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Environmental Management Practices in the Lebanese Pharmaceutical Industries: Drivers, Barriers and Incentives

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A project submitted in partial fulfillment of the requirements for the degree of Master of Science in Environmental Sciences to the Interfaculty Graduate Environmental Sciences Program (Environmental Health) of the Faculty of Health Sciences at the American University of Beirut

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AN ABSTRACT OF THE PROJECT OF

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Although there are many types of environmental management practices or initiatives that reduce environmental risks and improve environmental performance, they showed insignificant results compared to environmental management systems (EMS). The ISO 14001 standard (EMS) is a voluntary initiative that provides guidance and assistance for organizations by helping them develop their own systematic and formal environmental management system, which focuses on management processes and promotes continuous environmental improvement. Even though the ISO 14001 standard has become more acclaimed and globally accepted, its adoption rate in Lebanon is still very low compared to that of other countries. Furthermore, little is known about the applicability of the standard regarding the pharmaceutical sector, since there is only one certified pharmaceutical industry in Lebanon.

This research project attempted to provide a clear understanding of the Lebanese pharmaceutical industries' current environmental strategies, priorities, perceptions, drivers, barriers, and incentives regarding the implementation of the voluntary EMS ISO 14001 standard. An in-depth interview guide was formulated and interviews were conducted with SMEs pharmaceutical industries. The findings revealed a significant lack of knowledge about the standard among the pharmaceutical industries. The main perceived drivers for adopting the standard are for the sake of enhancing the environmental performance, improving the companies' image, and overcoming international trade. The main perceived barriers for acquiring the standard are the fact that there is a lack of governmental support (and incentives) and the fact that this standard is not being legally required or enforced by the government. Governmental bodies and certification bodies are the main supporting organizations when it comes to implementing the standard. The main problem is that adopting the EMS ISO 14001 standard is not perceived as being a priority for the Lebanese pharmaceutical industries. The majority of the Lebanese pharmaceutical industries are neither interested nor willing to adopt the ISO 14001 standard since they acquired the ISO 9001 standard, GMP and are – at present – obtaining the current Good Manufacturing Practices (cGMP), which, according to them, makes them professional enough. Hence, the EMS promoters should play an important role in illustrating or elaborating on the importance of ISO 14001 standard. Furthermore, the Lebanese government should also promote the voluntary EMS concepts among the industrial sector in Lebanon and support firms (through incentives, loans…etc) to adopt ISO 14001 standard.

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CHAPTER 1

INTRODUCTION

1.1 Introduction

The progressively increasing pressure to reduce environmental risks and to improve environmental performance led many organizations to adopt preventive approaches such as environmental management systems (EMS) and to conduct environmental audits. An EMS is a management process that requires firms to identify and control their environmental impacts (Bansal and Hunter, 2003). Considering that the export market share is becoming more complex and competitive, many kinds of international standards and strict environmental regulations are required. For the Lebanese pharmaceutical industries to be able to enter and compete in the international market share they are advised to implement or integrate environmental standards into their industrial operations and systems. Even though reducing environmental risks is considered as an important issue, managers have a different point of view. They always argue that environmental strategies are detrimental to the production efficiency, cost control, and managerial goals of the industries' profit (Gallarotti, 1995). In other words, organizations are not ready to invest in any non-profitable or non-productive sector such as environmental risk reduction.

Based on the need that was expressed by the United Nations Conference on Environment and Development (UNCED), the International Organization for Standardization (ISO) developed the ISO 14000 series environmental management

standards. The ISO 14001 standard is part of the ISO 14000 series and sets the criteria for an environmental management system (Bansal and Bonger, 2002; Fryxell and Szeto, 2002). The ISO 14001 is a set of guidelines that can help an organization: (1) strengthen its environmental policy; (2) identify its environmental aspects, goals, and objectives; (3) implement specific programs necessary for achieving these environmental goals; (4) monitor and evaluate its effectiveness to correct any deficiencies found; and lastly (5) review its management program in order to support continuous improvement (Morrow and Rondinelli, 2002). It is a voluntary process that has no legal requirements and does not set performance standards (Massoud et al., 2010). The ISO 14001 can be integrated with other management functions. As a result, it can help companies meet their environmental and economic goals. It aims at assisting industries to continuously improve their environmental performance. There are many proposed reasons regarding why firms should seek to implement and acquire the ISO 14001 certification standard. These reasons include but are not limited to being able to: respond to customer pressures and access the markets, improve regulatory compliance, increase market share, improve reputations and reduce cost from improved efficiencies, enhance risk management practices and improve the overall work climate (Fryxell and Szeto, 2002).

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 must not be prohibited. Thus, pharmaceutical industries should start dealing more efficiently with environmental issues. Pharmaceutical industries consist of businesses that are involved in formulating, manufacturing, and processing medicinal chemicals and pharmaceutical products.

Environmental impacts vary from material inputs to the manufacturing processes, to the pollution of soil, air, and water resources (Berry et al., 2000).

In Lebanon, pharmaceutical industries are operating at low production levels with respect to the available production capacities. There are twelve industries that manufacture pharmaceuticals and biomedical products and the sector is generally characterized with lack of quality control, weak consumer protection, high health costs and lack of statistics and transparency. Lebanese pharmaceutical exports mainly destined to Arab countries. Some Western countries import specific types of medications. Trade liberalization initially focused on the elimination of trade barriers such as custom duties, quotas, and import taxes. However, as trade liberalization advanced, non-tariff barriers such as protecting the environment, human health and safety were emerging as reasons for limiting imports.

The proactive environmental management practices of certain leading international pharmaceutical companies showed positive results. The progress was assessed based on resource conservation and waste reduction, and also based on the considerable reductions in hazardous emissions. Progress was evidenced in many ways such as: in the reduction of toxic and ozone-depleting emissions, in the reduction of material usage, in the reusing and recycling material that had been disposed as wastes, and in the application of the analysis that was needed for eliminating or reducing any negative environmental effects caused by the production processes (Berry and Rondinelli, 2000). Industries that do not adopt international standards can rapidly loose competitive advantages with other industries. Thus, pharmaceutical industries are recommended to adopt environmental management systems/practices in order to manage these environmental challenges and reduce all kinds of risk. Or at the very least,

restructure their industries in such a way that they reduce the negative environmental impacts, to the best of their capabilities (Moutchnik, 2003).

Since ISO 14001 standard is voluntary and not legally required, its adoption rate in the developing countries like Lebanon is very slow compared to that of other developed countries. Nowadays, due to the increasing environmental impacts of the industries and the advanced restriction on trade liberalization with other countries, adopting an EMS as a framework for integrating environmental protection policies and programs should be encouraged.

1.2 Research Objectives

The specific objectives of this project are to:

I. I. Know the existing strategies used for responding to environmental risks in the Lebanese pharmaceutical industries.

II. Understand the industries perception about Environmental Management practices, particularly the ISO 14001 EMS.

III. Assess the barriers and limitations regarding the implementation of an EMS.

IV. Understand the drivers and incentives for implementing an EMS (ISO 14001).

1.3 Research Significance:

This research helps in providing a clear understanding of the Lebanese pharmaceutical industries' priorities, perceptions, and barriers regarding the implementation of the EMS ISO 14001 standard. The discussions may help suggest more applicable strategies necessary for developing countries like Lebanon. Furthermore, policy makers may benefit from the findings in order to recognize the

motivations that might encourage the Lebanese pharmaceutical industries to adopt, implement, and certify to the ISO 14001 standard.

CHAPTER 2

LITERATURE REVIEW

2.1 Pharmaceutical Industries and Environmental Impacts

As global environmental awareness developed and trade liberalization increased, more difficulties and challenges were linked to non-tariff barriers such as trading restrictions or limitations between countries. These specified regulations and thus, limitations were established to protect both the environment and human health. The increase in trade liberalization led to a greater competition between industries resulting in more environmental degradation and more consumption of renewable and non-renewable natural resources (Matouq, 2000; Mohammad, 2001).

International trade liberalization and the global economy within the developed countries facilitated the possibility that various types of industries could penetrate or break through the market worldwide without any significant barriers (WTO, 1999). Nowadays, due to the rapid expansion of industries and their economic growth in the developed countries, natural resources that are unable to be restored by nature are being consumed with very high rates leaving behind high amounts of residues that cannot be absorbed (Hart, 1997; Shirvastava, 1995a). In order to guarantee the availability and accessibility of natural resources for the upcoming generation, a necessary change is

required. Industries are requested to play an important role in the process of achieving a better balance with nature, hence helping obtain a better environment.

Although Pharmaceutical industries are not considered as “dirty” compared to other industries, they certainly face new challenges in controlling and preventing environmental pollution as they expand (Berry et al., 2000). Some studies (Berry and Rondinelli, 2000) show that pharmaceutical industries are growing worldwide at approximately 8 % per year and that they are expected to grow more rapidly in the future. Rondinelli (2000) indicated that as pharmaceutical industries expand and merge globally, the increased visibility of multinational pharmaceutical companies and their expanding size and output will require them to deal with environmental problems more effectively and efficiently. Thus, international leading pharmaceutical industries are rapidly moving towards integrating proactive EMS into their overall business strategies. Leading pharmaceutical industries can now recognize their social responsibilities towards their employees, the community in which they are located, as well as their customers and stakeholders. In addition, they can now own up to their responsibility of eliminating or minimizing environmental impacts in their production processes. Some leading firms have already started to include clean manufacturing practices and pollution prevention means in their operations and processes through conducting product life cycle analysis in order to minimize environmental impacts and reduce waste (Rondinelli et al., 2000).

Pharmaceutical industries consist of businesses that are involved in formulating, manufacturing, grinding, and processing medicinal chemicals and pharmaceutical products. Their finished products are sold worldwide in different dosage forms such as ointments, capsules, tablets, solutions, powders, and suspensions.

In the production of pharmaceutical products, a chemical synthesis process is carried out which includes: reaction, purification, separation, and drying. This process requires the usage of catalysts, intermediates, solvents, and reactants and results in the production of residual waste, air emissions, and wastewater that will produce residual waste, air emissions and wastewater.

Pharmaceutical production processes generate wastewater that is capable of polluting streams, rivers, and ground waters if not properly managed. Wastewater that is generated from the chemical synthesis is produced from equipment cleaning, pumps, solvents, catalysts, and reactants. The generated wastewater is high in chemical oxygen demand (COD), biochemical oxygen demand (BOD), and suspended solids with high pH levels (Berry et al, 2000). Moreover, the processes of purification, separation, and drying are known to produce wastewater pollutants, which are generated from equipment cleaning wash waters, leaks, used solvents, and spills. Manufacturing pharmaceutical products produces residual wastes from unused raw materials, waste filters, rejected tablets and capsules from drug formulation processes, reactor bottom wastes, waste packaging, and residues from fermentation. The Environmental Protection Agency (USEPA) in the U.S. reports that 177 million pounds of pollutants are released form pharmaceutical industries of which 57% scatter into air, 17 % dissolve to surface waters and 25% dissolve underground (WTO, 1999).

Two of the important air pollutants emitted are the VOC emissions and the fugitive emissions which are believed to cause health problems. The VOC emissions are generated from the reactor vents, non-filtering systems, acid gases and the handling of materials. Fugitive emissions are emissions that originate from pumps, valves, solvent vapors, and purification tanks. Particulate matter, odiferous gasses and extraction

solvent vapors are emitted from fermentation processes. Extraction of natural products from plants, animal tissues, and roots with the usage of solvents such as phenol, ammonia, chloroform and toluene can also lead to the release of vapors (Berry et al, 2000).

