Sustainability and Internal Control Systems in the Food and Pharmaceutical Sectors

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Sustainability in the food and the pharmaceutical industry has become a hot topic as the several cases of malpractice reported by worldwide media in recent years shows. This research aims at identifying the reasons for the diffusion of non-ethically sustainable practices in these sectors, by evaluating the effectiveness of the company's internal controls. To achieve this aim, a content analysis was performed considering the largest European pharmaceutical and food companies, listed on one or more of the main stock exchanges. Main findings underline many internal controls' vulnerabilities to corruption.

1. Introduction

The majority of worldwide food and pharmaceutical companies guarantee the integrity and safety of their products in order to obtain the consumers' confidence, by assuring the most relevant interest for people, that is safeguarding human health. Despite the above stated commitment, from the last century, widespread economic and geographic food fraud and pharmaceutical scandals occurred ever more frequently, with a great impact on consumers' health.

Considering the significant relevance of human health in generating malpractice, the possible governance measures to be implemented to combat corruption should be analysed at all relevant levels (institutions, research centres, management and corporate policy makers, etc.), especially after taking into account forecasts about demographic and environmental development. According to the most recent estimates carried out by the United Nations and the Washington University, the worldwide population could reach 9 billion in 2050 and it could grow potentially to 11 billion by the end of the century, in case no corrective measures[1] are promptly adopted.

The above stated forecast is strictly linked to: the exploitation of the world's resources; economic development; environmental and food sustainability; the awareness of all players involved in the process aimed at ensuring the planet's safety; the next generation's health. The whole food system (starting from the agricultural processes up to the industrial and commercial chain) is involved in an important challenge to radically increase food production and, at the same time, to completely change the way it is produced. According to current

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trends, food demand could increase by 70% by 2050 following demographic and economic growth.

Considering the above mentioned forecasts, Governments and food companies are concerned about the way of coping with the forecasted demographic growth whose sustainability is greatly influenced by the current availability of resources and especially by the probability of conservation of these resources over the coming years. The above mentioned forecast about demographic development and the population's increased age (especially in the industrialised countries) due to better nutrition, sanitation, healthcare, education and economic well-being are relevant factors impacting on the pharmaceutical sector. In detail, the increased number of elderly people implies on the one hand, a rising demand for pharmaceuticals and, on the other hand, the risk of corruption due to the wide economic interests involved. Potential unethical conduct in the pharmaceutical sector could significantly damage the population as the relevance of the pharmaceutical industry is mainly linked to the specific need the sector has in coping with human health. Access to drugs is often about life and death; because pharmaceuticals have curative and therapeutic qualities, they cannot simply be regarded as ordinary commodities. In order to combat corrupt practices, companies should implement effective and sound control systems, according to specific principles such as transparency, global responsibility, sustainability, compliance with laws and regulations.

Considering the increasing diffusion of corruption in the food and pharmaceutical industries, the present study is aimed at verifying if malpractice and non-sustainable practices 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?

A review of international business literature – as reported in paragraph 2 – suggests that existing studies have focused typically on specific aspects of corruption and sustainability, without them being related to internal controls. In fact, sparse attention has been given to the internal control's contribution in preventing and combating corruption in both the food and the pharmaceutical sector. There is a lack of scholarly research concerning the potential reduction of corruption in case of sound and effective internal control systems in food and pharmaceutical companies. This study attempts to fill this gap and add to the existing research through a content analysis aimed at evaluating the internal controls implemented by selected European food and pharmaceutical companies.

This paper is structured as follows, Section 2 shows a literature review on corruption, sustainability and internal controls; it also provides a general background in terms of main corruption weaknesses of the selected sectors. Section 3 describes the research approach. Section 4 deals with the main results of the present research and the last section contains some concluding remarks, trying to answer the above mentioned question.

2. Literature Review and Theoretical Background

In recent years, the emergence of new sustainable development's paradigms aimed at stakeholder relationship management (Steurer et al, 2005 and Cassano et al, 2014) prompted the emphasis on interdependence in stakeholder relationship management and the integration of economic, social and environmental responsibility (Porter and Teisberg, 2006; Esty and Winston, 2008; Przychodzen and Przychodzen, 2013 and Eccles et al, 2014). The importance of sustainability has also led to numerous interventions by major

international institutions and companies. This has led them to increase their focus on the adoption of methods and tools of governance and control to help improving not only the economic performance but also the social and the ecological ones (Cassano et al, 2014).

