations to the model that Carroll presented in 1991 (Schwartz & Carroll, 2003, p.505-508). The hierarchy of the components suggests that philanthropic responsibilities are the most important, since they are at the top, but Carroll believed that economic responsibilities are fundamental. Also the whole structure of the pyramid is not the most effective, since the four categories are separated and therefore misinterpreted as mutually exclusive domains. Scholars have been arguing as well over the philanthropic responsibilities. Some say this category is of a voluntary nature and therefore cannot be a responsibility and a part of the pyramid. Also that philanthropy is economically motivated. One critique is also that these four responsibilities have only partial definitions.

Because of these limitations Carroll and Schwartz (2003 p.508) renewed the model by presenting **the Three Domain Model of CSR** (refer to Figure 1). It consists of economic, legal and ethical domains. The philanthropic category is subsumed under the economic and

legal domains. The three domains are formed in a Venn diagram format that indicates the importance of all three to the same extent, one overlapping the other. Because of its form we can then look at seven different categories.

Figure 1: The Three Domain Model of CSR



Source: M. S. Schwartz & A. B. Carroll, *Corporate Social Responsibility: A Three-Domain Approach*, 2003, p. 509.

The first category is **purely economic**. It encompasses activities that are purely economic in nature, must have an economic benefit, are illegal, comply with the law and are considered to be amoral or unethical (Schwartz & Carroll, 2003, p. 513). In the pharmaceutical industry we can see a lot of cases where companies invest in such activities.

The second category is **purely legal** and includes actions that are not considered ethical and have no economic benefit. These activities must take place because of the legal system. The line between legal or ethical and economical is thin, and therefore it is hard to determine its pure legal intention (Schwartz & Carroll, 2003, p. 515).

The third one is **purely ethical**. Every pure ethical action without any economic or legal implication falls into this category. Companies perform such activities because they are based on at least one moral standard. The first standard is conventional, and is defined by norms which have been accepted by the organization, the industry, the profession, or society in reference to formal codes of conduct or ethics. The second is consequentiality standard, in which an action is considered ethical when it promotes the good of society and is intended to produce the greatest benefit for society, when compared to other alternatives. The last one is deontological standard and it contains activities which reflect consideration

of one's duty or obligation. An example of purely ethical doing is when the pharmaceutical company Merck and Co. developed and distributed a free pill that cured people of river blindness even though no profits from sales were generated (Schwartz & Carroll, 2003, p. 511-516).

The fourth category and the first one overlapping is the **economic/ethical** domain. Activities are economic and ethical at the same time, so as to say that good ethics makes good business. It would usually comply with the law, otherwise it would be unethical. Giving to charity is a good presentation of this domain because it is an ethical action that can have economic benefits (Schwartz & Carroll, 2003, p. 516).

Fifth category is the **economic/legal** domain. There are very few actions that can be considered purely economic and legal and not ethical as well. If companies act according to the law, they also act ethically. Exceptions are the companies that act opportunistically for economic gain. An example is when they operate in the third world countries because of fewer environmental restrictions and cheaper labour force (Schwartz & Carroll, 2003, p. 517).

The **legal/ethical** domain is the sixth category of the model. Activities that are legally required and also ethical fall into this domain. Such actions may have an indirect affect on economic benefit but there are very few of them. An example is when pharmaceutical companies provide HIV/AIDS drugs at below cost in African countries (Schwartz & Carroll, 2003, p. 518).

The last overlapping domain that connects all three main categories is the **economic/legal/ethical** domain. Legal system and ethical standards fall into this domain. For being socially responsible companies should seek to operate in this central segment. An example is when Wal-Mart stopped selling cigarettes in Canada, which was good for public image and motivated by legislative and ethical changes (Schwartz & Carroll, 2003, p. 518-519).

The Three Domain Model of CSR eliminates philanthropic category and subsumes it within economic and ethical category (Schwartz & Carroll, 2003, p.525). The new model portrays more completely and accurately the relationships between the three central CSR domains: economic, legal, and ethical. It also helps eliminate the hierarchical relationship among the categories, which are presented in Carroll's pyramid. This new model intends to provide a more appropriate theoretical framework for categorizing CSR activities.

## 1.4 BUSINESS ETHICS

The word ethics is used to describe rules or principles that define the right or wrong conduct. Ethical rules embody the idea of morality, what is morally right or wrong (Davis & Frederick, 1985, p.76-77). These rules attempt to provide guidelines for human behaviour that will preserve society's notion of morality. For society ethical standards and morality are essential for the preservation and continuation of organized life. Beauchamp and Bowie (2004, p.1) believe that morality cannot be purely a personal policy or code and is not confined by the rules of professional codes of conduct adopted by corporations. The terms ethical theory and moral philosophy point to the nature of right actions, in contrast to morality.

**Business ethics** are the principles and standards that guide the behaviour of individualists and groups in the world of business like managers, employees, consumers, special interest groups, etc. (McAlister, Ferrell, & Ferrell, 2005, p. 96-97). The most basic standards have been codified as regulations to encourage companies to conform to society's expectations of business conduct. Ethical problems in business generally come from a conflict of interest between primary and secondary stakeholders, as well as the conflicts that arise inside a group (Jaklič, 2005, p. 283).

According to Carroll (1996, p.111) there are two branches of moral philosophy, descriptive ethics and normative ethics. **Descriptive ethics** includes describing, characterizing and studying the morality of people or society. It compares different moral codes and systems and mainly focuses on "what is" the prevailing set of ethical standards in the business community. An example of descriptive ethics are the Forbes magazine polls that report what business executives believe is morally acceptable and what is not. On the other hand, **normative ethics** seeks to uncover, develop and justify basic moral principles and therefore tries to propose principles for distinguishing right from wrong in the business context. It deals with "what ought to be" or "what ought not to be" in business practice. Problems like famine, environmental pollution and sexual discrimination can be some examples of normative ethics. Beauchamp and Bowie (2004, p.6) later extend this theory and add another branch, that is **conceptual ethics**. Here the meaning of central terms in ethics such as right, obligation, justice, responsibility, is analyzed. The analysis of what is moral and what is immoral is a typical case of conceptual study.

Traditional ethical theories have developed through history. They can apply to any situation and are more of a normative nature. Crane and Matten (2004, p. 90) divide these theories into two groups, consequential and non- consequential. Consequential theories (egoism and utilitarianism) are based on the intended outcome or a goal of a certain action. Non- consequential theories (ethics of duties and rights and justice) are based on the underlying principles of the decision-makers motivation. There are four main theories that Crane and Matten (2004, p. 90-107) describe:

- **Egoism:** an action is morally right if the decision maker decides to pursue his short-term desires or his long-term interest. It is based on the pursuit of self interest and desire and the maximization of both. The contributor of this theory is Adam Smith. In the 1700's he argued that the pursuit of self-interest is acceptable because it produces a morally desirable outcome for society through the "invisible hand" of the marketplace.
- **Utilitarianism:** an action is morally right if it results in the greatest amount of good for the greatest amount of people affected by an action. In analyzing two possible actions in a single business decision, we assign a certain utility to each consequence or person, and the action with the highest aggregate utility is morally correct. Man is controlled by avoidance of pain and gain of pleasure. Contributor of the theory in the 1800's is a British philosopher John Stuart Mill.
- **Ethics of duties:** the main contributor is a German philosopher, Immanuel Kant. In the 1780's he saw humans as rational actors who could decide upon principles of ethical behaviour for themselves. He developed the 'categorical imperative', a theoretical framework that should be applied to every moral issue. It consists of three parts called maxims. The first one checks if an action could be performed by everyone and if it is consistent. The second maxim focuses on human dignity and respect that should never be ignored. The third maxim is the element of universality. If rational actors would all act in the same way and as an example, if somebody would want their actions to be reported in the press.
- **Ethics of rights and justice:** In the 1640's, a British philosopher, John Locke, conceptualized the notion of natural rights as rights to life, freedom and property. Natural rights are certain basic, important entitlements that cannot be taken away and therefore should be respected and protected in every action. Rights typically result in the duty of other actors and therefore making them two sides of the same coin.

