# Corporate Responsibility and Ethical Culture in Pharmaceutical Industry

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## Abstract

*The characteristics of pharmaceutical sector imply a high risk of corruption with a considerable damage for the industry, the healthcare system and the whole community. The pharmaceutical companies have an important role for a generalized recovery of effectiveness in the health sector, so many international institutions intervened with models of ethical code that represent the minimum standards the companies should respect to reach good ethical practices. At present, most of the companies have well-structured code of ethics/conduct, but it frequently seems not favor corporate behaviors ethically correct sharing priorities in the triple bottom line. The paper makes considerations about the role of the ethical code on building strong value-driven cultures as tool of corporate responsibility in the pharmaceutical industry. The aim is to demonstrate how difficult is the coherence between the values declared in the code and the effective behavior when the corporate ethical culture fails.*

**Keywords:** Corporate responsibility; Ethical culture; Pharmaceutical industry; Stakeholder relation management; Sustainability

## *1. Introduction*

The concepts of sustainability and ethical behaviour particularly involve healthcare professionals, emphasizing the close interrelationship between governments, public and private hospitals, research institutes, other health professionals (doctors, pharmacists, etc...), pharmaceutical companies and citizens.

Corruption is a pervasive problem affecting the health sector, with wide negative effects on health status and social welfare. In this context, the pharmaceutical companies have an important role for a generalized recovery of effectiveness in the health sector, taking into account: the global action of these companies; the frequent and relevant relationships with all operators in the sector, with relations that typically exclude the end user of the service; the crucial role in the prevention of incorrect behaviors; the promotion of an ethical culture and sustainability in healthcare.

A company oriented to sustainable development is clearly aware of its responsibilities towards the various stakeholders and adopts methods and tools of governance that will improve its economic, social and ecological performance. We are talking about an approach based on a broad vision of responsibility, on a modern interpretation of the links between the long-term success and the equitable resolution of the interests of all stakeholders (Salvioni, 2003; Steurer et al., 2005; Bansal, 2005; Scherer, Palazzo, and Matten, 2009; Sun and Cui, 2014).

Pharmaceutical companies must therefore be geared to the integration of economic goals and socio-ecological one, emphasizing the interdependence of economic, social and environmental responsibility in order to the optimization of the results compared to stakeholders' expectations.

The increasing emphasis on the affirmation of governance oriented to global responsibility and the stakeholder relationship management, involves a greater accentuation on principles and values of the dominant internal and external relations, as well as the innovation of processes designed to ensure a systematic, coordinated, effective and efficient approach for the sustainable development.

In this sense, international recommendations and national rules have recently proliferated promoting an increasing emphasis on tools and management processes oriented to the improvement of corporate responsibility. In fact, the concepts of sustainable development and corporate social responsibility (CSR) are strictly interrelated.

The concept of CSR is widely discussed in the literature (Davis, 1960; Levitt, 1958; Drucker 1982; Aupperle et. al., 1985; McGuire et. al., 1988; Carroll, 1991,1999; McWilliams and Siegel, 2001; Whetten et. al, 2002; Knox and Maklan, 2004; Salzmann et al., 2005; Harwood, et. al., 2011). Even if there is no a clear and unbiased definition of this, the existing ones are to a large degree congruent. Thus, it is concluded that the confusion is not so much about how CSR is defined, as about how CSR is socially constructed in a specific context (Dahlsrud A., 2008). According to Weber, CSR is considered as a sub area of corporate sustainability, which aims to integrate the economic, environmental and social aspects of business in a global strategy (Weber, 2008).

Many authors recognize the opinion the CSR should be integrated in the corporate strategy (Andrews, 1980; Ansoff, 1983; Lenz and Engledown, 1986; Carroll, 1984, 1987; Freeman, 1984; Camillus and Datta, 1991).Without a clear understanding of strategic benefits that may accrue to the organization, it is more likely that top management will not invest in CSR practices, which contribute to the long-term success of the firm (Burke and Logsdon, 1996).

The efficiency of the healthcare system depends also on the maintenance of satisfactory levels of effectiveness by pharmaceutical companies. This involves the activation of developmental pathways closely focused on:

- The involvement and appreciation of the stakeholders' expectations, primarily those with which the company has not a direct relation;
- The rational and equitable translation of expectations in appropriate strategic directions;
- The transfer of the top guidelines in management behaviours;
- The monitoring of the consistency among stakeholders' aspirations, management objectives and results for the optimization of firm's performance and relations.

According to the logic of the "triple bottom line" (Elkington, 1994; Henriques and Richardson, 2004; Colbert and Kurucz, 2007), the statement and the sharing of values oriented to responsible and sustainability vision represent the conditions for the behaviours' coordination and standardization, cultural heritage for the company's success. Culture emerges as a key factor driving the development of effective ethics. The internalization of values and principles shared by the top management and the organization facilitates the correct implementation of governance processes, promotes the adoption of an effective and efficient management approach, facilitates the creation of positive relations between the company and its stakeholders and the risk control (Knox and Maklan, 2004; Salvioni, 2010; Gandini et al., 2014).

The dissemination of an ethical culture affects every firm's behaviour, determining the conditions of consonance and internal sharing, the confirmation of corporate image, the achievement of consent and management effectiveness. The existence of a strong culture, shared by the leaders and the organization and permeating the entire network of business relations, is therefore crucial for the social interaction and the optimization of pharmaceutical companies' performance. Furthermore, it helps to improve the conditions of sustainability in the whole health systems.

In this context the corporate values need to be communicated and made part of a shared belief system: according to the assumption in the CSR literature ; Dickerson and Hagen, 1998; Diller, 1999; Kolk et al., 1999) the codes of ethics and the codes of conduct are used to govern CSR issues. For other researchers (Bondy et al., 2008) the codes are more often used as tools for governing traditional business issues, such as ensuring compliance with laws and regulations and guiding employees in terms of expected workplace behaviour, than as tools for governing CSR. The high risk of corruption that characterizes the pharmaceutical sector has induced the existing literature about the industry agrees that the CSR can be considered a valid company's approach to combat unethical behaviours (Scherer and Palazzo, 2008; West, 2012). We share this approach, but emphasize that simply adopting and distributing a code of ethic/conduct is not enough to assure CSR effectiveness.

In line with these considerations, the paper aims to enhance the existing studies in the pharmaceutical sector by means of a qualitative research guided by the question about the effectiveness of codes of ethics/conduct as tools for ethical companies' behaviours. In this regard, we argue that a managerial approach founded on a strong ethical culture has a profound impact on pharmaceutical companies' misconduct and, therefore, has evident potential to reduce the current corruption in the health sector.

The article begins by first illustrating the main characteristics of the pharmaceutical sectors and their influence on the CSR companies' approach. The next section is about the code of ethics as formal tool to adopt ethical behaviours; in this part, the interventions by international and European pharmaceutical associations are described. Finally, the study focuses on the diffusion of the code of ethics in the official web sites of the European parent listed companies. For the selected companies, moreover, the research collects media information regarding scandals occurred in the last decade in order to make considerations about the coherence between the ethical principles affirmed in the code of ethics and the behaviours assumed by the company in the worldwide markets.

## *2. Characteristics of Pharmaceutical Industry and CSR Approach*

The pharmaceutical industry is a key asset of the European economy: it manages an enormous quantity of resources, it combines a large production value with high levels of innovation and it has an enormous responsibility to carry because of its influence on the human health and disease prevention. In fact, in the last decades the life expectancy has further increased thanks to new medicines (Lichtenberg, 2012), with positive influence in the reduction of costs also in lot of areas of healthcare (for example, hospitals and long-term care).
According to the European Classification of Economic Activities system (NACE Rev.2) adopted in the EU Member States through Council and Parliament Regulations, the pharmaceutical industry (identified by division number 21) includes the manufacture of basic pharmaceutical products, pharmaceutical preparations, medicinal chemical and botanical products. In Europe it accounts for more than 3,818 companies, with operational revenue of EUR 427.936.094 employing 1.350.830 workers altogether (Amadeus Database, 2014). The major sectors of the pharmaceutical industry are chemical drugs, generics, over-the-counter drugs, active pharmaceutical ingredients, excipients, biological, biosimilars (International Trade Administration Office of Health and Consumer Goods, July 2010).

**Table 1: The Industry Numbers in Europe (Values in EUR Million)**

| **Industry (EPFIA Total)** | **1990** | **2000** | **2011** | **2012** |
|---|---|---|---|---|
| Production | 63,010 | 125,301 | 205,622 | 210,000 |
| Exports | 23,180 | 90,935 | 288,573 | 305,000 |
| Imports | 16,113 | 68,841 | 212,135 | 225,000 |
| Trade balance | 7,067 | 22,094 | 76,438 | 80,000 |
| R&D expenditure | 7,766 | 17,849 | 29,192 | 30,000 |
| Employment (units) | 500,879 | 534,882 | 700,010 | 700,000 |
| R&D employment (units) | 76,126 | 88,397 | 115,695 | 116,000 |
| Market value at ex-factory prices | 41,147 | 86,704 | 160,603 | 163,000 |
| Market value at retail prices | 64,509 | 140,345 | 235,017 | 238,500 |
| Payment for pharmaceuticals by statutory health systems | 40,807 | 76,909 | 125,603 | 126,800 |

Source: EPFIA, The Pharmaceutical Industry in Figures, Brussels, 2013

Since 2002, the EU has become the largest producer and exporter of pharmaceuticals on a global scale. While in the 2009 the largest producers were France followed by Germany, Italy and the UK (Ecorys, 2009 Vol I), two years later the first producer was Germany, followed by Italy, the UK and France (Epfia, 2013 [1]). In 2011, the European pharmaceutical industry invested about EUR 29,000 million in R&D. According to the 2012 EU Industrial R&D Investment Scoreboard, the pharmaceuticals and biotechnology sector amounts to 17.7% of total business R&D expenditure worldwide.

