

Environmental management practices in the Lebanese pharmaceutical industries: implementation strategies and challenges

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Abstract This research attempts to provide an understanding of the Lebanese pharmaceutical industries' environmental management strategies, priorities, and perceptions as well as drivers, barriers, and incentives regarding the implementation of the voluntary ISO 14001 Environmental Management System. Accordingly, a semistructured in-depth interview was conducted with the pharmaceutical industries. The findings revealed a significant lack of knowledge about the standard among the industries. The main perceived drivers for adopting the ISO 14001 are improving the companies' image and overcoming international trade. The main perceived barriers for acquiring the standard are the lack of government support and the fact that ISO 14001 is not being legally required or enforced by the government. Moreover, results revealed that adopting the ISO 14001 standard is not perceived as a priority for the Lebanese pharmaceutical industries. Although the cost of certification was not considered as a barrier for the implementation of ISO 14001, the majority of the pharmaceutical

industries are neither interested nor willing to adopt the Standard if they are not exposed to any regulatory pressure or external demand. They are more concerned with quality and safety issues with the most adopted international standard among the industries being the ISO 9001 quality management system. This study highlights the aspect that financial barriers are not always the hurdles for implementing environmental management strategies in developing countries and underscores the need for regulatory frameworks and enforcement.

Keywords Pharmaceutical industries · Management practices · Challenges · Lebanon

Introduction

Worldwide, it is expected that the utilization of pharmaceuticals will increase due to a growing and aging population, an augmented reliance on drug treatment, in addition to the development of new drugs. Given that pharmaceuticals are necessary for the health and well-being of individuals, their use cannot be prohibited. Thus, pharmaceutical industries should start dealing more efficiently with environmental issues. These industries are involved in formulating, manufacturing, and processing medicinal and pharmaceutical products. Accordingly, environmental impacts may arise from material inputs to the manufacturing processes, to the pollution of soil, air, and water resources (Berry and Rondinelli 2000). Safety and toxicological tests are constantly carried out on pharmaceuticals in order to investigate and examine their side effects

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on humans and animals. However, the possible environmental impacts during their manufacturing as well as the effects that they could have on the environment are not well understood (Boxall 2004) and generally neglected (Brunet et al. 2014). In 1970, pharmaceuticals were first recognized or identified as potential environmental contaminants and have raised concerns recently for their persistent input and potential threat to the ecological environment and human health (Liu and Wong 2013). Manufacturing operations are associated with high levels of water consumption (Shukla and Gottschalk 2013) and are considered as one of the largest users of organic solvents per amount of the final product (Slater et al. 2006; Boltic et al. 2013). Progressively, the level of environmental scrutiny of pharmaceutical industries is increasing, thus necessitating the need for the devolvement and implementation of environmentally acceptable manufacturing operations (Ramasamy et al. 2014).

Globally, pharmaceutical industries are growing at approximately 8 % per year, and they are expected to grow more rapidly in the future with 10.6 % growth in the Middle East (Berry and Rondinelli 2000). Considering that the export market share is becoming more complex and competitive, many kinds of international standards and strict environmental regulations are required. Moreover, due to the continuous increase of the public pressure in addition to the increase in material and energy costs, pharmaceutical companies are progressively integrating proactive environmental approaches into their overall business strategies such as ISO 14001 Environmental Management System (EMS). The EMS is useful for the analysis of environmental risks and impacts as well as environmental compliance (Ferenhof et al. 2014). It serves as a third-party guarantee of quality and environmental performance improvement in addition to providing organizations a more competitive position (Testa et al. 2014). The ISO 14001 is a voluntary standard with no legal requirements (complies with national or regional legislation). It focuses on management processes of the organization rather than on the specific environmental outcomes. It does not set a performance standard. It does not dictate absolute environmental performance requirements but instead serves as a framework for assisting organizations in developing their own EMSs. The ISO 14001 standard is flexible enough to be applied to any type and size of the organization.

Industries that undergo the certification of ISO 14001 will certainly have many advantages at the environmental, economic, and managerial levels (Campos 2012). Berry

and Rondinelli (2000) reported that since the implementation of EMS, industries began reducing toxic and ozone-depleting emissions, reducing material usages, reusing and recycling material that had been disposed as wastes, applying analysis to eliminate or reduce any negative environmental impacts from the productivity processes, and investing in other projects that reduce the environmental impacts of their operations. Several studies assert the positive association between environmental management practices such as ISO 14001 adoption and environmental performance (Molina-Azorín et al. 2009; Testa et al. 2015). The EMS can advance the systematic identification, implementation, and follow-up of environmental management practices (Granly and Welo 2014) and constitutes one of the most important elements of corporate sustainability and a value driver (Zobel 2013; De Giovanni and Zaccour 2014; Gotschol et al. 2014).