However, even though the focus of European legislation is very detailed on the safety of food (including the checks and tests carried out in specific areas for residues and contaminants in food and feed), an actual corrective intervention program on food fraud is still completely absent. The food scandals observed in recent years and future expectations for world economy, would suggest more and more attention for the topic; for this purpose, some measures are being studied and shown in the European Action Plan to strengthen the rules and controls in Member States in order to combat food fraud.

The recent worldwide food scandals underline the level of urgency for corrective action and control in the sector in terms of regulation and governance, and, at the same time, they express the system's exasperation with respect to the wrong policy choices. Thus, for example, there is the presence of horsemeat in bovine products (in response to the limitless demands for animal products). Likewise, melamine has been found in milk and milk powder for infants in levels exceeding the legal limits (emphasising the diversity of regulations in the various Member States). Chilli powder has been adulterated by introducing Sudan dyes with harmful effects to consumers' health (highlighting the need to raise consciousness about the continued use of abusive advertising in promoting "beautiful" rather than "healthy" food).

In spite of its high relevance, there is mounting evidence of increasing corruption in the pharmaceutical sector too (Almici and Gandini, 2014), even when a Code of ethics is adopted (Salvioni et al, 2015); indeed, the European Commission estimates that € 120 billion is lost to corruption each year throughout the 27 member States (Nielsen, 2013), while approximately 56 billion euros are lost annually to fraud and corruption in the health sector (Gee et al, 2011). In addition, many scandals relating to corrupt practices in the pharmaceutical sector have been reported by worldwide media in recent years. Without assuming any responsibility regarding their truthfulness, it is worth mentioning – as some examples – the case of GlaxoSmithKline, involved in a criminal investigation in Poland in 2014 for bribing doctors to promote its lung drug Seretide and AstraZeneca accused of making kickbacks (Tobin, 2013).

The above stated evidence is mainly due to specific sector features that 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; Vian, 2007 and Almici, 2015). In detail, asymmetry of information and the "Principal-agent" relationship are the main factors promoting corrupt practices by healthcare providers against patients or the reimbursement system. In this regard, corruption may take the form of bribery in the provision of medical services, undue reimbursement claims, fraud and embezzlement. The complexity of the medicines' chain and the high number of players involved create several opportunities for corruption, especially where authorisation (corruption in marketing authorisation), procurement (procurement corruption) and marketing processes (improper marketing relationships) are concerned.

Corruption in marketing authorisation may occur, for example, in the authorisation stage in paying government officials to register drugs without the requisite information; deliberately delaying the registration of a pharmaceutical product to favour market conditions for another supplier; slowing down the registration procedures to solicit payment from a supplier (Gale, 2011). Procurement corruption may take place in all phases of the procurement process including 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 ones (false invoicing, changing contract agreements) (Di Tella and Savedoff, 2001).

With reference to both the food and the pharmaceutical sector, a review of the international literature underlines that the existing studies have 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 and Guetat, 2006) or on b) the analysis of the causes of corruption (Shleifer and Vishny, 1993; Rose-Ackerman, 1997; Collier, 2002; Sandholtz and Gray, 2003; Park, 2003; Aggarwala and Goodell, 2009 and Goldsmith, 2009) and on the related measures (Lancaster and Montiloa, 1997; Eigen, 2002; Svensson, 2005; Spector et al, 2005; Kaufman et al, 2008 and Graycar et al, 2010). Only a few studies analyse the effect of corruption on the food and health sector (McPake et al, 1999; Gupta et al, 2002; Azfar, 2005; Cohen et al, 2002; Salvioni et al, 2015 and Almici, 2015) or other specific issues such as market segmentation for genetically modified food and pharmaceuticals (Nonis and Hudson, 2013), while almost no authors have studied the role of internal controls for combatting corruption and, thus, promoting sustainability. This research aims at filling the above mentioned literature gap, by verifying the actual internal control practices of selected European companies through a content analysis. More precisely, the present study tests the following assumption:

A: Corruption in food and pharmaceutical sectors is also due to the ineffectiveness of internal controls.

3. Research Methodology

In order to answer the above research question, a content analysis (Weber, 1990; Neuendorf, 2002 and Krippendorff, 2004) is carried out considering the top twenty largest European food and pharmaceutical companies by operating revenue, listed on one or more of the main stock exchanges in December 2014 and with a functioning website. The company selection – considering only the parent companies - makes use of Amadeus database and refers to:

- Class 10 - Manufacture of food products – and class 11 - Manufacture of beverages;
- Class 21 – Manufacture of basic pharmaceutical products and pharmaceutical preparations, as revised in 2008.