Even though safety and toxicological tests are continuously carried out on pharmaceuticals in order to investigate and examine their side effects on humans and animals, the possible environmental impacts during their manufacturing - as well as the effects they could have on the environment - are not well-understood (Boxal. A.., 2004). Various pharmaceutical compounds are known to affect the organisms in the environment since they comprise different biological compounds. Furthermore, the pharmaceutical broken-down products are known to have unexpected impacts on the environment. In 1970, pharmaceuticals were first recognized or identified as potential environmental contaminants. This is because once pharmaceuticals are released into the environment; they are automatically distributed and transported to the water, air, soil or sediment. A U.S geological study in 2002 detected the presence of organic wastewater contaminants which showed the presence of pharmaceuticals in soils, stream waters, ground waters, stream sediments, and surface waters (Kolphin et al , 2002). The continuous improvement of analytical capabilities and the new available assessment techniques have detected a broader range of pharmaceutical classes in the environment such as hormones, steroids, antibiotics, anti-depressants, and psychoactive drugs (Hirsch et al , 1999). Even though pharmaceuticals have existed for a very long period of time in the environment, researches have only recently tried to determine their quantity. Pharmaceuticals enter the environment in many ways. They can be released after being consumed, discarded (after being unused or collected residuals in

packaging), or released during manufacturing and handling. Typically, the pharmaceuticals' pathway to the environment is mainly through waste stream: domestic solid wastes (landfill leachate), domestic wastewaters (waste water treatment plants or septic systems), industrial discharges (hospitals and manufacturing facilities), and animal agricultures (aquaculture facilities or food production facilities). If pharmaceuticals are discharged to the sewer, it is generally known that they undergo treatment in a wastewater treatment plant. Irrespective of the level of wastewater treatment, pharmaceutical compounds cannot be effectively eliminated. Thus, the observed presence of pharmaceuticals in the environment has encouraged and prompted public interest regarding the potential contamination of drinking water which showed the presence of as well as its adverse ecological effects (Buxton et al, 2005). Moreover, public awareness has helped shed light on the various ways that medications are disposed and handled. It has also helped reveal how the industries deal with waste treatment technologies and how they apply effective management practices necessary for eliminating pharmaceuticals or other organic chemicals from ground waters, surface waters, and liquid and solid wastes. Developed countries and concerned non-governmental organizations are struggling to eliminate or prevent pharmaceuticals in both solid wastes and wastewaters. Although experts and community members remain slightly concerned about the environmental aspects of incinerators, they are found to be the best technique that could be used for the destruction of all unwanted or disposed pharmaceuticals Incinerators are preferred since they can destroy wastes by using high temperatures, thus reducing the waste volume by 95-96% and the solid mass of the original waste by 80-85% (Barnes et al, 2004).

2.2 Environmental Initiatives

2.2.1. Sustainability Initiatives

Environmental sustainability has become a critical focus in industrial activities. All types of organizations are undergoing pressure in order to manage and improve their environmental performance. In response to the environmental impacts, some developed countries tried to adopt regulations like tradable pollution permits and environmental taxes but studies revealed that they yielded insignificant results (WRI, 2001). Therefore, in an attempt to help and encourage corporations to deal with their environmental issues, several national and regional environmental regulations/initiatives and procedures were issued by international organizations or by concerned governments.

Voluntary sustainable initiatives require that the pharmaceutical industries: (1) include principles and guidelines for their manufacturing processes; (2) share practical information and organize discussion forums; (3) support transparency, open dialogue, and communication; (4) provide educational and training opportunities; and (5) perform research and consulting services. Integrating sustainability is widely recognized as an essential driver that adds value to pharmaceutical companies. Pharmaceutical companies are moving forward with sustainable initiatives by acting on - and committing to - sustainability as much as they possibly can.

Ensuring successful integration or the implementation of sustainability initiatives depends on: (1) the establishment of the sustainability concept (such as vision Statement; (2) top management guidance and support; (3) the involvement of external and internal stakeholders at all levels; (4) management systems and frameworks needed for supporting sustainability initiatives (such as assigning responsibilities and

developing objectives); and (5) continuous improvement, reviewing and measuring of processes and the establishing of processes and reviews.

Integrating sustainability is a long-term process. During this process, companies begin by: (1) defining their sustainability visions; (2) determining how they are related to their operations, customers, and social and environmental impacts; and (3) identifying the companies' weaknesses and strengths (GEMI, 2001). After identifying their sustainability vision that is based on missions, values, and traditions, pharmaceutical companies tend to develop their initiatives, goals, strategies, and objectives. Companies will then mobilize their resources, prioritize their activities, and monitor sustainability. Firms must be able to detect if and when change is needed and then, they must have the intention and motivation for implementing this change through top management commitment, involvement, as well as through their recognizing of sustainability as being a management driven effort (Simon et al, 1995). Measuring and monitoring sustainability will assist the pharmaceutical companies in tracking their performance and goals. Integrating and committing to sustainability is known to provide pharmaceutical companies with important values through:

- Addressing society and social issues.
- Increasing competitiveness.
- Controlling or reducing wastes and their costs.
- Improving strategic planning, and decision-making.
- Constructing and strengthening relations with stakeholders.
- Improving reputation.
- Gaining more customers and employees.
- Increasing market share (new business opportunities).

- Eliminating or controlling liabilities and risks.
- Increasing productivity/profitability, efficiency, and performance.

Pharmaceutical companies that effectively integrate sustainability will succeed in their businesses. In other words, integrating sustainability means engaging sustainability initiatives in the firms' over-all business goals through including people, profit, and the planet in all the processes and decision-making activities. Pharmaceutical companies mainly depend on their self-interpretations of voluntary initiatives to effectively integrate sustainability, since presently there are no available standardized procedures for measuring, integrating, or even communicating sustainability (Leonard et al, 2004).

2.2.2. Corporate Social Responsibility

Due to the concern about business ethics and the shaken confidence of consumers in some facilities or businesses, Corporate Social Responsibility (CSR) has become increasingly important. The CSR includes elements such as environmental protection, social equity, and economic growth and is considered to have the same fundamental principles of quality management (Leonard et al, 1999). It is best described as "a balanced approach for organizations to address economic, environmental and social impacts in such a way that aims to benefit people, society, and community" (ISO, 2002). CSR considers numerous issues such as human rights, unfair business practices, organizational practices, environmental aspects; workplace and employee issue as well other issues dealing with occupational health and safety, society involvement, social development, marketplace, and customers. Thus, the idea of CSR has been lately adopted by pharmaceutical industries. Pharmaceutical companies that effectively integrate sustainability will succeed in their businesses. In other words, integrating

sustainability means engaging sustainability initiatives in the firms' over-all business goals through including people, profit, and the planet in all the processes and decision-making activities. Pharmaceutical companies mainly depend on their self-interpretations of voluntary initiatives to effectively integrate sustainability, since presently there are no available standardized procedures for measuring, integrating, or even communicating sustainability (Leonard et al, 2004).If CSR is adopted, ethical business practices will be promoted hence regaining the consumers' confidence. The main idea behind the CSR concept is the moral or ethical responsibility of the firm towards any individual that influences its activities or is affected by its operations. During the decision-making process, the company should have responsibilities not only towards its employees and shareholders but also towards other stakeholders such as buyers, suppliers, the government, as well as regional and local authorities (Carol et al, 1999).

The main emphasis and driver behind social responsibility is public pressure. Its objectives include: protecting the environment, ensuring sustainable development, protecting the consumers, and increasing their market. Some of the major benefits that are obtained when CSR is included in the pharmaceutical industries' corporate policy are: the enhancement of the company's reputation and image, the increase in wealth and investors for the company, the improvement of customer satisfaction, and the reduction in the employees' turn-over and absence (Vitezic.N., 2010). However, studies (Leonard.D. et al., 1999; Vitezic.N., 2010) show that leaders and top managers demonstrated a lack of social responsibility that could not be tolerated anymore. To avoid the skepticism regarding the performance of industries, firms should thoroughly endeavor to make all their operational business activities more transparent and sustainable, in order to reduce their environmental risks (Marshall et al, 2003).

2.2.3. Green approach and triple bottom line performance practices

Firms are starting to recognize: (1) the positive gains that can be obtained through environmental friendly pharmaceutical marketing strategies; and (2) the potential risks of the non-environmental friendly strategies (Kumar .S, 2012). Stakeholders and top managers are starting to show a great interest in green strategies and the triple bottom line practices (3BL). The concept of the 3BL practices is based on the idea of evaluating the organizational performance on the basis of environmental quality (planet), social justice (people), and economic success (profits). The green approach or movement is considered as "doing business while avoiding harm to the planet and the people" (Sustainable Enterprise, 2010). Due to the continuous increase of the public pressure in addition to the increase in material and energy costs, pharmaceutical companies are expected to start their commitment of applying green strategies in order to improve their environmental performance and reduce their impacts (Kleindorfer et al, 2005).

The reports of recent pharmaceutical industries in the UK and the US indicate that pharmaceutical industries are taking remarkable steps into going green. In order for pharmaceutical industries to become environmental friendly or responsible, they are taking the green chemistry approach. Johnson and Johnson, and Pifzer are starting to consider green projects as being one of their important priorities. Green chemistry is a sophisticated approach that uses chemical solvents with natural reagents in order to minimize the environmental impacts and become more environmentally friendly (i.e. natural solvents replace organic solvents with water). The main principle behind green chemistry is minimizing the usage of hazardous and unnatural chemicals. Industries such as Pifzer are discovering different ways of creating natural solvents and

eliminating the usage of harmful chemicals. This approach does not only show a responsible environmental attitude but also reduces the consumers' health risks caused by the hazardous chemicals being used in the process of manufacturing medicines (Smart, 2010). To exemplify, Merck Corporation follows the green chemistry approach, and has several initiatives taking place that include reducing solvents, using more water-based methods in their manufacturing procedures, and devising more programs for minimizing their wastes and effluents.

Pharmaceutical industries are seeking to meet their environmental goals by putting their efforts into energy conservation, emission reduction, and green chemistry processes. In 2011, Merck Corporation published its 2010 global responsibility report, which asserted its hard work and dedication in achieving environmental sustainability. The highlighted efforts were setting precise goals, and adopting and implementing projects for energy efficiency, green chemistry, and water conservation. According to the report, Merck reduced its water demand by 11% during 2010. Some of the strategies or plans used to reduce water consumption included assigning a responsible and qualified waste manager that could identify water-reduction opportunities as well as identify and implement the best practices needed. Certain examples of best practices include controlling and repairing all water circulation systems, re-using and recovering steam produced from production processes, optimizing production of water processes, and evaluating the total water cost in their projects. Also according to the report, Merck announced in 2008 the decision to decrease the company's global emissions by 12% in 2012 even though in 2009 it both accomplished and exceeded this reduction. As a result it set another goal to reduce an additional 10% of its emissions by 2015(PTSM, 2011). With respect to energy efficiency, Merck is considered to be highly responsible in

recognizing and implementing best practices or programs for reducing energy consumption. Because the overall energy consumption occurs in the manufacturing laboratories, offices, and warehouses, the Merck Corporation developed what they call "Best Practices Evaluation Tool," which is used to evaluate and identify the best opportunities needed for improvement. In 2005, the corporation set the goal of reducing its energy demand by 25% by the end of 2008(PTSM, 2011). The company ended up reducing 28% of its overall energy demand. Thus, it adopted another goal to reduce more than 10% by 2015. Practices adopted in their project to reach their goals according to energy efficiency include: applying various renewable energy initiatives, using heat recovery from circulating water systems, reassessing their production processes, and doing more green research (PTSM, 2011).

