Journal of Business and Economics, ISSN 2155-7950, USA
November 2015, Volume 6, No. 11, pp. 1868-1882
DOI: 10.15341/jbe(2155-7950)/11.06.2015/005

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Corruption in the Pharmaceutical Sector: Is the Internal Controls System the Weakest Link?

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Abstract: Corruption in the pharmaceutical industry has become a hot topic as the several cases of misconducts reported by worldwide media in recent years. The present research aims at identifying the reasons of the diffusion of corrupt practices in this sector, focusing on the evaluation of the effectiveness of company's internal controls. More exactly, the analysis is carried out to verify if the compliance controls-actually implemented in pharmaceutical companies-need a strong improvement to combat corruption, or otherwise, they are sound and well functioning. In order to achieve the above stated aim, a content analysis is performed considering the top twenty largest European pharmaceutical companies by operational revenue, listed on one or more of the main stock exchanges in December 2014. Main findings underline that compliance controls implemented in the selected companies are weak with regard to some aspects and, thus, vulnerable to corruption.

Key words: pharmaceuticals; corruption; compliance; internal controls
JEL codes: M10, M16

1. Introduction

The relevance of pharmaceutical industry is mainly linked to the specific need the sector has to cope with: the human health. Because pharmaceuticals have curative and therapeutic qualities, they cannot be regarded simply as ordinary commodities. Access to drugs is often about life and death; thus corruption in the pharmaceutical sector cannot be ignored, in relation to its potential negative effects on health and welfare of citizens (McPake et al., 1999; Gupta et al., 2002; Azfar, 2005; Lewis, 2006; Rose, 2006; Gandini et al., 2014).

In spite of the high relevance of pharmaceutical industry, there is mounting evidence of the increasing corruption in this sector; indeed, the European Commission estimates that € 120 billion is lost to corruption each year throughout the 27 members States (EUobserver, 2013), while approximately 56 billion euro is lost annually to fraud and corruption in health sector (Gee, Button & Brooks, 2011). In addition, many scandals relating to corrupt practices in pharmaceutical sector have been reported by worldwide media in recent years. Without assuming any responsibilities on their truthfulness, it is worth mentioning — as some examples — the case of GlaxoSmithKline, involved in 2014 in a criminal investigation in Poland for bribing doctors to promote its lung drug Seretide (Reuters, 2014) and Astra Zeneca accused of making kickbacks (The Independent, 2013).

According to a general meaning, corruption may be defined as "the use (…) of power for (…) profit,

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preferment, or prestige, or for the benefit of a group or class, in a way that constitutes a breach of law or of standards of high moral conduct" (Gould et al., 1964).

Evidence shows that corrupt behaviuors take place even when the company adopts a Code of ethics or a Code of conduct promoting ethical practices; in many cases, the declarations reported in these codes remain only a formal intent that differs from what the companies actually do (Salvioni et al., 2015). In this situation, the attention should be concentrated on the effectiveness of internal controls; indeed, in presence of well-functioning control systems, corruption should not exist. Internal controls — especially the compliance ones — carry out a preventive anti-corruption action by detecting and deterring corrupt practices; in this way, internal monitoring supports governance bodies' decisions, facilitating the fulfilment of the all stakeholders' expectations (Salvioni et al., 2012). In this regard, OECD asks Member countries to encourage companies do develop and adopt adequate internal controls, ethics and compliance programs with the aim to prevent and detect foreign bribery (OECD, 2009).

Starting from the observation of the above-outlined situation, the present study aims at answering to the following research question:

Why is there corruption even when internal control systems are implemented? Are the internal controls the weakest link in the corporate anti-corruption system?

A review of the international business literature suggests that existing studies have typically focused either on (a) the effects of corruption on economic growth (Husted, 1999; Mauro, 1995; Treisman, 2000; Paldam, 2001; Akhter, 2004; Gonzalez-Velasquez, 2004; Serra, 2006; Guetat, 2006), or on (b) the analysis of the causes of corruption (Shleifer & Vishny, 1993; Rose-Ackerman, 1997; Collier, 2002; Sandholtz & Gray, 2003; Park, 2003; Aggarwala & Goodell, 2009; Goldsmith, 2009) and on the related measurement (Lancaster &Montiloa, 1997; Eigen, 2002; Svensson, 2005; Spector et al., 2005; Kaufman, Kraay & Mastruzzi, 2008; Graycar et al., 2010). Only a few studies analyse the effect of corruption on the health sector (McPake et al., 1999; Gupta et al., 2002; Azfar, 2005; Cohen et al., 2002; Salvioni et al., 2015).