**Table 2: EU Member States' Pharmaceutical Production (2011)**

| | EUR million | Units employed |
|---|---|---|
| Austria (AT) | 2,541 | 11,175 |
| Belgium (BE) | 7,714 | 32,167 |
| Bulgaria (BG) | 157 | 9,300 |
| Croatia (HR) | 433 | 6,000 |
| Cyprus (CY) | 180 | 1,140 |
| Czech Republic (CZ) | n.a. | 2,300 |
| Denmark (DK) | 7,672 | 20,223 |
| Estonia (EE) | n.a. | 400 |
| Finland (FI) | 1,293 | 5,436 |
| France (FR) | 19,578 | 103,900 |
| Germany (DE) | 26,935 | 105,435 |
| Greece (EL) | 846 | 13,700 |
| Hungary (HU) | 2,665 | 22,600 |
| Ireland (IE) | 19,700 | 24,000 |
| Italy (I) | 25,137 | 65,000 |
| Latvia (LV) | 108 | n.a. |
| Lithuania (LT) | n.a. | 1,370 |
| Luxembourg (LU) | n.a. | n.a. |
| Malta (MT) | n.a. | 445 |
| Netherlands (NL) | 6,180 | 15,000 |
| Poland (PL) | 2,623 | 31,000 |
| Portugal (PT) | 1,533 | 8,502 |
| Romania (RO) | 587 | 22,000 |
| Slovakia (SK) | n.a. | 3,000 |
| Slovenia (SI) | 1,642 | 12,200 |
| Spain (ES) | 14,022 | 37,971 |
| Sweden (SE) | 6,582 | 13,185 |
| United Kingdom (UK) | 20,206 | 65,000 |

Source: Elaboration from EPFIA, The Pharmaceutical Industry in Figures, Brussels, 2013

**Table 3: EU: The First Ten Parent Listed Companies**

| Company | Country | Operational Revenue (EUR) | Number of employees |
|---|---|---|---|
| Bayer | DE | 41.054.000 | 112,246 |
| Glaxosmithkline | UK | 33.454.246 | 99,817 |
| Astrazeneca | UK | 21.295.944 | 53,500 |
| Fresenius | DE | 19.290.000 | 163,746 |
| Convidien | IE | 8.756.000 | 42,109 |
| Shire | UK | 3.444.298 | n.a. |
| Paul hartmann | DE | 1.801.838 | 10,130 |
| Richter Gedeon | HU | 1.120.781 | 10,982 |
| Krka | SI | 1.036.010 | 4,448 |
| Orion | FI | 986.704 | 3,495 |

Source: Amadeus database, 08/04/2014.

The pharmaceutical industry has peculiar characteristics due to:

- The great variety of stakeholders involved;
- The characteristics of demand and offer;
- The significant role of the Governments;
- The high degree of regulation.

All these industry's peculiarities can influence CSR approach of pharmaceuticals companies. Due to the number of ethical issues associated with pharmaceutical business and the vulnerability of the people to its product, CSR has a high relevance in the industry. Since CSR is a voluntary engagement by company, it depends on the relationship with relevant stakeholders, the particular product offered and the political/law environment where the company operates.

**Great Variety of Stakeholders**

The first characteristic of the pharmaceutical industry is the great variety of stakeholders involved and the big impact of the company's outputs and outcomes for them. Consistent with the CSR literature, stakeholders can be defined as groups or individuals who benefit from or are harmed by, and whose rights are violated or respected by, corporate actions (Freeman, 1984; Freeman and Moutchnik, 2013). According to a logic of global responsibility and sustainable development, the expectations of different stakeholders must be considered and appropriately valued by the companies (Salvioni and Gennari, 2014). This is the concept of 'license to operate' that means the company's right to exist based on societal acceptance and good stakeholder relations (Hansen and Schrader, 2005; Weber, 2008). This approach improves the company's performance in the long-term and reduces the risk of opportunistic behaviours that are detrimental for the whole community, but it must be shared by the company's organization and considered as a guide for the company's strategies. In addition, the European Commission underlines the importance of the management oriented to stakeholder relation in the pharmaceutical sector as a condition for a good corporate governance and well-functioning marketplace.

**Characteristics of Demand and Offer**

The demand side of the pharmaceutical industry is characterized by a complex interrelationship between the company and some relevant stakeholders as patients, healthcare professionals, healthcare organizations, insurance providers and reimbursement systems for prescription medicines. Furthermore, the ultimate consumer (the patient) does not coincide with the decision maker (usually the prescribing doctor) and he/she does not sustain the entire medicines' costs (considering the co-participation of the national health system).

By the side of the offer, two types of companies operate: the so-called originators (usually big companies) are active in research, development, manufacturing, marketing and supply of innovative medicines. These medicines are patent protected, to safeguard the high R&D investments (Bérard and Perez, 2014), but when the patent protection expires generic manufacturers can enter the market with medicines that are equivalent to the original ones, but sold at lower prices. The 'generic' companies are in general smaller than the 'originator', their R&D is limited and they have a more regional dimension.

The pharmaceutical sector suffers substantial problems related to the failure of competition, which is linked to the existence of barriers to entry. Since the 'originators' spent a lot of resources in R&D activity (17% of their turnover during the period 2000-2007) and, on average, only one or two of every 10,000 substances synthesized in laboratory will become a marketable medicine, the relationships with the marketplace is vital.

The need to innovate translates into a competition to be the first to discover and patent new molecules suitable to be developed into pharmaceutical products, which are eventually launched into the market. The 'originators' must manage direct competition among patented products (produced by other originators) prescribed for the same treatment and, at the same time, they must compete with generics' producers, these last characterized by marketing expenditures much more higher than the amount allocated to R&D activities (European Commission, 2008).

This is why the industry is characterized by the dominance of a relatively small group of big pharmaceutical companies, which represent a significant part of the annual European turnover.

This situation of time-based competition to obtain a predominant position into the marketplace reflects on the relationship with the great variety of stakeholders characterizing the pharmaceutical industry and can create a ground vulnerable to corrupt practices and unfair competition (Brondoni, 2012). The aversion for bribery and corruption is one of the typical ethical aspects of CSR: to truly eradicate the corruption, it has firstly to become socially unacceptable and consequently unacceptable by companies.

**Significant Role of the Governments**

The pharmaceutical companies (originator as generic ones) are subject to governments' policies and strict regulations, in particular as regards marketing authorization and national measures for pricing and reimbursement. Governments represent one of the most influential stakeholders in the pharmaceutical industry. In fact governments are the largest client of pharmaceutical products in most countries and they are charged with the duty and ability to develop, monitor, and enforce the regulations about the pharmaceutical industry (West, 2012). National governments must: secure public health policy objectives (public health, patient access to safe and effective medicines, high quality of care); contain health care expenditure; promote healthcare policies that don't hamper the development of the pharmaceutical sector (Ecorys, 2009, I).

Governing bodies or political institutions serve an important role in driving and developing CSR (West, 2012). Moon and Vogel (2008) have identified three areas in which governing bodies have developed, purposively or accidentally, drivers for CSR (West, 2012). First, where government assumes a more central role, there is often less adoption of voluntary CSR initiatives. Vice versa, when government has a more retracted role the CSR is considered a balancing factor.

Second, the inadequacy or lack of regulations promotes the creation of international and national CSR's initiatives (Scherer and Palazzo, 2008). The globalization has induced to a situation characterized by the process of deregulation in some countries and by the inability to regulate in others: the development of a global civil regulation could be considered a tool to balance the power of global firms and the action of governments for regulating them (Moon and Vogel, 2008, p. 309).

Third, the CSR policies are promoted by some governments in different ways (regulation of social reporting, promotion of voluntary codes, etc.) and by international organizations (UN, World Bank, OECD, etc.), but there has been little hard regulation that stringently dictates and enforces CSR engagement (West, 2012).

This lack of a common CSR philosophy means that activities of particular companies are often short-term and inconsistent, which hinders evaluation of the CSR impact of the industry on both the community and the environment (Volodina et al., 2009).

**High Degree of Regulation**

The high degree of regulation aims at achieving different objectives, which range from supporting innovation, ensuring a good quality of public health, keeping public expenditure under control (Ecorys, 2009, II) to guaranteeing a well-functioning marketplace.

Whereas the EU holds competences over trade, competition and competitiveness, healthcare regulation, including pharmaceutical financing and reimbursement policies, is a largely exclusive competence of the EU member States. For this reason, the regulation differs depending on: the State tradition and the decision-making structure; the culture and the embedded healthcare system; the market characteristics (Ecorys, 2009, II).