2.3 Environmental Management Systems

An EMS as identified by Tibor and Feldman, (1996) is "an aspect of an organizations overall management function that determines and implements the organization's environmental policy'. In other words, an EMS is a systematic transparent process known worldwide for: (1) prescribing and implementing environmental policies, goals, and responsibilities; and (2) continuously auditing its required elements. EMS nowadays has become an essential topic since it involves combining both the environmental and business dimensions, taking into consideration environmental factors in every decision, as well as product processes and developments (Sarkis, 2003). An EMS is based on the Plan-Do-Check–Act cycle (PDCA) or the Total Quality Management (TQM) business concept of continuous improvement through which a procedure or a plan is developed, implemented, and then reviewed or audited

continuously. The nature of this process ensures that EMS is both progressive and proactive. An EMS dictates requirements for the organization's structure, practice, responsibilities, resources, processes and procedures (Bansal et al., 2002). The growing attention and importance of adopting an EMS is mainly due to the increased environmental deterioration worldwide identified through the increasing pollution levels, diminishing raw materials, and global warming and increasing wastes (King and Lenox , 2001; Lai et al ., 2010). The implementation of proactive environmental management systems will allow industries to operate more efficiently and professionally as well as to increase their opportunities for expanding their wealth (Berry et al ,2000).

Some of the known EMS standards are the British Standard (BS 7750), the international organization for standard (ISO 14001), and the Eco - management and audit scheme (EMAS).

2.3.1. The British Standard –BS 7750

The BS 7750 was issued by the British Standards Institution (BSI) in 1991. Regardless of the size and type of organization, BS 7750 provides assistance regarding how to implement a systematic and effective EMS. It gives detailed information about how firms can guarantee fulfillment and compliance with environmental objectives and policies. However, the BS 7750 does not set or define any specific environmental performance, objective, or target for organizations and businesses. Moreover, Carty (1993) indicates that the BS 7750 is simply an internal management system without external reporting requirements. The only specified performances are that it meets the standards requirements with a commitment for continuous improvement (IISD, 1996).

Environmental audits and reviews are essential in this standard, and the standard neither discusses nor specifies the qualifications of the individual who would perform these audits. BS 7750 was one of the main reasons behind the development of the EMS ISO 14001 specified document (IISD, 1996).

2.3.2. ECO-Management and Audit Scheme (EMAS)

The ECO-Management and Audit Scheme (EMAS) is a voluntary registration scheme that has been available since 1993 for industrial organizations. It was adopted within the European countries. According to Carty (1993), it is a scheme which permits industries to be committed to improving their environmental performance by establishing an EMS and publicly reporting their performance. EMAS's main aim is to reward and recognize a business that goes beyond the minimum required official compliance and improves environmental performance continuously. EMAS is a demanding and challenging system that requires internal and external auditing (the results of these should also be published). These requirements have a strong impact on the company's image. Therefore, many firms are not willing to adopt or participate in such a system (Dixon et al, 2005).

2.3.3. ISO 14000 Series

The ISO 14000 series is the most common international environmental management series of standards that obviously has an encouraging contribution to protect the environment globally and to promote sustainable development. The ISO 14000 series is a series of international standards used for environmental management that was issued in1996. It permits organizations to engage in environmental efforts and

continuous performance evaluation according to internationally approved criteria (IISD, 1996). The main characteristic of the ISO 14000 series is that they are voluntary that is to say, not legally required. The objectives of the ISO 14000 series include: reduction in waste resource depletion and pollution, enhancement of environmental awareness among the community and employees, harmonization with national environmental regulations and laws, and the promotion of a voluntary standard approach for environmental issues. It mainly provides a proposal for industries to demonstrate their commitments to environmental protection by suggesting an international approved plan for pollution prevention and sustainable development. (Zutshi et al, 2004). Even though many organizations may have already the components of an EMS, the ISO 14000 series - through the implementation of the ISO 14001 - will provide them with a systematic approach that will help them achieve the companies' goals (Könnölä,, 2007; IISD, 1996). The ISO 14000 series is expected to become an important factor in policy, business, and trade.

2.3.3.3 ISO 14001 Standard

The ISO 14001 standard explains the concept of EMS as being "The set of managerial activities which defines the environmental policy, objectives and which implements these activities by means of planning for environmental objectives, measurement of results and the control of environmental aspects" (ISO,2008). In other words, the ISO 14001 standard is established in order to assist organizations in reducing their negative environmental impacts (Kataria et al., 2011). In the 14000 series, ISO 14001 is the only standard that can be certified since it is the most widely recognized EMS model. Studies (Bansal et al., 2002; Rondinelli et al., 2000) indicate that it has the

widest geographical industrial coverage compared to other EMS certification systems. It has been developed to integrate environmental aspects into processes and product standards (Massoud et al., 2010). ISO 14001 is a specific standard that provides guidance for the development of a suitable comprehensive, formal, and systematic EMS. It is a set of procedures or guidelines, by which an organization has to develop its environmental policy, identify its products and activities that are connected with the environment, identify its regulatory requirements, identify its targets and objectives, and identify its priorities for reducing environmental impacts. Then, it has to adjust its organizational structure with respect to: training, documenting, assigning responsibilities so that these objectives and targets are met, and lastly, checking and reviewing the management system as shown below in Figure 1(Bansal et al ., 2003).

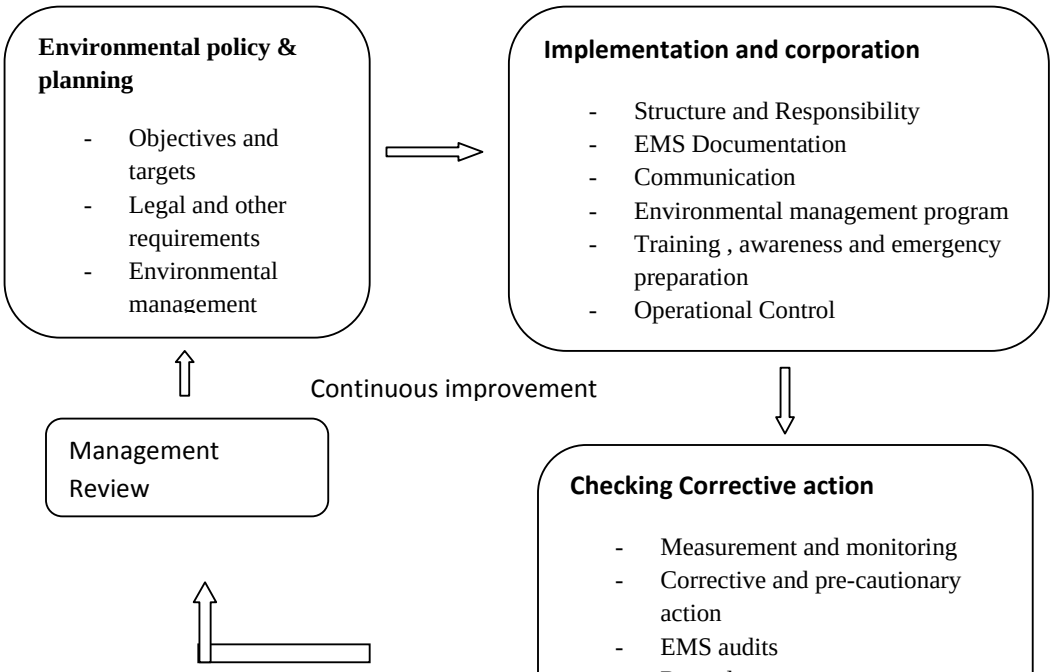

Figure 1: Key elements of ISO 14001

To be able to implement and meet ISO 14001 principles, organizations should apply the following:

(1) Environmental Policy and planning: organizations are supposed to define or develop their environmental policy, in which they should be able to analyze and recognize the environmental impacts of their overall operations and define their objectives and targets for environmental improvement. Then the organizations are required to develop an environmental management program in order to meet their objectives and targets.

(2) Implementation and corporation: organizations are supposed to obtain or develop a clear framework such as the required resources or the mechanisms needed for adopting their environmental management plan.

(3) Checking and corrective action: organizations should be able to monitor and evaluate their environmental performance and to implement precautionary and corrective actions regarding any deficiency in the system.

(4) Management Evaluation: organizations should continuously review the EMS plan at all intervals in order to improve its overall environmental performance (Dixon et al., 2005).

The ISO 14001 is a voluntary standard with no legal requirements (complies with any 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 environmental management systems. It mainly helps an organization achieve its objectives through clearly stating "what it is going to be achieved", "who is going to do it and how", "how progress is going to be monitored" and "when is each particular task going to be completed" (Curkovic, 2005; Casadesu´s, 2007). The ISO 14001 can also be integrated with other management functions available in the organization. The advantage of implementing the ISO 14001 standard is that it is flexible enough to be applied to any type and size of the organization (Kateria et al., 2011). Industries that do not adopt international standards can rapidly loose competitive advantages with other industries.

2.3.2.2 ISO 14001 Certification

There are two methods based on which an organization can obtain the ISO 14001 conformance: either through a "Third party certification" or through a "Self declaration conformance".

Third party certification: An independent qualified individual performs a complete comprehensive audit of the organization's EMS and its compliance with ISO 14001 standard. If the organization meets the requirements, it will be certified (Bansal et al, 2002).

Self declaration conformance: Organizations are capable of adopting the ISO 14001 standard as a model and following its EMS performance without being externally certified. However, without an auditing process, organizations are unable to ensure that the EMS is achieving its actual purpose (Shah, 1996; Bansal et al , 2003)..

2.3.3.3 Cost and Duration of ISO 14001 EMS :

ISO 14001 implementation and certification requires both the time and cost, which vary from one company to the other. According to the industries, both the cost and time needed to implement and certify the ISO 14001 are considered significant. With respect to the time needed to obtain the certificate, organizations in the US and Spain reported a range between 8 to 19 months (Babakri, 2003). The time needed to implement and certify ISO 14001 standard depends on the type and size of the organization.

According to Freeman (1997), the cost value for the ISO 14001 certification ranges between $10,000 and $128,000. EMS maintenance cost per year ranges between $5,000 and $10,000 to sustain the ISO 14001. The cost mainly depends on the EMS

methods used (whether they are sophisticated or not), and it also depends on the size and type of the industry (Bansal et al.,2003). Managers should carefully analyze the applicability of the ISO 14001 EMS to their firm before deciding whether to adopt the EMS or not. Benefits and costs also depend on the number of employees, the products manufactured, as well as on the size of the facility. Mainly the expenses are related to documentation, employee training, the changes in processes, internal and external auditing, the assembling of the information needed for implementation and certification, registration maintenance, and the changes in the organizational operations (such as the installation of treatments units) (Patrouni.A. , 2001).