Sparse attention has been given to the internal control's contribution to prevent and combat corruption in the pharmaceutical sector. There is a lack of scholarly research concerning the potential reduction of corrupt practices in case of effective and sound internal control systems in pharmaceutical companies. This study attempts to fill this gap and add to the existing research by a content analysis aimed at evaluating the internal controls implemented by selected European pharmaceutical companies and the interrelationships between these monitoring systems and the diffusion of corrupt practices.

The objective is to verify if corruption practices occurring in the pharmaceutical sector are due to the ineffectiveness of internal controls, especially the compliance ones. The main findings reported in Section 4 underline that compliance controls are weak with reference to specific aspects such as the compliance program's content and the compliance bodies' appointment; in this regard, internal controls are not fully effective to prevent corruption, but they need a strong improvement.

To answer the above stated research question, this paper is divided into five sections. The Section 1 is an introduction to the research, while in Section 2, the analysis is focused on: the pharmaceutical's industry characteristics; the main weaknesses to corruption; the most widespread corrupt practices occurring in the pharmaceutical sector; the relevance of internal controls to combat corrupt practices. In Section 3, the research methodology is presented and in Section 4 the main findings are shown. The final section contains some concluding remarks taken from the results explained in Section 4.

2. Theoretical Background

2.1 The Pharmaceutical Industry and Its Main Vulnerabilities to Corruption

The pharmaceutical industry is a key asset of the European economy, playing a critical role in restoring Europe to growth and ensuring future competitiveness in global markets. In 2014, it invested an estimated € 30,500 million in R&D in Europe, by employing directly around 707,000 people and generating three to four times more employment indirectly (Efpia, 2015). European pharmaceutical industry accounts for more than 3,818 companies, with a total market value in 2013 — at ex factory prices — of € 163,000 million and a value of exports reaching more than € 300,000 million in the same year (Table 1). The relevance of the pharmaceutical industry is likely to be improved as the demand for drugs may rise because of: the increase in the chronic disease burden owing to the ageing population; the higher risk of pandemics due to globalization and urbanization; the emergence of new diseases.

Table 1 The Pharmaceutical Industry in Europe (values in € million)

Industry (Epfia total)	1990	2000	2012	2013
Production	63,010	125,301	213,003	217,500
Exports	23,180	90,935	312,377	316,500
Imports	16,113	68,841	224,811	226,500
Trade balance	7,067	22,094	87,566	90,000
R&D expenditure	7,766	17,849	30,035	30,630
Employment (units)	500,879	534,882	693,195	690,000
R&D employment (units)	76,126	88,397	115,196	115,000
Pharmaceutical market value at ex-factory prices	41,147	86,704	160,574	163,000
Pharmaceutical market value at retail prices	64,509	140,345	237,240	240,800

Source: European Federation of Pharmaceutical Industries and Associations, the Pharmaceutical Industry in Figures, Brussels, 2014.

According to the European Classification of Economic Activities system (NACE Rev.2), stated by the European Commission and adopted in the EU Member States, the pharmaceutical industry (division 21 of NACE) refers to the manufacture of basic pharmaceutical products and pharmaceutical preparations. In detail, pharmaceuticals may be distinguished in

(1) chemical drugs, developed as a result of extensive research and clinical trials;

(2) generics, consisting in duplicative copies of chemical drugs containing the same active ingredient;

(3) over-the-counter drugs, differing from chemical ones and generics in that consumers do not need prescriptions to purchase the drugs;

(4) active pharmaceutical ingredients, consisting in components of medication;

(5) biologicals, deriving from living material (human, animal, microorganism or plant);

(6) biosimilars, referring to specific versions of biological products (International Trade Administration, 2010).

The pharmaceutical sector-above outlined–is characterized as being particularly susceptible to corruption (Vian, 2007) due to specific industry's features. More exactly, no other sector has the specific mix of uncertainty, asymmetric information and large numbers of dispersed actors that characterise the pharmaceutical industry. These aspects combine in ways that systematically create opportunities for corrupt practices, while making it difficult to ensure the transparency and accountability that would inhibit this (Transparency International, 2006).

In detail, the most relevant pharmaceutical industry's vulnerabilities to corruption are indicated as follows.