The globalization has provided global companies great power in choosing the location and legal system in which they wish to operate and have the potential to create high levels of competition (Scherer and Palazzo, 2008). The regulation can force standards and preventing non-correct behaviors but it could be not sufficient. The responsibility of global companies, which involve a great variety of interests, is more than simply respecting mandatory provisions: a company oriented to sustainable development is clearly aware of its social responsibility towards different stakeholders (Salvioni and Bosetti, 2006). In this situation, the pervasion of an ethical culture into the company can be supported by voluntary rules (formalized in code of ethics/conduct) which emphasize the principles and the values as basis of the corporate social responsibility.

## *3. CSR and Code of Ethics in the Pharmaceutical Industry*

The adoption of codes of ethics and conducts distinguishes the best practices of corporate governance (Salvioni and Astori, 2013). The code of ethics (value-based) considers the shared values of social responsibility inspired by the respect and the protection of all stakeholders' interests whom the company interacts with. Schwartz (2001) defines this code as a written, distinct and formal document which consists of moral standards used to guide employee or corporate behaviours. The code of conduct (rules-based) defines the behaviors to hold in face of particular situations.

The code of ethics and the conduct one are strictly connected since particular behaviours depend on principles and values the company places in its mission (Arrigo, 2006). Therefore, they should act more on behalf on guiding tools ex ante than an audit reports ex post.

The idea that the code of ethics could prevent and impede incorrect behaviours is not a new one (Helin and Sandström, 2007). Following the numerous scandals in the last decades, the question of how code of ethics are related to more ethical behaviours seems to haunt scholars in business ethics (Adams et al., 2001). Two decades ago, Stevens (1997) concluded that many studies about code of ethics were based on content analysis and lacked information on how the codes were communicated in the organization. So, there was still a knowledge gap on whether companies behaved more ethically in terms of being socially responsible, avoiding corruption, etc. as a result of implementing the code of ethics (Helin and Sandström, 2007). The matter about the real effectiveness of ethical code as tool of corporate responsibility is not closed. Béthoux, Didry and Mias (2007) carried out a lexical classification process on 175 codes adopted by 166 companies. The analysis reveals that CSR is based on a notion of 'commercial' responsibility that is linked to the marketing of products and to the necessity of meeting consumers' expectations, while the social dimension is mostly linked the protection of the environment in which the company operates, in order to guarantee the conditions for a sustainable development of its activities.

At the same time, the ethical code should represent a formal document of corporate communication with the aim to convey the corporate identity to the multiple audiences of stakeholders. A good corporate communication creates corporate image and reputation that connote the estimation of the company and can lead to competitive advantage (Perkins, 1995; Fombrun, 1996; Gray and Balmer, 1998). A good enduring reputation requires more than just an effective communication effort: it requires a meritorious corporate identity. So, if the values expressed in the code of ethics are not respected by the company itself, corporate reputation falls with many direct and indirect costs.

Since the single ethical code is a voluntary company's act, the important sphere of influence of pharmaceutical companies on society has stimulated the definition of guidelines by national and international associations, with a great participation of involved stakeholders.

The European Commission, in its commitment to renew the EU strategy to promote CSR, launched a process with enterprises and other stakeholders to develop codes of good practices for self and co-regulation exercises (for example sector codes of conducts on societal issues relevant for the sector), with should improve the effectiveness of CSR (European Commission, 2011). Furthermore, the self-regulation is considered one of the tools in the fight against corruption in the health sector (European Commission, 2013).

Increasingly development agencies recognize corruption as the single greatest obstacle to economic and social development. Corruption is at the heart of an entrenched vicious cycle: bad governance produces corruption and corruption destroys the basis of good governance (WHO, 2008, p.7). The unethical behaviours that characterize the pharmaceutical industry are in part due to the high market value of pharmaceutical products. Furthermore, the pharmaceutical sector is highly regulated, so if institutional checks are too cumbersome and processes too slow, subjects may be tempted to corrupt for advancing the practices in a market characterized by a time-based competition. Another factor making the pharmaceutical sector particularly vulnerable to corruption is the information imbalance among the various players: information is not shared equally and not all players have the necessary information to make informed judgments and independent assessments of the quality, safety and efficacy of medicines (WHO, 2008 [1]).

The adoption of a CSR approach implies the sharing of behavioural rules to safeguard all stakeholders' interests. In this context, the self-regulation and the adoption of codes of ethics underpins the sharing of ethical values, which are global and accepted as fundamental for the sustainable development of the community.

At supranational level the World Health Organization has published some guidelines and recommendations specifically addressed to pharmaceutical system to promote an effective, efficient and ethical management inside it, in favour of the economic growth and health in all levels of society (WHO, 2013; WHO, 2008 [2]).

These global values are continued at international level. The European Commission has promoted a Platform on Ethics based on volunteer participation and dedicated to enhancing collaboration among interested member states and all relevant stakeholders, with the main objective to propose some basic principles with regards ethics and transparency in the pharmaceutical sector.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), that represents the pharmaceutical companies and associations across the globe, supports self-regulation as the most appropriate mechanism for ensuring ethical marketing and promotion of medicines by pharmaceutical companies. The IFPMA published for the first time in 1981 a code of practice (updated in 2012) which is a reference internationally accepted.

The European pharmaceutical industry refers to the European Federation of Pharmaceutical Industries and Associations (EFPIA). Its members are the national industry associations of 31 pharmaceutical producing countries in Europe. EFPIA's primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in bringing to market medicinal products that improve human health worldwide, encouraging competition among pharmaceutical companies.

As has already been mentioned, the pharmaceutical sector is characterized by high definite investments and uncertain results. This situation induces the companies to strive to achieve important volume of sales and profit margin for the development of future research. In this context, the most relevant stakeholders are healthcare professionals (medical practitioners, pharmacists, consultants, etc.) and healthcare organizations. In fact, these stakeholders are the intermediaries between the pharmaceutical company and its final consumer. A high degree of information asymmetry between providers of care and final consumers exercising demand for services to become healthy generates a high risk of corruption in the relation between the company, healthcare professionals (HCPs) and healthcare organizations (HCOs).

EPFIA is conscious of the importance of an objective and transparent information in the relations between pharmaceutical companies, HCPs and HCOs. With this in mind EPFIA has adopted in 1991, with effect on 1 January 1992, the Code on the Promotion of prescription-only medicines to, and interactions with, healthcare professionals (EFPIA HCP Code) inspired to IFPMA Code. This Code, revised in 2004 and 2007, reflects the requirements of Council Directives 92/28/EEC and 2001/83/EC which recognize the role of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise. The EFPIA Code seeks to promote a greater transparency around industry's interaction also with HCOs and it approved in 2007 (updated in 2011) the EPFIA Code of practice on relationships between the pharmaceutical industry and patient organizations. These two codes promote an environment where the public can be confident that choices regarding their medicines are made based on the merits of each product and the healthcare needs of patients.

The EPFIA Codes sets out the minimum standards which EPFIA considers must apply. So, in a manner compatible with their respective law and regulations, national member associations must adopt in their national codes provisions,at a minimum, no less rigorous than the provisions contained in the EPFIA Codes. Each member association must also establish adequate procedures for ensuring that each of its member companies complies with the requirements of member association's national code.

The EPFIA Codes include the following provisions that we have labelled in smooth areas depending on the typology of the activity done.

**Table 4: Provisions of EPFIA HCPs and HCOs Codes**

| **HCPs Code** | | **HCOs Code** | |
|---|---|---|---|
| **Provisions** | **Area** | **Provisions** | **Area** |
| Marketing authorization (art.1) | Promotion | Non-promotion of prescription-only medicines (art.1) | Promotion |
| Information to be made available (art.2) | Transparency | Written agreements (art.2) | Promotion |
| Promotion and its substantiation (art.3) | Promotion | Use of logos and proprietary materials (art.3) | Promotion |
| Use of quotations in promotion (art.4) | Promotion | Editorial control (art.4) | Promotion |
| Acceptability of promotion (art.5) | Promotion | Transparency (art.5) | Promotion |
| Distribution of promotion (art.6) | Promotion | Contracted Services (art.6) | Supporting activity |
| Transparency of promotion (art.7) | Promotion | Single company funding (art.7) | Supporting activity |
| No advice on personal medical matters (art.8) | Advice/Consultancy | Events and hospitality (art.8) | Promotion |
| Informational or educational materials and items of medical utility (art.9) | Transparency | Enforcement (art.9) | Compliance |
| Events and hospitality (art.10) | Promotion | Model template for written agreements between the pharmaceutical industry and patient organisations (Annex I) | Promotion |
| Donation and grants that support healthcare or research (art.11) | Supporting activity | Implementation and Procedure Rules (Annex II) | Compliance |
| Fees for service (art.12) | Supporting activity | | |
| Sponsorship of healthcare professionals (art.13) | Promotion | | |
| The use of consultants (art.14) | Advice/Consultancy | | |
| Non-interventional studies of marketed medicines (art.15) | R&D | | |
| Medical samples (art.16) | Promotion | | |
| Prohibition of gifts (art.17) | Promotion | | |
| Pharmaceutical company staff (art.18) | Company's staff | | |
| Enforcement (art.19) | Compliance | | |
| Awareness and Education (art.20) | Compliance | | |
| Implementation and procedure rules (Annex A) | Compliance | | |
| Guidelines for internet websites (Annex B) | Transparency | | |

According to a study on corruption in the healthcare sector commissioned by the European Commission of Directorate-General Home Affairs (October 2013), procurement corruption and improper marketing relations are the most common typologies of corruption between the pharmaceutical company and the healthcare providers.