The costs of implementation and certification in the developing countries will be much higher than those in the developed countries because of the lack of infrastructure and the needed technological information in the developing countries (Campos.L. 2012). Critics argue that the cost of documenting, developing, and certifying EMSs may discourage many small – medium sized industries from seeking certification (Carraro and Leveque ,1999). .

2.3.3.4 Motivations:

Several studies have been conducted worldwide to identify the reasons behind companies' motivations for adopting the ISO 14001 standard. According to Gonzalez et al (2008), while the ISO 9000 is driven by the customers the ISO 14001 is driven by regulators, stakeholders, and the community. The most common motivations cited by the proponents of the ISO 14001 standard (Fryxell and Szeto, 2002 ; Prajoga et al., 2012) are:

- Meet customer demand.
- Gain competitive advantages.

- Comply with environmental regulations.
- Overcome export barriers.
- Comply with top management demand.
- Improve environmental performance.
- Enhance relationship with stakeholders.
- Improve company/product image.
- Show good intentions and integrity.
- Reduce operational cost.
- Increase operational efficiency.

U.S surveys indicated that 94% of the population would buy environmental friendly products and even 90% would be ready to pay more for buying such products (Raines et al., 1992). Therefore, when it comes to operational decision-making, examining the environmental performance of the suppliers has become a major factor (Zutshi et al., 2004). All motivating factors differ according to the type and size of the industry as well as the country they exist in.

2.3.4.5 Benefits and advantages of ISO14001

Industries that undergo the certification of the ISO 14001 will certainly have many advantages at the environmental, economic, and managerial levels (Campos.L, 2012). Hillary (1999) examined the implementation of the ISO 14001 standard in the U.K and identified that there were external and internal benefits. Internal benefits include: organizational benefits (improved work and safety situations, enhanced environmental information), individuals benefits (increased employee awareness and motivation), and financial benefits (cost savings). External benefits include: communication benefits (enhanced public image), environmental benefits (enhanced

environmental performance), and profitable benefits (gained competitive advantages and an increase in the number of customers).

According to a study performed by Petrouni (2001), some of the major benefits resulting from implementing the ISO 14001 are:

- Increase in the market share: 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. The adoption of the ISO 14001 may help industries that are involved in traditional trade to avoid continuous inspection and multiple permits. Also, the ISO 14001 may enhance or boost the domestic market share of the industry, since it may lead to customers insisting that their suppliers meet certain environmental requirements.
- Cost reduction : although it is complicated and difficult to find out if the EMS is responsible for the entire reduction in the overall management costs, certain specific reduced costs may be recognized in some areas such as:
  - Material savings, material reuse and recycling, material substitution (Jump, 1995).
  - Other operating costs such as energy savings, lower insurance premium (since insurance can be easily obtained by companies that have confirmed EMS), and reduced packaging costs (Kuryllowicz , 1996).
  - Environmental management costs such as a reduction in the cost of hazardous waste discharge, legislation expenses, penalties and environmental liabilities. With EMS registration, the liability risks of the industry will be reduced since it will be able to clearly display that it is well

prepared and applies the necessary preventions and requirements (Chang et al, 1998).

- Improved customer satisfaction: Customers would be more satisfied when the quality of the product is improved. Also, the ISO 14001certification serves as conformity reassurance for customers in such a way that it provides conformity through a third part certification or verification.
- Improved efficiency of processes and operations: such as increased administrative and manufacturing efficiency in the organization.
- Improved image and responsibility: For some organizations implementing an EMS may improve the company's image or its credibility regarding its environmental agreements.
- Improved working climate: The EMS would mostly develop environmental awareness among the employees resulting in improved operations and enhanced employee morale (through gearing their helpful thinking towards the environment). Most importantly, it would lead to positive communication and cooperation the managers and employees (Petrouni et al, 2001).

Due to the gap that exists between the results and the expectations/outlook of adopting the ISO 14001, industries that are presently implementing the ISO 14001 standard may get frustrated and thus discourage other industries from implementing this standard (Evangelinos and Halkos, 2002). Nevertheless, studies conducted worldwide on certified ISO 14001 industries indicated that the organizations were pleased with their ISO EMS even though they were not expecting any profitable benefits from its adoption. From their point of view, the most important motivation for implementing the standard was that they wanted to be an

environmental friendly organization and enhance employees' awareness (Summers, 2002).

2.4 Pharmaceutical industries performance

The environmental performance reports of leading multinational pharmaceutical industries indicate that they are seeking to integrate corporate responsibility and environmental safety and protection into their overall business processes and strategies.

According to Berrry and Rondinelli (2002), leading pharmaceutical industries are seeking to reduce environmental impacts in response to the environmental challenges. Their approaches include:

(1) Developing integrated Environmental Health and Safety programs (EHS) and adopting clean manufacturing and pollution prevention processes in all their operations and processes:

For example, the Johnson & Johnson organization has an effective corporate environmental policy that meets or exceeds legal standards (i.e. goes beyond compliance) and customer expectations. It is considered as one of the companies that reacts directly or proactively with any environmental development and complies completely with all the environmental regulations and laws. In addition, it continuously promotes and encourages employees, customers, communities, and suppliers to develop awareness/knowledge about environmental issues.

Glaxo-Wellcome, for instance, also it shows responsibilities towards environmental health and safety during its decision-making and planning projects. It also assesses how it can minimize the impacts of its operations on the environment.

Eli Lilly and Bristol-Myers Squibb organizations use programs like “New Product Environment Requirements Tracking (NPERT)” and “Product Life Cycle (PLC)” respectively. The NPERT is a program that identifies all the regulatory and environmental quality requirements from chemicals to raw-materials in production processes. The NPERT program works with all the departments to recognize or select strategies for waste management and pollution prevention. It helps reduce emissions in order for the company to save costs in its waste disposal and manufacturing process. The PLC is an approach to eco-efficiency by designing or developing products that are of good standards with regards to the quality and EMS performance. The continuous PLC reviews help the companies reduce and identify environmental impacts at all operational levels, thus resulting in potential savings.

(2) Reducing or eliminating hazardous emissions and wastes:

The environmental management effort of leading pharmaceutical industries such as Johnson and Johnson 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 et al.,2000).

During the expanding of its sales and outputs, the Glaxo-Wellcome organization, as a result of its EMS, was able to reduce its vapor emissions by 25% and its VOCs emissions by 17%. At SmithKlein Beecham industries, almost all ozone depleting compounds were phased out and carbon monoxide (CO) decreased by 65%.

Bristol-Myers Squibb also eliminated all ozone-depleting compounds, decreased the release of toxic elements by 90% and reduced solvent releases from 20 million pounds to 12 million pounds. Lastly, Abott Laboratories reduced toxic material by 50% through its EMS(Berry et al.,2000).

(3) Reducing and recycling material: Through reducing raw material's toxicity and minimizing packaging impacts, and using recyclable and recycled materials (i.e. packages) in their operations, leading pharmaceutical organization decreased the overall environmental impact of the product, including consumption by the consumers.

For example Johnson & Johnson and SmithKlein Beecham reduced packaging waste by 12 % and 7% respectively. Bristol-Myers Squibb, Eli Lilly and Glaxo-Wellcome, imposed that all their organizational sites establish waste minimization programs and goals. Annual reports were required for the top management departments. Abott Laboratories reuses materials that were previously supposed to be discharged as wastes. It was reported that it reduced its packaging material by 16 million pounds through its packaging and management program(Berry et al.,2000).

(4) Conserving energy, water and other natural resources: Due to the industries' concern regarding cost savings, regulatory compliance, as well as environmental protection, the industries tried to reduce water and energy consumption and carefully value other natural resources.

For example, Britsol-Myers Squibb lowered water consumption to almost half its original amount and decreased energy usage every year. At SmithKlein Beechaman, energy and water usage was reduced by 33% and 47%, respectively. Abott

Laboratories reduced energy consumption by 65%, and avoided 39,000 tons of its air pollutants (Berry et al.,2000).

Many authors Berry and Rondinelli (2000) conclude 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 (Berry and Rondinelli, 2000).

2.5 Challenges and disadvantages of Implementation

Implementing an EMS is a complex process and comes with various challenges at all stages of its implementation. These challenges vary depending on the country, and the size and type of the organization (Biondi et al., 2000). Public awareness and social responsibilities are rare and not found in countries that are facing political, social, and economic problems. Studies conducted by Hillary (1999) indicated that the most significant barriers are:

- Standard complication and complexity.
- Lack of management's commitment.
- High cost of maintenance and implementation.
- Lack of know-how and technical skills.
- Lack of human and financial resources.
- Doubts about benefits.
- Lack of incentives.
- Lack of market demands from stakeholders.

Baumsat (2001) reported that the major challenges for large and medium-sized industries are not technical challenges (such as professionals and specialists), but

rather other challenges regarding the handling of their market issues (such as the competitive advantages and the low demand of environmental friendly products by their suppliers or even customers).

Major challenges such as the lack of a suitable infrastructure, absence of effective and efficient policies, ineffective environmental regulations, shortage of power as well as human resources and financial constraints, were found in the developing countries (World Bank, 2004). It becomes more complicated and sometimes impossible to implement environmental regulations in the absence of adequate infrastructure like wastewater facilities, treatment plants, and sewer networks (Massoud et al., 2010). Due to the unavailable resources and capabilities in the developing countries, huge amounts of investments are required in order to achieve compliance with the ISO 14001 standard (Yirideo et al, 2003). Environmental regulations and policies in developing countries are still general, out-of-date, and intentionally vague and constrained due to the inadequate communication and coordination between the authorities. Therefore, firms are not committed to any national standard or regulation (Islam et al., 2001). Adopting, implementing, and certifying the EMS in organizations is expected to require extra financial and human resources (Hillary et al., 2004). Knowledge, technical skills, and expertise (in recommending certain techniques) are required in order to implement the ISO EMS in any organization. Therefore, industries in the developing countries are recommended to request technical and financial support from developed countries, in order to establish, and implement the EMS as well as conduct audits and trainings (Massoud et al., 2010).

Moreover, due to the lack of finances, human resources, and political will, as well as due to the inefficient and incompetent legal frameworks, enforcement of the

environmental regulations will remain ineffective and unsuccessful. Furthermore, all the responsible and liable institutions that ensure or guarantee compliance and fulfillment are themselves underfunded, unclear, and include contradictory objectives (Mauri et al , 2002).

Even though the implementation of various voluntary management standards is becoming an important task for organizations irrespective of their size, and nature of business, managers will continue experiencing resistance and facing challenges when implementing and maintaining such systems (Campos.L, 2012).

Although various perceived benefits and motivating factors exists in the implementation of the EMS such as the ISO 14001, several authors (Curkovic, 2005; Gbedemah, 2004; Van Hoc, 1999) criticized and highlighted some disadvantages regarding its implementation. The ISO 14001 is criticized because:

- It is not a performance standard, it is only a process standard.
- It is a bureaucratic documentation driven process due to its requirements and extensive documentation.
- Does not guarantee environmental performance due to the absence of an environmental measurement performance (such as fuel and natural resources consumption limitations and emissions limitations).
- It is not considered as a product standard; since all the products manufactured by certified organizations cannot be labeled as ISO 14001certified (such as “organic product” labels).
- It is not related to customers.
- It is a weak and very general standard compared to the other more sophisticated types of EMS.