Main criticisms of traditional ethical theories are that they are too abstract, too reductionist, too objective and elitist (Matten & Crane, 2004. p. 110-118). As a result there have been recent attempts to develop theories with greater flexibility. Contemporary ethical theories have developed in the last decade. There are four main contemporary theories. **Virtue ethics** states that morally correct actions are those of a virtuous characters, therefore a virtuous character is the first step for moral behaviour. **Feminist ethics** prioritizes empathy, harmonious and healthy relationships, caring for one another and avoidance of harm. **Discourse ethics** provides a process of norm generation through rational reflection on real life experience, to solve ethical conflicts. **Postmodern ethics** locates morality in an emotional moral impulse towards others. People should question everyday practices and listen to their emotions and inner convictions about what is right or wrong.

Whatever the methods and theories used throughout history, there is still a problem to this day for businesses to decide what is ethical and perceived as moral. The definitions above give us a framework for a better understanding of business ethics and the distinction

between right and wrong. Companies have to embody morality into their corporate responsibility programs in order to act ethically towards the society.

## **2. PHARMACEUTICAL INDUSTRY AND CORPORATE SOCIAL RESPONSIBILITY**

CSR is not limited to the office or manufacturing plant but also extends into society. People should expect to be treated fairly regardless of race, culture, or social standing. There is a thin line between drugs being produced in hope of easing suffering or in order to return the highest possible profit. In this sense, it needs to be very good at explaining the nature of its business and balance social and shareholder expectations since a business, claiming to regard the preservation of life and curing of diseases above all, should act morally and excel above the standards and practices of the common corporation. In this second chapter of my thesis I will explain some key issues of the pharmaceutical industry and its commitment to CSR.

### **2.1 PHARMACEUTICAL INDUSTRY**

The pharmaceutical industry is under constant pressure by its stakeholders with hopes of developing and distributing pharmaceuticals and drug-related products and services, that are cost efficient but still maintain reasonable profit margins (Smith, 2008, p. 306-307). As in any industry, producing efficiently means lowering the price, developing significant products and services faster. The pharmaceutical industry is confronted by difficult challenges, both economically and politically. Customers, governments, and the general public are among the most demanding outside stakeholders that affect the industry. The immense poverty-related health problems of the world have become challenging for corporate social responsibility of the pharmaceutical industry. One of the main issues that the industry should be dealing with is the HIV (human immunodeficiency virus) or AIDS (Acquired Immune Deficiency Syndrome) crisis. Large pharmaceutical corporations have been under pressure to give up intellectual property rights, to reduce prices to be compatible with the standard of patients living in poverty for a better access to medicines (Leisinger, 2005, p. 578). All of these issues need to be addressed for the industry to repair its public image and restore its relationship with society.

### **2.2 INTELLECTUAL PROPERTY RIGHTS AND PATENTS**

The World Trade Organization (WTO) defines intellectual property rights (IP) as: “[...] the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time.” (Intellectual property rights, 2011). The concept of IP extends from the idea that an individual has a fundamental right to control the production and distribution of his or her labour (Gewertz & Amado, 2004, p.295). Physical property is easily protected, yet in order for an individual

to maintain his intellectual property or the rights to his/her idea is much more complicated. There is an ongoing tension in the pharmaceutical industry between IP's and the right to affordable healthcare. Michael P. Ryan (2005, p.545) believes that the right to life is fundamental and that IP's and patents by contrast are not god-given rights.

The pharmaceutical industry perceives the patented system as an essential part of a business model (Barton, 2004, p.146-147). The basic concept of the patented system is that the inventor is entitled to a limited monopoly, usually for twenty years. This right may result in high prices during this period and the profits provide the basis for the pharmaceutical industry to invest in a highly costly development process necessary to bring new drugs to the market. When the patent term expires the prices fall and the generic manufacturers can enter the market.

Development of drugs to treat HIV patients represents both the triumph and the tragedy of pharmaceutical patent protection. Some of these drugs come too late for too many, however the patented system and the profits that pharmaceutical companies earn, enables these drugs to enter the market. On the other hand, this also means that the drugs would be priced beyond the reach of many patients.

### **2.2.1 Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)**

In some developing countries the patented system applies only for protection of producing drugs, since they are convinced that the access to products is more important, so the products themselves should not be patented (Barton, 2004, p.147-148). A number of countries have adopted compulsory licensing, that is a legal process under which governments can authorize the use of a patented technology without the consent of the patent owner. In practice, compulsory licenses have rarely been formally granted. To achieve extensions of the patented protection, the United States and other developing countries reached The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement in January 1995. This Agreement requires the member nations of WTO to live up to the standards of intellectual property protection.

WTO (2006, p. 2) issued a TRIPS and Pharmaceutical patents Fact sheet in September 2006. It states: "The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet social goals. For patents, it allows governments to make exceptions to patent holders' rights such as in national emergencies, anti-competitive practices, or if the right-holder does not supply the invention, provided certain conditions are fulfilled."

WTO's (2006, p. 2) article 27 of the TRIPS states that: "[...] patents shall be available for any inventions, whether products or processes, in all fields of technology, [...]". Also article 31 establishes procedural limitations on when a country can grant a compulsory licence. The person or company applying for a licence must always first try to get it



voluntarily from the right holder on reasonable commercial terms. If a compulsory licence is issued, adequate remuneration must be paid to the patent holder. For national emergencies, circumstances of extreme urgency or public non-commercial use or anti-competitive practices, there is no need to try for a voluntary licence. For pharmaceutical patents, this flexibility has been clarified and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. It allows countries to use parallel importation for the purpose of promoting public health, as well as use compulsory licensing to manufacture or import generic medicines. It was put into practice in 2003 with a decision enabling countries that cannot make medicines themselves, to import pharmaceuticals made under compulsory licence.

These trends and the recent agreements, most important for the developing world, will likely have major impacts on the United States and the rest of the developed world (Barton, 2004, p.152). One impact arising from the differential pricing concept is the need to prevent import of the low-price products into the developed world. Such imports would cut into the patent-protected market of the developed world and affect incentives to develop new products.

### **2.3. PRICE CONTROL**

Aggressive pricing policies, pursued by large pharmaceutical companies have been a huge ethical question lately. High costs of new conventional drugs and a steep rise for many other drugs already in the market, has intensified criticism by government agencies, the media and general public. This, resulting in high profits in the pharmaceutical industry, seems to be unethical and unreasonable. However, to identify what is an unethical price or an unreasonable profit is quite difficult.

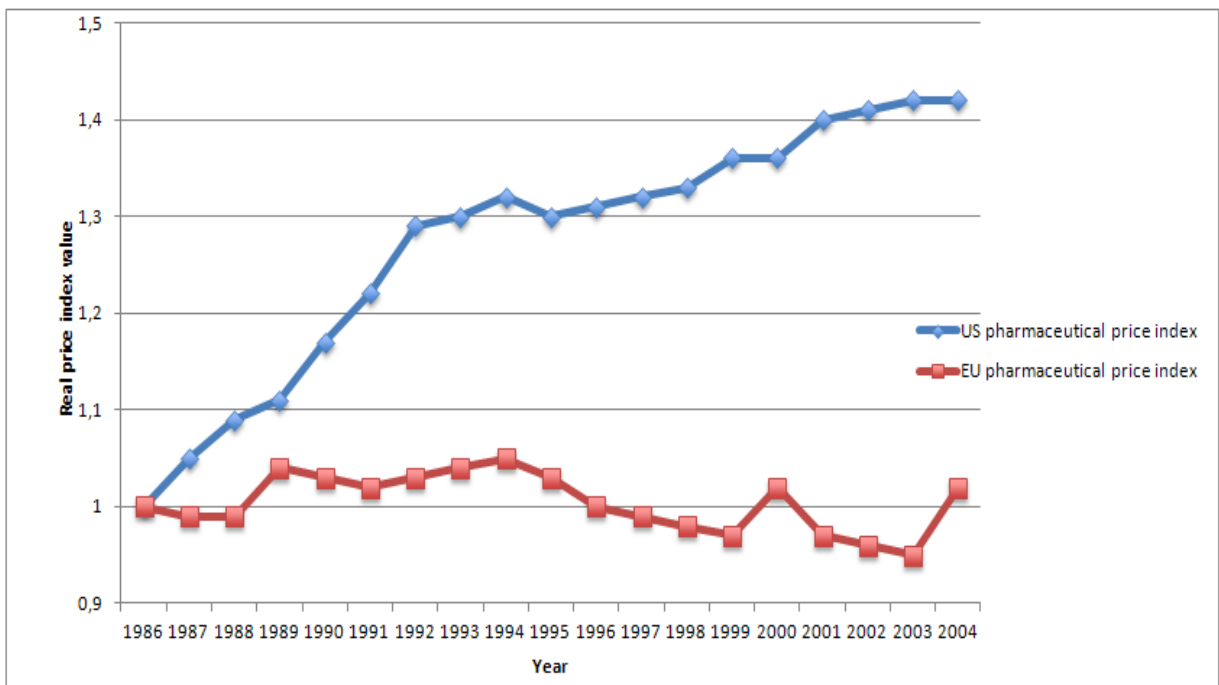
#### **2.3.1 European Union Model versus United States Model**