(1) Asymmetry of information

In the pharmaceutical sector there is a high degree of asymmetry of information especially referring to the interrelations among patients, producers, medical professionals and payers for health, such as government agencies and health insurers. Information is not shared equally among health sector actors: health care professionals are better informed of the technical features of treatment than patients who, otherwise, cannot judge whether the prescribed treatment is appropriate or shop around for the best price, as they are ignorant of the costs, alternatives and precise nature of their needs; pharmaceutical companies know more about their products than the prescribing doctors; patients have specific information about their health that are not available to medical care providers or insurers; providers and insurers may have better information about the health risks faced be specific categories of individuals. The existence of asymmetric information among the various parties in a market, can result in inefficiencies in the market equilibrium and in a greater vulnerability to corrupt practices, as the lack of information implies difficulties in monitoring pharmaceutical players' activities.

(2) "Principal-agent" relationship

Patients are aware they don't feel well but they rely on health professionals to act as their agents in diagnosing and treating diseases; the principal-agent problem in health care asserts that prescribing doctors, being the imperfect agents of patients, will act to maximize their profits at the expense of the patients' interests. Indeed, doctors have an interest in improving the health of their patients, but their choices of treatment also may affect their income, professional status and working conditions. In this regard, "principal-agent" relationship may increase the opportunities for corruption, by promoting practices aimed at achieving personal gain rather than the patients' interests.

(3) The large number of actors involved

Pharmaceutical industry is characterized by the high number of actors involved and by the complexity of their multiple forms of interaction. These actors may be identified in: the government regulators (health ministries, parliament, specialized commission); payers (social security institutions, government office, private insurers); providers (hospitals, doctors, pharmacists); consumers (patients); suppliers (medical equipment and pharmaceutical companies). The presence of so many actors exacerbates the difficulties of monitoring information, promoting transparency and even identifying corruption when it occurs. Indeed, the involvement of a high number of actors increases the interests that might encourage corrupt practices; actors may be tempted to abuse their positions for direct financial gain, to increase their prestige, political influence and power, or to expand their market share. In presence of a large number of stakeholders involved, when corruption is detected, it may be difficult to attribute it to a specific actor, reducing the control systems' effectiveness.

(4) Complexity of medicine chain

The high number of actors involved is also due to the extreme complexity of medicine chain which often involves up to thirty different parties before the product reaches the end user, thus creating the opportunity of carrying out corrupt practices. In detail, the main medicine chain's stages are the following: manufacturing, indicating the process of production of pharmaceuticals (WHO, 2003); registration and marketing authorization; selection aiming at choosing the most cost-effective and appropriate drug for a population's health; procurement which indicates the process of acquiring the needed quantity of pharmaceuticals; distribution and prescription. The complexity of medicine chain increases the number of opportunities for corruption and the difficulties to detect it (Radulescu et al., 2008).

(5) Limitation of competition

Market competition is limited as pharmaceuticals are patent protected after their introduction and heavy investments in R&D are needed. Indeed, the offer side of pharmaceutical industry is characterized — on the one hand — by a limited number of big companies (the so called "originator companies") engaged in carrying out research and — on the other hand — by a great number of smaller companies than the "originator" with a limited "R&D" (the so called "generic companies") active in producing — after the patent protection's expiration — pharmaceuticals equivalent to the original ones, but sold at a lower price. In this context, R&D is a high barrier to entry as a medicinal product reaches the market, an average of 12-13 years will have elapsed since the first synthesis of the new active substance (Efpia, 2015); besides, only one to two of every 10,000 substances synthesised in laboratories will successfully pass all stages of development required o become a marketable drug. This situation may induce pharmaceutical companies to adopt unethical behaviours to increase market share, by placing their products through — for example — prescription influencing.

(6) Government's role and degree of regulation

In the pharmaceutical industry, Government has a significant role as it must secure health policy objectives: protecting public health; guaranteeing patent access to safe and effective medicines; improving the quality of care; ensuring that pharmaceutical expenditure does not become excessive so as to undermine these specific goals (European Observatory on Health Systems and Policies Series, 2004).

The achievement of the above stated objectives implies a high degree of regulation as well, whose primary sources are the individual EU member states and the European Commission; even if the pharmaceutical industry is highly regulated, more enforcement and stronger regulation are needed especially with regard to specific stages of medicine chain which are high vulnerable to corruption (i.e., procurement).

2.2 The Most Relevant Corruption Practices in the Pharmaceutical Industry

The vulnerabilities reported in the previous paragraph increase the likelihood that corruption will occur and that it will be difficult to detect, punish and deter the related practices. In Table 2 the main pharmaceutical system's weaknesses match the related most widespread corrupt practices.