- It is a burden to small-medium enterprises (SME).
- It can become a technical barrier regarding trade (TBT) in developing countries. If the ISO 14001certfication becomes a requirement for trade organizations that are unable to implement it (due to its cost and difficulty) could be prohibited from gaining access to the international market share. Thus, the ISO 14001 could become a non-tariff barrier in trade instead of helping facilitate the removal of trade barriers altogether.

CHAPTER 3

METHODOLOGY

3.1 Recruitment and profile of the pharmaceutical Industries

Collecting the data began by identifying the names and numbers of Lebanese pharmaceutical industries from the Lebanese pharmacist Order. A total number of 12 uncertified and 1 ISO 14001 certified Lebanese Pharmaceutical industries were identified; where-by their contact information and names were obtained. The 12 industries were contacted by phone or email to get their approval to participate in the study. Each concerned official individual was informed that he/she will be contacted later for more additional information on the subject.

Geographically, the Lebanese Pharmaceutical Industry establishments are mostly located in North Lebanon, Bekaa, Mount Lebanon, and Beirut. From the total of 12 Lebanese pharmaceutical industries contacted, only 8 responded, representing an approximately 70% response rate. The other 4 Lebanese pharmaceutical industries refused to participate in the study stating that negative environmental impacts are not part of their manufacturing process. Furthermore, in their point of view, the ISO 14001 was not considered as being an important concept or topic to discuss.

The 8 pharmaceutical industries that did reply constituted: four industries that formulate medications/drugs; these industries are named I1, I2, I3, I4, two pharmaceutical industries that formulate intrevenal serums; these industries are named I5 and I6, one pharmaceutical industry that formulates para-pharmaceutical products (cosmetics); this industry is named I7, and lastly, one pharmaceutical industry that

formulates biomedical product equipments; and this industry is named I8. The industry establishment dates vary between 1962 and 1999. Moreover, the overall number of employees among the 8 industries varies between 32 and 250 workers at most. The 8 interviewed industries market their products locally and regionally primarily in KSA, Iraq, Gulf, Syria, Yemen…etc. Table 2 summarizes the profile of the industries.

Table 1: Summary of the industries' profile.

Industry Name	Industry products	Established Year	Number of Employees	Respondent Position
I1	pharmaceutical products (medications/drugs)	1970	50	Operational Plant Manager/Owner
I2	pharmaceutical products (medications/drugs)	1962	250	Quality Manager
I3	pharmaceutical products (medications/drugs)	1968	196	Quality Manager
I4	pharmaceutical products (medications/drugs)	1980	100	Operational Plant Manager/Owner
I5	Intravenal serums	1999	32	Operational Plant Manager/Owner
I6	Intravenal serums	1973	130	Quality Manager
I7	Cosmetics	1993	100	Quality Manager
I8	Biomedical products	1998	40	Operational Plant Manager/Owner

Pharmaceutical Industries I1 and I2 are considered as being among Lebanon's leading manufacturers of pharmaceutical products. They are characterized as such due to the high quality of their pharmaceutical products. They engage in the production of a wide range of pharmaceutical products such as tablets, capsules, liquids, powders, solutions, and dry syrup antibiotics, suspensions, creams, ointments, eye drops, suppositories..etc. that are used for therapeutic purposes particularly in cardiology, neurology, gastrology, and even in the case of diabetes, infections, and others.

Industries I3 and I4 also deal with the production of pharmaceutical products such as solids, liquids, powders, tablets, and sterile and non- sterile formulation products needed for therapeutic purposes in order to be used particularly for problems with the respiratory and gastro intestinal systems.

Pharmaceutical industries I5 and I6 are considered as being leading industries in Lebanon in manufacturing intravenous, dialysis solutions and powders, dialysis blood lines, PVC Tube Extrusions (I.V. Solutions, I.V. Ampoules, and I.V administration sets) and disposable medical devices. In other words, they manufacture packaged intravenous fluids, as well as other products that can be mixed with sterile water to prepare a solution for intravenous administration. Industry I7 is a para pharmaceutical industry that manufactures a wide range of cosmetics. Finally, industry I8 manufactures disposable biomedical devices (solid elements) that are used during obstetrics mainly in hospitals.

The common manufacturing process (flow chart) of all the pharmaceutical products from the reception of the raw materials until the dispensing of the finished products, with inputs and outputs, except for I8, is depicted in Figure 2 below:

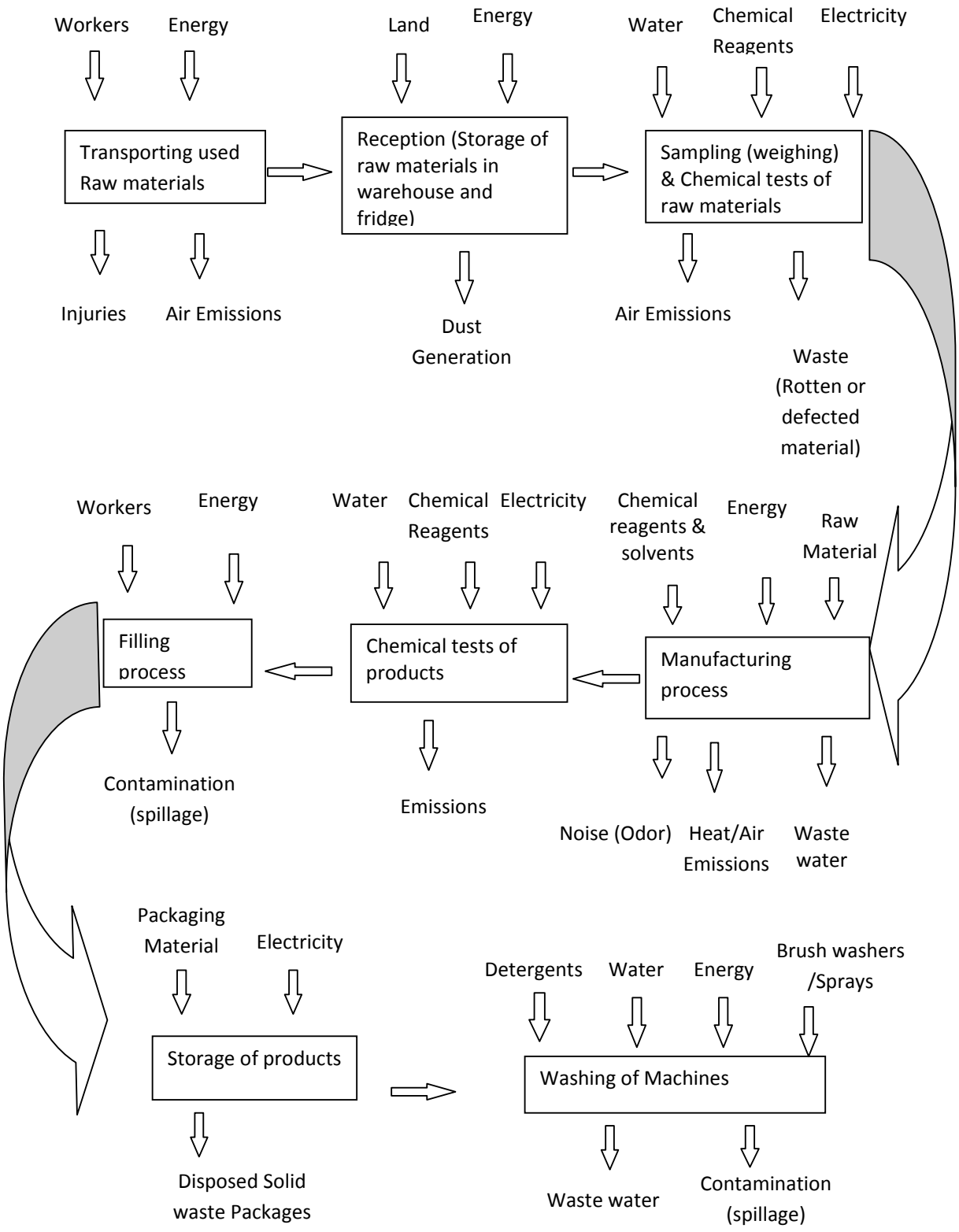

Figure 2: Flow chart of pharmaceutical industries

However, I8 manufactures disposable biomedical product used during obstetrics in hospitals. The biomedical product is manufactured manually, then a small number of machines - like injection molding (gold plating the product) and electro polishing (polishing the product using acids) – are used.

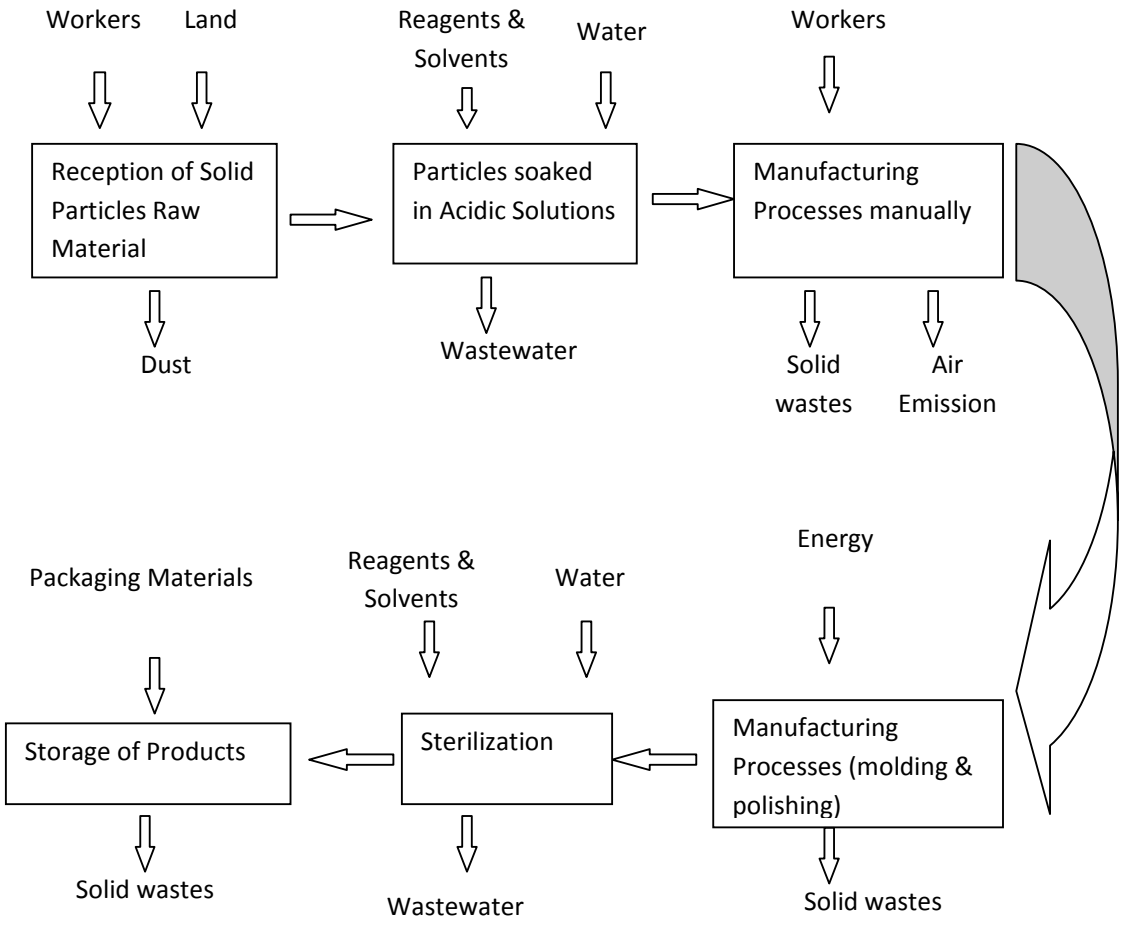

Figure 3: Flow Chart of pharmaceutical industry (I8)

All the industries that responded are ISO 9000 certified, but neither one of them is ISO 14001 certified. The industries comply with GMP (Good Manufacturing Practice), since it is mandatory to do so in Lebanon. Furthermore, they are also required to comply with the latest modified new edition of the GMP referred to as cGMP

(Current Good Manufacturing Practice); which requires them to employ systems and technologies that are up-to-date in order to comply with the regulations.

