TECHMIND RESEARCH
ISSN: 2291-2118
International Journal of Research in Business and Technology
Volume 5 No.1 August 2014

Regulatory Compliance Motivated Manufacturing Issues In Indian Small & Medium Scale Pharmaceutical Enterprises

A.B. Bhasi[1], A.Gurtoo[2], P.V.Shouri[3], K.A.Zakkariya[4]
[1,4]Cochin University of Science & Technology,
Cochin - 682022, Kerala, India.
bhasiab@gmail.com
[2]Indian Institute of Science, Bangalore -560012, India
[3]Model Engineering College,
Cochin – 682021, Kerala, India.
pvshouri@gmail.com

Abstract-*In the past few decades, there has been increased attention and concern towards the potential damaging effects of industrial pollutants on the global eco-system. To combat these effects, countries have enacted their own environmental regulatory laws and standards. However removal of the pollutants at the source and keeping the product standards according to the regulatory compliance level becomes a major concern for the manufacturing sector, particularly to Small and Medium Scale Enterprises (SMEs). Focus of this study is on Indian Pharmaceutical Small and Medium Scale Enterprises (PSMEs), aimed at identifying and prioritizing the reasons, nature and magnitude of vulnerable regulatory issues to environmental compliance. Stratified random sampling design is adopted for data and prioritization of the issues arising out of compliance measure is done using Analytical Hierarchy Process (AHP). The study and related reviews brings out the relevance of strategic interventions from government, regulatory organizations and industry associations for improving the sustainable business environment of SMEs.*

General Terms-Regulatory issues, Environmental regulations, sustainable business environment

Keywords-*Adaptation; environmental regulation; PSMEs; regulatory compliance; vulnerability*

1. INTRODUCTION

The growth in technology and the related industrial emissions over the last two centuries contributed heavily in damaging the world's natural system. In order to combat this effect every country has formulated environmental laws and regulations. The purpose is to prevent and reduce environmental problems caused by production process, product use, and product disposal (Gurtoo and Antony, 2007). This also aids in protection of the environment and biodiversity by regulating the resource usage (Kulkarni et al., 2006). However due to various socio-political and economic issues, its implementation as per the regulatory requirement becomes a real challenge to the industries, particularly to SMEs involved in manufacturing. Some of the related issues are discussed below.

1.1. Stringency of Environmental Regulation

The level and stringency of environmental regulation increased worldwide since the early 1970s. These regulations have been forcing manufacturers to install cleaner, efficient and pollution abatement technological systems (Jaffe et al., 1995). In addition to possessing knowledge of current regulations affecting operations, managers must also need to track numerous future challenges to their process. In general, vast resources need to be expended while complying with the environmental laws (Miller, 1998). However, research and climate change imperatives show that the manufacturing industry cannot continue to merely treat the symptoms of environmental problems. Instead, a more comprehensive procedure is required to reduce pollution through prevention practices. Product awareness and expectations of the customers are also driving this environmental concern to a certain extent.

1.2. Issues in Environment Regulations and Compliance by Firms

Several complexities govern the environmental regulatory compliance process in manufacturing firms. Some important variables taken for the study are highlighted in the reviews as:

- Research shows heavy productivity slow down during the time of implementing environment regulations (Porter, 1991). This mainly attributed to the rearrangement of production process from pollution bearing technologies to efficient technologies, which leads to higher production

cost, low productivity and affects the firm's ability to survive in the competitive market (Porter, 1991).

- Environment regulations vary across countries and regions. Stringent regulation in some nations increase the compliance costs and reduces the international competitiveness of the firms (OECD, 1989; Gollop and Roberts, 1983; Gray, 1987; Barbera and McConnell, 1990; Jaffe et al., 1995).
- In several high income countries, environmental regulations often go beyond specifying discharge standards, but specify control technologies and processes (OECD, 1989).
- In most cases the response of industry to tighter regulation has been attributed to the effect of market pressures and heightened corporate social responsibility for ensuring environmental protection (Salter, 1992).
- Strict compliance by large organizations pushes the manufacturing process and product standard upwards, making it difficult for SMEs to cope with the regulatory requirement (Gurtoo and Antony, 2007).
- With differences in flexibility of compliance, SMEs in some countries often shift their base to more flexible areas for cost advantage over other firms (Porter and Linde, 1995; Stafford, 2000; Gouldson, 2004; Esty, 2001).
- Even within similar regulatory contexts, the form that these rules take can potentially impact business location, making production in some regions more economical than others (Porter, 1991).
- Environmental regulations favor large incumbents at the expense of small firms (Brock et al., 1986; Carlton, 1990; Dean and Brown, 1994).