Table 2 Vulnerabilities to Corruption and Related Corrupt Practices

Weaknesses to corruption	Corrupt practices
Asymmetry of information	Bribery in medical services delivery Undue reimbursement claims Fraud and embezzlement
"Principal-agent" relationship	Bribery in medical services delivery Undue reimbursement claims Fraud and embezzlement
Large number of actors involved	Procurement corruption Improper marketing relations Corruption in marketing authorisation
Complexity of medicine chain	Procurement corruption Improper marketing relations Corruption in marketing authorization
Limitation of competition	Improper marketing relations
Government's role and degree of regulation	Procurement corruption

Asymmetry of information and the "Principal-agent" relationship are the main factors promoting corrupt practices carried out by healthcare providers against patients or the reimbursement system. In this regard, corruption may take form as: bribery in medical services delivery, undue reimbursement claims, fraud and

embezzlement. Bribery in medical services delivery consists of informal payments from patients to healthcare providers to obtain access to healthcare, preferential treatment, better quality of healthcare, false sick leave statement. Undue reimbursement claims occurs when healthcare providers request reimbursement of unnecessary or not delivered treatment as well as in case of use of maximum allowable reimbursement levels for less complicated case (upcoding). Fraud and embezzlement takes place when public or prepaid pharmaceuticals are sold by healthcare providers for private gain or in case of sale of counterfeit medicines.

The complexity of medicine chain and the high number of actors involved create several opportunities to corruption, especially with reference to authorisation (corruption in marketing authorisation), procurement (procurement corruption) and marketing processes (improper marketing relations).

Corruption in marketing authorization may occur in the authorization stage, in case — for example — of: paying government officials to register drugs without the requisite information; delaying deliberately the registration of a pharmaceutical product to favour market conditions for another supplier; slowing down the registration procedures to solicit payment from a supplier.

Procurement corruption may take place in all phases of the procurement process including the pre-bidding (corruptive needs assessment, circumvention of tender procedures, tailored tendering), the bidding (bribery and kickbacks during the bid evaluation; favouritism; collusion and/or market division in bidding) and the post bidding (false invoicing, changing contract agreements) (Di Tella & Savedoff, 2001). With reference to the embedding degree, it is possible to identify an isolated procurement corruption — carried out on a company-procurement officer basis — and a systemic procurement corruption when the phenomenon is deeply embedded in the political functioning of the State. With regard to the way it is carried out, procurement corruption can be direct — when a bribe is offered to a public official or, more commonly, indirect by the use of tailored terms of reference.

Improper marketing relations covers all the interrelationships among the industry, healthcare providers and regulators, including direct prescription influencing, indirect prescription influencing and undue positive list promotion. In general, improper marketing relations occur when a pharmaceutical company provides any type of gifts (money, leisure activities, etc.) to doctors or medical institutions in order to stimulate prescription of preferred drugs to patients, instead of another similar product that is offered by a competing company (Gale, 2011).

Improper marketing relation is promoted, as well, by the limitation of competition in the pharmaceutical sector, while low regulation's enforcement facilitates procurement corruption.

2.3 Internal Controls and Corruption

The OECD *Recommendation for further Combating Foreign Bribery of Foreign Public Officials in International Business Transactions*, adopted in 2009, asks Member countries to encourage companies to: develop and adopt adequate internal controls, ethics and compliance programs or measures for the purpose of preventing and detecting bribery; create specific monitoring bodies, independent of management, such as audit committee or supervisory boards. In support of this provision, the OECD issued in 2010 a *Good practice guidance on internal controls, ethics and compliance* addressing anti-corruption programs for global economies and calling for companies to adopt many of the leading practices based on effective internal controls. More exactly, companies should adopt policies characterised by: a strong, explicit and visible support and commitment from senior management to the company's internal controls; a clearly articulated and visible corporate policy prohibiting foreign bribery; emphasis on individual employee responsibility for compliance; strong internal controls in place

to ensure recordkeeping and prevention of concealment of bribery; support for whistle-blowing activity; appropriate disciplinary measures; periodic reviews aimed at updating and improving the compliance program; communication and anti-corruption training; focus on specific areas such as hospitality, entertainment and expenses, customer travel, political contributions, charitable donations and sponsorships, facilitating payments.

European Commission — in its "Anti-corruption report" to the Council and the European Parliament (EU, 2014) — emphasizes the relevance of internal control's role to counter corruption, as well; indeed, in this report, EU underlines that "control mechanisms play an important role both for the prevention and the detection of corruption".