Even if the research's aim is to verify whether there is a direct connection between controls and corrupt practices in selected sectors, not all the selected companies have been involved in scandals relating to corruption; indeed, in the present research, unethical behaviour is seen generally as a trend characteristic of the analysed sectors. The content analysis is carried out on the last annual report for all companies and also on the compliance programs, provided as a separate document, for any food companies and for 11 pharmaceutical companies; the processed data are those disclosed on the companies' website thorough the annual report or the compliance program.

To check the effectiveness of internal (especially compliance) controls 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 bodies' involvement.

- The internal control process.
- The internal control bodies involved in the implementation of anti-bribery monitoring activities.
- The communication process between internal control bodies.

More precisely, 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 compares the compliance controls actually implemented with the international regulation's recommendations.

4. Results

The analysis is carried out on companies' compliance programs, annual reports, code of conduct and code of ethics, with regard to the above international guidelines. International guidelines recommend the implementation – in all companies controlled by the parent – of a compliance program to prohibit bribery in any form (direct or indirect). This document should include detailed policies and procedures that address: conflict of interest, bribes in any form, political contributions, prohibition or facilitation payments, gifts, hospitality and travel expenses.

The 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 involved in this activity. International guidelines also recommend the implementation of a widespread compliance control process, such as risk management and internal audits involving internal control bodies. Moreover, compliance controls should be carried out by specific bodies such as the compliance committee, the compliance officer and the supervisory committee introduced in Italy through Legislative Decree 231/2001. Companies should also implement an effective line of communication between the internal control bodies and the employees. The implementation of a whistleblowers protection policy is also recommended.

Table 1: Code of ethics and Code of conduct disclosure

	Code of ethics	%	Code of conduct	%
Pharmaceutical	7	35%	13	65%
Food	4	20%	10	50%

Data shown in Table 1 refers to the website disclosure of the company's adoption of the Code of ethics and/or the Code of conduct, both of them including a general statement regarding implementation of ethical principles. With reference to the selected companies in the pharmaceutical industry, 7 out of 20 adopt and publish their Code of ethics, while 13 out of 20 disclose their Code of conduct; companies that disclose their Code of conduct outnumber those of the Code of ethics. This datum only indicates the extent the above documents are disclosed; furthermore, it is possible that some companies adopt these codes without publishing them. On the contrary, in the food industry, 7 out of 20 companies adopt neither the Code of ethics nor the Code of conduct (or do not give information about them). Among the companies analysed, only one has both a Code of ethics and a Code of conduct; the other 13 companies mainly adopt the Code of Conduct. 2 out of 10 companies declare their adoption of the Code of conduct without publishing it on their website.

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Table 2: Compliance program's adoption and its extent

	Compliance program's adoption	%	Adoption in all the subsidiaries	%
Pharmaceutical	18	90%	15	75%
Food	12	60%	11	55%

Table 2 summarises the results on the adoption of the compliance program by the selected companies: in the pharmaceutical sector, almost all of them (18 out of 20) implement a compliance program and 15 out of 20 adopt the same compliance policy for all their subsidiaries. With regard to the disclosure's source, 10 out of 18 companies publish their compliance program as a separate document with respect to the annual report, while only one company provides the compliance program in the annual report; 7 companies do not provide any indication about the disclosure's source.

The majority of food companies have a compliance program (60%): however, compliance program diffusion is significantly higher in pharmaceutical companies (90%). 7 out of 12 food companies provide compliance program guidelines in their annual report, while the remaining 5 companies provide them in other documents. 11 out of 12 companies implement the compliance program throughout all subsidiaries.

Table 3: 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	%
Pharmaceutical	3	17%	6	33%	2	11%	3	17%	3	17%
Food	10	83%	12	100%	4	33%	5	42%	11	92%

With reference to the compliance program's policies and procedures, the disclosure is very low; on average, only 4 out of 18 pharmaceutical companies publish this information, focusing on bribes in general (Table 3). 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 shown in Table 6 show, on the one hand, a too limited focus of compliance programs and, on the other hand, the need for major improvements.

As in the pharmaceutical companies, in food companies, compliance programs focus mainly on corruption in general. However, it seems that food companies give more prominence to "conflict of interest" and "gifts, hospitality and travel expenses"; otherwise, disclosures relating to "political contributions" and "payments" remain low.

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Table 4: 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	
Pharmaceutical	6	33%	7	39%	8	44%	7	39%	6	33%
Food	8	67%	4	33%	5	42%	6	50%	5	42%

Table 4 underlines a low disclosure level with reference to the above stated aspects; on average, in the pharmaceutical companies only 7 out of 18 provide information about the governance 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 management whose commitment is to the development of bribery prevention procedures, and key decisions concerning bribery and the communication of the anti-bribery stance. 11 out of 12 food companies provide information about governance bodies' commitment in the compliance program; the data collected show that the board is primarily responsible for the compliance program's implementation, followed by management.