Given that EMS implementation and certification is progressively developing due to the market force, certified industries will have the opportunity to expand and access international markets. Also, the ISO 14001 certification serves as conformity reassurance for customers in such a way that it provides conformity through a third-party certification or verification. The ISO 14001 certification offers significant economic benefits to multinational adopting organizations, of which operational efficiency, worldwide recognition of product/brand, marketing advantages, enhanced competitiveness, and better waste management resulting in cost reduction (Curkovic et al. 2005; Studer et al. 2006). Although benefits of certification cannot be applied equally to all organizations or may not be valuable for some, there are potentially important financial, market, and trade advantages for some organizations, especially export-oriented ones. The ISO 14001 certification may be used as an approach to properly demonstrate environmental commitment, overcome trade barriers, and obtain the confidence of its stakeholders (Wu et al. 2007; Higgins et al. 2008).

Although the ISO 14001 EMS model is proposed to promote continual environmental improvement, the standard does not find definite requirements for environmental performance, other than a commitment to compliance with relevant regulations. The literature to date is equivocal regarding the relationship of ISO 14001 and environmental performance improvement. Many studies found that the implementation of ISO 14001 brings benefits on environmental and economic performances, whereas others did not notice any quantifiable or evident benefit (Iraldo 2009).

The reports of recent pharmaceutical industries in the UK and the USA indicate that they are taking remarkable steps into going green or adopting the green chemistry approach which minimizes the usage of hazardous and unnatural chemicals. For instance, the environmental management efforts of a leading pharmaceutical industry resulted in the reduction of toxic chemical release by 91 %, hazardous waste by 25 %, and non-hazardous waste by 48 %. It also reduced packaging material wastes by 12 % (Berry and Rondinelli 2000). Hillary (1999) examined the implementation of the ISO 14001 standard in the UK and identified that there are external and internal benefits. Internal benefits include the following: organizational benefits (improved work and safety conditions), individual benefits (increased employee awareness and motivation), and financial benefits (cost savings). External benefits include the following: communication benefits (enhanced public image), environmental benefits (enhanced environmental performance), and economic benefits (competitive advantages and increased number of customers).

In Lebanon, there are 12 industries that manufacture pharmaceuticals and biomedical products. Lebanese pharmaceutical exports are mainly destined to the Arab countries. Some Western countries import specific types of medications. The specific objectives of this research project are to

- Characterize the existing strategies used for responding to environmental risks in the Lebanese pharmaceutical industries
- Assess the industries' perception about environmental management practices, particularly the ISO 14001 EMS
- Identify the barriers and limitations regarding the implementation of an EMS
- Assess the drivers and incentives for implementing an EMS (ISO 14001)

Methodology

Recruitment and profile of the pharmaceutical industries

A total number of 12 pharmaceutical industries were identified according to the Order of Pharmacist in Lebanon. The 12 industries were contacted by phone

and/or email to get their approval to participate in the study. Geographically, the industries are located in North Lebanon, Bekaa, Mount Lebanon, and Beirut. A total of eight industries responded, representing approximately 70 % response rate. The industries constituted of the following:

- Four industries that formulate medications/drugs named I1–I4
- Two pharmaceutical industries that formulate intravenous serums named I5 and I6
- One pharmaceutical industry that formulates parapharmaceutical products named I7
- One pharmaceutical industry that formulates biomedical product equipments named I8

The four pharmaceutical industries that declined to participate in the study stated that negative environmental impacts are not part of their manufacturing processes. The eight interviewed industries market their products locally and regionally, primarily in Iraq, Kingdom of Saudi Arabia (KSA), Gulf, Syria, and Yemen. A summary of the profile of the industries is presented in Table 1.

I1 and I2 are considered as Lebanon's leading manufacturers of pharmaceutical products, as they engage in the production of a wide range of pharmaceutical compounds such as tablets, capsules, liquids, powders, solutions, dry syrup antibiotics, suspensions, creams, ointments, eye drops, and suppositories. I3 and I4 also deal with the production of pharmaceuticals such as solids, liquids, powders, tablets and sterile and nonsterile

Table 1 Summary of the industries' profile

| Industry | Year of establishment | Number of employees | Respondent position |
|----------|-----------------------|---------------------|---------------------------------|
| I1 | 1970 | 50 | Operational plant manager/owner |
| I2 | 1962 | 250 | Quality manager |
| I3 | 1968 | 196 | Quality manager |
| I4 | 1980 | 100 | Operational plant manager |
| I5 | 1999 | 32 | Operational plant manager |
| I6 | 1973 | 130 | Quality manager |
| I7 | 1993 | 100 | Quality manager |
| I8 | 1998 | 40 | Operational plant manager/owner |

formulation products needed for therapeutic purposes in order to be used particularly for problems with the respiratory and gastrointestinal systems. I5 and I6 are considered as the leading industries in Lebanon in manufacturing intravenous, dialysis solutions and powders, dialysis blood lines, PVC tube extrusions, and disposable medical devices. I7 is a para-pharmaceutical industry that manufactures a wide range of cosmetics. I8 manufactures disposable biomedical devices that are used during obstetrics mainly in hospitals.