As we can see in Table 4, the promotion activity is the most regulated by the Code because of its sensitive to the risk of corruption and it seems to confirm the conclusion of the research carried out by Béthoux et al. (2007) about the propensity to limit the CSR to marketing responsibility.

The effectiveness of a self-regulation code is strictly connected with the provision of compliance activities with the aim to monitor on the adoption of behaviours coherent with the rules and the enforcement of sanctions in the case of injuries. These provisions intend to bring down ex ante the risk of not compliance with the rules and, so, the risk of behaviours tending to corrupt. The compliance activity needs of figures specifically assigned to control and connected procedures and it can be exercised inward and outward the company. Furthermore, the provisions of the ethical code are extended to all company's subsidiaries.

**Table 5: The Compliance to EPFIA Codes**

| | **External Control** | | **Internal Control** | **Sanctions** |
|---|---|---|---|---|
| (§) | **Supervisory body** | **Responsibilities** | **Supervisory body** | |
| **EPFIA Codes** | Member association | Establishes appropriate complaint procedures for breaches of their respective code | At least one senior employee who supervises the company and its subsidiaries to ensure that the standards of the applicable code are met | Each member association shall include in its national code provisions governing the imposition of sanctions |
| | EPFIA Codes Committee | Monitors the adoption of compliant national codes | | |
| **AT (2009)** | CoC Committees of Experts of the 1st and 2nd Instance | Negotiate and decide about disputes relating to the violation of the Code, are responsible for complaints, conduct procedures in the case of violations of the Code | N.A. | Yes |
| **BE (2012)** | Bureau of Proceedings | Pronounces in a sovereign capacity and in the final resort on the admissibility of any incoming dossier and on the subsequent course of action | N.A. | N.A. |
| | The Visas Bureau | Pronounces on requests for advance visas (about non-interventional studies) | | |
| | The Bureau for Control on Written Communication | Exercises control over the compliance of the written communication of companies addressed to healthcare professionals | | |
| | The Chamber of Investigation | Carries out, on the instructions of the Bureau of Proceedings, the investigations necessary to collect incriminating or exonerating elements in cases where the facts have not been assembled of sufficient elements of proof of a violation of the rules of behaviour of this Code. | | |
| | The Committee for Deontology and Ethics in the Pharmaceutical | Considers complaints | | |

| | **External Control** | | **Internal Control** | **Sanctions** |
|---|---|---|---|---|
| (§) | **Supervisory body** | **Responsibilities** | **Supervisory body** | |
| | Industry | | | |
| | The Chamber of Appeal | Pronounces on appeals against the merits of a decision taken by the DEP Committee | | |
| **BG (2013)** | Ethics Commission at ARPharM | Controls the observance of the Ethical Code, receives complaints, gives interpretations about the Code | Yes | Yes |
| **HR (2011)** | Ethical Council and Ethics Committee | Decide about complaints and impose sanctions | Yes | Yes |
| **CY (2013)** | Disciplinary Committee | Upholds the Code | N.A. | Yes |
| **CZ (2012)** | Ethics Committee | Supervises the compliance with the Code, submits relevant proposal to the AIFP' Board about revocation of a company's membership | Yes | Yes |
| **DK (2011)** | Ethical Committee for the Pharmaceutical Industry in Denmark | Ensures the control of the Danish Ethical Rules for Promotion of medicinal, controls filed cases and handle appeals, provides guidance on and training in the rules products towards Healthcare Professionals | Yes | Yes |
| **EE (2010)** | Ethics Committee of the Association of Pharmaceutical Manufacturers | Handles of complaints and administer the sanctions | Yes | N.A. |
| **FI (2013)** | Supervisory Commission and two Inspection Boards subjected to it. | Monitor the compliance with the Code | Pharmaceutical companies | Yes |
| **FR (2011)** | N.A. | N.A. | N.A. | N.A. |
| **DE (2012)** | N.A. | N.A. | Compliance officer | N.A. |
| **EL (2013)** | First Degree Committee and Second Degree Committee | Deals with reports/complaints | Pharmaceutical companies | Yes |
| **HU (2012)** | MAGYOSZ-AIPM Communications Ethics Committee | Identifies cases of violation of the Code, defines the rules of procedure for dealing with such cases and publish position statements to promote enforcement of the Code | yes | Yes |
| **IE (2013)** | Code Council | Administers the Code and hear the complaints | Yes | Yes |
| **IT (2012)** | Supervisory Committee | Has investigative, proactive and consultative functions; fact-finding function regarding alleged violations of the Code; guideline-setting function | N.A. | Yes |
| | Single-Judge Tribunal | Considers the sanctions proposed by the Supervisory Committee and delivers his/her decisions concerning the sanctions | | |
| | Jury | At the request of associate bodies, the Jury | | |

| | External Control | | Internal Control | Sanctions |
|---|---|---|---|---|
| (§) | **Supervisory body** | **Responsibilities** | **Supervisory body** | |
| | | provides opinions on the Code; decides appeals on the basis of all the elements collected by the Supervisory Committee and the Single-Judge Tribunal | | |
| **LV (2011)** | Body constituted by a non-industry chairman and, besides any industry members, members authorized by the relevant association | Receives and processes complaints, to determine sanctions and to publish appropriate details regarding the same | Yes | Yes |
| **LT (2012)** | Pharmaceutical Marketing Ethics Committee | Has the supervision of the Code, examination of reported violations of the Code, imposition and enforcement of sanctions | Yes | Yes |
| **LU (2013)** | Not member of Epfia. The Association has a Deontological Code in original language | N.A. | N.A. | N.A. |
| **MT (2012)** | National body of the member association | Handles complaints | Yes | Yes |
| **NL (2007)** | Oversight Committee of the GFB Foundation | Accepts the complaints | N.A. | N.A. |
| **N (*) (2008)** | Norwegian Association of Pharmaceutical Manufacturers | Provides the Secretariat with all information and promotional material used in marketing | N.A. | N.A. |
| **PL (2011)** | Disciplinary Court | In the case of parties fail to solve the disputes amicably or the cases of possible violation of the Code | Yes | Yes |
| **PT (2011)** | Council of Ethics of APIFARMA | Supervises the implementation of the Code | Yes | Yes |
| **RO (2012)** | Arbitration Committee | Discusses and judges the complaint, inflicts sanctions | Yes | Yes |
| **SK (2012)** | Ethics Committee | Supervises and enforces the Code and its proper implementation and compliance | Yes | Yes |
| **SI (2012)** | Committee of Forum of International Research & Development Pharmaceutical Companies | Establishes adequate procedures for the compliance with EPFIA Code and national Code, makes recommendations for any changes in the Code, acts as a voluntary and self-regulating control body for all members of the Association | N.A. | Yes |
| **ES (2014)** | Code of Practice Committee for the Pharmaceutical | Ensures the effective application of the code | Code of Practice Surveillance Unit and Compliance | Yes |

| | **External Control** | | **Internal Control** | **Sanctions** |
|---|---|---|---|---|
| (§) | **Supervisory body** | **Responsibilities** | **Supervisory body** | |
| | Industry | | Officer | |
| | Jury of the Association for Self-Regulation of Commercial Communications | Interprets the Code, ensuring the effective application of the code | | |
| **SE (2013)** | Compliance officer of Sweden industry organisation (LIF) | Provides advice and training | N.A. | Yes |
| | Pharmaceutical Industry's Information Examiner (IGM) | Compliance with the rules | | |
| | Information Practices Committee (NBL) | Establishes further standards in the area of drug information | | |
| **UK (2012)** | Prescription Medicines Code of Practice Authority | Advice, guidance and training on the Code. It administers the complaints procedure; arranges for conciliation between companies and for the scrutiny of advertising and meetings on a regular basis | Yes | Yes |

(§) Last updating (*) It is not a member of EU but it is a member of EPFIA

As we can see in Table 5 the information are available for almost all countries. As regard the external control, the supervisory bodies are constituted, first, by members appointed by the national associations and experts of pharmaceutical industry recognized ethically correct. In some cases, the supervisory body includes judges and non-industry personalities. The external supervisory body not only can manage the procedures about complaints and imposes sanctions but can also promote the enforcement of the national code covering a guideline function.
The internal control is entrusted to at least one senior employee or, in some cases, to the corporate compliance function. Few countries do not specify which subject in the company plays this role. The effectiveness of the ethical code's provisions is connected to a penalty system able to discourage unethical behaviours which damage the single company and the image of the whole pharmaceutical industry. The sanctions generally vary according to the magnitude of the violation and its possible risk to patient health, the impact on the industry competition and on the society in general.

## *4. Scandals in Pharmaceutical Industry and Code of Ethics*

This section, first, introduces the more common kinds of corruption in the pharmaceutical industry, that the EPFIA Code should prevent, and illustrates some scandals in Europe. Then, it reports the situation of the European parent listed company operating in the pharmaceutical industry, with reference to the coherence between the ethical values declared in the codes of ethics and the ethical culture reflected in their conduct.

### 4.1 Corruption and Scandals in the Industry

The presence of the ethical code and effective compliance system should promote the sharing of ethical values into the company and the development of an ethical culture in the corporate governance, starting from the strategy until the behaviour of all members of the organization.