Susceptibility to corruption is a systematic feature of pharmaceutical's industry, and controlling it requires the implementation of effective and sound internal control systems, consisting of specific tools and procedures aimed at achieving the company's goals and the risks containment by ensuring the information transparency, the assets' safeguard and the compliance with laws and regulation. Indeed, internal control has been defined as "a process, effected by an entity's board of directors, management and other personnel, designed to provide reasonable assurance regarding the achievement of objectives in the following categories: effectiveness and efficiency of operations; reliability of reporting; compliance with applicable laws and regulations" (Committee of Sponsoring Organizations of the Treadway Commission, 2011, 2013).

In general, the internal control system is composed of all the operational mechanisms adopted by the company to promote the governance's effectiveness (Salvioni, 2005, 2012); thus, each company can implement different control procedures taking into account the specific company's goals and the bodies in charge, according to global responsibility, ethical conduct and sustainable development principles (Almici, 2012).

The main bodies involved in internal controls are the internal audit, the risk manager, the compliance officer, the compliance committee and the supervisory committee introduced by the Italian decree 231/2001, while the principal goals pursued by these bodies are in summary as follows: the risk assessment (risk management); the control of the adopted procedures, the transparency of company's practices and the consonance between ethical recommendations and actual behaviours (internal auditing); the assurance of compliance conditions with laws, regulation, procedures and internal Codes of ethics (compliance controls).

With reference to the fight against unethical conducts, the most relevant internal controls are the compliance ones, carried out — as above stated — by the compliance officer, the compliance committee and the special supervisory board introduced by the Italian decree 231/2001 concerning the legal responsibility of companies. In the present study, the attention is, thus, mainly focused on the compliance controls; the other forms of internal monitoring activities (such as, the risk management and internal auditing) are considered in terms of their contribution to compliance controls effectiveness.

In order to combat corruption, corporate governance bodies and management should implement compliance controls mainly based on:

- the implementation of a global anti-corruption compliance program extending beyond laws;
- the introduction of corporate policies and procedures regarding gifts, entertainment, business courtesies and facilitation payment;
- the development of corruption risk and control evaluation activities to better understand and respond to risk arising from bribery and corruption in global markets;
- the implementation of audits assessing the company's compliance program and corresponding policies, procedures and controls;

- the assessment of the quality of existing compliance program activities to identify gaps or areas for enhancement.

3. Research Methodology

Considering the increasing diffusion of corruption in the pharmaceutical industry, the present study is aimed at verifying if misconducts are due to the ineffectiveness of internal controls; in this regard the research question inspiring the study is the following:

Why is there corruption even when internal control systems are implemented? Are the internal controls the weakest link in the corporate anti-corruption system?

In order to answer to the above stated research question, a content analysis (Weber, 1990; Neuendorf, 2002; Krippendorff, 2004) is carried out considering the top twenty largest European pharmaceutical companies by operational revenue, listed on one or more of the main stock exchanges in December 2014 and with a functioning website (Table 3). The company selection — considering only the parent companies — makes use of Amadeus database and refers to class 21 — Manufacture of basic pharmaceutical products and pharmaceutical preparations, as revised in 2008. Even if the research's aim is to verify if there is a direct connection between controls and corrupt practices in the pharmaceutical sector, not all the selected companies have been involved in scandals relating to corruption; indeed, in the present research, unethical behaviours are observed as a trend characterising, in general, the analysed sector.

Table 3 Sample of Companies

Company	Country	Operational revenue (millions of €)	Stock exchanges
Bayer Aktiengesellschaft	DE	41,054	Frankfurt Stock Exchange
GlaxosmithklinePlc	UK	33,454	London Stock Exchange
Fresenius Se & Co. Kgaa	DE	20,331	Frankfurt Stock Exchange
AstrazenecaPlc	UK	18,965	London Stock Exchange
Merck Kommandit-Gesellschaft	DE	11,233	Frankfurt Stock Exchange
Novo Nordisk A/S	DK	11,196	Nasdaq OMX – Copenhagen
Shire Plc	UK	3,444	London Stock Exchange
H.Lundbeck A.S.	DK	2,044	Nasdaq OMX – Copenhagen
Paul Hartmann A.G.	DE	1,847	Frankfurt Stock Exchange
Gedeon Richter Plc	HU	1,182	Budapest Stock Exchange
Krka, TovarnaZdravil, D.D.	SI	1,133	Ljubljana Stock Exchange
Orion OYJ	FI	1,013	Nasdaq OMX – Helsinki
HikmaPharnaceuticals PLC	UK	984	London Stock Exchange
RecordatiS.p.a.	IT	942	Italian Stock Exchange
Virbac	FR	746	Euronext Paris
Boiron	FR	622	Euronext Paris
Jazz Pharmaceuticals PLC	IE	441	Nasdaq National Market
DiasorinS.p.a.	IT	436	Italian Stock Exchange
Alkermes PLC	IE	418	Nasdaq National Market
Guerbet	FR	394	Euronext Paris