Study design

The qualitative research method, in particular, the in-depth interview approach, was adopted in our study in order to examine and explore some of the concepts and facts in details as well as establish a comprehensive understanding of the interviewees' opinions or points of view (Crouch and McKenzie 2009). The aim of this approach is to collect data qualitatively, through a formulated open-ended interview guide, which will provide the respondent time and opportunity to answer freely. As a result, the interviewer may probe wherever necessary to gain the required data. The main advantage of using this method is that it allows the interviewer to clarify or explain the complex questions and further investigate the information needed (Millard 2011).

Data collection

An interview guide was formulated which included open-ended questions related to the objectives of the study. This guide helped focus the interview without resorting to fixed questions with specific wordings or specific answers. Any leading questions that could influence respondents' answers were carefully avoided or clarified during the interview. Table 2 shows the in-depth questions of the interview that were related to the study's objectives. A copy of the interview guide was sent to the industries ahead of time. The interviews were conducted in both English and Arabic, and all the data was documented by note taking. The interviews began with general straightforward questions regarding the industry and its manufacturing products. The second part of the interviews composed of controversial open-ended questions that were related to the objectives of the study.

Data analysis

During the data analysis, all the required notes were combined, documented, and organized. Then, and based on the stated objectives, appropriate and content analysis was performed to comprehensively evaluate and assess the respondents' transcripts. This type of approach ensures that all the scattered information is put together to achieve a complete review. Analyzing the data was performed using matrices and grids in order to organize and summarize the findings. To prevent the outcome from being subjective, data analysis was approached systematically. Furthermore, to support the findings of the study, direct quotations from the participants were used. The information that the industries provided was treated confidentially, and the names of the companies were not mentioned in this paper. Before carrying out the interview, the interviewees were informed that the name and data collected will remain anonymous and that all confidential and specific information gathered will only serve the analytical purposes of this project.

Results and discussion

Profile and perception

The interviewed pharmaceutical industries can be considered as SMEs, since they are almost all small-owned businesses. Furthermore, the greater part can be considered as exporters as they market their products locally and regionally. None of the interviewed pharmaceutical industries has an environmental department or employees that are responsible or devoted to deal with environmental issues. This outcome is expected, since environmental departments or positions mostly exist in international sister-joined organizations, unlike locally owned companies or industries that exist in Lebanon. The lack of environmental regulations may have also contributed to this issue.

Environmental impacts and initiatives of the pharmaceutical industries

Based on the industry production type and the raw materials consumed, each type of industry generates its own type of industrial wastes that greatly impacts the environment. The major environmental impacts that are

Table 2 Summary of the questions to be addressed linked to the objectives of the study

| Objectives | Related question |
|---|---|
| I. Characterize the existing strategies used to respond the environmental risks | <ul style="list-style-type: none"> • What are the perceived environmental impacts of your industry? • What are the initiatives taken to improve environmental performance? |
| II. Assess the industries’ perception about Environmental Management Practices particularly the ISO 14001 EMS | <ul style="list-style-type: none"> • What do you know about EMS in general and ISO 14001 in particular? • Why EMS should be implemented in your point of view? • What will be the advantages and disadvantages of the EMS if your industry adopts it? |
| III. Identify the barriers and limitations to implementing an EMS | <ul style="list-style-type: none"> • What do you think are the challenges that the industry will face in the implementation of an EMS? • How will your industry face all the challenges if it adopts an EMS? |
| IV. Assess the drivers and incentives for implementing an EMS | <ul style="list-style-type: none"> • What can motivate you to implement an EMS? • Who are the relevant governmental bodies, institutes, or organizations that would likely be more suitable to support your organization quest to acquire ISO 14001 EMS certification |

related to the manufacturing of pharmaceuticals include high levels of water consumption, wastewater generation, and energy consumption. Generated solid wastes, noise pollution, and air emissions may also raise concerns for a number of pharmaceutical industries. A summary of the reported environmental impacts is presented in Table 3.