1.3. Compliance cost and profitability

Regulations are regarded as generating costs that businesses will never recover (Gingrich, 1995; Walley and Whitehead, 1994). Better environmental performance comes only when the firms divert resources to reduce their emissions and sacrifice profits. In contrary some studies show that better pollution control performance improves profitability in the long run and reduces marketing risks (Porter and van de Linde, 1995). The list of positive impacts include increased domestic and international market share, increased speed of supplying or delivering of firm's products due to compliance standards and increased firm's ability to adapt flexibly to different client demands due to technological excellence (Jayadevappa, 1996; Ashford, 1993; Bragdon and Marlin, 1972; Spicer, 1978). In addition to the various manufacturing related costs, environmental regulation indirectly affects firms operating cost by imposing other constraints on its production process; like increased general and administrative costs, money spend in engaging legal staff to obtain license, permits and other regulatory support (Jayadevappa, 1996).

1.4. Resource Constraints in Small and Medium Scale Enterprises

Small and Medium Scale Enterprises (SMEs) occupy a place of strategic importance due to its substantial contribution to the national income, employment opportunities, foreign exchange through exports and entrepreneurship development (Visvanathan and Kumar, 1999). In spite of all the merits the bulk of industrial pollution in India is caused by SMEs, which account for over 40% of the hazardous waste, as compared to 13% generated by the large scale industry (Frijns et al., 1999). They are constrained in terms of infrastructural resources like technology, capital and human resources. This resource shortage prevents them from implementing proactive strategies with a fear that such initiatives may reduce their profitability. Literature on SMEs and regulatory compliance highlighted the relevance of capacity and resource related issues under compliance. Though the regulators are concerned about pollution standards, managements focus is on productivity for survival. This can negatively impact their marketing possibilities in developed countries with stringent regulations on imports (Dasgupta, 1997).

Pharmaceutical industry is one among the highly regulated sector worldwide due to the life saving nature of products. Generation of hazardous wastes of varied nature during manufacturing operation makes it more difficult to comply with the regulatory standards. Pharmaceutical Small and Medium Enterprises (PSMEs) are the most affected due to resource constraints compared to their larger counterparts. The present study is designed to provide some insight into the manufacturing related vulnerabilities faced by the Indian PSMEs during environmental compliance. The study also proposes to identify the dimensions of strategic interventions needed from government, regulatory organizations and industry associations to develop a more sustainable business environment to the Indian PSMEs.

2. AHP MODEL

Christian et al. (2009) brought out that firms actually postpone strategic decisions on environment due to higher levels of regulatory uncertainty. As the regulations change unexpectedly, for environmentally-regulated firms innovation becomes very difficult (Birnbaum, 1984). The net effect of this will be reduced innovation and poor compliance, which can force environmentally-regulated firms at a competitive disadvantage (Caves, 1982; Guttmann et al., 1992; Scherer and Ross, 1990). In some cases, un-regulated firms reduce pollution because of the level of abatement incentives provided by factors like customer choices and international trade possibilities are much more than abatement costs (Pargal and Wheeler, 1996). A significant distinction is found between the big companies and small ones, where the smaller companies face the issue of financial inability and lack of access to

funds for process change (Yasamis, 2007). The AHP model presented in Fig. 1 is developed by incorporating all the above mentioned concerns. Infact, the criteria and alternatives are selected specifically to address the concerns.

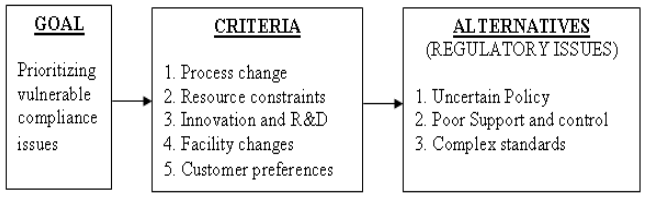

Fig 1: AHP model

Pilot study provides priority indicators to regulatory compliance which is used for final survey. The survey target senior executives of 430 PSMEs all over India. Final survey provides 71 data points, collected by online and direct interactions. The data is segregated as medium and small according Micro, Small and Medium Enterprises Development Act, 2006 (MSMED Act, 2006) for organizational size. The data analysis is done using AHP, a highly preferred tool for prioritizing and decision making. The pair wise comparison scale used in this study is given in Table. 1.