In the United States, prescription drug prices are mainly unregulated (Vernon, 2002, p.22). In most other countries prices are regulated, either directly through price controls, as in France and Italy, indirectly through limits on reimbursement under social insurance schemes, as in Germany and Japan, or indirectly through profit controls in the United Kingdom.

The perceived potential for manufacturers to exploit a monopoly position when facing relatively inelastic demand for medicines has led many countries to regulate prices for at least some portion of the pharmaceutical market (Santoro & Gorrie, 2005, p. 254). Europe, Canada, Australia and other developed countries have strong price controls to provide greater access to medication for their citizens. The effect was in some way that then the American citizens shouldered the burden of paying for innovative drugs.

One of the ways to measure the effects of European regulation or US pressure on pharmaceutical prices is to compare real pharmaceutical price indexes for the EU and US. Figure 2 shows real growth of pharmaceutical prices for the US and EU from 1986 to 2004. For each year the pharmaceutical price index is divided by the consumer price index (CPI), and these real index numbers are compounded year to year, with 1986 as the base year. European price controls have effectively kept pharmaceutical prices from rising faster than general consumer prices. On the other hand US real pharmaceutical prices increased in almost every year. Real price increases started in 1993 and kept going up in 2000 and 2004.

*Figure 2: Cumulative real pharmaceutical price inflation for the EU and US, with base year of 1986 = 1, computed by dividing the pharmaceutical price index by the consumer price index*



*Source: J. Golec, & J. A. Vernon, Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms, 2010, p. 617.*

Lack of reasonable prices can be attributed to the function of the American free market and the oligopolistic nature<sup>1</sup> of the pharmaceutical industry (Spinello, 1992, p. 617). In the United States (US) certain medicines are simply unavailable for many people due to the industry's pricing scheme. Currently, the American market has no specific price control on non-government drug sales. On the other hand, on the European market pricing levels are determined by negotiations with pharmaceutical companies. Consequentially these prices

<sup>1</sup> OECD (Organization for Economic Cooperation and Development) defines oligopoly as a market characterized by a small number of companies who are mutually dependent in their pricing and output policies (Oligopoly, 2011).

cover companies manufacturing and distribution costs and much less research and development (R&D) costs.

The link between profitability of companies and R&D is very important in the pharmaceutical industry. Table 1 shows how the EU companies profitability and R&D spending compares with that of the US companies. The study focuses on the affects of price regulation on companies' sales and R&D spending, requiring that a company has a minimal amount of product sales, at least 10% of assets. Profitability is measured by total companies' assets. The intensity of company R&D is measured by R&D spending. Table 1 illustrates that the US companies have growing assets and growing R&D spending, much faster than the EU companies. Between 1993 and 2004, the EU companies' assets more than doubled but the US ones more than quadrupled. The US R&D spending has grown 3.7 times over, while the EU R&D has increased about 3.3 times.

*Table 1: Comparison of total assets and R&D spending (\$US, billions) for EU and US firms from 1993 to 2004*

| Year | Number of firms |      | Total assets |       | R&D spending |      |
|------|-----------------|------|--------------|-------|--------------|------|
|      | US              | EU   | US           | EU    | US           | EU   |
| 1993 | 77.0            | 15.0 | 105.3        | 98.1  | 10.6         | 8.3  |
| 1994 | 93.0            | 19.0 | 139.6        | 127.6 | 11.5         | 10.2 |
| 1995 | 110.0           | 20.0 | 161.2        | 145.0 | 14.4         | 13.1 |
| 1996 | 120.0           | 24.0 | 173.2        | 175.0 | 16.2         | 14.5 |
| 1997 | 133.0           | 28.0 | 181.8        | 177.5 | 18.2         | 13.4 |
| 1998 | 143.0           | 30.0 | 211.8        | 168.2 | 22.0         | 14.7 |
| 1999 | 132.0           | 35.0 | 232.7        | 215.7 | 23.1         | 17.1 |
| 2000 | 112.0           | 38.0 | 246.6        | 216.7 | 24.2         | 19.7 |
| 2001 | 113.0           | 38.0 | 297.1        | 226.1 | 31.7         | 19.5 |
| 2002 | 112.0           | 37.0 | 333.6        | 237.2 | 33.3         | 23.6 |
| 2003 | 104.0           | 32.0 | 426.2        | 261.8 | 40.6         | 26.8 |
| 2004 | 96.0            | 30.0 | 467.7        | 255.3 | 39.6         | 27.4 |

*Source: J. Golec, & J. A. Vernon, Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms, 2010, p. 618.*

Some critics say that the solution in the American market is government regulation, more similar to the European model, but big pharmaceutical companies resist such regulation as a threat to the stability of their powerful industry (Spinello, 1992, p. 617-618). The argument is that this premium prices are justified due to huge costs of developing new drugs and the risks connected to this, since a very small percentage makes it through the process. There are also expensive law suits caused by product liability. High prices therefore cover future research and compensate for many commercially unsuccessful drugs.

Regardless of these arguments, studies which compare the performance of various U.S. industries show that the pharmaceutical industry has consistently been one of the most profitable, with rates on equity and on investments that are among the highest off all industries (refer to table 2). Table 2 shows three different measures of return. The first one is profit as a percentage of sales, the second is profit as a percentage of shareholder's equity, and the third is profit as a percentage of total corporate assets. We can see that the pharmaceutical industry has the highest return on sales and the second highest returns on equity and assets. Personal computers companies have a much higher return on equity and a slightly higher return on assets. Considering this, pharmaceuticals certainly are very profitable.

*Table 2: Three Measures of Return for the Pharmaceutical Industry and Five Other Industries in %*

|                  | <b>Drugmakers ( Major)</b> | <b>Money Center Banks</b> | <b>Personal Computers</b> | <b>Aerospace Defense</b> | <b>Automakers</b> | <b>Semi-conductor Makers</b> |
|------------------|----------------------------|---------------------------|---------------------------|--------------------------|-------------------|------------------------------|
| Return on sales  | 16.83                      | 16.48                     | 6.41                      | 4.13                     | 2.39              | 13.45                        |
| Return on equity | 22.43                      | 13.81                     | 35.18                     | 12.39                    | 9.73              | 13.99                        |
| Return on assets | 11.07                      | 1.09                      | 12.69                     | 4.16                     | 1.46              | 9.84                         |

*Source: G. Heal, When Principals Pay: Corporate Social Responsibility and the Bottom Line, 2008, p. 97.*

The issue of ethical or fair pricing acquires a much greater significance when the product or service is not a luxury item but an essential one such as medicine. Should free market determine the price of essential goods such as pharmaceuticals? Also is it morally wrong to charge exceptionally high prices even if the market is willing to pay such a price.