Energy consumption is a major environmental impact in all the interviewed industries. The use of generators to supply the industry with the needed power as a result of the continuous electricity rationing in the country increases the consumption of fuels. There are no adopted strategies for decreasing the energy consumption or reduce emissions, except in I2, which is consuming green diesel because as the Quality Manager stated, “it is the purest diesel found.”

As for water consumption, I1–I7 reported that they consume vast amounts of water daily during the manufacturing process as well as during the cleaning

Table 3 Environmental impacts of the pharmaceutical industries

| Environmental impacts | Industry | | | | |
|----------------------------|----------|----|----|----|----|
| | I1–I4 | I5 | I6 | I7 | I8 |
| Water consumption | x | x | x | x | x |
| Wastewater generation | x | x | x | x | x |
| Energy consumption | x | x | x | x | x |
| Noise pollution | x | x | x | x | |
| Air emissions (dust, etc.) | x | x | x | x | |
| Solid waste generation | x | x | x | x | x |

of equipments, machines, and floors. Regarding I8, water consumption is mainly related to the process of soaking pieces of the products with certain kinds of acids. Wastewaters generated from the pharmaceutical production processes of I1–I4 are always high in biochemical oxygen demand (BOD) and chemical oxygen demand (COD) due to the usage of chemical reagents. Moreover, they contain detergents and total suspended particles with high pH levels. According to I7, their generated wastewater contains bacteria and sometimes has high pH levels. With regard to I5 and I6, their wastewater has nontoxic wastes with very low BOD, COD, and pH levels since the components of the manufacturing serums are originally found in the environment. I8 reported that its wastewater is 87 % acidic.

None of the interviewed industries reported a strategy to reduce water consumption. With regard to wastewater, I1, I4, I5, I6, and I7 discharge the generated wastewater in the local sewers without treatment. I8 has a cesspool for the storage of wastewater which is later taken by a contracted company specialized in dealing with acids. I3 and I2 treat the generated wastewater with chlorine before discharge. As quoted by one of the interviewed managers:

Wastewater is discharged in an underground neutralization pit to be treated with chorine, since it is a cheap commonly used disinfectant. It is then discharged into the local sewers.

I2 and I3 dispose their solid waste materials (unused/rejected products or raw materials) in a “storeroom”

located inside the industry. Managers reported that they could not find feasible solutions for these products. Moreover, they cooperate with a cardboard recycling company to collect waste packaging materials such as boxes, leaflets, and papers. The other industries dispose their solid wastes with the municipal solid waste stream.

The utilization of chemical reagents and solvents in the manufacturing processes in almost all the interviewed industries results in VOC emissions. The current initiative applied to prevent indoor air pollution is the use of the heating, ventilation, and air-conditioning (HVAC) system with high-efficiency particulate air filters (HEPAs). The filters are used in the production zone, the weighing zone, and the laboratories. I4 reported the use of fuel filters for the generators to reduce air pollutants. None of the interviewed industries stated any strategy to reduce noise pollution.

Although the pharmaceutical industries listed their environmental impacts, the majority believe that their environmental issues are negligible and are not considered as a major impact on the environment relative to other types of manufacturing industries. This finding is consistent with the findings of Berry and Rondinelli (2000) who also indicated that pharmaceutical industries are not considered as “dirty” industries; however, they should control their environmental pollution due to their expansion. Moreover, even if the managers or owners of some of pharmaceutical industries (I7, I8) are more aware about the environmental issues and the ISO 14001 standard, they consider their current environmental strategies appropriate and hence are unwilling to introduce changes or modifications. According to a study conducted by Ortiz et al. (2013), small and medium enterprises (SMEs) are often unaware of their impact on the environment and lack the knowledge and expertise needed to implement and manage EMS. Several studies reported that since SMEs differ from large organizations with respect to financial and human resources as well as business models, the existing tools to promote sustainable practices are not customized to support them (Jenkins 2006; Bos-Brouwers 2010; Loucks et al. 2010; Granly and Welo 2014).

Furthermore, the current environmental management practices of the Lebanese pharmaceutical industries are not all useful or effective. Even though the chlorination of wastewater which is the case of I2 and I3 is easy to use and efficient, it has the potential to increase the toxicity of the discharged wastewater thus increasing

its harmful impacts on the environment. The usage of chlorine should typically act as final step in wastewater treatment. This result is expected due to the lack of technical knowledge and know-how particularly with the absence of an environmental specialist in the industry.

There are few environmental strategies that can be considered as relatively practical such as the consumption of green diesel (I2) and the utilization of HVAC systems (I1–I8). Green diesel does not create a black smoke which occurs when using the normal diesel for running an engine and reduces air emissions. Furthermore, it can be used on any type of engine without modifications (Holmgren et al. 2007). The installation of an HVAC system is mandatory in order to comply with good manufacturing practices (GMPs) or ISO 9000.