Table 1. AHP scale

Definition of scale	Score
Equally vulnerable	1
Somewhat more vulnerable	2
Moderately more vulnerable	3
Strongly more vulnerable	4
Definitely more vulnerable	5

3. RESULTS AND DISCUSSIONS

The AHP result on vulnerable characteristics to assess the most important vulnerable issue is shown in Table 2. Resource constraints are rated as the top issue, followed by difficulties involved in pharmaceutical innovation under compliance. Third rank observed is for the complexities involved in incorporating process change. Customer demands to products from green manufacturing is the fourth and plant facility change related issue being the last. The consistency ratio obtained for the analysis is well within the limits of 0.1

Table 2. AHP Result on vulnerability characteristics

Criteria (Level 2)	AHP weights	Rank
Process change	0.134	3
Resource constraints	0.397	1
Innovation and R&D	0.276	2
Facility changes	0.091	5
Customer preferences	0.102	4
P.E.Value	5.218123	
Consistency Index (CI)	0.054531	
Random Index (RI)	1.12	
Consistency ratio (CR)	0.048688	

Fig 2. shows the AHP weights for various criteria. The AHP results on regulatory factors given in Table 3 shows the complex regulatory standards prevailing in different nations are the most worried issue with a weight of 48%. The uncertainty prevailing among industrial sector to compliance is the second one and the nature of support and control from the regulators being the third. Consistency ratio obtained is slightly on the higher side, but within the limits.

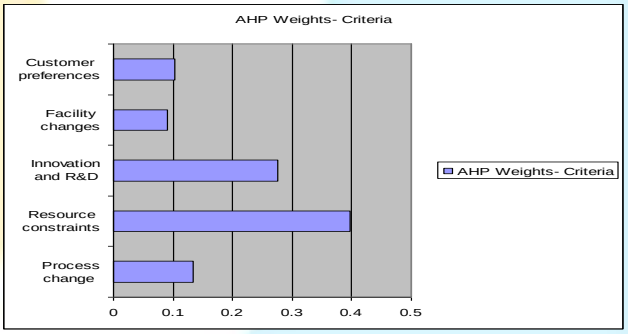

Fig 2: AHP results - criteria

Table 3 AHP results on regulatory factors (Alternatives)

Alternatives (Level 3)	AHP weights	Rank
Uncertain policy	0.328	2
Poor support and control	0.192	3
Complex standards	0.480	1
Principal Eigen Value	3.096097	
Consistency Index (C.I)	0.048048	
Random Index (R.I)	0.58	
Consistency Ratio (C.R)	0.082842	

Fig. 3 shows the AHP weights of various alternatives. To comply with the standards prevailing in national and international markets, regulated firms need to incorporate changes in the existing resources by spending large capital that rarely possible in SMEs. Compliance measures demands changes in layout, input resources, pollution control devices and even reformulation of the existing product mix (Ashford, 1993). These initiatives focused on fundamental shift, add visible environmental compliance cost along with other additional constraints on production process. Incorporating changes in process and product formulation in this sector needs special effort. Steps involved in getting acceptance from the regulatory bodies

make it vulnerable for the smaller firms, a specialty of pharmaceutical sector.

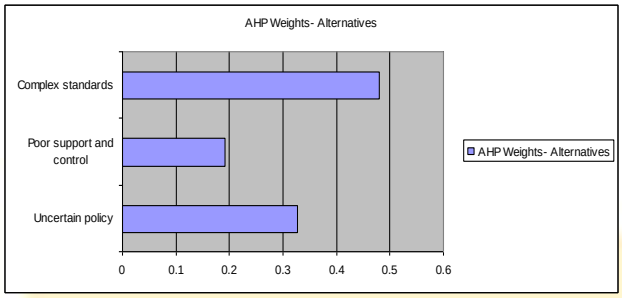

Fig. 3: Figure 3 Regulatory factors (Alternatives)

Regulatory uncertainty refers to the range of impacts that regulation can act up on cost and revenue processes within the firm. Due to uncertainty about government policies, decision makers are unable to assess risk involved for investment in new technologies. In addition to the knowledge about current regulations affecting operations, managers must also need to track numerous future challenges applicable to their processes. Frequent changes in environmental policy and regulation standards impede the management actions in many situations; keeping their investment plans pending anticipating further changes in policy. This in turn affects the product development, manufacturing and marketing functions to a certain extent.