3.2 Study Design

The methodology used in this study is the qualitative research method and focuses, in particular, on the in-depth interview approach. This approach was adopted in order to account for the small sample size of the industries, and in order to allow the research to examine and explore some of the concepts and facts in details (Crouh et al., 2006). Researchers use this type of in-depth interview to derive certain data and information in order to establish a comprehensive understanding of the interviewees' opinions or points of view (Berry, 1999). 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.

Moreover, it provides the interviewer or researcher with more detailed information, and could be used when addressing any critical topic or sensitive issue. As a result, the interviewer may probe wherever necessary to gain the required data (Berry, 1999). 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).

3.3 Data Collection

First, an extensive literature review was carried out in order to review the existing information and data related to: the growth and expansion of pharmaceutical

industries, their general environmental impacts, and the different proactive environmental management practices employed as well as the various barriers and facilitators.

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 (Millard, 2011). Any leading questions that could influence respondents' answers were carefully avoided or clarified properly during the interview. Table 1 shows the in-depth questions of the interview that were related to the study's objectives.

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

Objectives	Related Question
I. Know what the existing strategies used to respond the environmental risks.	➢ What are the perceived environmental impacts of your industry? ➢ What are the initiatives taken to improve environmental performance?
II. Understand their perception about Environmental Management practices particularly the ISO 14001 EMS.	➢ 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. Asses the barriers and limitations to implementing an EMS.	➢ 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. Understand the drivers and incentives for implementing an EMS.	➢ 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

Second, the industries were contacted by phone in order to introduce the researchers to the Owners or General Managers for the sake of getting their approval to be included in the research study and also for the sake of identifying the individuals that should be interviewed. A copy of the interview guide was sent to the industries ahead of time. Then, the interviewees from the industries (operational plant managers/owners, quality managers) were contacted by phone to set up the meeting and arrange the appointments. A semi structured in - depth interview was conducted with each industry. The meetings with I1, I5, and I8 were carried out with the Operational Plant Managers/Owners. The interviews of I2, I3, I4, I6, and I7 were conducted with the Quality Managers.

The interviews were conducted in both English and Arabic, and all the data was documented by note-taking. The interviews began with general straight forward questions regarding the industry and its manufacturing products. The second part of the interviews comprised of controversial open-ended questions that were related to the objectives of the study.

3.4 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 asses 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, 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. Finally, results and discussions of the study were reported.

3.5 Ethical consideration

The information that the industries provided was treated confidentially and the names of the companies were not mentioned in this report. 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. Moreover, the project was submitted to the Institutional Review Board (IRB) at the American University of Beirut for approval.

CHAPTER 4

RESULTS

4.1 Environmental Impacts and initiatives of the Pharmaceutical Industries.

Each industry from the 8 uncertified industries was asked about its major environmental impacts and the current initiatives or strategies taken to improve its environmental performance. In total, the environmental impacts of all the 8 are: (1) energy consumption, (2) water consumption, (3) wastewater generation, (4) solid waste generation, (5) Air emissions (Dust…etc), and (6) noise impacts.

Table 3: Environmental Impacts of the Industries

Industries / Environmental Impacts	I1,I2,I3,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

The energy consumption of all the interviewed industries, except I8, originates from different sources such as machines, air compressors, lightings in the industry, and electrical office equipments. Due to the non-stop conditioning and monitoring of various parameters such as proper heating and ventilation, air-conditioning, controlling airborne particles, dust and microorganisms, and maintaining room temperatures and

space moisture, HVAC (heating ventilation and air conditioning) systems must remain running 24hrs a day, thus consuming huge amounts of energy. The use of generators to supply the industry with the needed power increases the consumption of fuels. According to I8, and as mentioned before since they manually manufacture biomedical products, their energy consumption is considered low compared to the other industries. With respect to all the interviewed industries, there were no main strategies adopted for decreasing the energy consumption, except with I2, which was consuming green diesel fuel because - as the Quality Manager remarked -*"it is the purest diesel found"*.

As for water consumption and wastewater, I1, I2, I3, I4, I5, I6, and I7 consume large amounts of water daily during the manufacturing process as well as during the cleaning of equipments, machines, floors. Regarding I8, water consumption occurs mainly to soak pieces of the products with certain kinds of acids. Wastewater generated from the pharmaceutical production processes of I1, I2, I3, and I4 is always high in BOD and COD due to the usage of chemical materials (reagents). Moreover, it contains detergents and totally suspended particles with high pH levels. According to I7, their generated wastewater contains bacteria and sometimes has high pH levels. With regards to I5 and I6, their generated wastewater has non-toxic wastes with very low BOD, COD, and pH levels since the components of the manufacturing serums are originally found in the environment. As for I8, its wastewater was 87% acidic.

Each of the above mentioned industries adopted a different method to treat its wastewater. The current strategy of I8 involves getting rid of wastewater through depositing it in a cesspool to be taken by a contracted company specialized in dealing with acids. As for I1, I4, I5, I6, and I7, they discharge it in the local sewers without treatment. According to I3 and I2 as quoted by the interviewed mangers -*"wastewater is*

released 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".

According to the current strategies implemented for solid waste disposal, I2 and I3 dispose their rejected solid waste materials (unused/rejected products or raw materials) in what they consider a "*rejected storeroom"* located inside the industry. Moreover, managers reported that they could not find suitable solutions for these products. I2 and I3, cooperate with a carton recycling company to collect waste packaging materials such as boxes, leaflets, and papers. Industries I1, I4, I5, I6, I7, and I8 dispose all their solid wastes along with their municipal solid waste. However, the amount of solid wastes generated in I5, I6, and I7 are considered low compared to the other industries, since they are either re-used or returned to the supplier.

Due to the utilization of some reagents and solvents in the manufacturing processes in I1, I2, I3, I4, I5, I6, and I7, VOC emissions, acid gases, and solvent vapors are generated. The current initiative applied to prevent indoor air pollution is the use of the HVAC system with HEPA (high efficiency particulate filters). The filters are used in the production zone, the weighing zone, and the laboratories. Additional current initiatives are applied at I4 to prevent outdoor air pollution; mainly the use of fuel filters for the generators.

As for noise pollution, no applied strategies were identified in I1, I2, I3, I4, I5, I6 and I7.

In addition, all the interviewed respondents do not have any individual or department committed to working on the environmental issues. Furthermore, half of the

respondent industries are less familiar with the ISO 14001 standard compared to other industries

4.2 Industries' perception about EMS

When the respondent industries were asked about their knowledge regarding the EMS – ISO 14001 standard, I7, I4, and I8 reported that they are familiar with EMS. Regarding the ISO 14001 standard, they realize that it is a voluntary system that is implemented to protect the environment through industries adopting several ways for waste treatment in order to reach their targets in an efficient and simple way. The other respondent industries either have no idea about the ISO 14001 EMS or are less familiar with it. Figure 4 below shows the industries' knowledge about the ISO 14001 standard: Knowledge

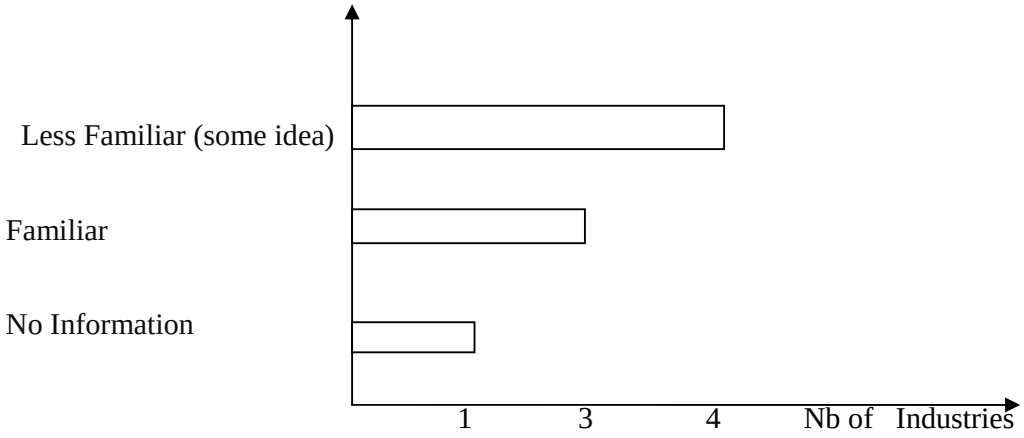

Figure 4: Knowledge about ISO 14001.

The 8 interviewed respondents were asked why they believe the EMS should be implemented and whether their organization would consider adopting the ISO 14001 standard in the near future. According to all of the industries' points of views, any unmanaged environmental issue 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: *"that a system should be implemented to manage the unused/rejected products, materials, and emissions properly without disturbing or affecting the environment"*.

However, all of these industries, except I4, do not consider implementing ISO 14001 since they believe it is the least of their priorities at the moment. The quality manager in I7 clarified: *"In a developing country like Lebanon, no one cares about the environment, so why should we?"* The majority of the industries agree that the ISO 14001 certification would bring no added value to their competitive market. They all also claimed that none of their suppliers, business partners, or customers ever requested them to acquire the implementation. The interviewees also reported that their current environmental strategy is not a barrier for exporting their products to their local and regional markets. Another reason they would not seek to implement it is because it is only a voluntary process which is not enforced by the Ministry of Environment. However, and only according to I4, the implementation of the 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.

4.3 Drivers and Advantages of ISO 14001 implementation.

The drivers reported by the respondents regarding the implementation of the ISO 14001 standard were as follows: (1) Enhance the company's image (2) Enhance

environmental performance (3) Overcome international market trade (4) Overcome international market trade (4) Reduce operational cost.

Table 4: Drivers of the pharmaceutical Industries.

Industries / Drivers	I1	I2	I3	I4	I5	I6	I7	I8
Enhance environmental performance and better environment.	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

The 8 respondent industries were asked about the advantages of implementing the ISO 14001 standard, and accordingly the perceived advantages of acquiring the ISO 14001 were: (1) obtaining a certificate only; (2) adhering better to the rules (rather than remaining in a state of chaos with lots of unresolved issues); (3) developing a better environment to live in; and (4) offering awareness for employees regarding the environment.