## **2.4 ACCESS TO MEDICINES**

The state of public health care in developing countries, particularly with relation to HIV/AIDS, is one of the most pressing international problems of our time. Poverty and non sufficient resources significantly restrict access to essential medicines in most of Sub-Saharan Africa, the Caribbean and parts of Asia and Central America. High prices of antiretroviral (ARV) drugs<sup>2</sup> have been the main obstacle in increasing access, of people with HIV/AIDS, to life-saving treatment. Efforts of developing countries governments' to reduce the prices of ARV drugs have encountered fierce resistance of patent holding multinational corporations as well as their host countries.

James Cochrane (2000, p.47-48), the former Chief Executive Officer (CEO) of the British pharmaceutical company GlaxoSmithKline admits to these issues in the pharmaceutical industry: " The cost of antiretroviral drugs is, of course, one obvious barrier to their wider use. In this context, my industry points out that the price of our products is heavily influenced by their research and development costs of \$350-500 million a product [...]

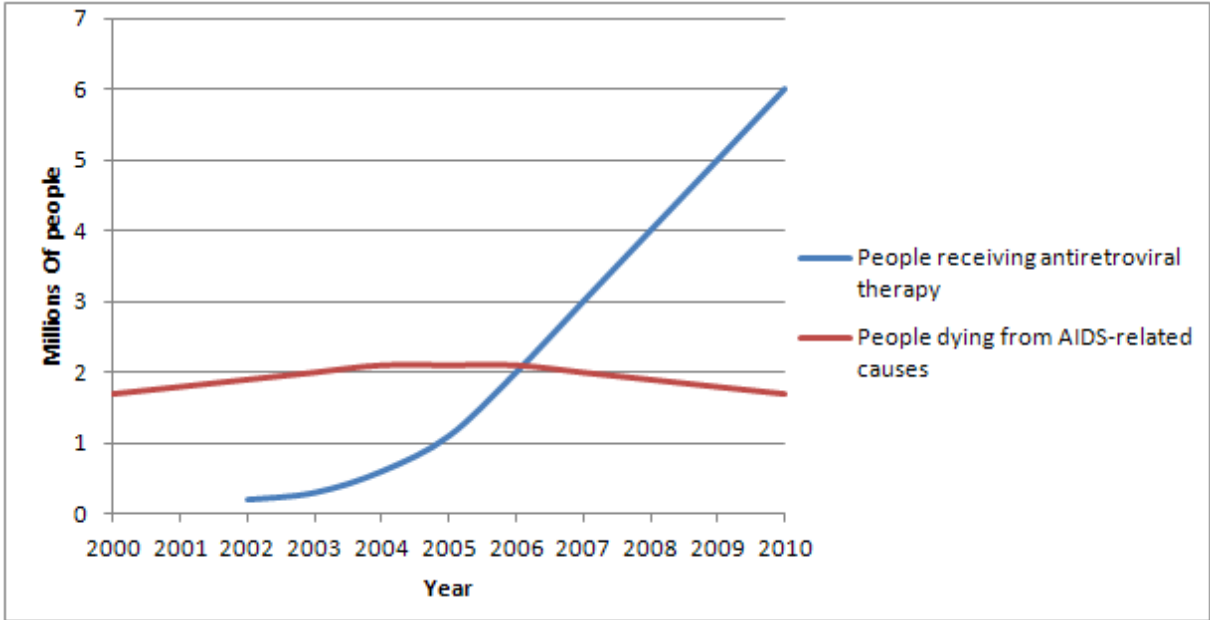
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<sup>2</sup> Antiretroviral drugs hold back the reproduction of retroviruses, that are viruses composed of RNA rather than DNA (Antiretroviral drugs, 2011). The best known of this group is HIV, the causing agent for AIDS.

however, the medicines developed have generally been beyond the reach of people in low-income and middle-income countries."

In contrast to the comment made by James Cochrane in 2000, the WHO's Progress Report 2011 on HIV/AIDS shows a rapid scale-up of antiretroviral therapy in low- and middle-income countries, especially during the past five years (refer to Figure 3). We can see that in recent years, access to these is still growing, but the number of people dying is not proportional to what they are receiving. Every year, there is a growing number of people newly infected by HIV, therefore the number of medicines received still has to rise in the coming years.

Figure 3: Number of people with access o antiretroviral therapy and the number of people dying from AIDS-related causes, low- and middle-income countries, 2000–2010



Source: WHO, *Global HIV/AIDS response: Epidemic update and health sector progress towards Universal Access. Progress Report, 2011*, p.6.

Addressing the global access-to-medicine problem demands the collaboration of multiple international and national stakeholders. Several organizations have attempted to define what should be expected from the industry, but because many stakeholders, including the pharmaceutical industry itself, were not consulted, such initiatives did not have any significant impact on industry practices.

### 2.4.1 The concept of essential medicines

The concept of essential medicines was launched in 1977 with the publication of the first World Health Organization's Model List of Essential Medicines (Hogerzeil, 2004, p.1169). Since then, it has been revised every two years. Its content and process are intended to be a model for developing countries. To this day, the original concept is seen as a breakthrough in international public health. Now, 156 developing countries have a national list of

essential medicines. They are also used by the UNICEF, the United Nations High Commissioner for Refugees, and many non-governmental organisations (NGO's).

In 2002, WHO completed an overhaul of the process to update the Model List (WHO, 2002, p.15). WHO gives a definition of essential medicines: "Essential medicines are those that satisfy the priority health care needs of the population [...] intended to be available within the context of functioning health systems at all times, in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford." Under the new definition, 12 antiretroviral medicines for HIV had been listed irrespective of high cost (Hogerzeil, 2004, p. 1169). This now implies that these medicines should become affordable to all patients needing them.

#### **2.4.2 Drug donations**

Drug donations are necessary and quite valued when they appropriately meet the needs of the ones receiving it. However, the lack of international regulation on drug donation procedures allows some companies to take an unfair advantage of the situation. WHO guidelines for drug donations, describe four core principles that should be respected and guaranteed (WHO, 2008, p.580). The first one is to guarantee a maximum benefit for the recipient; the second one refers to the respect for the wishes and authority of the recipient. The third guideline is no double standards in quality, and the last one providing effective communication between the donor and the recipient. Unfortunately, these are just guidelines and not international regulations. Many relief operations reveal that a lot of donations made by pharmaceutical companies fail to meet the recipient's needs. The main issues regarding donations lie in the fact that the drugs are often very close to expiration date when arriving, or are labelled in languages not understandable to recipients. Some companies send unusable drugs to nations which are not prepared to dispose of them safely and properly. In the end, the recipient of the donation manages the medicines as waste. Once the donation is received into a country it cannot be send back because it is considered a hazardous cargo. The medicines that remain from these processes represent a major health problem for the local authorities. For the reasons stated above drug, donations need to be better regulated, particularly in humanitarian crises.

In 2009, WHO made an extensive research of the academic and lay literature to identify reports about drug donations. The research also included the revision of all the drug donation cases that have occurred from 2000 to 2008 (WHO, 2010, p.923). They found 95 articles describing 96 incidents of drug donations between 2000 and 2008. 50 occurred in disaster situations, 43 were long-term donations and 3 were part of drug recycling programmes. The most frequently reported problem, linked to disaster-related drug donations, was a failure to meet the needs of the country. Five of the 12 recipient countries involved had compiled a list of the medicines they needed, yet two such countries reported that the majority of the donated drugs were unsolicited, unnecessary or insufficient. In 3 of the 12 cases of disaster-related donations, the donated medicines had expired or did not

meet the WHO guideline requiring a remaining time of use of at least one year or, in exceptional cases, of at least one-third of the drug's total time of use, when it was donated. After the disasters, excess drugs received were destroyed or kept in health facilities for later use, but reports provided no indication that the related costs were covered by the donors.