The content analysis is carried out on 2013 annual report for all companies and also on the compliance programs, provided as a separate document, for 11 companies; the processed data are those disclosed on companies' website thorough the annual report or the compliance program.

To verify the effectiveness of internal controls — especially the compliance ones — the content analysis focuses on the following aspects:

- the disclosure via website of the company's Code of ethics and the Code of conduct;
- the implementation of a corporate compliance program, focusing on its adoption, related procedures and governance's bodies involvement;
- the internal control process;
- the internal control bodies involved in the implementation of anti-bribery monitoring activities;
- the communication process among internal control bodies.

More exactly, the information disclosed by the selected companies is collected in an Excel database created according to the most relevant international guidelines such as the OECD Recommendation for further Combating Foreign Bribery of Foreign Public Officials in International Business Transactions (2009) and the OECD Good practice guidance on internal controls, ethics and compliance (2010). In this regard, the analysis puts in comparison the compliance controls actually implemented with the international regulation's recommendations.

4. Results

Data reported in Table 4 refer to the disclosure via website of the company's adoption of the Code of ethics and/or the Code of conduct, both of them including a general statement of ethical principles' implementation. With reference to the selected companies, 7 out of 20 adopt and publish their Code of ethics, while 13 out 20 disclose their Code of conduct; the no-disclosure companies are more with reference to the Code of ethics than the Code of conduct. This datum only indicates the disclosure extent of the above stated documents; furthermore, it is possible that some companies adopt these codes without publishing them.

Table 4 Code of Ethics and Code of Conduct's Disclosure

	Code of ethics	Code of conduct
Number of companies	7	13
Not disclosed	13	7
Total	20	20

International guidelines recommend the implementation — in all the companies controlled by the parent one — of a compliance program to prohibit bribery in any form (direct or indirect). Table 5 summarizes the results about the adoption of this document by the selected companies: almost the total of them (18 out of 20) implement a compliance program and 15 out of 20 adopt the same compliance policy for all the controlled companies. With regard to the disclosure's source, 10 out of 18 companies publish their compliance program as a separate document in respect to the annual report, while only one company provide the compliance program in the annual report; 7 companies do not provide any indication about the disclosure's source.

Table 5 Compliance Program's Adoption and Adoption's Extent

	Compliance program' s adoption	Adoption in all the controlled companies
Number of companies	18	15
Not disclosed	2	3
Total	20	20

International guidelines recommend the inclusion in the compliance program of detailed policies and

procedures to address: conflict of interest, bribes in any form, political contributions, prohibition or facilitation payments, gifts, hospitality and travel expenses. With reference to these aspects, the disclosure is very low; on average, only 4 out of 18 companies publish this information, focusing on bribes in general (Table 6). Otherwise, little attention is given to the other areas such as "conflict of interest", "political contributions", "prohibition or facilitation payments", "gift, hospitality and travel expenses". Thus, results reported in Table 6, show, on the one hand, a too limited focus of compliance programs and, on the other hand, the need of a strong improvement of them.

Table 6 Compliance Program's Policies and Procedures

	Compliance program				
	Conflict of interest	Bribes in any form	Political contributions	Prohibition or facilitation payments	Gift, hospitality and travel expenses
Number of companies	3	6	2	3	3
Not disclosed	15	12	16	15	15
Total	18	18	18	18	18

International regulation recommend that Board of directors as well as the CEO should be responsible for ensuring the compliance program's implementation; at the same time, top-level management should be engaged in: the development and determination of bribery prevention procedures; any key decision making relating to bribery risk; the communication of the organisation's anti-bribery stance. Table 7 underlines a low disclosure level with reference to the above stated aspects; on average, only 7 companies out of 18 provide information about the governance's bodies commitment in the compliance program's implementation. With reference to the disclosing companies, collected data show a general governance bodies' commitment, especially with regard to the CEO and the management whose engagement refers to the development of bribery prevention procedures, the key decision making concerning bribery and the communication of the anti-bribery stance.

