ABSTRACT

In the past few decades, there has been increasing concern towards the potential effects of industrial pollutants on our eco-system. Each country has developed and enacted stringent environmental regulatory standards to address this concern. Several studies conducted in the general area of regulatory impact show significant direct impact of these regulations on organizations which includes product redesign; process redesign; use of environment friendly raw material; incorporating systems and mechanisms for life cycle management, waste management systems, recycling and reuse; and developing structures and mechanisms to monitor compliance. Pharmaceutical industry in particular, due to the generation of variety of hazardous waste during manufacturing, maintenance and housekeeping operations, is one among the highly regulated industrial sector globally. Following these stringent regulatory standards is a major concern for the Pharmaceutical Small and Medium Enterprises (PSMEs). The financial and human liabilities and resource shortages associated while incorporating abatement technologies and related procedural changes make them highly vulnerable to these compliance standards.

This study aims to investigate two aspects of environment regulation compliance in the PSMEs, namely,

- to identify the nature and magnitude of vulnerabilities encountered by Pharmaceutical Small and Medium Enterprises (PSMEs) in India while complying with environmental regulations, and
- to explore the adaptation mechanisms followed by the Pharmaceutical Small and Medium Enterprises (PSMEs) in India, in complying with environmental regulations.

Literature explorations in the area of environmental regulation, enforcement, compliance, pharmaceutical industry and SMEs, gave limited studies with focus on India. However, studies with focus on economically developed countries indicated some clear trends. One, PSMEs were seen to encounter significantly higher vulnerability in manufacturing and operations than in regulations, marketing, organizational policy or human resource, while complying with environment
regulations. Two, they were seen to feel significantly concerned about regulator and regulatory management. Three, the PSMEs had more external and management focus than technological and process change, in coping with environmental regulation compliance. Four, environmental compliance measures (nature of vulnerabilities and adaptation mechanisms) reflected significant differences among small and medium size pharmaceutical firms. Five, these environmental compliance measures had significant differences between different locations/regional clusters.

These five trends formed our five hypotheses, to be investigated in the Indian scenario. A questionnaire based survey was administered online and face to face. The sampling design followed was stratified random and the total sample size taken for the final analysis was 71. The survey targeted the senior executive officers of pharmaceutical firms across India. Unstructured discussions and interactions with experts in the field were also carried out to understand the gravity of each concern.

Data was analyzed using the Analytic Hierarchy Process (AHP) for exploring and prioritizing vulnerability concerns, factor analysis for identifying the general adaptation mechanisms and systems practiced, and cluster analysis for assessing the underlying relationship among vulnerability concerns and adaptation patterns of firms under study.

Findings of the analysis highlighted several significant drivers of the interaction between the PSMEs and the environment regulations. Some of them are as follows: One, conforming to literature finding, our study also found manufacturing related problems as the most significant concern for the PSMEs. However, unlike the Western countries, it was the poor quality of raw material available in the market that was the main concern, and not the need for intensive capital investment in abatement technologies. Additionally, the Ayurvedic companies went against the general tide and highlighted organizational strategy as their most significant vulnerability. Investigations revealed the steady global market decline for this sub-sector and need for new innovations to meet the changing global needs. Two, marketing was a significantly higher concern for the PSMEs than regulator and regulatory management. Marketing has special relevance in the pharmaceutical industry as it deals with health and life saving issues for the people, and this got highlighted in our
results. Three, the study found external management factors as the most followed coping / adaptation mechanism pursued by the PSMEs. Conforming to literature findings, our study also demonstrated smaller firms as significantly more vulnerable to adaptation in comparison with medium scale firms.

The study highlighted the attempt at balancing the local and global by the Indian PSMEs. While the process orientation was towards meeting international standards, the management of resources, marketing and regulatory requirements had a focus on the local pressures. The study provides some insight into the vulnerabilities and adaptation efforts of the Indian PSMEs and brings out the relevant strategic interventions from government, regulatory organizations and industry associations to develop a more sustainable business environment for the Indian PSMEs.