Table 5: Compliance control 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 a review of specific deficiencies		Segregation of duties		Monitoring of bribery prevention procedures	
Pharmaceutical	18	90%	19	95%	19	95%	19	95%	16	80%	0	0%	12	60%
Food	5	25%	15	75%	9	45%	12	60%	19	95%	0	0%	3	15%

Results concerning the practices carried out with regard to the above stated aspects are shown in Table 5: almost the totality of the selected pharmaceutical companies are compliant with the international recommendations, focusing on the implementation of regular reviews of internal controls and of fraud risk assessment, as well as on specific checks on functions impacting on financial transactions.

The data collected in the food companies shows a high diffusion of reviews of internal controls and risk assessment; however, there is limited focus on specific anti-corruption controls ("checks over accounting and record keeping" and "monitoring of bribery prevention procedures").

Table 6: Appointed compliance control bodies

	Compliance officer	%	Compliance committee	%	Risk manager	%	Internal audit	%	Supervisory committee (L.D. 231/2001)	%
Pharmaceutical	8	40%	4	20%	6	30%	14	70%	2	10%
Food	2	10%	2	10%	18	90%	12	60%	3	15%

Table 7: Compliance officer and Compliance committee's composition and function

	Pharmaceutical	%	Food	%
Compliance officer (Co)				
Holding a managerial position	8	100%	1	50%
Disclosure of duties and functions	4	50%	1	50%
Supervision of Co's activity	8	100%	-	-
Compliance officer Committee (Coc)				
Separate committee	3	75%	1	50%
	3	75%	-	-
Members	(Chief Compliance officer, Chief financial officer, heads of legal affairs, internal audit and corporate compliance departments		(Audit committee)	
Meetings' frequency	-	-	-	-
Disclosure of duties and functions	3	75%	2	100%
Coc's Chairman	-	-	-	-
Oversight of Coc's activity	1	25%	2	100%

Table 8: Risk manager, internal audit and Supervisory committee's (LD 231/2001) composition and function

	Pharmaceutical	%	Food	%
Internal audit				
Disclosure of duties and functions	12	86%	12	100%
Involvement in the compliance program's implementation	7	50%	7	58%
Supervision of internal audit's activity	14	100%	12	100%
Risk manager				
Disclosure of duties and functions	6	100%	17	94%
Involvement in the compliance program's implementation	2	33%	8	44%
Supervision of risk management's activity	4	67%	17	94%
Supervisory Committee (L.D. 231/2001)				
Disclosure of duties and functions	2	100%	3	100%
Involvement in the compliance program's implementation	2	100%	3	100%
Supervision of Supervisory Committee's activity	2	100%	3	100%

Tables 7 and 8 show the evidence related to the composition and function of the above stated bodies, while Table 6 shows data about the appointment of these bodies. The internal audit function is the most widespread in the selected pharmaceutical companies, as it is present in all the 14 disclosing companies; whereas the compliance committee is the least present (only 4 companies out of 14). Compliance officers and risk managers are not widespread; only 8 companies out of 14 and 6 companies out of 14 respectively (Table 6). In this sense, the presence of compliance control bodies (compliance officer and compliance

committee) is weak and should be strengthened. With regard to their composition and function, data shown in Table 7 underline that the compliance officer's functions are disclosed in only 4 companies out of 8, while in all 8 companies, the compliance officer's activity is subject to the other body's supervision (generally that of the Board of directors). Otherwise, the compliance committee's activity is subject to the Board of directors' control just in one case; no information is provided regarding the chairman or the meeting's frequency, while data concerning the composition indicate that – in general – the body is a separate committee comprising the heads of specific compliance functions.

In the food companies, risk management and internal audit are the most involved compliance bodies; the Supervisory Committee is present in all three Italian companies. As for the pharmaceutical companies, there is a low presence of specific compliance bodies (Compliance officer and Compliance committee).Compliance officer disclosure is very low as just one company gives information about this role; with regard to the Compliance committee, one of the two companies has a separate committee, while the other has an Audit and Compliance Committee. This seems to confirm the involvement of "traditional" control bodies in the implementation of compliance programs.

Table 8 shows data about the other internal control bodies supporting compliance activities, such as the risk manager, the internal auditor and – with reference to Italian companies – the supervisory board introduced by Legislative Decree 231/2001. With regard to the internal auditor, in all the 14 disclosing companies in the pharmaceutical industry, its activity is controlled by the Board of directors or the Audit committee, while its involvement in the compliance program's implementation is only reported in 7 companies. Evidence about risk management underlines a lesser involvement in compliance's implementation; only 2 companies out of 6 confirm this aspect, while supervision of its activity is carried out in almost all the companies with a risk management function.