Table 7 Board of Directors, CEO and Management's Involvement in the Compliance Program's Implementation

	Board of directors' commitment	CEO's commitment	Management's commitment		
			Development of bribery prevention procedures	Key-decision making	Communication of the anti-bribery stance
Number of companies	6	7	8	7	6
Not disclosed	12	11	10	11	12
Total	18	18	18	18	18

With reference to the compliance control process, international guidelines recommend the implementation of the following steps:

- inclusion in the internal controls — aiming at countering bribery — financial and organization checks over accounting and record keeping practices and other processes related to the compliance program;
- internal control systems' regular review and audit;
- review and control of all functions impacting on financial transactions, by an officer of higher level than the one performing the task;
- introduction of a fraud specific risk assessment including internal and external risks;
- development of a risk assessment process including the review of deficiencies in employee training, skills and knowledge, lack of clear financial controls, lack of clear anti-bribery messages from the top-level

management, lack of clarity in the organisations' policies for hospitality, promotional expenditure, and political charitable contributions;

- introduction of measures to segregate duties between custody of assets and verification tasks, management tasks and authorization tasks, management tasks and accounting tasks, accounting tasks and payment tasks;
- implementation of a process to monitor and evaluate the effectiveness of the bribery prevention procedures.

Results concerning the practices carried out with regard to the above stated aspects are reported in Table 8: almost the totality of the selected companies are compliant with the international recommendations, focusing on the implementation of regular review of internal controls and of fraud risk assessment, as well as on specific checks on functions impacting on financial transactions.

Table 8 Compliance Controls Process

	Checks over accounting and record keeping	Internal controls regular review	Control of all functions impacting on financial transactions	Introduction of a fraud risk assessment	Development of a risk assessment process including the review of specific deficiencies	Segregation of duties	Monitoring of bribery prevention procedures
Number of companies	18	19	19	19	16	-	12
Not disclosed	2	1	1	1	4	20	8
Total	20	20	20	20	20	20	20

According to international regulation, compliance controls should be carried out by specific bodies such as the compliance committee, the compliance officer and the supervisory committee introduced by the Legislative Decree 231/2001 (the last one only for Italian companies that in the sample are only two); their activity should be supported by other internal controls bodies including the risk manager and the internal auditor.

In Tables 10 and 11 it is shown the evidence related to the composition and the functioning of the above stated bodies in the selected pharmaceutical companies, while Table 9 reports data about the appointment of these bodies. Internal audit function is the most widespread one, as it is present in all the 14 disclosing companies; otherwise, compliance committee is the less present (only 4 companies out of 14). Compliance officer and risk manager are not really diffused as well; respectively only 8 companies out of 14 and 6 companies out of 14 (Table 9). In this sense, the presence of compliance control bodies (compliance officer and compliance committee) is weak and it should be strengthened. With regard to the their composition and functioning, data reported in Table 10 underline that in only 4 companies out of 8, the compliance officer's functions are disclosed while in all the 8 companies, compliance officer's activity is subjected to the other body's oversight (generally the Board of directors' one). Otherwise, compliance committee's activity is subjected to the Board of directors' control only in one case; no information is provided with reference to the chairman or the meeting's frequency, while data concerning the composition indicate that — in general — the body is a separate committee composed by the heads of specific compliance functions.

Table 9 Appointed Compliance Controls Bodies

	Compliance officer	Compliance committee	Risk manager	Internal audit	Supervisory committee (L.D. 231/2001)	Not disclosed
Number of companies	8	4	6	14	2	6
Total	8	4	6	14	2	6

Table 10 Compliance Officer and Compliance Committee's Composition and Functioning

	Number of companies	Not disclosed
Compliance officer (Co)		
Holding a managerial position	8	-
Disclosure of duties and functions	4	4
Oversight of Co's activity	8	-
Compliance officer Committee (Coc)		
Separate committee	3	1
Members	3 (Chief Compliance officer, Chief financial officer, heads of legal affairs, internal audit and corporate compliance departments	1
Meetings' frequency	-	4
Disclosure of duties and functions	3	1
Coc's Chairman	-	4
Oversight of Coc's activity	1	3

Table 11 reports data about the other internal control bodies supporting compliance activities, such as the risk manager, the internal auditor and — with reference to the Italian companies — the supervisory board introduced by the Legislative Decree 231/2001.