Nevertheless, the effectiveness of code of ethics and compliance procedures seem to be threatened by the numerous scandals involving the pharmaceutical industry in the last decade.

Many different schemes used to defraud the health care system have been identified (FBI, 2006). Some of them regard:

- Good manufacturing practice violation: it incurs when manufacturing processes, trained personnel, internal control over the manufacturing processes, laboratory controls, accurate records are not adequately guaranteed;
- Off label marketing violation: it occurs when a drug is marketing and promoting for an unauthorized used.
- Best price reporting violation: best price means the lowest price practiced to any wholesaler, retailer, provider, health organization. The indication of the best price is important to determine the medical reimbursement rate from governments or insurance companies. Therefore, best price fraud can occur when companies falsely report indicating a higher best price;
- Continuing medical education fraud: it concerns on dissemination of scientific and educational literature act, sponsored by companies with the aim to promote specifics pharmaceutical products.

In recent years the scandals, especially regarding cases of corruption, gained a lot of media attention and spurred the public debate.

Corruption in the pharmaceutical sector could occur throughout all stages of the supply chain, like authorization, selection and procurement.

The risk connected to corruption practices is acquiring increasingly importance in the compliance programs and internal auditing procedures adopted by the companies.

> *"Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of anti-bribery laws, or allegations of such violations, could disrupt our business and result in a material adverse effect on our results of operations, financial condition and cash flows" (Convidien Code of conduct, 2012).*

Even if the sector is highly regulated, risk driver of corruption practices could be identified in the information asymmetry, market power, high regulation, poor investment in research and training.

Probably, at the base of the problem there is the lack of moral values, as affirmed in an interview reported in the EU Study on corruption in the healthcare sector.

> "*One of the causes of the emergence of corruption in the healthcare sector is the lack of moral values that characterise the mains stakeholders who are involved in the business of pharmaceuticals and medical equipment. Another cause is the fact that legal sanctions have minor deterrent effects, as the risks related to the possibility of being 'caught' are generally counted in the risk clauses inserted in the business contracts. The risk of being caught is therefore taken into consideration by pharmaceutical companies and is given a financial value. The economic power of pharmaceutical companies is also another important factor. It relates to the productive resources available that give them the capacity to influence (and sometimes make) and enforce economic decisions, such as allocation of resources. Through this economic power, laboratories might be able to influence the decision-making processes and outcomes of public authorities." (EU Study on corruption in the healthcare sector, 2013).*

In the pharmaceutical industry the main typologies of corruption take the form of procurement corruptionand improper marketing relations (EU Commission, 2013) and these are the primary risks the EPFIA Code tries to prevent and reduce.

Procurement corruption presupposes a relation between pharmaceutical industry and healthcare providers and can occur in all phases of the procurement process, like pre-billing (corruptive needs assessment, circumvention of tender procedures, tailored tendering), bidding (bribery and kickbacks during bid evaluation, favouritisms, collusion and/or market division in bidding), post-bidding (false invoice, changing contract agreements).

Bribes can be made to individual through money, leisure, trips, favouring relatives, offering discounts or to medical institutions, through money, conference participation, free supply of materials, research funding and monetary or not monetary sponsorship.

Procurement corruption risk is in part due to the high sophistication of the product that influences the degree of control in the procurement procedures and can increase when there is a limited competition in the market of pharmaceuticals and/or there is a relationship between industry and physicians/providers in the development of new pharmaceutical products. Experts estimate that 10%-25% of public procurement spending in health is lost to corruption (WHO, 2013).

Procurement corruption can be direct or indirect. Indirect corruption can occur by use of tailored terms of reference, in cooperation with a public official in charge of setting the term of procurement; by use of intermediaries that know the market; excluding competitors, disqualifying their products; by collusion, when competitors agree to divide procurements or geographical areas between themselves. In order to the method of corruption practices, most of the time, briberies are made with money, as revealed by media in many cases. Other methods could be the use of kickbacks, by the offer to recognize to the official a share of the profits or other advantages for the deal. Corruption can occur also trading in influence, with non-monetary kickbacks, like the guarantee of a re-election or a job promotion. It is not possible to exclude also hypothesis of corruption through extortion. Obvious consequences of procurement corruption can be traced in overpricing goods and services and/or goods and services at inferior quality.

Corruption in the pharmaceutical industry can also be related to improper marketing relations, regarding, for instance, the registration of medicines and pharmacies, drug selection for positive list or direct or indirect promotion with physicians. Improper marketing relation can also regard inducement. This form of corruption can be identified with actions aim to stimulate directly or indirectly a preference to buy or use a product or promote a loyalty to a certain product by giving benefits. The players of this corruption practices are pharmaceutical industry and healthcare providers (doctors, association, and institution) or healthcare regulators (Ministry of health, agencies, insurance board, healthcare authorities, and inspectorates). Through improper marketing relations, the pharmaceutical industry tries to influence the prescription of medicines, to obtain positive list promotion or to acquire authorization and certification for some products. The influence of the prescription can occur through direct or indirect bribery, with money, gifts or benefits. Positive list promotion mean influence providers or regulators to include products in the list of drugs admitted in the market and reimbursed by insurance or public funds. The corruption, in these cases, can concern offering money, gifts, hospitality (conference, meeting, dinners, trips), sponsorship (research and equipment), consultancy contracts.

As observed in the EU Study on corruption in the healthcare sector (EU Commission, 2013), the attention of the industry seems to shift from individual practitioners to opinion leaders. In other terms, the strategy seems oriented to reduce the benefits offered to individuals, paying more attention to the opinion leaders of medical community and academics, due to their influence in the market and in the procurement decision process.

The risk of corruption of physicians could increase when there is not enough public money to assure researches and professional training, so that pharmaceutical sponsorship can obtain more consent. The scandals regarding this kind of corruption underline the necessity to impose, also with legislative intervention, the declaration of conflict of interest, in a public and transparent way.

Even if it's not avoidable the strictly relation between pharmaceutical companies and physicians, due to the characteristics of the industry and the needs of the researches in developing and testing new products, it's relevant to plan procedures of control aim to avoid conflict of interest and, so, the possible negative consequence to prices, fair competition, quality of products and healthcare system.

Improper marketing relations cases occur across many different European countries. The EU studies on corruption in the sector (EU Commission, 2013) analyse recent cases from a variety of EU member states. Some of them are reported below.

In relation to the direct prescription influencing, for example, the study reports the case of a representative of Ratiopharm Company that was found guilty of corruption because of a payment up to 18.000 euro to panel doctor in Germany. The pharmaceutical company recognized to panel doctors a 5% bonus of manufacturer's prices when they prescribed the company's medicines.

A similar case happened in Croatia, where the authorities arrested more than 26 employee and management of Farmal on suspicion of paying doctors to prescribe company's drugs; 350 doctors were alleged to have received bribes.

A case of indirect prescription influencing is reported by Swedish media. The case regards a study trip sponsored by various medical devices and pharmaceutical companies. Through the sponsorship, every person could pay only 30 euro instead of 390 euro.

An example of undue positive list promotion has been discovered in Finland, where twelve professionals, sponsored or employed by Pfizer, attended scientific meetings. The lobbying action of the company was finalized to get four attending members of the national advisory committee on vaccination to recommend their new vaccine to adults. A similar case happened in Netherlands where physicians had benefits for a meeting in 2010 regarding the use of product not allowed in the Dutch market. The company invited the physicians, hoping the product will be allowed in the future for treatment of chronic migraines. Six physicians received money for participating in order to promote the results of the company-financed clinical trials. At the end, the pharmaceutical company, Allergen, was fined with 45.000 euro by the Health Care Inspectorate.

In relation to the irregularities with authorization of medicines, the EU Commission report the scandal Mediator, a diabetic's drug produced by Servier Laboratories, that, according to the French health ministry, has killed at least 500 people from heart-valve damage. About 5 million people were given the drugs between 1976 and 2009. This was years after being banned in Spain and Italy and the product was never authorized in the UK and USA. The head and founder of the company was charged of aggravated deception, manslaughter and corruption in a related trial.

Strictly connected to the procurement corruption and the improper marketing relations types, corruption is sometimes due to a misuse of high-level position. It can happen through revolving door corruption, regulatory state capture, trading in influence, conflict of interest, favouritism or nepotism. Revolving door corruption can be the consequence of the movement of people between different roles, in the industry, in the legislators or regulators offices, guaranteeing reciprocal privileges. Regulatory state capture happens when regulators, instead of take care of public interests, act for industry's interests, without the necessary independence. Trading in influence is the practice of using one's influence in government or connections with persons in authority in order to influence over the decision-making processes and to obtain favours or preferential treatment for another, usually in return for loyalty, money, material or immaterial undue advantages. Conflict of interest occurs when individuals or institutions are involved in multiple interests, one of which could possibly corrupt the motivation. Favouritism, nepotism and clientelism involve the favouring of not the perpetrator of corruption but someone related to them, such as a friend, family member or member of an association. Examples would include hiring a family member to a role they are not qualified for or promoting a staff member who belongs to the same political party as you, regardless of merit.

### 4.2 Code of Ethics and Ethical Culture

The European pharmaceutical industry is characterized by the presence of numerous companies, some of them listed in the financial market.