4.4 Challenges and Barriers of the ISO 14001 Implementation.

The major perceived challenges documented by all of the 8 respondent industries regarding the implementation of the ISO 14001 standard were: (1) increasing general awareness of the personnel and their sense of responsibility towards

improving the environment and actively participating in the implementation and the maintenance of EMS; (2) identifying all of the environmental impacts and taking the most effective actions needed for monitoring and preventing them; (3) finding the most effective /suitable measures and techniques; and (4) dealing with the government in order to obtain the needed information (a task that is considered rather difficult).

The common barriers reported by all the respondents for implementing the ISO 14001 standard were as follows: (1) lack of governmental support; (2) No legal requirements; (3) unclear benefits; (4) lack of knowledge; (5) time -demanding; (6) Not required for export; and (7) Not a customer demand.

The 8 respondent industries where asked about the disadvantages of implementing this ISO 14001 standard. The perceived disadvantages of acquiring the ISO 14001standard were: (1) Consumes time (become overloaded); (2) Requires more control and commitment from the top management; (3) Costs a lot with respect to the implementation and annual external audits.

4.5 Supporting Organizations and Incentives.

The most suitable organizations perceived to support the Lebanese pharmaceutical industries' quest to adopt the ISO14001 EMS standard and face the challenges and acquire the certification are:

- Governmental bodies: -Ministry of Industry.

  -Ministry of Environment.

- Certification bodies : Apave, SGS…etc
- Foreign Consultancy firms.

The common incentives reported by all 8 of the respondents for implementing regarding the implementation of the ISO 14001 were 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.

CHAPTER 5

DISCUSSION

5.1 Profile and Perception.

The majority of the respondent pharmaceutical industries in our sample can be considered as SMEs, since they are almost all small-owned businesses. This result is consistent with the fact that the industrial sector in Lebanon according to the Ministry of Industry is generally considered as SMEs (MoI, 1998). Furthermore, the majority of the respondents can be considered exporters, since they market their products locally and/or regionally (KSA, Iraq, Gulf, Syria, Yemen) but their products are not marketed or exported internationally. According to the Ministry of Economy and Trade, this result is expected given that manufactured pharmaceutical products in Lebanon are not considered to be one of the industrial products that are exported internationally (MoET, 2007).

Although the respondent pharmaceutical industries in our sample have similar opinions regarding how environmental issues should be handled and managed properly, environmental departments or individuals that are responsible or devoted to deal with environmental issues do not exist. 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. This is due to the pressure that is mainly exerted by international head companies on their sister companies forcing them to deal with their environmental issues. The absence of environmental departments or positions in locally-owned companies that do not have sister international organization (i.e. as the case with the respondents); is mainly attributed to

the lack of enforcement by the government (where by the government does not require or impose that they deal with their environmental issues).

During the meetings and interviews with the respondent managers/owners (I1, I2, I3, I5, I6) it was clearly noticed that there is a misconception between environmental management system, quality management practices and GMP/cGMP. There is no distinction between the guidelines of the GMP and the cGMP (i.e. the organization does not obtain its GMP/cGMP certificate as “cGMP Certificate 2013” or as “GMP Certificate 2013”; only the date of obtaining the certificate is mentioned). However, it is required that the pharmaceutical companies follow the GMP in each step, and that they be updated with their latest GMP norms. Therefore, the term current was included i.e. cGMP. The cGMP is important because it has become a pre-condition for exporting health-care products for some countries worldwide. It also forces the manufacturing organizations to give up old practices and adopt more advanced and latest production processes. Companies that fail to comply with cGMP guidelines may face serious consequences such as fines, withdrawal of products. Furthermore, another important remark was also deduced from the discussions where the majority of the respondent mangers or owners considered that the cGMPs were enough. From their point of view, the GMP includes all their needed requirements and practices. GMP/cGMPs play a major role since they are considered to be a quality assurance asserting that all the medicinal products are constantly produced and controlled according to the appropriate quality standards. In other words, the GMPs require that the processors, manufacturers, and packagers of the medicinal products obtain proactive steps in order to ensure that their products are effective, pure, and safe (i.e. to ensure the quality of the pharmaceutical products). Moreover, 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, thus categorizing the GMP as unrelated to environmental issues. The reason behind this misconception is mainly due to the low level or lack of environmental knowledge. This misconception did not occur with I4, I7, and I8, mainly due to the fact that they recognize environmental issues and are more familiar than the other industries regarding the standard.

The results shows that, except for I4, almost all the pharmaceutical respondent industries that acquired TQM (ISO 9000), are not interested in implementing the ISO 14001 standard showing that they are not willing or ready to acquire the EMS certification in the near future. This result about the pharmaceutical industries is consistent with the findings of Shall (2000), who reported that - Lebanese ISO 9001 certified industries are least interested in taking the next steps for pursing the EMS-ISO 14001 certification ,compared to other management systems. Additionally, they are satisfied with either improving their ISO 9000 system or acquiring other TQM. On the other hand, the findings of Curkovic (2001), Karapetovic (2008), and Prajoga (2012), reported that companies with TQMs are more likely and willingly to implement and certify to ISO 14001 standard. In addition, since only one industry (I4) is interested in adopting the ISO 14001 standard among all the respondent pharmaceutical industries (because it is re-structuring and re-designing its industrial plant layout and because it wants to be an example or model for the other industries to follow), this further confirms our outcome showing that due to the lack of incentives and inadequate infrastructures available, acquiring the ISO 14001 certification is the least of the priorities of the Lebanese pharmaceutical industries. Moreover, this indicates that

TQMs – and not environmental issues- are still the main priority among the industries. Hence, Lebanese pharmaceutical industries are not likely to consider the adoption of the voluntary ISO 14001 EMS, before acquiring cGMPs or achieving other types of management certifications (such as the ISO 22000) or re-structuring their plant (i.e. if it is in need of re-structuring).

5.2 Impacts and current strategies.

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 were related to the manufacturing of pharmaceuticals include high levels of water consumption, wastewater generation, and energy consumption. Generated solid wastes, noise pollution, air emissions (dust…etc) may also be a concern for some pharmaceutical manufacturing industries.

Even though the pharmaceutical industries listed their environmental impacts, the majority believe that their environmental issues are negligible and are not considered a major impact on the environment when compared to other types of manufacturing industries. This finding is consistent with the findings of Berry et al (2002), who also indicated that pharmaceutical industries are not considered as “dirty” industries; however, they should control their environmental pollution due to their expansion. Therefore, knowing that all the respondent pharmaceutical industries do not have an environmental department in their industries; and also given the fact that there is an absence of a systematic and efficient EMS needed for evaluating and monitoring their environmental performance, our resulted outcome is considered both unexpected and significant. Moreover, even if the mangers or owners of some of the pharmaceutical

industries (I7, I8) are more aware about the environmental issues and the standard, as our earlier finding show; according to them, their current environmental strategies suit them and hence, they are unwilling to change their habits. This outcome is expected due to the lack of concern about the environment in Lebanon, indicating that the majority of the Lebanese pharmaceutical industries have no good-will or integrity necessary for improving their environmental performance.

The analysis of our results regarding the current environmental management practices of the Lebanese pharmaceutical industries indicates that not all practices are useful or considered as being effective strategies. This outcome was deduced during the further analysis of the current strategies. For instance, Victoria (2002), in her report about wastewater treatments, considers that chlorination alone (as used in I2 and I3) is not always considered a best practice in wastewater treatments. Even though, it 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. Similarly, the reports of the Chemical Chlorine Council indicate that although chlorination plays an important role in wastewater treatments for the removal of pathogens, pharmaceuticals, chemical and physical impurities, 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 in Lebanon. In other words, our outcomes was supported when we discovered: (1) industries that are incapable of finding an appropriate solution for the disposing of solid waste materials and thus dispose them in a "rejected storeroom" (i.e. I2 and I3); (2) the disposing of acid into a cesspool without treatment (i.e.I8); (3) noise pollution (i.e. I1,I2,I3,I4,I5,I6,I7); and (4) the discharging and disposing of wastewater into local sewers (i.e.I1,I4,I5,I6 and I7), and the solid wastes into municipal wastes

(i.e.I1,I4,I5,I6,I7 and I8) without providing a suitable treatment. This outcome is also supported by Mezher (2000), who reports that technical skills and knowledge are needed in Lebanon in order to have environmentally friendly companies.

However, there are a few practical current environmental strategies applied in some of the Lebanese pharmaceutical industries such as the consumption of green diesel (I2) and the usage of HVAC system (I1→ I8).With regards to green diesel, this current strategy is consistent with Hepoworth (2009). Hepworth (2009) indicates that green diesel does not create any black smoke (occurs when using normal diesel for running an engine), because it does not contain any particulates, nitrous compounds, or aromatics which are considered harmful. Furthermore, it can be used on any type of engine without modifications. During pharmaceutical manufacturing, the pharmaceutical facilitates are obligated to install HVAC systems to comply with GMP or ISO 9000. That said, only one strategy (green diesel) can be considered applicable or efficient among the current practices, indicating that more has been said than done with respect to the environmental issues in the pharmaceutical industries.

Due to the continuous uncontrolled and un-monitored disposal of different types of wastes into the environment without any suitable treatments, the Lebanese pharmaceutical industrial sector is not considered to be environmentally sustainable.

5.3 Barriers

All of the 8 respondent pharmaceutical industries had the same common barriers. Our analysis of the results showed findings that were similar to those mentioned found by Mehzer (2000); namely: the lack of governmental communication and cooperation, lack of technical skills and lack of experienced and qualified local

consultants are the main obstacles. These are the main obstacles that the Lebanese manufacturing industries are facing their attempt to improve their environmental performance. The resulted outcome was predictable, due to the lack of political will or stability, inefficient legal frameworks, and lack of financial resources in a developing country such as Lebanon. The Ministry of Environment (2001) supports this argument, reporting how the resulted poor environmental performance of the industrial sector is due to the inadequate or improper infrastructure and the absence of adequate industrial zones in the region. For that reason, I4 is re-structuring its plant layout so that it would not face infrastructure issues during the implementation of ISO 14001. Accordingly, the lack of governmental support in providing: (1) adequate industrial zones; (2) proper infrastructure (such as power and sewer networks); (3) applicable wastewater and solid waste management; and (4) financial incentives, makes it difficult for the Lebanese pharmaceutical industries to acquire or comply with the standard.

"Uncertain Benefits" and "Lack of Knowledge" are considered to be the main barriers with respect to the mangers'/owners' lack of knowledge about the industries' significant environmental impacts and their lack of adequate skills needed for formulating environmental programs and policies. This finding is consistent with the findings of Curkovic (2005), who reported that beneficial uncertainty and skepticism regarding the implementation of the ISO 14001 standard exist due to the lack of expertise and professional advice, resources, and governmental support. This outcome is mainly due: (1) to the lack of know-how; (2) the lack of government support and corporation support in promoting the EMS ISO-14001 standard; and (3) the shortages in the needed technical skills and knowledge. Thus, the Lebanese pharmaceutical industries will face many challenges and obstacles in implementing the standard.