One study case of good practice is the Merck's Mectizan donation programme, which started in 1988, showing good compliance with the WHO drug donation guidelines (WHO, 2010, p.926). It meets existing needs and complies in terms of quality assurance, presentation, packaging and labelling as well as information management. Users are educated about the product and the result of treatment is monitored. In 1988, Merck began to provide Mectizan to treat onchocerciasis (river blindness) in communities located in African and Latin American countries as well as in Yemen. Merck distributes the medicine as part of a community-based programme that also provides vitamin A, eye care services and insecticide-treated bed nets. Prior to the donation programme in 1988, the rate of infection with river blindness was greater than 60 % in some areas and the resulting rate of blindness was as high as 10 %. There was also a high rate of transmission. The percentage of the eligible population that gets treated is estimated at 65 %. The programme's sustainability depends on continued support of drug distribution.

Another case study, which on the other hand, shows bad compliance with the WHO drug donation guidelines, is the response to the tsunami that affected Sri Lanka in 2004 (WHO, 2010, p.924). Following the tsunami, medical assistance was received from 278 donors, including 98 local organizations and NGOs, 150 international organizations and 30 foreign governments. Although Sri Lanka's Ministry of Health issued a list of requested medications, many donations were inappropriate or appropriate but excessive. Of all the 56 tonnes drugs received, only 10 % were on the list of the requested medications. If multiple long-term donation programmes within a region are not properly monitored, the same individuals could be unknowingly signed for a clinical trial and suffer the effects of drug interactions.

### **2.4.3 Corporate Social Responsibility for access to medicines**

Successful pharmaceutical companies contribute to the respect, protection, and fulfilment of the right to health in the context of normal core competence business activities. But beyond this core contribution, pharmaceutical companies are also perceived to have a moral responsibility to do more.

The United Nations (UN) initiative, named The Millennium Development Goals, defines eight international development goals which all the 193 UN member states and at least 23 international organizations have agreed to achieve by the year 2015 (The Millennium Development Goals, 2011). The main purpose of this initiative is to encourage

development by improving social and economic conditions in the world's poorest countries.

Klaus M. Leisinger (2009, p.16-17) describes a few important points of Millennium Development Goal 8, that sets out the target for the international community and pharmaceutical companies, to provide access to affordable, essential drugs in developing countries. The list contains 6 main points:

- Differential pricing, reduced prices for selected drugs against poverty-related diseases for use in least developed countries, particularly for medicines with patent protection.
- Donations for disease elimination programmes or emergencies also referring to WHO Guidelines for drug donations.
- Research and development investments for diseases, affecting poor people in the developing world.
- Support for health and development goals in developing countries.
- Work with stakeholders to ensure access-to-medicines initiatives, incorporated into national systems and priorities.
- Exploring opportunities for production in developing countries including the use of voluntary licenses, where these measures would increase sustainable access to medicines.

While governments continue to hold the primary responsibility for ensuring access to healthcare and to essential medicines, pharmaceutical companies are expected to assume their share of responsibility (Leisinger, 2009, p.18). Without a multi-stakeholder approach that includes national governments, the international community, NGOs, and the private sector, even the well-intended efforts of single actors will have little sustainable impact.

### **3. THE FUTURE OF CORPORATE SOCIAL RESPONSIBILITY IN THE PHARMACEUTICAL INDUSTRY**

The pharmaceutical industry and its companies are under increasing pressure from governments to cut costs and restrict access to their products. The lack of basic medicines in the developing world is perceived to be blamed on pharmaceutical companies. Therefore, in the future, the pharmaceutical industry's commitment to CSR is very important in restoring its public image.

Diego Esteban (2008, p.78) believes that pharmaceutical companies should focus their attention to CSR by focusing their strategies on three areas. First, they must be more transparent and better at communicating their policies and procedures for testing and marketing products. The debate about the trade-off between patents and access to medicines in the developing countries needs to be resolved in order to maintain product R&D and to ensure access to medicines. More effective communication is very important. Secondly, the pharmaceutical industry is likely to face a more challenging people



management environment in the future. The industry otherwise is strong in employee relations issues such as diversity, remuneration, and personal and professional development as well as employee voluntary programme engagement. It is in either case expected to become tougher because of increased employee turnover caused by expansions in developing and emerging markets. Finally, it will have to manage ongoing environmental challenges relating to waste management and the efficient use of key resources, such as water. Water management will be important in the expanding bio products sector which tends to require large amounts of water during the manufacturing process.

In today's literature, most scholars believe that transparency would increase the credibility of the pharmaceutical industry (Nussbaum, 2009, p.71-72). The NGO's are therefore calling for transparency and disclosure. This is necessary for the credibility of the pharmaceutical companies' CSR actions. With the lack of regulation by public bodies, the pharmaceutical industry should engage in actions of self-regulation that would go beyond doing what is legal, but instead address what is the right and moral thing to do.

## **CONCLUSION**

There is a constant ongoing debate about whether the pharmaceutical industry is doing a good job of providing a good platform for a functioning healthcare system. Many believe that this is not the case and that the industry is not transparent and mainly that the medicines are just too expensive and therefore unreachable for many people. In spite of this perceived image the industry has, it is trying in some ways, to improve itself. No matter what the pharmaceutical companies are doing, there is one area in which they can show their stakeholders and the wider community that they are trying their best. Therefore, pharmaceutical companies should implement the CSR principles into their strategies. Profits have a major role in the industry, but in order to obtain higher profits in the long run, pharmaceutical companies must build high brand awareness and company awareness towards consumers and its stakeholders. The concept is to become more socially responsible towards consumers and the environment. The way to a sustainable world contains opportunities and risks, and will radically change the ways in which companies do business.

The purpose of my thesis was to explore whether the industry is committed to CSR activities in a way of acting ethically. Based on several points or issues that I presented, I found that the pharmaceutical industry still has problems with its CSR activities. Intellectual Property Rights and patents are preventing developing countries to have access to drugs or to produce them for a lower price. In spite of the TRIPS Agreement and later the Doha Declaration, which both provide flexibilities for countries to produce and import drugs for a lower price through generic manufacturing and compulsory licensing, in reality this is not being practiced, since the patented protection is convenient for pharmaceutical

companies. One of the main CSR activities that I focused my attention on was the pricing policies or controls in the pharmaceutical industry. Here, I cannot make a clear statement without doing further research. Are price controls more effective or not, is a difficult question. It does limit the price of drugs, but on the other hand it also limits the incentives to produce new, innovative drugs. On this topic, the pharmaceutical industry still has a lot of research to do, since it has been criticised in the past for its high profits. Probably the most important issue that I was researching in my diploma thesis is a chapter of access to essential drugs. I believe that the industry is doing poorly in this case, for there are still so many existing barriers for the developing world and so many people dying from infectious diseases, without the proper treatment. Several donations made by pharmaceutical companies in the past have not been sufficient or did not meet the needs of the recipient. I believe that in this case the pharmaceutical industry has not been acting ethically or accordingly to its CSR activities. In the end of my diploma thesis, I presented some guidelines for a better future of CSR in the pharmaceutical industry, which I believe is important for the industry to act upon.

In spite of my research, my personal opinion is that companies are violating their social responsibility if they exploit anyone in an attempt to make a profit. They are disregarding their moral obligation to society. Pharmaceutical companies often use their leverage to exploit the public. Drugs are researched and developed only if the corporation expects profit. Infectious diseases kill millions of people worldwide, yet pharmaceutical companies develop only a low number of drugs to prevent the spread of these diseases. Furthermore, pharmaceutical companies spend great amounts of money on marketing. It is completely absurd that sometimes marketing budgets are higher than R&D budgets. For millions of people in the USA, however, this is often a reality. Without question, pharmaceutical companies have a moral obligation to society to provide the people, especially the poor, with affordable medication. Presently, they are disregarding this responsibility and therefore are struggling with their Corporate Social Responsibility.