With regard to the internal auditor, in all the 14 disclosing companies its activity is controlled by the Board of directors or the Audit committee, while its involvement in the compliance program's implementation is reported in only 7 companies.

Evidence about risk management underlines a less involvement in compliance's implementation; only 2 companies out of 6 confirm this aspect, while the oversight of its activity is carried out in almost the companies with a risk management function.

No weaknesses are reported with regard to the Legislative Decree 231/2001's Supervisory Board appointed only in the two selected Italian companies; indeed, for both companies, collected data underline the body's involvement in the compliance program's implementation and the oversight of its activity.

Table 11 Risk Manager, Internal Audit and Supervisory Committee's (LD 231/2001) Composition and Functioning

	Number of companies	Not disclosed
Internal audit		
Disclosure of duties and functions	12	2
Involvement in the compliance program's implementation	7	7
Oversight of internal audit's activity	14	-
Risk manager		
Disclosure of duties and functions	6	-
Involvement in the compliance program's implementation	2	4
Oversight of risk management's activity	4	2
Supervisory Committee (L.D. 231/2001)		
Disclosure of duties and functions	2	-
Involvement in the compliance program's implementation	2	-
Oversight of Supervisory Committee's activity	2	-

International guidelines recommend the implementation of an effective line of communication among the internal controls' bodies and the employees, ensuring the reporting of the consequences of breaching policies, the bribery prevention procedures, the business benefits of rejecting misconducts and the actors involved in the development of bribery's prevention procedures. It is also recommended the implementation of a protection of

wistleblowers policy.

Table 12 shows that in 5 companies out of 8, there is an effective line of communication between the compliance officer and the employees, while the presence of a line of communication between the compliance officer and the compliance committee is observed in 3 out of 4 companies.

Collected data underline a low degree of communication if the focus is referred to the internal control's bodies as only 6 out of 20 companies confirm the presence of effective communication process. Otherwise, a good evidence is reported with regard to the communication's aspects as the majority of the selected companies comply with the international guidelines (on average, 15 out of 20 companies). A similar result is reported by data concerning the implementation of a wistleblowers policy, as 14 out of 20 companies ensure the presence of a secure and accessible channel through which employees can raise concern without risk of reprisal.

Table 12 Compliance Controls Communication Process

	Number of companies	Not disclosed
Presence of an effective line of communication between the compliance officer and the employees	5	3
Presence of an effective line of communication between the compliance officer and the compliance committee	3	1
Presence of an effective line of communication among the compliance control bodies	6	14
Internal and external communication includes:		
a commitment to carry business fairly, honestly and openly	16	4
a commitment to zero tolerance towards bribery	16	4
the consequences of breaching policies	13	7
the bribery prevention procedures in place, including any protection for confidential reporting of bribery (wistle-blowing)	15	5
the business benefits of rejecting bribery	-	20
the actors involved in the development and implementation of bribery's prevention procedures	15	5
Presence of a secure and accessible channel through which employees can raise concern without risk of reprisal (Protection of wistleblowers policy)	14	6

5. Concluding Remarks

In this study, the compliance controls of the 20 selected pharmaceutical companies have been analysed in order to verify if corruption in the above stated sector is due to a potential ineffectiveness of internal control systems. Indeed, even when the company publishes its Code of ethics or its Code of conduct, corruption practices often occur without being limited by the company's commitment to implement the ethical principles stated in those documents. This research is, thus, aimed at verifying if the compliance controls in place are actually suitable for preventing misconducts or, otherwise, their weakness facilitates corruption diffusion.

The collected data are those disclosed by the selected companies; in this regard, research results are, thus, influenced by the company's disclosing attitude. On the basis of the evidence reported in Section 4, it is possible to identify some specific internal controls vulnerabilities to corrupt practices.

Firstly, even if the compliance program is widely adopted by the selected companies, its content should be improved as the collected data show a limited focus only on specific aspects by neglecting other relevant areas for combating corruption practices.

Secondly, evidence underlines a gap with reference to the compliance bodies that are not present enough; more exactly, the compliance officer and the compliance committee are appointed only in a limited number of

companies, influencing the effectiveness of the related controls.

Thirdly, the internal auditing and risk manager's involvement in the implementation of compliance program should be strengthened as the collected data underline a low involvement of the above stated bodies.

The above reported findings demonstrate that corruption in the pharmaceutical sector is also due to specific compliance controls' weaknesses; in this regard, an effective fight against misconducts requires a general improvement of the monitoring activities actually implemented by the pharmaceutical companies.

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