In the Lebanese regulatory system or governmental laws, EMS development is not legally required. Therefore, the firms are not obligated to adopt the ISO 14001standard and be certified, making this a barrier for the Lebanese pharmaceutical industries. This finding is consistent with the findings of Mehzer (2000), who indicated that the lack of relevant or appropriate environmental laws and regulations is considered a critical barrier for acquiring the ISO 14001 standard. Even though there are several laws, decrees, and ministerial decisions that govern environmental management in Lebanon (MoE, 2011), as long as the Lebanese government does not enforce an integrative set of environmental laws or regulations the environmental situation in Lebanon is not expected to improve. The respondent mangers/owners admitted that their industries would implement the ISO 14001 standard if they faced any kind of legislation obligations or if their customers demanded that they acquire the EMS. Thus, legislators or regulators are capable of playing an important role in triggering an environmental change in the pharmaceutical industries.

"Time demanding" was considered as another barrier according to the interviewed managers/owners. This could be attributed to the absence of environmental departments or positions and the lack of knowledge among the industries regarding the ISO 14001 standard; which is consistent with our earlier findings.

"Not a customer demand", and "Not required for export" were equally perceived as barriers for acquiring the ISO 14001. This finding shows that the implementation of the ISO 14001, by pharmaceutical industries, is neither driven by customer demand nor required for the facilitating of the current export. 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 so long as they are not exposed to any regulatory pressure or external demand.

According to Bansal (2002) and Prajoga(2012), the cost of implementation of the 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. Thus, more operating expenses are necessary for the implementation; a possible burden for the organization. Hence, our expected finding that was identified during the discussion was that the "cost of certification" was not considered as a major barrier for the pharmaceutical industries. Knowing that pharmaceutical industries manufacture important products needed daily for human beings' health demands, our resulted outcome is expected: financial costs or funding for implementing the standard are not considered a main issue. Furthermore, the managers/owners are not convinced with its beneficial outcomes, and are neither willing nor interested in investing in any non-profitable or non-productive areas such as environmental risk reduction.

According to the respondent pharmaceutical industries, the disadvantages of implementing the ISO 14001 standard are both logical and expected. In other words, the reported drawback, that it is "time-consuming" is expected, since there are no environmental departments and positions in the industries. Since managers/owners must commit to the principles, achieve the goals and targets of their environmental policy and monitor the environmental management system. It is expected that this would require control and commitment from the top management, which is considered as a disadvantage according to the 8 respondents. Moreover, even if the cost of certification is not considered as a barrier among the Lebanese pharmaceutical industries, from their

point of view, it is a disadvantage because the financial returns when dealing with environmental issues are not easily obtained.

5.4 Drivers

Our finding is consistent with those of many authors (Morrow, 2002; Benito, 2006; Fryxell, 2002; Prajoga, 2012; Florida et al, 2000), who reported that the major motive for the EMS adoption was mainly for the sake of improving environmental performance. On the other hand, this finding contradicts with the findings of Mezher (2002), who reports that the main driver for adopting the ISO 14001 among the Lebanese manufacturing industries, if adopted, is to maintain access to the international market. This is an interesting finding, since according to the Ministry of Environment, the Lebanese government or national regulations do not provide any incentives for acquiring the ISO 14001 EMS. Usually, and according to Fryxel (2002), this driver is viewed as a response to external regulatory pressures. However, due to the weak regulatory enforcement of the standard in Lebanon, pharmaceutical industries could have chosen this driver since it is only a voluntary process. On the other hand, our analysis shows that I7 is not motivated by this factor although they are familiar with the standard. This is supported by a direct quote from the I7 manager who states that "*In a developing country like Lebanon, no one cares about the environment, so why should we?"*This is also due to the lack of concern from the industry about the environment, which is due (or originated) from the lack of concern from the government or ministries regarding the environmental issues.

Our finding is consistent with the results of Petrouni (2001) and IISD (1996) who indicate that adopting the ISO 14001 improves the company's image. This resulted outcome is expected, since ISO implementation and certification will lead to reduced

environmental liabilities and risks related to environmental compliance; hence, it improves the company's image. In other words it is an expected motive, since it might offer the Lebanese pharmaceutical industries; a green corporate image, indicating that they care about their local, national and global environment. Maintaining a good company image is highly important and required (nowadays due to the high public pressure) in the Lebanese pharmaceutical industry, since they are industries dealing with health and medicinal products.

"Overcoming international market trade" is perceived another driver for acquiring the EMS ISO 14001 standard. This finding is consistent with the findings of Fryxel (2002) and Zutshi (2004), who report 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 complying to it will help industries overcome international trade barriers. This outcome is expected in our report; since all the respondents are not considered as international exports. Furthermore, since the ISO 14001 standard is well-recognized in the market, and might provide valuable advantages in the competitive international market (Bellesi.F., 2005), adopting this standard could facilitate the pharmaceutical industries access into the international market because of the cleaner image and perceived reliability these markets would begin to posses as a result of the certification, thus increasing their market share. However, some respondents (i.e. I5, I6 and I7) do not consider this as a motive, since adopting the ISO 14001 standard is not a compulsory criteria for accessing international markets.

Our results contradict the findings of Morrow (2002) and Berry (2000), who report the reducing of operational costs as being a major driver. This resulted outcome

indicates that the industries/managers in I1, I2, I3, I5 and I6 are not convinced or do not recognize the financial/economical benefits that could result from acquiring the ISO 14001 standard ; making them unaware of the potentials of the cost reduction that could take place as a result of enhancing improving environmental performance. This can be linked back to the lack of knowledge among the managers/owners (i.e.I1, I2, I3, I5 and I6) regarding this standard, which in turn, is caused by governments/regulators and policy makers failing to promote EMS. On the other hand, I4, I7, and I8 consider this as a motive, since they are familiar with the ISO 14001 standard, and are aware of the benefits on the long run.

Furthermore, an interesting finding that was revealed during the discussions is that "Meeting Customer Demands" or "Used as Market Tool" (local/regional) were not perceived as motives for acquiring the ISO 14001 EMS among all the respondent pharmaceutical industries. This is because the respondents claim that none of their regional or local customers and suppliers require or oblige them to acquire the ISO 14001. In other words, 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 weak. According to the respondent pharmaceutical industries, their local and regional market will be unaffected if the organization is ISO 14001 certified. The reason behind this finding is mainly due to the low demand from their local or regional customers, who are not interested or concerned about their environmental performance. Since they are pharmaceutical industries that deal with human health demands, they are more concerned with the quality of the product. Nowadays, even if the concept of EMS (ISO 14001) is emerging and becoming

an important topic, the local and regional market of the Lebanese pharmaceutical industries still only considers the safety and quality issues instead of the environmental ones.

5.5 Incentives and Supporting Organizations

Pharmaceutical Lebanese industries are still facing environmental problems due to the lack of knowledge, inadequate training, and the lack of responsibilities on behalf of government and other corporations. Mehzer's (2000) report is consistent with our incentives, since it indicates that new technical skills (such as wastewater treatment methods, spillage controlling, water and dust analysis…) are needed in order to have an environmental friendly industry. Nowadays, various projects, universities and programs are improving the educational sector in Lebanon with regards to the environmental issues but more should be done to provide the know-how and the required environmental knowledge and experience. Therefore, the demand for enhancing organizational capacities (such as know-how and capacity-building) for all types of treatments for the pharmaceutical industry is suggested.

Even though governmental loans for environmental funding and tax exemption for certified companies are predictably being demanded, they are unlikely to occur in the near future due to the economical and financial problems, and also due to the lack of low coordination between the Lebanese politicians. Additionally, even if the Ministry of Environment established some environmental laws, all the regulations and policies need to be enforced and put into implementation in order to ensure a better environmental performance in Lebanon.

Mainly, the incentives still need to be put into implementation. However, the major obstacles in implementation are mostly related to the overlapping and interrelated responsibilities of concerned authorities who are not able to reach an agreeable consensus on any proposed financial incentive.

Obviously the respondents considered that; technical assistance, capacity-building, and training and implementation support, were all important for the adopting of the ISO 14001 EMS. So a supporting approach or plan- through the ministries -is required, and, it should aim to provide information and technical support.

Since they are considered as being able to play a direct role in environmental and industrial issues, governmental bodies such as the Ministry of Environment and the Ministry of Industry are predicted to be among the major organizations that support the Lebanese Pharmaceutical industries in their quest to acquire the ISO 14001standard. 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 ISO 14001 standard. Matouq's (2000) report is consistent with our findings, as it indicates that the most difficult steps in the implementation of the ISO 14001 are: documenting, identifying environmental impacts and adequate techniques, and training and achieving staff awareness. Private or local consulting firms were not found to be as a supporting organization among the pharmaceutical industries when it comes to adopting the ISO 14001 EMS. This is mainly attributed to the limited (incomplete) services they provide due to the lack of experience and knowledge in ISO 14001 consultations. For that reason, industries resort to foreign consultants that are specialized in environmental solutions in order to provide them with the necessary information and techniques.

According to the respondents, certification bodies (APAVE, SGS..etc) support Lebanese pharmaceutical industries in adopting the ISO 14001 standard . This is expected since they assist them in identifying their environmental aspects, performing continuous personal training for employees and establishing suitable techniques to reduce environmental risks. Therefore, regulatory enforcement needs to be combined with financial incentives in order to support and encourage industries in adopting EMS.

CHAPTER 6

Conclusions and Recommendations

6.1 Conclusion

- The majority of the pharmaceutical industries consider that their environmental issues are negligible in comparison to other types of manufacturing industries and that there exists a common misconception between environmental management practices and quality management practices and GMPs.

- The Lebanese pharmaceutical industrial sector is not considered to be environmentally sustainable, due to the continuous uncontrolled and un-monitored disposal of different types of wastes into the environment without any suitable treatments.

- Lebanese pharmaceutical industries are more concerned with quality and safety issues more than environmental issues. The most adopted international standard among the industries is the ISO 9001 quality management system followed by the GMPs. Adopting the ISO 14001 standard is the least of the priorities of the Lebanese pharmaceutical industries.

- The lack of proper waste management infrastructure followed by inadequate industrial zones, lack of political will, and instability, are 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 EMS ISO-14001 standard, and shortages in the needed technical expertise skills and professional knowledge, will 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.

- 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 most significant barriers delaying the adoption of ISO 14001 standard is the lack of governmental support and incentives, not being legally required and demanded by customers.

- Poor adoption of ISO 14001 standard EMS in Lebanon is due to: the lack of the governmental environmental strategy/approach (support), lack of the public environmental awareness and due to the customers' attitude towards the environmental issues.

- Ministry of Environment, Ministry of Industry and certification bodies are perceived to play an important role in supporting the pharmaceutical industries in implementing ISO 14001 EMS.

- Pharmaceutical industries are unlikely to adopt ISO 14001 EMS before acquiring the new edition cGMPs or achieving other types of management certification (such as ISO 22000), and unless it becomes more popular, demanded by customers' or legally required.

6.2 Recommendations:

- EMS promoters should play an important role to enlighten or elaborate more on the importance of ISO 14001EMS and illustrate (explain) the relationship between ISO 14001 EMS certification and enhanced environmental performance in the Lebanese Pharmaceutical industries.

- The Lebanese government should promote voluntary EMS concepts among the industrial sector in Lebanon and support firms (through incentives, loans…etc) to adopt the ISO 14001.

- Regulatory frameworks need to be enforced and joined with financial incentives (such as tax exemption…etc) in order to support and encourage the Lebanese pharmaceutical industries in adopting EMS.

- The Lebanese government should establish an environmental financial funding through international funding organizations, and promote professional training within the Lebanese industries to encourage the adoption of EMS ISO 14001.

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