Industries' perception about EMS

I7, I4, and I8 reported that they are familiar with ISO 14001 EMS and realize that it is a voluntary standard that requires firms to identify and control their environmental impacts. The other interviewed industries either have no idea about the ISO 14001 EMS or are less familiar with it. When asked why they believe that the EMS should be implemented and whether their organization would consider adopting the ISO 14001 standard in the near future, all industries reported that unmanaged environmental issues may damage the surroundings and result in the loss of confidence among neighbors and shareholders. In addition, they agree that environmental issues should be handled properly, as quoted by the operational plant manager of I8 who stated that

Environmental issues must be handled based on certain guidelines that every individual in the organization is familiar with, in order to achieve a better environment.

Moreover, the quality manager of I2 explained

A system should be implemented to manage the unused/rejected products, materials, and emissions properly without disturbing or affecting the environment.

All interviewed industries, with the exception of I4, do not consider implementing ISO 14001 since they

consider it the least in their priority list. The quality manager of I7 said

In a developing country like Lebanon no one cares about the environment, so why should we?

The majority of the industries agree that ISO 14001 certification would bring no added value to their competitive market. They also claimed that none of their suppliers, business partners, or customers ever requested from them to acquire the standard. Moreover, they reported that their current environmental strategy is not a barrier for exporting their products to the regional markets. The fact that ISO 14001 is a voluntary standard is an additional reason for not adopting the EMS. These results are consistent with the findings of Shall (2000) who reported that Lebanese ISO 9001-certified industries are least interested in taking the next steps for pursuing the ISO 14001 certification. Considering that they are currently restructuring and redesigning their industrial plant layout, I4 was the only industry that reported that ISO 14001 standard is considered to be among their priorities in the near future because they wish to set an example or model for other industries to follow.

During the meetings and interviews with most of the industries, it was noticed that there is a misconception between EMS, quality management practices, and GMPs. In Lebanon, firms that fail to comply with GMP guidelines may face serious consequences such as fines and withdrawal of products. The GMP regulations mainly require a quality approach to manufacturing (quality and safety measures), enabling companies to minimize or eliminate instances of contamination, mix-ups, and errors. As such, managers consider that the GMP includes all the needed requirements. The reason behind this misconception is mainly the low level or lack of environmental knowledge. The quality in the pharmaceutical industry has become a significant topic particularly after the launching of the FDA current good manufacturing practices (cGMP) for the 21st century (Woodcock 2004). As such, industries are required to comply with the cGMP which requires them to employ systems and technologies that are up-to-date in order to comply with the regulations. The cGMP has become a precondition for exporting health care products for certain countries.

Drivers to implementing ISO 14001

The drivers to implementing ISO 14001 standard as stated by the interviewed industries are summarized in Table 4. Our findings are consistent with the findings reported by many authors (Florida and Davison 2001; Fryxell and Szeto 2002; Prajogo et al. 2012), who stated that the major motive for the EMS adoption was mainly improving environmental performance. Furthermore, our findings are consistent with the results of Petroni (2001) who indicated that adopting the ISO 14001 improves the company's image. This outcome is expected, since ISO 14001 implementation and certification will lead to reduced environmental liabilities and risks associated with environmental compliance; hence, it improves the company's image as well as provides a green corporate impression.

"Overcoming international market trade" is perceived as another driver for acquiring the ISO 14001 standard. This finding is consistent with the findings of Fryxell and Szeto (2002) as well as Zutshi and Sohal (2004), who reported that the ISO 14001 certification is adopted among industries to overcome international market barrier. Additionally, according to Gbedemah (2004), the setting up of the ISO 14001 standard and compliance to it will help industries overcome international trade barriers. However, some industries (I5–I7) do not consider this as a motive, since adopting the ISO 14001 standard is not a compulsory criteria for accessing international markets. The various motives for adopting an EMS vary among the different studies including but are not limited to ensure regulatory compliance, enhance the firm's reputation, and ensure environmental performance (McGuire 2014).

Our results contradict the findings of Morrow and Roddinelli (2002) who report that the reduction in operational costs is considered as a major driver. This indicates that a number of the industries/managers are not convinced or do not recognize the financial/economical benefits that could result from acquiring the ISO 14001 standard. This can be linked back to the lack of knowledge among the managers/owners regarding this standard, which, in turn, is caused by governments/regulators and policy makers failing to promote the EMS.