Our qualitative research focuses the attention on the European parent listed companies (Table 6), operating in pharmaceutical industry, in order to make some considerations about the coherence between the values contained and declared in the codes of ethics and the involvement in scandals. In fact, if the ethical culture does not affect every company's behaviour, the code of ethics remains a declaration of no value and doesn't contribute to the conditions of corporate global responsibility and health system's sustainability.

In particular, we analyse the availability of the corporate codes of ethics, since all the companies examined are members of national associations that adhere to EPFIA Code.

The research has considered only the companies that have published their own code of ethics in a structured document, in English language and available for viewing and/or downloading from the official website.

For the 57 selected companies, moreover, the research collects media information regarding scandals occurred in the last decade, in order to verify the coherence between the ethical principles affirmed in the codes and the behaviours assumed by the company in the worldwide markets.

The paper reports some information regarding the scandals, as founded in the media, without assuming any responsibility on their truthfulness. In other terms, the focus of the research is to verify the sensibility of the companies to the sustainability needs, through the adoption and the publication of the code of ethics and the effective behaviours in the last decade.

The research pays attention to the parent listed companies because of the more stringent rules and laws imposed by the financial market, in addition to the sector specific rules and laws. In fact, it is well known that listed companies are subjected to rigorous rules regarding the transparency of their external communication and are subjected to possible negative impacts on the stock price and reputation in consequence of a scandal.

**Table 6: European Pharmaceutical Parent Listed Companies**

| **Company name** | **Country** | **Company name** | **Country** |
|---|---|---|---|
| BAYER AKTIENGESELLSCHAFT | DE | BURIAL DMITRY | CY |
| GLAXOSMITHKLINE PLC | UK | SINCLAIR IS PHARMA PLC | UK |
| ASTRAZENECA PLC | UK | ADVANCED MEDICAL SOLUTIONS GROUP PLC | UK |
| FRESENIUS SE & CO. KGAA | DE | JSC BIOSINTEZ | RO |
| COVIDIEN PLC | IE | BIOTIKA, A.S. | SK |
| SHIRE PLC | UK | SKYEPHARMA PLC | UK |
| PAUL HARTMANN AG | DE | VENOMA HOLDINGS LTD | RO |
| GEDEON RICHTER PLC | HU | ALLIANCE PHARMA PLC | UK |
| NOVO MESTO | SI | ALLERGY THERAPEUTICS PLC | UK |
| ORION OYJ | FI | LAVIPHARM SA | EL |
| HIKMA PHARMACEUTICALS PLC | GB | ECO ANIMAL HEALTH GROUP PLC | UK |
| VIRBAC | FR | GALYCHFARM PUBLIC JSC | AT |
| FAMILLE BOIRON | FR | ACTAVIS PLC | RS* |
| DIASORIN SPA | IT | ACTIVE BIOTECH AB | SE |
| ALKERMES PLC | IE | CARDIO3 BIOSCIENCES | BE |
| ALK-ABELLO AS | DK | BULGARSKA ROZA SEVTOPOLIS AD | BG |
| SWEDISH ORPHAN BIOVITRUM AB | SE | PHARMSYNTHEZ OPEN JOINT-STOCK COMPANY | RU* |
| DECHRA PHARMACEUTICALS PLC | UK | OXFORD BIOMEDICA PLC | UK |
| LABORATORIOS FARMACEUTICOS ROVI SA | ES | MEDIGENE AG | DE |
| FAES FARMA, SA | ES | TIGENIX | BE |
| FI&P HOLDINGS | AT | TAIHUA PLC | UK |
| CLINIGEN GROUP PLC | UK | AGENNIX AG | DE |
| BAVARIAN NORDIC AS | DK | BYOTROL PLC | UK |
| SOFARMA AD | BG | IDL BIOTECH AB | SE |
| GRINDEKS AS | LV | BIOSYNEX | FR |
| BIOTON S.A. | PL | IXICO PLC | UK |
| ALKALOID A.D. SKOPJE | MK* | CONPHARM AB | SE |
| ALGETA ASA | N* | FUTURIS AS | PL |
| OLAINFARM AS | LV | | |

(*) Not in the EU
Source: Amadeus Database – Bureau Van Dijk, april 2014

As results, 77% of the 57 companies (Table 6), even if listed in financial markets, have not published their code of ethics, in a structured English language document.

As described in section 3, the EPFIA Codes set out the minimum standards which EPFIA considers must apply. Thus, member companies should be obliged to adopt a code of ethics coherent to the national and European standards. By the way, for some companies, even if it is not possible to affirm they do not have adopted the code of ethics, it is possible to underline the absence of the code in the official web site, underlying the lack of transparency about their own ethical principles with stakeholders.

When published, the codes of ethics seem to be well structured, according to the EPFIA provisions. Some example could represent common declared principles.

*"Bayer's corporate culture is an important factor in the company's success. Central to this culture are our values: Leadership, Integrity, Flexibility and Efficiency, summarized by the term LIFE.*
*In the marketing of our products and services, Integrity means: "To comply with laws, regulations and good business practices".*
*We are committed to ethical sales & marketing practices that meet the standards set by external regulations & codes of practices, in particular:*
*- all laws and regulations dealing with marketing practices;*
*- all applicable global, regional and local industry codes relevant for our business;*
*- privacy of customer or consumer information and data protection;*
*- recommendation and promotion only of lawful uses, e.g. no off-label promotion for medicinal products". (Bayer Code of Conduct,2012)*

Another example taken from code of conduct could regards Fresenius SE & Co. KGaA

"*We want to achieve our market position through the outstanding quality of our products and services as well as through our performance, not through unfair business practices.*
*No employee shall make any illegal agreements with business partners which may have as their object or effect the restriction of competition. Not only are written and oral agreements forbidden, but also concerted practices which attempt to or restrict competition or any conduct that is designed to do so.*
*Fresenius employees shall not treat customers or suppliers in an unfair and unprofessional manner. Offers and proposals must be evaluated objectively on the merits of price and performance.*
*Fresenius business partners shall not be subject to any illegal restrictions in setting prices or establishing purchasing relationships with their business partners". (Fresenius SE & Co. KGaA Code of ethics and business conduct, 2014*)

The above-mentioned concepts allow the reader to claim how the ethical codes contain the principal terms of integration according to the triple bottom line, which can facilitate the effectiveness and efficiency of the overall internal control systems, if they are applied correctly in the development of all management behaviours. In particular, the codes include a set of management guidelines suitable for setting up a cultural change in contexts where, for a long time, the economic performance has been favoured even at the expense of the most basic principles of global responsibility.

In recent years, sustainability has formally assumed the value of business driver. Its application has involved the bigger companies that have articulated systems of reporting, internal control system and well-structured codes of ethics. The companies should be dominated by the concept that the adoption of sustainable policies is necessary in order to defend the competitive advantage and reduce risks.

Several companies have activated processes of organic and complete risk management, enlarged their own internal control systems even according the best practices of corporate governance emphasized in different countries, created well-structured and largely effective codes of ethics.

In some cases, it is clearly declared the attention to the compliance risk, especially in relation to the risk of active and passive corruption.

Nevertheless, corporates' scandals are frequent and show weaknesses concerning conflict of interests and the research of economic profit without taking care of laws and ethical principles, in damage to the fair competition and to the quality of the healthcare system.

In fact, there are cases of companies, well known in the international scene, which are involved in scandals adopting behaviours in contrast to the logic of sustainability and ethical principles formally mentioned in the codes of conduct. Some of them are mentioned below.

Bayer was involved in more than one scandal since the Eighties first for contaminated haemophilia products, then for contaminated rice used in drugs and resulting from experimental trials, the suspension of a birth-control pill by the French authorities because the medicine seems to increase the risk of blood clots.

GSK has been involved in a recent scandal because of illegal promotion of prescription drugs, failure to report safety data, bribing doctors and promoting medicines for use unauthorized. On July 2012, the company pleaded guilty and agrees to a $ 3 billion settlement (Bloomberg, 2012).

Another case regarding GSK concerns the recent suspect of corruption in China. China police has charged the former British boss of drug master GSK PLC's China business and other colleagues with corruption, after a probe found the firm made billion of Yuan to bribe doctors and hospitals (Reuters, 2014).

These scandals seem to be in contrast to the ethical principles affirmed in the GSK's code of ethics or, at least, seem to underline the weakness and/or the complexity of the internal control system in a multinational company operating worldwide. GSK code of ethics declares:

> "*We are committed to meeting the highest ethical standards in the way we do business.*
> *All of us – the company, employees and anyone acting on our behalf – must obey company policies and all laws in any country where we operate, including specific anti-corruption laws.*
> *GSK has zero tolerance towards bribery and corruption. We will not make, offer to make, or authorize payment to a third party (e.g. sales agent, distributor or intermediary) with knowledge that all or part of the payment will be offered or given to any individual to secure an improper advantage, obtain or retain businesses (GSK Code of Conduct, 2014).*"

Last year authorities visited large international drugs manufacturers including Novartis AG, Sanofi SA, Eli Lilly & Co and Bayer AG as part of a broad investigation into the sector (Reuters, 2014).

In addition, AstraZeneca has been involved in the recent China scandal, as company suspected of making kickbacks (The Guardian, 2014). In 2013, Police has investigated AstraZeneca's work in China and has detained one of the drug maker's executives (The Independent, 2013).