## **POVZETEK**

V današnjem svetu je prisotno vedno večje povpraševanje ter potreba po družbeni odgovornosti. Podjetja začenjajo razumeti, da je delovanje v skladu z družbeno odgovornimi aktivnostmi pomemben del poslovanja in naj bi zaradi tega imelo isto težo kot katerakoli druga funkcija v podjetju. Družbena odgovornost je koncept, ki povezuje podjetja z interesnimi skupinami, največkrat z zaposlenimi, upravljalci, delničarji, nevladnimi organizacijami, in pa tistimi na katere ima podjetje posredni ali neposredni vpliv. Farmaceutska industrija je, tako kot katerakoli druga industrija, pod neprestanim pritiskom zaradi svojega načina delovanja. Glede na vedno večji interes medijev in ljudi, ki želijo imeti odkrito in pregledno zdravstveno politiko, se farmaceutska industrija ne more več izogibati pogovorom na to temo. Farmaceutska podjetja se želijo predstaviti kot pomemben del zdravstva, katerih glavni namen je zdraviti ter preprečevati različne bolezni po vsem svetu. Na žalost pa velikokrat le po načelu čim večjega dobička, kar pa je v nasprotju z namenom njihovega delovanja. Ta podjetja naj bi namreč delovala prvenstveno v interesu zdravstva in pacientov in ne predvsem v korist delničarjev in menedžerjev. Prav zaradi take percepcije se farmaceutska industrija vse bolj osredotoča na družbeno odgovorno aktivnost kot glavni del svoje strategije, ker si želi popraviti ugled in dokazati javnosti svojo verodostojnost.

Namen moje diplomske naloge je predstaviti družbeno odgovornost farmaceutske industrije, torej, glavni cilje je ugotoviti ali farmaceutska industrija deluje v skladu s to odgovornostjo, se pravi etično in moralno, in ali izpolnjuje enega svojih temeljnih ciljev, pomagati ljudem po vsem svetu.

Diplomska naloga je sestavljena iz treh delov. V prvem delu je teoretsko predstavljen koncept družbene odgovornosti z definicijo, zgodovino ter teoretičnim modelom družbene odgovornosti za boljše razumevanje. Prvi del se zaključuje s poglavjem o poslovni etiki. Drugi del prikazuje farmaceutsko industrijo ter njeno povezanost z družbeno odgovornostjo. Tu so predstavljene glavne teme oziroma problemi industrije, kot so intelektualna lastnina, cenovni nadzor oziroma cenovna politika ter dostopnost zdravil. Znotraj poglavja sem razložila tudi razlike v cenovni politiki Združenih držav Amerike (ZDA) ter Evropske unije. Predstavila sem tudi problem donacije zdravil in predloge za bolj učinkovito družbeno odgovornost glede dostopnosti zdravil. V zadnjem, tretjem delu, pa sem predstavila še prihodnost družbene odgovornosti v farmaceutski industriji, povzela glavne ugotovitve ter podala svoje mnenje.

## **DRUŽBENA ODGOVORNOST**

Koncept družbene odgovornosti je vedno bolj pomemben del vsakdanjega poslovanja. Od podjetij se pričakuje, da ne omejujejo več svojih aktivnosti ter ciljev na ustvarjanje dobička, temveč da imajo večjo vlogo v družbi, kjer se vedejo odgovorno do vseh svojih interesnih skupin, saj niso neodvisni od okolja, ki jih obdaja.

Poznamo veliko različnih definicij družbene odgovornosti. Nekako je še danes težko opredeliti ta koncept. Podjetja naj bi odgovarjala za tista dejanja, ki vplivajo na ljudi, skupnosti in pa tudi na širše okolje. Dejanja, s katerimi škodujejo okolici, morajo biti zaznana in hkrati tudi popravljena, kar včasih pomeni, da se pač morajo odreči delu dobička za pozitiven družbeni vpliv. Cilj naj bi bil maksimizacija skupne družbene blaginje za lastnike, interesne skupine in družbo v celoti, s prepoznavanjem vseh vplivov, ki jih podjetja povzročajo, ter z zmanjšanjem tistih, ki so negativni.

Ena najpomembnejših definicij družbene odgovornosti je piramida družbene odgovornosti, ki jo je razvil Archie B. Carroll (1991, str.40) in se nanaša na štiri različne odgovornosti, ekonomsko, zakonsko, etično in filantropsko. V piramidni shemi si sledijo hierarhično, od ekonomske na dnu, sledijo ji zakonska, etična ter filantropska odgovornost na vrhu. Omenjeni model ima sicer tudi nekaj pomanjkljivosti, ki jih je kasneje odpravil prenovljeni tridimenzionalni model družbene odgovornosti, ki sta ga razvila Carroll in Schwartz (2003, str.508) ter vsebuje ekonomsko, zakonsko in etično odgovornost. Te odgovornosti se med seboj prepletajo, tako da sestavljajo sedem različnih kategorij. Prva je zgolj ekonomska in vključuje dejanja, ki imajo ekonomsko korist, so nezakonita in neetična. Druga kategorija je zgolj zakonska in vključuje dejanja, ki so neetična in nimajo ekonomskih koristi. Tretja je zgolj etična kategorija z dejanji, ki nimajo ne zakonske, ne ekonomske podlage. Četrta kategorija je ekonomsko/etična in vsebuje dejanja dobroteljnosti. Peta kategorija je ekonomsko/zakonska. Dejanja podjetij, ki padejo v to kategorijo je težko definirati zaradi zakonske narave, kajti če je dejanje zakonsko je obenem tudi etično. Šesta kategorija je zakonsko/etična ter vsebuje dejanja, ki so zakonsko predpisana in obenem etična. Zadnja, sedma kategorija, je ekonomsko/zakonsko/etična. Leži v sredini kroga in tukaj si podjetja prizadevajo delovati, saj imajo ekonomsko korist, upoštevajo zakone ter obenem delujejo etično.

Večkrat se pojem družbena odgovornost povezuje s pojmom poslovne etike, čeprav obstajajo razlike. Pojem etika se definira kot skupek pravil in principov, ki opredeljujejo pravična ali napačna dejanja (Davis & Frederick, 1985, str.76-77). Etična pravila vsebujejo idejo moralnosti in poskušajo podati smernice za družbeno vedenje. Za družbo so etični standardi ali pravila pomembni za ohranitev organiziranega življenja. Koncept poslovne etike pa vsebuje principe in standarde, ki usmerjajo vedenja posameznih ljudi ter različnih skupnosti v poslovnem svetu (McAlister, Ferrell, & Ferrell, 2005, str.96-97). Najbolj osnovna pravila so zapisana kot predpisi, ki vzpodbujajo podjetja, da se prilagodijo družbeno sprejetemu poslovnemu vedenju.

Zgornje definicije nam dajejo teoretični okvir za boljše razumevanje poslovne etike in družbene odgovornosti. Podjetja morajo vključiti moralnost v svoje programe družbene odgovornosti, da bodo lahko delovala etično v družbi.

## **DRUŽBENA ODGOVORNOST IN FARMACEVTSKA INDUSTRIJA**

Farmacevtska industrija je multimilijardna industrija, ki jo v svetovnem merilu sestavlja ogromno število podjetij. Namen farmacevtske industrije je razvoj in distribucija zdravil ter storitev, povezanih z zdravstvom, ki so stroškovno učinkovita in obenem prinašajo razumen dobiček (Leisinger, 2005, str.578). Kot v katerikoli drugi industriji, učinkovita proizvodnja pomeni zniževanje cen ter hitrejši razvoj produktov in storitev, in s tem zagotoviti sredstva za zdravstvo ljudi po vsem svetu. Ne glede na to, obstaja tanka črta med tem, kdaj so zdravila proizvedena za lajšanje bolezenskih simptomov, kdaj pa za ustvarjanje čim večjega možnega dobička. Zaradi narave svojega delovanja naj bi farmacevtska industrija delovala bolj moralno kot kakšna druga korporacija. Zaradi različnih obtožb v javnosti glede delovanja, so farmacevtska podjetja pod neprestanim pritiskom interesnih skupin naj se odpovejo intelektualni lastnini, zmanjšajo cene zdravil ter omogočijo boljše dostopnost zdravil po celem svetu. Tovrstni pritiski prisilijo farmacevtsko industrijo v natančnejše definiranje narave svojih poslov in družbeno odgovornih aktivnosti, hkrati pa najti ravnotežje med družbenimi pričakovanji in pričakovanji svojih delničarjev. Intelektualna lastnina in patenti, cenovna politika ter dostopnost zdravil so teme, katerim se posvečam v svoji diplomski nalogi glede družbeno odgovornega delovanja farmacevtske industrije.