An interesting finding that was revealed during the discussions is that "meeting customer demands" or "used as market tool" were not perceived as motives for acquiring the ISO 14001 EMS among all the

Table 4 Drivers to implementing ISO 14001 as reported by the pharmaceutical Industries

| Drivers | Industry | | | | | | | |
|-------------------------------------|----------|----|----|----|----|----|----|----|
| | I1 | I2 | I3 | I4 | I5 | I6 | I7 | I8 |
| Enhance environmental performance | x | x | x | x | x | x | | x |
| Enhance the company's image | x | x | x | x | x | x | x | x |
| Overcome international market trade | x | x | x | x | | | | x |
| Reduce operational cost | | | | x | | | x | x |

interviewed pharmaceutical industries. This may be attributed to the fact that none of their regional or local customers and suppliers requires them to acquire the ISO 14001 standard. Thus, the Lebanese pharmaceutical industries are significantly less influenced by stakeholders or customers concerned in the firm's environmental performance. This outcome is expected given that the local customer awareness of environmental problems in Lebanon is still deficient. Considering that they are pharmaceutical industries that deal with human health demands, they are more concerned with the quality of the product.

Challenges and barriers to implementing ISO 14001

The major perceived challenges reported by all of the interviewed industries regarding the implementation of the ISO 14001 standard are as follows:

- Encouraging employees to actively participate in the implementation and the maintenance of the EMS
- Identifying all the environmental impacts and taking the most effective actions needed for monitoring and preventing them
- Finding the most effective/suitable measures and techniques
- Dealing with the government in order to obtain the needed information

All industries reported that the lack of governmental support; not being a legal requirement; unclear benefits; lack of knowledge, resources, and time; and the fact that ISO 14001 is not required neither for export nor by customers are major barriers for implementing the EMS. Indeed, the lack of adequate industrial zones, proper infrastructure, waste management facilities, and financial incentives makes it difficult for the Lebanese industries to acquire or comply with the standard

(Massoud et al. 2010). As such, they perceived the disadvantages of implementing the standard as increasing employee workload, top management commitment in addition to implementation, and periodic audit cost. Thus, it can be deduced from the attitude of the managers/owners that the pharmaceutical industries are not willing or likely to acquire the voluntary ISO 14001 standard as long as they are not exposed to any regulatory pressure or external demand.

According to Bansal and Bonger (2002) and Prajogo et al. (2012), the cost of implementing ISO 14001 EMS is considered significant, since major changes may be required in the manufacturing process and continuous environmental monitoring is needed in order to comply with the standard. As such, more operating expenses are necessary for the implementation, a possible burden for the organization. In our study, the "cost of certification" is not considered as a major barrier for the pharmaceutical industries. The managers/owners are not convinced with the beneficial outcomes of the standard and are neither willing nor interested in investing in any nonprofitable or nonproductive areas such as environmental risk reduction. As stated by one of the industries

Financial returns when dealing with environmental issues are not easily attained.

Supporting organizations and incentives

The organizations perceived to support the Lebanese pharmaceutical industries' quest to adopt the ISO 14001 EMS standard and face the challenges are as follows:

- The Ministry of Industry (MOI) and the Ministry of Environment (MOE)
- Certification bodies
- Foreign consultancy firms

The common incentives for implementing ISO 14001 standard as reported by all interviewed industries are as follows:

- Governmental loans
- Establishment and enforcement of regulations and policies
- Enhancement of knowledge, training, and technical skills
- Tax exemption for certified companies
- Governmental agreements with the industries

The major obstacles in implementing the above-recommended incentives are mostly related to the overlapping and interrelated responsibilities of concerned authorities who are not able to reach a consensus on any proposed financial incentive. Since they are considered as being able to play a direct role in environmental and industrial issues, governmental bodies such as the MOE and the MOI are predicted to be among the major organizations that support the Lebanese pharmaceutical industries in their quest to acquire the ISO 14001 standard. Foreign consultant firms can also be supporting organizations since without any expert advice, organizations are unable to start the implementation due to the difficulties and complexity of the ISO 14001 standard.

Conclusions

The majority of the pharmaceutical industries consider that their environmental issues are negligible in comparison to other types of manufacturing industries. Moreover, there exists a common misconception between environmental management practices and quality management practices. Lebanese pharmaceutical industries are more concerned with quality and safety issues with the most adopted international standard among the industries is the ISO 9001 quality management system followed by the GMPs. Lebanese pharmaceutical industries are not willing or likely to acquire the voluntary ISO 14001 standard if they are not exposed to any regulatory pressure or external demand. The lack of expertise and knowledge about environmental issues, in general, resulted in beneficial uncertainty and skepticism regarding the implementation of the ISO 14001 standard.