In the AstraZeneca Code of conduct they affirm:

> *"We must not offer or give money or anything else of value either as an inducement to make, or as a reward for making, any decision favourable to the interests of AstraZeneca.*
> *This includes providing such benefits to government officials (including those from national and local governments and those serving in public international organizations) and other healthcare professionals and organizations, patients, suppliers, charities and patient groups, whether companies or individuals.*
> *AstraZeneca also does not permit agents, contractors, advisors or other third parties working on our behalf to engage in this type of conduct.*
> *As well as not offering bribes, we must also not accept them.*
> *Offering or making payments to government officials to obtain favourable treatment, to secure business, or to obtain an improper advantage is a crime in every country in which we do business, whether such payments are in cash or in kind. It is also a crime in many countries to make these types of payments to government officials of another country, and also a crime in most jurisdictions to pay commercial bribes to persons who are not government officials". (AstraZeneca Code of Conduct,2014 )*

Another case reported by media regards the Bulgarian company Sopharma. Sopharma, controlled by OgnyanDonev who, until a year before the scandal, was a member of the supervisory board of the State Authority National Insurance Fund. He has managed to supply more than 70% of the medicines required by (state) hospital and more than 50% of prescripted medicines. Moreover, the deputy Health Minister of Bulgaria, Gergana Pavlova, a former high-ranking employee of Sopharma, was the political supervisor in the BoykoBorisov cabinet in charge of medicines and hospital supplies. The case has been under UE investigation (Novinite, 2012).

*"The present Code determines the rules of conduct of the Employees of Sopharma AD and aims at establishing standards for ethical and professional conduct in all aspects of their activities to prevent the possibility of allowing expressions of bureaucracy, corruption and other illegal activities, thus increasing public confidence in their professionalism and morale and strengthening the authority of the Company". (Sopharma Ethical code of conduct, 2007)*

In 2011, the media pay attention also to the Latvian company Grindeks because of a career switch. A person employed by the pharmaceutical company as a deputy director for marketing and trade and deputy for research and development, in fact, since 1999, worked at the Ministry of Welfare and Ministry of Health on various positions.

*In its activities, Grindeks adheres high ethical principles and has included them in many company's rules and regulations. For the ethical behaviour principles to be put into the company's daily life and improve them even further, Grindeks is planning on developing and implementing a comprehensive code of ethics. The basic principles of ethics will cover such areas as scientific and clinical research ethics, patient safety and pharmacovigilance, collaboration with health care professionals and health organizations, avoiding conflict of interest, cooperation with patient organizations, etc.(Grindeks Corporate Social responsibility Report, 2011)*

## *5. Discussion and Conclusion*

Starting from the belief of the high contribution by the pharmaceutical companies to sustainable development, this paper makes some considerations about the formal aspects of the corporate social responsibility and the effective ones. According to the recent study of the European Healthcare Fraud and Corruption Networks, the cost that European countries must bear every year because of fraud and corruption in their health systems amounts to 56 billion euro. It is a considerable damage to the community, which has led several international institutions to intervene for the dissemination of responsible behaviours in the health sector.

First, the study shows that in European pharmaceutical companies there are different stage sin the evolution of global responsibly managerial approach. From the analysis of the European listed parent companies operating in the pharmaceutical industry we noticed that, in most cases (77% of the 57 companies analysed), they do not even publish their codes of ethics. Only a few number of the European listed companies (23% of the 57 companies analysed) seems effectively oriented to implement stakeholder engagement and to be accountable. Today, successful companies are expected to adopt, maintain and strengthen governance systems based on transparent and complete information disseminated all over the world.

When published, the ethical codes contain principles and values of sustainability which are essential for the business. By the way, also in this situation things are not often looking too good. The scandals in the sector highlight cases of behaviours not oriented to global responsibility that imply the unfulfilling diffusion of an ethical culture both in single companies and in the whole industry.

The frequency and the importance of scandals involving pharmaceutical companies seem to demonstrate how difficult is the transfer of the principles of corporate responsibility in the management behaviours and this despite the growing attention to the adoption of tools for the dissemination of an ethical culture.

The pharmaceutical companies that, at least formally, have increased their attention to the interaction between stakeholder relation management and economic, social and environmental responsibility, seems to be in the first stage of managerial changing. In this regard the existence of a strong culture, which is shared by the top managers and the organization and permeates the entire net of the company's relations is, therefore, a critical element.
Code of ethics represents an important self-regulation tool for sharing the ethical principles within organization and with stakeholders, affirming the sensibility of companies to the corporate responsibility, but, a lot of time, it is used more as a document to formally obtain public consents than as a guide for correct and fair behaviours.
The codes represent the strategic value given to global responsibility, whose implementation requires transparency, sharing coherence of individual behaviour and control.

The formal importance often given to the codes of ethics limits the function of prerequisite for the effectiveness of the corporate responsibility. As a direct tool, it contributes to: generate consensus, clarity and coordination between managers and organization, sharing and comprehension of the objectives and priorities in the triple bottom line.

The adoption of the code of ethics needs to be supported by the implementation of an effective internal control system. In this sense, the design of control systems cannot ignore:

- The analysis of the existent culture;
- The evaluation of the ability of control act to transfer principles of corporate responsibility and coherent values;
- The control of the processes of cultural growth activated by the company and their coherence with the issues expressed by the top managers; the timeliness of the complaint for behaviours in contrast to the goals of sustainability.

In this regard, the control of compliance risk, the introduction of bodies spreading ethical culture (Ethic Officer, Ethics Committee, etc.), as well as the activation of concrete collaboration between the latter and the internal control bodies are relevant.

It is also necessary that the audit committees are completely aware of the importance of the widespread of the sustainable culture for ensuring the effectiveness of the internal control systems.

The full assumption of responsibility values in all corporate decisions and actions makes it easier to overtake the emergence of corruption in the pharmaceutical industry, to gain approval from stakeholders, but also to obtain resources needed for growth and limit corporate risks.

The European pharmaceutical companies have to recognize that ethical culture is the key factor driving the development of effective ethics. The biggest obstacle to decrease of companies' misconduct seems to be the gap between the values they articulate in their codes and their operational value.

## *References*

Adams, J. S., Tashchian, A. & Shore, T. H. (2001) Codes of Ethics as Signals for Ethical Behavior. Journal of Business Ethics, 29, 199–211.

Andrews, K. R. (1980). The Concept of Corporate Strategy. Homewood: Richard D. Irwin.

Ansoff, H. I. (1983). Societal strategy for the business firm. Advances in Strategic management, 1, 3-29.

Arrigo, E. (2006) Code of Conduct and Corporate Governance. Symphonya Emerging Issues in Management, 11(1), 93-109. http://dx.doi.org/10.4468/2006.1.07arrigo

Aupperle, K., Carroll, A., and Hatfield, J., (1985). An empirical examination of the relationship between corporate social responsibility and profitability. Academy of Management Journal, 28, 446-463.

Bansal, P. (2005). Evolving sustainability: A longitudinal study of corporate sustainable development. Strategic Management Journal, 26, 197–218.

Bérard, C. & Perez, M. (2014) Alliance dynamics through real options: The case of an alliance between competing pharmaceutical companies. European Management Journal, 32, 337-349.

Béthoux, É., Didry, C. &Mias, A. (2007) What Codes of Conduct Tell Us: corporate social responsibility and the nature of the multinational corporation. Corporate Governance: An International Review, 15(1), 77-90.

Bloomberg (2012) GlaxoSmithKline agrees to pay $ 3 billion in U.S. drug settlement. http://www.bloomberg.com/news/2012-07-02/glaxosmithkline-agrees-to-pay-3-billion-in-u-s-drug-settlement.html

Bondi, K., Matten, D. & Moon, J. (2008) Multinational Corporation Codes of Conduct: Governance Tools for Corporate Social Responsibility? Corporate Governance: An International Review, 16(4), 294-311.

Brondoni, S.M. (2012). Innovation and Imitation: Corporate Strategies for Global Competition. Symphonya. Emerging Issues in Management,1,10-24. http://dx.doi.org/10.4468/2012.1.02brondoni

Burke, L. & Logsdon, J. M. (1996). How Corporate Social Responsibility Pays Off. Long range Planning, 29(4), 495-502.

Camillus, J. C. &Datta, D. K. (1991). Managing strategic issues in a turbulent environment. Long Range Planning, 24(2), 67-74.

Carroll, A. B. & Hoy, F. (1984). Integrating corporate social policy into strategic management. Journal of Business Strategy, 4(3), 48-57.

Carroll, A. B., Hoy, F. & Hall, J. (1987). The integration of social policy into strategic management. S. P. Sethi& C. M. Falbe (Eds.), Business and Society: Dimensions of Conflict and Cooperation (pp. 449-470). Lexington: Lexington Books.

Carroll, A. B. (1991). The pyramid of corporate social responsibility: Toward the moral management of organizational stakeholders. Business Horizons, 34(4).

Carroll, A. B. (1999). Corporate social responsibility: Evolution of a definitional construct. Business & Society, 38(3), 268-295.

Colbert, B.A. &Kurucz, E.C. (2007). Three conceptions of triple bottom line business sustainability and the role for HRM. Human Resource Planning,30, 21–29.