Research & Development is regarded as the key to the growth of pharmaceutical industry. Considerable improvement in life expectancy and health all over the world are the result of a investment in research on drugs. Though India is emerging as the most favored destinations for collaborative R&D research and manufacturing on pharmaceuticals, the present level of spend on R&D is much lower as compared to most of the developed countries. Complex regulatory formalities made the process more complicated for the SMEs involved in research and product modifications. For research and development in this sector it is essential to provide suitable incentives to those units which are genuinely engaged in R&D.

Brand approval system prevailing in the country is having lot of impact on the performance of SMEs and it appears inappropriate for the pharmaceutical sector. The problems that are commonly encountered in the market are many to the sector. It is a common feature that, number of products has either the same brand or name which we could not easily distinguish. In some cases the product composition of brands reportedly changed without any change in the brand name, termed as misbranding. The lack of transparency in licensing procedures is major reason identified for this. The regulatory support on technical and legal matters is also missing due to resource constraints.

PSMEs are finding it difficult to raise funds to upgrade their manufacturing plants as per the standards, resulting in the closure of many facilities. The environmental concerns arising out of difficulties in hazardous waste disposal in PSMEs are to be addressed by the government and regulatory bodies. To improve the compliance prospects of PSMEs, industrial arrangements between domestic SMEs, large local firms and MNCs for the knowledge transfer seem to be ideal. This will certainly result in narrowing down the regulatory and technology gap. This is possible with the support of government and regulatory organizations through some policy changes. Hence, emphasize is that the policy makers and regulatory agencies need to take a leading role in persuading industries to unite and to achieve voluntary environmental standards This should be coupled with appropriate support in the form of technical / financial incentives of various forms like, low interest loans, tax deductions on environmental compliance equipments etc. In effect, a strong centralized regulatory regime is needed to effectively monitor GCP guidelines, to facilitate the sector to excel in the markets.

4. CONCLUSIONS

Lack of accurate and timely information on emerging environmental policy instruments produces unintended adverse effects on developing countries. A number of policy measures need to be devised for the regulatory support to utilise the untapped talents within the nation. To reduce the likelihood of international trade restrictions distinct policy and strategic measures need to be adopted in the existing set up. Setting up of importing countries testing and certifying centres, harmonizing the product and process standards, technology transfer, financial assistance and transparency in information about the policies at the regional, national and international level are some of the techniques adopted by developed nations. To practice this, PSMEs in particular need strong policy interventions from within and also from external regulatory regime that support organizations. Recent regulatory initiatives from the government like the National Drug Authority (NDA) are the stepping stones towards this end.

REFERENCES

[1] Ashford, N.A. (1993). Understanding Technological Responses of Industrial Firms to Environmental Problems: Implications for Government Policy, in Fischer, K. and Schot, J. (Eds.), *Environmental Strategies for Industry*, Island Press, Washington DC.

[2] Barbera, Anthony J. and Virginia, D. McConnell. (1986). Effects of Pollution Control on Industry Productivity: A Factor Demand Approach, *The Journal of Industrial Economics.* XXXV, 161-172.

[3] Birnbaum, P.H. (1984). The choice of strategic alternatives under increasing regulation in high technology companies, *Academy of Managememt Journal*, 27, 489–510.

[4] Bragdon, J. H. and Marlin, J. (1972). Is pollution profitable?, *Risk Management*, 19 (4), 9-18

[5] Broke, W. A. and Evans, D. S. (1986). The economics of small business: their role and