The lack of proper waste management infrastructure, followed by inadequate industrial zones, lack of political will, and instability, is considered to be among the

obstacles/challenges, which make it complicated for the Lebanese pharmaceutical industries to acquire or comply with the standard in order to improve their environmental performance. Furthermore, lack of know-how and lack of government collaboration in promoting the ISO 14001 EMS and shortages in the needed technical expertise skills and professional knowledge make the Lebanese pharmaceutical industries face many challenges in the implementation of this standard.

Improving environmental performance, enhancing the company's image, and overcoming trade barrier are the most significant drivers for adopting the ISO 14001. With respect to the market share, the ISO 14001 EMS certification, if adopted, is to be used as a useful tool that facilitates pharmaceutical industries access to the international market and not as a market tool that increases their market share in the local/regional market. The most significant barriers delaying the adoption of the ISO 14001 standard is the lack of governmental support and incentives, not being legally required and demanded by customers. The Lebanese government should promote voluntary EMS concepts among the industrial sector in Lebanon and support firms to adopt the ISO 14001. Regulatory frameworks need to be enforced and joined with financial incentives (such as tax exemption) in order to encourage the Lebanese pharmaceutical industries to implement the EMS.

References

- Bansal, P., & Bonger, W. (2002). Deciding on ISO 14001: economics, institutions, and context. *Long Range Planning Journal*, 35, 269–290.
- Berry, M., & Rondinelli, D. (2000). Environmental management in the pharmaceutical industry: integrating corporate responsibility and business strategy. *Environmental Quality Management*, 9(3), 21–35.
- Boltic, Z., Ruzic, N., Jovanovic, M., Savic, M., Jovanovic, J., & Petrovic, S. (2013). Cleaner production aspects of tablet coating process in pharmaceutical industry: problem of VOCs emission. *Journal of Cleaner Production*, 44, 123–132.
- Bos-Brouwers, H. E. J. (2010). Corporate sustainability and innovation in SMEs: evidence of themes and activities in practice. *Business Strategy and the Environment*, 19(7), 417–435.
- Boxall, A. (2004). The environmental side effects of medication. *European Molecular Biology Organization (EMBO)*, 5(12), 1110–1116.
- Brunet, R., Guillén-Gosálbez, G., & Jiménez, L. (2014). Combined simulation-optimization methodology to reduce the environmental impact of pharmaceutical processes: application to the production of penicillin V. *Journal of Cleaner Production*, 76, 55–63.