Dahlsrud, A. (2008) How Corporate Social Responsibility is Defined: an Analysis of 37 Definitions. Corporate Social Responsibility and Environmental Management, 15, 1–13. http://dx.doi.org/10.1002/csr.132

Davis, K. (1960). Can business afford to ignore social responsibilities? California Management Review, 2, 70-76.

Dickerson, C. & Hagen, K. (1998) Corporate Codes of Conduct. American Society of International Law. Proceedings of the Annual Meeting, Washington, 265-277.

Diller, J. (1999) A social conscience in the global marketplace? Labour dimensions of codes of conduct, social labelling and investor initiatives. International Labour Review, 138(2), 99-129.

Drucker, P. (1982). The New Meaning of Corporate Social Responsibility.California Management Review, 26, 53-63.

Elkington, J. (1994). Towards the sustainable corporation: Win-win-win business strategies for Sustainable Corporationable Development. California Management. Review, 36, 90–100.

Ecorys (2009) Competitiveness of the EU Market and Industry for Pharmaceuticals. In Welfare Implications of Regulation Vol. I. Rotterdam.

Ecorys (2009) Competitiveness of the EU Market and Industry for Pharmaceuticals. In Markets, Innovation & Regulations Vol. II. Rotterdam.

European Federation of Pharmaceutical Industries and Associations (2013) [1] The Pharmaceutical Industry in Figures. Brussels.

European Federation of Pharmaceutical Industries and Associations (2013) [2] EPFIA HCP Code, Brussels.

European Commission – Competition DG (2008) Pharmaceutical Sector Inquiry Preliminary Report. Brussels.

European Commission (2011) Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. A renewed EU strategy 2011-14 for Corporate Social Responsibility. Brussels.

European Commission – Directorate-General Home Affairs (2013) Study on Corruption in the Healthcare Sector. Luxembourg.

FBI (2006) Financial crimes to the public Report. http://www.fbi.gov/stats-services/publications/fcs_report2006

Fombrun, C. (1996). Reputation. Realising Value from the Corporate Image. Boston: Harvard Business School Press

Freeman, R. E. (1984) Strategic Management: a Stakeholder Approach. Boston: Pitman.

Freeman R.E., Moutchnik A. (2013) Stakeholder Management and CSR: Questions and Answers, Umwelt Wirtschafts Forum, Springer Verlag, Bd. 21, 1 http://link.springer.com/article/10.1007/s00550-013-0266-3

Gandini, G., Gennari, F. & Cassano, R. (2014) Global responsibility and strategic risk management. Journal of Business management and Applied Economics, 3(5), 1-17.

Gray, E. R. &Balmer, M. T. (1998). Managing Corporate Image and Corporate Reputation. Long Range Planning, 31(5), 695-702.

Hansen, U. & Schrader, U. (2005) Corporate Social Responsibility alsaktuelles Thema der Betriebswirtschaftslehre. Die Betriebswirtschaft, 65(4), 373-395.

Harwood, I., Humby, S., & Harwood, A. (2011). On the resilience ofcorporate social responsibility. European Management Journal, 29(4), 283–290.

Helin, S. &Sandström, J. (2007). An Inquiry into the Study of Corporate Codes of Ethics. Journal of Business Ethics, 75(3), 253-271.

Henriques, A., Richardson, J. (2004). The Triple Bottom Line: Does It All Add Up?, London: Earthscan.

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) (2012). IFPMA Code of Practice. Geneva. www.ifpma.org

International Trade Administration Office of Health and Consumer Goods (2010) Pharmaceutical Industry Profile. http://trade.gov. July

Knox, S. &Maklan, S. (2004). Corporate social responsibility: Moving beyond investment towards measuring outcomes. European Management Journal, 22(5), 508–516.

Kolk, A., Van Tulder, R. & Welters, C. (1999)International codes of conduct and corporate social responsibility: can transnational corporations regulate themselves? Transnational corporations,8(1), 143-180.

Lenz R. T. &Engledow, J. L. (1986). Environmental analysis: the applicability of current theory. Strategic Management Journal, 7(4), 329-346.

Levitt, T. (1958). The dangers of social responsibility. Harvard Business Review, September-October, 41-50.

Lichtenberg, F. R. (2013) The Effect of Pharmaceutical Innovation on Longevity: Patient Level Evidence from the 1996-2002 Medical Expenditure Panel Survey and Linked Mortality Public-use Files. Forum for Health Economics & Policy, 16(1), 1-33.

McGuire, J., Sundgren, A. &Schneeweis, T. (1988). Corporate social responsibility and firm financial performance. Academy of Management Journal, 31, 854-872.

McWilliams, A. and Siegel, D. (2001). Corporate social responsibility: A theory of the firm perspective. Academy of Management Review, 26, 117-127.

Moon, J. & Vogel, D. (2008) Corporate Social Responsibility, Government and Civil Society. In A. Crane (Eds.), The Oxford Handbook of Corporate Social Responsibility (pp. 303-323). Oxford: University Press.

Perkins, A. (1995). Corporate identity: what's in a name?. Harvard Business Review, 73(2), 11.

Reuters (2014). China police charge British former head of GSK in China with bribery, http://www.reuters.com/article/2014/05/14/us-china-glaxosmithkline-idUSBREA4D03720140514

Reuters (2014). RPT-Big Pharma beware: GSK China case may be just the beginning. http://www.reuters.com/article/2014/05/18/gsk-china-corruption-idUSL3N0O40AG20140518

Salvioni, D.M. (2003). Corporate Governance and Global Responsibility. Symphonya. Emerging Issues in Management,8(1),44-54. http://dx.doi.org/10.4468/2003.1.05salvioni

Salvioni, D.M. & Bosetti, L. (2006). Corporate Governance Report and Stakeholder View. Symphonya. Emerging Issues in Management11(1), 24-46 http://dx.doi.org/10.4468/2006.1.03salvioni.bosetti.

Salvioni, D. M. (2010) Intangible Assets and Internal Controls in Global Companies. Symphonya. Emerging Issues in Management20(2), 39-51http://dx.doi.org/10.4468/2010.2.04salvioni

Salvioni, D.M. & Astori, R. (2013). Sustainable Development and Global Responsibility in Corporate Governance. Symphonya Emerging Issues in Management25(1), 1-25. http://dx.doi.org/10.4468/2013.1.03salvioni.astori.

Salvioni, D.M. & Gennari, F. (2014). Corporate Governance, Sustainability and Capital Markets Orientation. International Journal of Management and Sustainability, 3(8), 469-483. www.pakinsight.com

Salzmann, O., Ionescu-Somers, A. & Steger, U. (2005). The Business Case for Corporate Sustainability: Literature Review and Research Options. European Management Journal, 23(1), 27-36.

Scherer, A. & Palazzo, G. (2008). Corporate Social Responsibility, Government and Civil Society, Crane, A. (Eds), The Oxford Handbook of Corporate Social Responsibility (pp.413-431). New York: Oxford University Press.

Scherer, A. G., Palazzo, G., & Matten, D. (2009). Globalization as a challenge for business responsibilities. Business Ethics Quarterly, 19(3): 327-347.

Schwartz, M. (2001) The nature of the relationship between corporate codes of ethics and behaviour. Journal of Business Ethics, 32(3), 247–262.

Steurer, R., Langer, M., Konrad, A., Martinuzzi, R. A. (2005). Corporations, Stakeholders and Sustainable Development: A Theoretical Exploration of Business-Society Relations. Journal of Business Ethics, 61 (3): 263-281.

Stevens, B. (1997). Business Communication and the Ethical Context. In H. Murphy, H. Hildebrandt and J. Thomas (Eds), Effective Business Communication, 7th ed. (pp. 95-116).

Sun, W. & Cui, K. (2014). Linking corporate social responsibility to firm default risk. European Management Journal 32, 275-287.

The Guardian (2014). GlaxoSmithKline faces criminal investigation by Serious Fraud Office. http://www.theguardian.com/business/2014/may/28/serious-fraud-office-investigates-glaxosmithkline

The Guardian (2004). Papers detail Labour donor's vaccine deal http://www.theguardian.com/uk/2004/jun/29/politics.freedomofinformation

The Independent (2013). AstraZeneca executive detained after Chinese police raid Shanghai HQ. http://www.independent.co.uk/news/business/news/astrazeneca-executive-detained-after-chinese-police-raid-shanghai-hq-8727173.html

Volodina, A, Sax, S. & Anderson, S. (2009). Corporate Social Responsibility in Countries with Mature and Emerging Pharmaceutical sectors. Pharmacy Practice, 7 (4), 228-237. www.pharmacypractice.org.

Whetten, D.A., Rands, G. &Godfrey, P. (2002) .What are the responsibilities of business to society? In A.M. Peetigrew, T. Howard and R. Whittington (Eds), Handbook of Strategy and Management (pp. 373-409). London: Sage.

Weber, M. (2008). The business case for corporate social responsibility: A company-level measurement approach for CSR. European Management Journal, 26, 247-261.

West, T. (2012). Corporate Social Responsibility within the Pharmaceutical Industry. Thesis for the Degree of Doctor of Philosophy, University of Saskatchewan, CDN.

World Health Organization (2008) [1]. A Framework for Good Governance in the Pharmaceutical Sector. Geneva.

World Health Organization (2008) [2]. Good Governance for Medicines. Curbing Corruption in Medicines. Regulation and Supply

World Health Organization (2013). Guideline on Country Pharmaceutical Pricing Policies, Geneva.