regulation in the US economy, Holmer and Meier, New York.
[6] Carlton, D. W. (1990). The theory of allocation and its implications for marketing and industrial structure. National Bureau of Economic Research, Working paper No. 3786
[7] Caves, R. (1982). American Industry: Structure, Conduct, Performance. Prentice-Hall, Englewood Cliffs, NJ.
[8] Christian, Engau and Hoffmann, V. H. (2009). Effects of regulatory uncertainty on corporate strategy—an analysis of firms' responses to uncertainty about post-Kyoto policy, Environmental Science and Policy, 12 (7), 766-777.
[9] Dasgupta, N. (1997). Greening small recycling firms: the case of lead smelting units in Calcutta, Environment and Urbanization. 9 (2), 289-306.
[10] Dean T. J. and R. L. Brown. (1994). Pollution regulation as a barrier to new firm entry: Initial evidence and implications for future research, *Academy of Management Journal*, 38, 288–303.
[11] Esty, D. C. (2001). Bridging the trade-environment divide, Journal of Economic Perspectives, 15(3): 113-130.
[12] Frijns, Jos and Bas Van, Vliet. (1999). Small-Scale Industry and Cleaner Production Strategies. Institute for Housing and Urban Development Studies, Rotterdam, The Netherlands
[13] Gingrich, N. (1995). To renew America. Harper Collins, New York
[14] Gollop, Frank M. and Mark J. Roberts. (1983). Environmental Regulations and Productivity Growth: The Case of Fossil-fueled Electric Power Generation, Journal of Political Economy, 91 (40), 654-674.
[15] Gouldson, A. (2004). Cooperation and the capacity for control: regulatory styles and the evolving influence of environment regulations in the UK, Environment and planning C: Government and policy, 22:583-603.
[16] Gray, Wayne B. (1987). The Cost of Regulation, OSHA, EPA and the Productivity Slowdown, American Economic Review, 77 (5).
[17] Gurtoo, A., and Antony, S. J. (2007). Environmental regulations: Indirect and unintended consequences on economy and business, Management of Environmental Quality, 18 (6), pp 626 – 642.
[18] Jaffe, A. and R. Stavins. (1995). Dynamic incentives of environmental regulation: the effects of alternative policy instruments on technology diffusion, Journal of Environmental Economics and Management, 29, pp. S43-S63.
[19] Jayadevappa, R. (1996). Free Trade and Environmental Regulation: A Study on NAFTA. Ph.D. dissertation. University of Pennsylvania
[20] Kulkarni, V. and Ramachandra, T. V. (2006). Environmental management. Common wealth of learning, Canada.
[21] Miller, P. E. (1998). Analyzing effects of regulatory compliance in manufacturing, Industrial Management & Data Systems, 108–112.
[22] Organization for Economics Cooperation and Development (OECD). (1989). Economic Instruments for Environmental Protection, OECD, Paris.
[23] Pargal, Sheoli and Wheeler, D. (1996). Informal Regulation of Industrial Pollution in Developing Countries: Evidence from Indonesia, The Journal Of Political Economy, 104 (6), 1314-1327.
[24] Porter M., van der Linde, C. (1995). Toward a new conception of the environment competitiveness relationship, Journal of Economic Perspectives, 9 (4), 97-118.
[25] Porter, M. E. (1991). America's green strategy, Scientific American, 264(4), 168.
[26] Salter, J. (1992). Corporate environmental responsibility: Law and practice. London, Butterworth
[27] Spicer, B. H. (1978). Investor's corporate social performance and information disclosure: An empirical study. Accounting Review, 53: 94-111.
[28] Stafford, S. L. (2000). The impact of environmental regulations on the location of firms in the hazardous waste management industry. Land Economics, 76(4).
[29] Visvanathan, C. and S. Kumar. (1999). 'Strategies for Implementing Cleaner Production in Asian Small and Medium Industries'. Journal of Cleaner Production, Vol. 7, pp. 127-134.
[30] Walley, N. and Whitehead, B. (1994). It's not easy being green, Harvard Business Review, 72(3), pp. 46-52.
[31] Yasamis, F. D. (2007). Assessment of Compliance Performance of Environmental Regulations of Industries in Tuzla (Istanbul, Turkey), Environmental Management, 39 (4), pp. 575–586.
[32] Fröhlich, B. and Plate, J. 2000. The cubic mouse: a new device for three-dimensional input. In Proceedings of the SIGCHI Conference on Human Factors in Computing Systems
[33] Tavel, P. 2007 Modeling and Simulation Design. AK Peters Ltd.
[34] Sannella, M. J. 1994 Constraint Satisfaction and Debugging for Interactive User Interfaces. Doctoral Thesis. UMI Order Number: UMI Order No. GAX95-09398., University of Washington.
[35] Forman, G. 2003. An extensive empirical study of feature selection metrics for text classification. J. Mach. Learn. Res. 3 (Mar. 2003), 1289-1305.
[36] Sannella, M. J. 1994 Constraint Satisfaction and Debugging for Interactive User Interfaces.

Doctoral Thesis. UMI Order Number: UMI Order No. GAX95-09398., University of Washington.

[37] Forman, G. 2003. An extensive empirical study of feature selection metrics for text classification. J. Mach. Learn. Res. 3 (Mar. 2003), 1289-1305.