No weaknesses are reported with regard to Legislative Decree 231/2001's Supervisory Board appointment in just the two selected Italian companies; indeed, for both companies, collected data underline the body's involvement in the compliance program's implementation and the supervision of its activity. In the food companies, the Supervisory committee is always involved in the compliance program's implementation; however, internal audit and risk management involvement is lower: if present, these bodies are involved in about 50% of the companies.

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Table 9: Compliance controls communication process

	Pharmaceutical	%	Food	%
Presence of an effective line of communication between the compliance officer and the employees	5	63%	1	100%
Presence of an effective line of communication between the compliance officer and the compliance committee	3	75%	-	-
Presence of an effective line of communication among the compliance control bodies	6	30%	12	60%
Internal and external communication includes:				
a commitment to carry on business fairly, honestly and openly	16	80%	13	65%
a commitment to zero tolerance towards bribery	16	80%	12	60%
the consequences of breaching policies	13	65%	7	35%
the bribery prevention procedures in place, including any protection for confidential reporting of bribery (whistle-blowing)	15	75%	10	50%
the business benefits of rejecting bribery	-	-	2	10%
the players involved in the development and implementation of bribery's prevention procedures	15	75%	11	55%
Presence of a secure and accessible channel through which employees can raise concern without risk of reprisal (whistleblowers protection policy)	14	70%	8	40%

Table 9 shows that in 5 pharmaceutical 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 evident in 3 out of 4 companies. Collected data underline a low degree of communication if the focus is on the internal control bodies as only 6 out of 20 companies confirm the presence of effective communication processes. Otherwise, with regard to communication, there is real evidence that 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 whistleblowers 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.

The selected food companies give little information about the communication between compliance bodies; however, there is a broader disclosure on the other control bodies, for which the companies declared the presence of communication. With regard to internal and

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external compliance communication, the majority of the companies observe the principles of fairness and honesty and of zero-tolerance towards corruption. In 8 out of 20 companies there is a channel through which employees can raise concern without risk of reprisal.

5. Conclusion

In this study, the compliance controls of the selected companies have been analysed in order to verify whether corruption in the above sectors is due to a potential ineffectiveness of internal control systems. This research is, thus, aimed at verifying whether the compliance controls in place are actually suitable for preventing malpractice, or else, their weakness facilitates the spread of corruption. The collected data are those disclosed by the selected companies; in this regard, research results are, thus, influenced by the company's attitude to disclosure.

Indeed, our study is limited by the informative source of our comparisons. The future development of our work intends to overcome such limitations by attempting to validate the results through a direct comparison with the management of the analysed companies (preparation and dispatch of a survey). Another of our study's limitations is that it is only based on a content analysis. On the basis of the evidence shown in Section 4, it is possible to observe, in both selected sectors, a general vulnerability of internal controls to corrupt practices. Indeed, evidence highlights that even if the selected sectors are highly regulated, the implementation of internal control systems should be greatly improved. In this sense, results underline a contrast between the law makers' great attention in regulating the food and the pharmaceutical chains and what companies actually do. Therefore, the findings highlight that the lever of success for the affirmation of the companies is represented, once more, by the strength of the entrepreneurial culture and from the structured system of laws and procedures.

In other terms, especially in the last decade, laws and procedures are the answer to malpractice in the business world. However, in the light of the findings and in answer to our research question, we highlight that the adoption of behaviour in line with the healthy principles of management is subordinate to corruption. The adoption of the stakeholder theory necessarily brings about the adoption of transparent policies, strategies and forms of control and the social responsibility of the management. Only if such conditions are met and implemented by the leadership, can we affirm that the introduction of the control system is effectively to direct and to verify the business conduct to achieve the objectives. It aims to bridge the gap found in literature for which almost no authors have studied the role of internal controls for combatting corruption and, thus, promoting sustainability.

The above findings demonstrate that unethical practices in the food and pharmaceutical sectors are also due to internal control weaknesses. Therefore, an effective fight against malpractice requires, on one hand, a general improvement of the monitoring activities actually implemented by the food and pharmaceutical companies; but on the other hand, to increase management training for the growth of the enterprise culture. In this sense, this paper is relevant to modern business administration studies as it offers food for thought for the real effectiveness of the control systems.

Endnotes

[1] The main corrective proposals under evaluation consider a greater investment in health and education (school enrolment rate) to allow women to have more decisional power about their lifestyle, with a slowing down effect on demographic increase.

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