Svetovna zdravstvena organizacija (WTO) definira intelektualno lastnino (IP) kot: "[...] pravico, ki je dana določeni osebi za miselno ustvarjalnost. Ponavadi izključno dana pravica avtorju do uporabe svojega izuma za določeno obdobje." (Intellectual property rights, 2011). Koncept intelektualne lastnine izhaja iz ideje, da ima določena oseba temeljno pravico nadzorovati proizvodnjo in distribucijo svojega lastnega dela (Gewertz & Amado, 2004, str.295). V farmacevtski industriji intelektualna lastnina predstavlja oviro do cenovno dostopnega zdravstva, vendar je kljub temu osnovni del poslovnega modela. Koncept patentnega sistema ali intelektualne lastnine omogoča avtorju izključno pravico do patenta za dobo dvajset let. Takšna pravica se lahko nato izraža v visokih cenah v tem obdobju in dobiček, ki je rezultat teh cen, predstavlja osnovo za investicije v visoko cenovni proces razvoja novih zdravil. Ko patentna pravica ugasne, cene padejo in na trg lahko vstopijo proizvajalci generičnih zdravil (Barton, 2004, str.146-147). Da bi dosegli bolj fleksibilen patentni sistem, so ZDA in ostale države v razvoju leta 1995 dosegle Sporazum o trgovinskih vidikih pravic intelektualne lastnine (TRIPS), ki omogoča državam v izjemnih razmerah, da uvedejo pravico do prisilne licence.

Cenovna politika farmacevtske idustrije je tema, o kateri se veliko razpravlja v današnjem času. Razvoj novih zdravil na trgu, ki jih spremljajo visoki stroški, je postala vsakodnevna debata vladnih agencij, medijev in širše družbe. Visoki dobički so zaradi take cenovne politike za javnost seveda nerazumni in neetični, s tem pa farmacevtske družbe dodatno ustvarjajo vtis družbeno neodgovornega delovanja. V ZDA so cene zdravil večinoma neregulirane (Vernon, 2002, str.22). Drugje pa so cene regulirane ali neposredno preko

cenovnega nadzora, kot v Franciji in Italiji, ali posredno preko povračil v okviru sheme socialnega zavarovanja, kot v Nemčiji in Japonski, ali preko nadzora dobičkov v Veliki Britaniji. Evropa, Kanada, Avstralija ter ostale razvite države so uvedle močan nadzor nad cenami za večjo dostopnost zdravil za svoje državljane. Na drugi strani pa morajo tako ZDA nositi stroškovno breme za inovacije in razvoj novih zdravil (Santoro & Gorrie, 2005, str.254).

Nekateri kritiki pravijo, da so previsoke cene zdravil v ZDA nerazumne, čeprav naj bi tako krili večino stroškov za raziskave in razvoj. Predlagajo vladno regulacijo cen, tako kot pri evropskem modelu, vendar se farmacevtska podjetja upirajo takšni regulaciji, saj naj bi ogrožala stabilnost industrije. Eden izmed glavnih argumentov so visoki stroški razvoja novih zdravil ter tveganja, ki so povezana s propadlimi inovacijami (Spinello, 1992, str.617-618). Ne glede na te argumente raziskave, ki primerjajo uspešnost večjih industrij v ZDA, kažejo, da je farmacevtska industrija najbolj konstantno dobičkonosnih, s stopnjo na kapital in investicije med največjimi v državi (Heal, 2008, str.97).

Trenutno stanje javnega zdravstva v državah v razvoju v povezavi s HIV/AIDS okužbami je eden največjih mednarodnih problemov. Revščina in nezadovoljiva sredstva omejujejo dostopnost do osnovnih zdravil v večini držav Afrike, Karibov, delih Azije ter srednje Amerike. Zaradi visokih cen protiretrovirusnih zdravil, potrebnih za zdravljenje HIV okužb, veliko okuženih ljudi po svetu ljudi nima možnosti dostopa do njih. Vlade držav v razvoju se trudijo znižati ceno osnovnih zdravil, vendar jih pri tem ovirajo velika multionacionalna farmacevtska podjetja, ki se močno držijo svojega patentnega sistema ter intelektualne lastnine. Bivši izvršni direktor britanskega farmacevtskega velikana GlaxoSmithKline, James Cochrane (2000, str.47-48) je opozoril na tematiko dostopnosti zdravil: "Cene protiretrovirusnih zdravil so očitna ovira dostopnosti za širšo uporabo. V tem kontekstu, moja industrija priznava, da so cene naših proizvodov zelo pod vplivom stroškov raziskav in razvoja, s približno 350-550 milijonov dolarjev stroškov na proizvod [...], vendar pa so ta zdravila na splošno izven dosega ljudi z nizkim in srednjim dohodkom." Zaradi tega so donacije zdravil zelo potrebne ter cenjene, kadar zadovoljijo potrebe tistih, ki jih prejemajo. Svetovna zdravstvena organizacija (WHO) je prav zaradi določenih primerov neprimernosti donacij izdala smernice za donacije zdravil, ki naj bi izboljšale sistem v humanitarnih krizah (WHO, 2008, str. 580). Brez pristopa interesnih skupin, ki vključujejo nacionalne vlade, mednarodne skupnosti, nevladne organizacije ter zasebni sektor, bodo imela tudi dobronamerna prizadevanja posameznikov malo trajnostni vpliv (Leisinger, 2009, str.18).

Za bolj učinkovit sistem družbene odgovornosti v farmacevtskih podjetjih v prihodnosti, naj bi podjetja usmerila svojo pozornost in strategije na tri različna področja (Esteban, 2008, str.78). Najprej bi morala delovati bolj transparentno ter izboljšati komunikacijo pri kompromisu med patenti in dostopom do zdravil v državah v razvoju. Kot drugo bi morala izboljšati upravljanje človeških virov, predvsem zaradi večje fluktuacije kot posledice globalizacije. Nazadnje bi morala industrija bolj učinkovito ravnati z uporabo ključnih

virov, z odpadki ter z vodo. Vsi ti ukrepi so potrebni za verodostojnost farmacevtske industrije in njenih družbeno odgovornih aktivnosti ter programov.

Farmacevtska industrija je v precejšnji meri tarča kritik glede učinkovitega zdravstvenega sistema, svoje transparentnosti in dostopnosti zdravil. Ne glede na očitke se trudi na veliko načinov izboljšati svojo javno podobo in delovati družbeno odgovorno. Edino na tak način lahko pokaže interesnim skupinam in širši javnosti, da še vseeno deluje po svojih najboljših močeh. Visoki dobički v industriji so upravičeni le, če deluje družbeno odgovorno glede okolja in svojih potrošnikov na dolgi rok.

Namen moje diplomske naloge je bil raziskati, ali je farmacevtska industrija predana svojim družbeno odgovornim aktivnostim ter ali deluje etično. Na podlagi tematik, ki sem jih obdelala, ugotavljam, da je farmacevtska industrija še precej daleč od transparentnega in etičnega delovanja. Intelektualna lastnina in patenti preprečujejo dostop do osnovnih zdravil ter onemogočajo cenovno znižanje le teh. Glede cenovne politike je težko določiti ali je cenovni nadzor boljša rešitev za dostopnost zdravil ali ne. Po eni strani omeji visoke cene zdravil, po drugi strani pa tudi zavira razvoj novih inovativnih zdravil. Kako omogočiti čim boljši dostop zdravil v državah v razvoju, je za farmacevtsko industrijo še vedno ne povsem rešljivo vprašanje. Zaenkrat je preveč omejitev za primerno zdravljenje ljudi, ki to najbolj potrebujejo. Donacije, ki jih farmacevtska podjetja izvajajo so večkrat neprimerne in ne ustrezajo smernicam, ki jih je podala Svetovna zdravstvena organizacija. Na koncu svoje diplomske naloge sem predstavila možnosti za boljši trajnostni razvoj družbene odgovornosti in mislim, da jih farmacevtska industrija pomalem že izvaja, vendar se bo morala še aktivneje udeleževati v prihodnosti.