- Campos, L. (2012). Environmental management systems EMS for small companies: a study in Southern Brazil. *Journal of Cleaner Production*, 32, 141–148.
- Crouch, M., & McKenzie, H. (2009). The logic of small samples in interview-based qualitative research. *Social Science Information*, 45(4), 483–499.
- Curkovic, S., Sroufe, R., & Melynyk, S. (2005). Identifying the factors which affect the decision to attain ISO 14000. *Journal of Energy*, 30, 1387–1407.
- De Giovanni, P., & Zaccour, G. (2014). A two-period model of closed-loop supply chain. *European Journal of Operational Research*, 232(1), 22–40.
- Ferenhof, H. A., Vignochi, L., Selig, P. M., Lezana, A. G., & Campos, L. A. S. (2014). Environmental management systems in small and medium-sized enterprises: an analysis and systematic review. *Journal of Cleaner Production*, 74, 44–53.
- Florida, R., & Davison, D. (2001). Why do firms adopt advanced environmental practices, and do they make difference? Thesis, Carnegie Mellon University.
- Fryxell, G., & Szeto, A. (2002). The influence of motivations for seeking ISO 14001 certification: an empirical study of ISO 14001 certified facilities in Hong Kong. *Journal of Environmental Management*, 65, 223–238.
- Gbedemah, F. (2004). Environmental Management System (ISO 14001) Certification in manufacturing companies in Ghana: prospects and challenges. Thesis, Lund University, Sweden.
- Gotschol, A., De Giovanni, P., & Vinzi, V. E. (2014). Is environmental management an economically sustainable business? *Journal of Environmental Management*, 144, 73–82.
- Granly, B., & Welo, T. (2014). EMS and sustainability: experiences with ISO 14001 and Eco-Lighthouse in Norwegian metal processing SMEs. *Journal of Cleaner Production*, 64, 194–204.
- Higgins, V., Dibden, J., & Cocklin, C. (2008). Building alternative agri-food networks: certification, embeddedness and agri-environmental governance. *Journal of Rural Studies*, 24, 15–27.
- Hillary, R. (1999). Evaluation of study reports on the barriers, opportunities and drivers for small and medium sized enterprises in the adoption of environmental management systems. London.
- Holmgren, J., Gosling, C., Marinangeli, R., Marker, T. (2007). A new development in renewable fuels: green diesel. www.uop.com.
- Iraldo, F. Testa, F., Frey, M. (2009) Is an environmental management system able to influence environmental and competitive? The case of the eco-management and audit scheme (EMAS) in the European Union. *Journal of Cleaner Production* 17: 1444–1452.
- Jenkins, H. (2006). Small business champions for corporate social responsibility. *Journal of Business Ethics*, 67(3), 241–256.
- Liu, J., & Wong, M. (2013). Pharmaceuticals and personal care products (PPCPs): a review on environmental contamination in China. *Environment International*, 59, 208–224.
- Loucks, E. S., Martens, M. L., & Cho, C. H. (2010). Engaging small- and medium-sized businesses in sustainability. *Sustainability Accounting, Management and Policy Journal*, 1(2), 178–200.
- Massoud, M. A., Fayad, R., Kamlah, R., & El-Fadel, M. (2010). Environmental Management System (ISO 14001) certification in developing countries: challenges and implementation strategies. *Environmental Science and Technology*, 44(6), 1884–1887.
- McGuire, W. (2014). The effect of ISO 14001 on environmental regulatory compliance in China. *Ecological Economics*, 105, 254–264.
- Millard, D. (2011). Management learning and the greening of SMEs: moving beyond problem-solving. *German Journal of Research in Human Resource Management*, 25, 178–195.
- Molina-Azorin, J. F., Tari, J. J., Claver-Cortés, E., & López-Gamero, M. D. (2009). Quality management, environmental management and firm performance: a review of empirical studies and issues of integration. *International Journal of Management Reviews*, 11, 197–222.
- Morrow, D., & Roddinelli, D. (2002). Adopting environmental management systems: motivations and results of ISO 14001 and EMAS certification. *European Management Journal*, 20, 159–171.
- Ortiz, A., Henry, I., & Monroy, C. R. (2013). Gestión Ambiental em Pymes Industrials (Environmental Management in Industrials SMEs). *Interciencia*, 38(3), 179–185.
- Petroni, A. (2001). Developing a methodology for analysis of benefits and shortcomings of ISO 14001 registration: lessons from experience of a large machinery manufacturer. *Journal of Cleaner Production*, 9, 351–364.
- Prajogo, D., Tang, A., & Lai, K. (2012). Do firms get what they want from ISO 14001 Adoption? *Journal of Cleaner Production*, 33, 117–126.
- Ramasamy, S.V., Titchener-Hooker, N., Lettieri, P. (2014). Life cycle assessment as a tool to support decision making in the biopharmaceutical industry: considerations and challenges. *Food and Bioproducts Processing*. In press.
- Shall, M. (2000) Quality Management Beyond ISO 9000:2000: a survey of certified companies in Lebanon. Thesis, American University of Beirut, Lebanon.
- Shukla, A., & Gottschalk, U. (2013). Single-use disposable technologies for biopharmaceutical manufacturing. *Trends in Biotechnology*, 31(3), 147–154.
- Slater, C. S., Savelski, M. J., Hesketh, R. P., Frey, E. (2006). The selection and reduction of organic solvents in pharmaceutical manufacture. In: Paper 17 Presented at the American Chemical Society 10th Green Chemistry and Engineering Conference, Washington.
- Studer, S., Welford, R., & Hills, P. (2006). Engaging Hong Kong businesses in environmental change: drivers and barriers. *Business Strategy and the Environment*, 15, 416–431.
- Testa, F., Rizzi, F., Daddi, T., Gusmerotti, N. M., Frey, M., & Iraldo, F. (2014). EMAS and ISO 14001: the differences in effectively improving environmental performance. *Journal of Cleaner Production*, 68, 165–173.
- Testa, F., Annunziata, E., Iraldo, F., Frey, M. (2015). Drawbacks and opportunities of green public procurement: an effective tool for sustainable production. *Journal of Cleaner Production*. In press.
- Woodcock, J. (2004). The concept of pharmaceutical quality. *American Pharmaceutical Review*, 7(60), 10–15.
- Wu, S., Chu, P., & Liu, T. (2007). Determinants of a firm's ISO 14001 certification and empirical study of Taiwan. *Pacific Economic Review*, 12, 467–487.
- Zobel, T. (2013). ISO 14001 Certification in manufacturing firms: a tool for those in need or an indication of greenness? *Journal of Cleaner Production*, 43, 37–44.
- Zutshi, A., & Sohal, A. (2004). Adoption and maintenance of environmental management systems: critical success factors. *Management of Environmental Quality: International Journal*, 15(4), 399–419.