## REFERENCE LIST

1. Antiretroviral drugs. In *Medical Dictionary*. Retrieved January 14, 2012, from: <http://medical-dictionary.thefreedictionary.com/Antiretroviral+Drugs>
2. Barton, J. H. (2004). TRIPS and the Global Pharmaceutical Market. *Health Affairs*. 23(3), p. 146-154.
3. Beauchamp, T.L. & Bowie, N.E. (2004). *Ethical Theory and Business*. (7<sup>th</sup> Ed.) New Jersey: Pearson Education, Inc.
4. Carroll, B. A. (1991). The pyramid of corporate social responsibility: Toward the moral management of organizational stakeholders. *Business Horizons*. 34, p. 39-48.
5. Carroll, B. A. (1996). *Business & Society: Ethics and Stakeholder Management*. (3<sup>rd</sup> Ed.) Cincinnati, Ohio: South-Western College Publishing.
6. Carroll, B.A. (1999). Corporate social responsibility: Evolution of a Definitional Construct. *Business & Society*, 38(3), p. 268-295.
7. Carroll, B.A., & Buchholtz K.A. (2000). *Business & Society: Ethics and Stakeholder management*. (4<sup>th</sup> Ed.) Cincinnati (Ohio): South-Western College.
8. Cochrane, J. (2000). Narrowing the Gap: Access to HIV Treatments in Developing Countries. A Pharmaceutical Company's Perspective. *Journal of Medical Ethics*. 26(1), p. 47-50.
9. Commission of the European Communities. (2001, 18<sup>th</sup> July). Green paper: Promoting a European Framework for Corporate Social Responsibility. Retrieved November 14, 2011, from: [http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001\\_0366en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0366en01.pdf)
10. Crane, A., & Matten, D. (2004). *Business Ethics*. Oxford: Oxford University Press.
11. Davis, K., & Frederick, W.C. (1985). *Business and society: management, public policy, ethics*. (5<sup>th</sup> Ed.). New York: McGraw-Hill.
12. Esteban, D. (2008). Strengthening corporate social responsibility in the pharmaceutical industry. *Journal of Medical Marketing*. 8(1), p. 77-79.
13. European Commission. (2011, 25<sup>th</sup> October). Communication from the Commission to the European parliament, the Council, the European Economic and Social Committee of the Regions: A renewed EU strategy 2011-14 for Corporate Social Responsibility. Retrieved November 29, 2011, from : [http://ec.europa.eu/enterprise/policies/sustainable-business/files/csr/new-csr/act\\_en.pdf](http://ec.europa.eu/enterprise/policies/sustainable-business/files/csr/new-csr/act_en.pdf)
14. Friedman, M. (1970). The Social Responsibility of Business is to Increase its Profits. *New York Times Magazine*. Retrieved November 17, 2011, from: <http://www.colorado.edu/studentgroups/libertarians/issues/friedman-ocrespbusiness.html>
15. Gewertz, N. M., & Amado, R. (2004). Intellectual Property and the Pharmaceutical Industry: A Moral Crossroad between Health and Property. *Journal of Business Ethics*. 55(3), p. 295-308.
16. Golec, J., & Vernon, J. A. (2010). Financial Effects of Pharmaceutical Price Regulation on R&D Spending by EU versus US Firms. *Pharmacoeconomics*. 28(8), p. 615-628.
17. Heal, G. (2008). *When Principals Pay: Corporate Social Responsibility and the Bottom Line*. New York, Chichester: Columbia University Press.



18. Hogerzeil, H. V. (2004). The Concept Of Essential Medicines: Lessons For Rich Countries. *British Medical Journal*. 329(7475), p. 1169-1172.
19. *Intellectual property rights*. Retrieved December 5, 2011, from: [http://www.wto.org/english/tratop\\_e/trips\\_e/tripfq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm)
20. Jaklič, M. (2005). *Poslovno okolje podjetja*. (3<sup>rd</sup> Ed.) Ljubljana: Ekonomska fakulteta.
21. Leisinger, K. M. (2005). The Corporate Social Responsibility of the Pharmaceutical Industry: Idealism without Illusion and Realism without Resignation. *Business Ethics Quarterly*. 15(4), p. 577-594.
22. Leisinger, K. M. (2009). Corporate Responsibilities for Access to Medicines. *Journal of Business Ethics*. 85(1), p. 3-23.
23. McAlister, D.T., Ferrell, O.C., & Ferrell, L. (2005). *Business and Society: A Strategic Approach to Social Responsibility*. (2<sup>nd</sup> Ed.). Boston: Houghton Mifflin Company.
24. Moura-Leite, R.C., Padgett, R.C. (2011). Historical background of corporate social responsibility. *Social Responsibility Journal*. 7(4), p.528-539.
25. Nussbaum, A. K. (2009). Ethical corporate social responsibility (CSR) and the pharmaceutical industry: A happy couple ?. *Journal of Medical Marketing*. 9(1), p. 67-76.
26. *Oligopoly*. Retrieved January 14, 2012, from: <http://stats.oecd.org/glossary/detail.asp?ID=3270>
27. Post, J.E., Lawrence. A.T., & Weber, J. (2002). *Business and Society: Corporate Strategy, Public Policy, Ethics*. (10<sup>th</sup> Ed.). New York: McGraw-Hill.
28. Ryan, M. P. (2005). Introduction: Ethical Responsibilities regarding Drugs, Patents, and Health. *Business Ethics Quarterly*. 15(4), p. 543-547.
29. Santoro, M. A., & Gorrie, T. M. (2005). *Ethics and the Pharmaceutical industry*. New York. Cambridge University Press.
30. Schwartz, S. M., & Carroll, B. A. (2003). Corporate Social Responsibility: A Three Domain Approach. *Business Ethics Quarterly*. 13(4), p. 503-530.
31. Smith, A. D. (2008). Corporate social responsibility practices in the pharmaceutical industry. *Business Strategy Series* . 9(6), p. 306-315.
32. Spinello, R. A. (1992). Ethics, Pricing and the Pharmaceutical industry. *Journal of Business Ethics*. 11(8), p. 617-626.
33. The Millennium Development Goals. In *Wikipedia*. Retrieved December 28, 2011, from: [http://en.wikipedia.org/wiki/Millennium\\_Development\\_Goals](http://en.wikipedia.org/wiki/Millennium_Development_Goals)
34. Vernon, J. A. (2002). Drug Research and Price Controls. *Regulation*. 25 (4), p. 22-25.
35. WBCSD. (2002). Corporate Social Responsibility: *The WBCSD' journey*.
36. World Health Organization. (2002). The selection and use of essential medicines. Report of the WHO Expert Committee. *Technical Report Series No. 914*. Geneva: WHO.
37. World Health Organization. (2008, August). Drug donations: What lies beneath. *Bulletin of the World Health Organization*. 86(8), p. 580.
38. World Health Organization. (2010, August). To give is better than to receive: compliance with WHO guidelines for drug donations during 2000–2008. *Bulletin of the World Health Organization*. 88, p. 922-929.

39. World Health Organization. (2011). Global HIV/AIDS response: Epidemic update and health sector progress towards Universal Access. *Progress Report*. Geneva: WHO.
40. World Trade Organization. (2006, September). TRIPS and pharmaceutical patents: Fact sheet. Retrieved December 10, 2011, from: [http://www.wto.org/english/tratop\\_e/trips\\_e/tripsfactsheet\\_pharma\\_2006\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf)