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Modelling the Enablers of Green and Sustainable Practices in Indian Pharmaceutical Industry- An ISM Approach

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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ABSTRACT

Rising environmental issues and production of hazardous waste by the pharmaceutical industry has created a harmful impact on society, the environment, and pharmaceutical companies' reputation. It has given rise to the need to adopt and integrate green and sustainable pharmaceutical company's practices to mitigate environmental degradation's negative effects. The aim is to identify hierarchical interrelationships between these variables and determine their significance through MICMAC analysis and Interpretive Structural Modelling (ISM). The study identified ten significant enablers by exploring literature review and consultation with the industry experts from the Indian Pharmaceutical sector, which led to an understanding of their interrelationships. A four-level model was derived through the ISM technique. Pressure from the customer was found to be the most important enabler, followed by top management commitment and regulation. These enablers carry high driving power. The model developed through this study will help the pharmaceutical companies and their managers to implement green processes systematically.

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1. INTRODUCTION

Globally pharmaceutical industry has been growing at a significant rate in recent years. Its valuation stood at 1.25 trillion USD till the end of 2019. The United States is a leading market for pharmaceuticals, followed by emerging countries such as Russia, Brazil, China, and India. The pharmaceutical sector is amongst the fastest growing sectors of the Indian Economy, with the potential to grow to 100 billion USD by 2025. 'Pharma Vision 2020' was launched by the Government of India to achieve global leadership in end-to-end manufacturing. India captured the international market with active pharmaceutical ingredients and engineered generic drugs produced innovatively. In the US market, India accounts for 30% (in volume) and 10% (in value) in USD 70-80 billion [1].

But back at home, the pharmaceutical industry faces roadblocks as Indian Environmental Ministry has classified Pharmaceutical manufacturing as a 'red category' on account of its production of hazardous waste. Discharging large quantities of drugs and toxic chemicals in nature has environmental consequences that can't be overlooked. Compared to other industrial pollution, effluent's impact on pharmaceutical manufacturing remains an unexplored problem and requires quick corrective actions [2].

With time, various groups and companies within the industry have brought significant changes in methodologies leading to green chemistry and engineering [3]. Pharmaceutical companies have realized that sustainability is a long-term value creation process [4]. The results benefit their business and stakeholders such as customers, employees, communities, investors, and suppliers [5]. In 2003 the green pharmacy concept was introduced. It was a combined environmental stewardship approach, preventing pollution and reducing waste by minimizing APIs in the environment [6]. Green pharmacy is the design of pharmaceutical products and processes that eliminate or reduce the use and generation of hazardous substances and the prevention/reduction of environmental/safety and health impacts at the source" [7] significantly. Companies have to recognize the environmental issues that risk their business and society and address them by adopting and implementing green pharmacy practices [8]. For companies to develop a "green process," there is a need for an integrated approach of green chemistry and green technology [9].

"Green Chemistry is the design of chemical products and processes that reduce or eliminate the generation of hazardous substance." It has been widely accepted in various industry and research areas along with pharmaceuticals due to its advantages. There is a need to provide affordable, sustainable produced medicine to the increasing patient population in the present times. Hence, improving the efficiency of the pharmaceutical industry is a very important factor [10].

Although there are enough knowledge and understanding of green practices and processes' advantages, it has still not been completely adopted in pharmaceutical companies. The literature available has not been able to provide a holistic approach to integrating these practices. The paper determines various enablers of green pharmaceutical practices through a detailed literature review and interaction with experts; the paper determines various enablers of green pharmaceutical practices. The extant literature further classifies green pharma enablers into internal and external factors depending on their influence. It helps companies understand and implement drivers that help them undertake green practices in India.

The model is developed with the Interpretive Structural Modelling technique and MICMAC analysis. The model presents a set of enablers and their interrelationships that help achieve green practices and processes in pharmaceutical companies. To the best of the researchers' knowledge, such a holistic study leading to a model that facilitates a pharmaceutical company's transformation into green pharma has not been conducted in the past. The study addresses this research gap.

2. LITERATURE REVIEW

The pharmaceutical manufacturers face a great threat in manufacturing the products showing environmental concerns of the consumers. The impact of the pollution on the quality of life was a serious concern in developed and developing countries with the huge number of

pharmaceutical industries. So to overcome the seriousness a new technology development paved the way for drug manufacturers the opportunity to create a green chemistry.

The literature comprises various enablers that have integration with green practices by pharmaceutical companies. The literature has been classified into internal and external enablers. The internal enablers are organizational factors such as top management commitment, product stewardship, and awareness of internal stakeholders, organizational capabilities, cost savings, supplier involvement, and technological enablers. External drivers include regulation, reputation, and pressure from the customers [11].

2.1 Top Management Commitment

The senior management's involvement is pivotal in clarifying Environmental Management information and values throughout the organization and encourages employees to take green initiatives. Their power and visibility help deliver environmental messages to all the employees. Top management should recognize the green teams formed and provide support to integrate environmental measures into their strategies [12].

Senior management has an important role to play. The various policies and procedures are made and motivate employees to participate in green initiatives and become responsible for the pharmaceutical industry's environment. Pro-active thinking of top management and incorporation of sustainability practices in vision-mission positively influences the pharmaceutical sector's environmental and economic performance [13].

2.2 Product Stewardship

Product stewardship is an act that involves all participants taking responsibility for reducing the negative impact on human health, environment, and Economy. It embraces the entire product life-cycle. The manufacturers have a greater ability to reduce the adverse impact and hence have greater responsibility [14]. It has been recognized that this factor is just as related to pharmaceutical products as any other warship. Designing an integrated system-wide approach to reducing the PPCs can benefit customers and manufacturers' environment [15].

2.3 Education and Awareness of Internal Stakeholders

Training and awareness programs about green management practices are a way to get closer to green management. Environmental awareness has a significant role in adopting green practices in manufacturing and implementing them [16]. Increasing stakeholder awareness is a very critical step in achieving overall sustainability in pharmaceutical manufacturing industries. Awareness and education about green chemistry are critical factors in India's implementation by both API manufacturers and generic drug pharma. Awareness as a driver puts pressure on employing green supply chain management practices [17].

2.4 Developing Organizational Capabilities

It is critical to integrate green chemistry and green engineering to design a sustainable pharmaceutical process [18]. With the correct tools and implementation of green engineering, it can greatly help adopt sustainable processes, products, systems, and the environment in general. The approach mainly deals with using less energy, cleaner solvents to make the process green and contribute to greening the industry [19].

2.5 Cost-Saving

Due to pressure to cut costs by the global healthcare industry, pharmaceutical companies now have to reduce their spending. Manufacturing expenses are considerably high, and therefore it requires cost-cutting initiatives. In the long run, adopting the green process is always cost-effective [20]. It opens doors for the environmental process, which aims to save energy and reduce waste disposal. It economically benefits the supply chain players and manufacturers and allocates resources on R&D further [21].

2.6 Supplier Involvement

In delivering lifesaving drugs and services, the pharmaceutical industry has harmed the environment in various ways. Hence, in a country like India, which is still developing, it is imperative to integrate green supply chain practices in this sector [22]. When environmental activities are conducted with suppliers, the results are more beneficial. Exchanging green information and

green production technology with the upstream and downstream suppliers and green consumers in the production process can benefit operational, economic, and environmental performance [23].

2.7 Technological Enablers

To design with integrating the 'green' in pharmaceutical, it is important to identify and measure technology's environmental impact. It helps in understanding the environmental issues along with operational and cost factors. New and improved technology will significantly help the pharmaceutical industry reduce its R&D cost, better understand the disease, and improve its ability to produce measurable treatments. The development of new technologies in the innovator pharmaceutical industry is directed towards more environmentally benign processes.

2.8 Regulation

Legislative compliance helps significantly in achieving sustainability in pharmaceutical companies giving flexibility and a competitive advantage. The company's manufacturing green drugs can provide with the patent extension [24]. Regarding Indian Pharmaceutical companies, environmental regulation is an important driver in adopting GC. In general, it is considered the most significant drive.

2.9 Reputation

A good corporate image has a very high value and has a very positive impact on its operations and dealing with external regulations. There are many ways to benefit a pharmaceutical company. It enhances loyalty and improves relations with various stakeholders such as regulators, customer groups, investors, and collaborating companies [25]. In implementing sustainable practices in pharmaceutical sectors, improving corporate image and reputation is an important external motivational factor. Reputation is the most important driver for green chemistry adoption by pharmaceutical companies in India.

2.10 Pressure from the Customers

The customers' pressure is a significant motivator for firms to adopt and integrate environmental objectives and sustainable practices [26]. Historically, it is believed that the customers' pressure has accelerated social and environmental conditions concerning manufacturing pharmaceutical products [27]. Pressure from customers and community stakeholders has a major role in successfully implementing and integrating green supply chain practices by producers of the pharmaceutical industry in India [22]. Customers such as the government and hospitals demand more clarity and information on sustainable practices. Customer demand is an important driver which helps 'big pharma' and generic manufacturers adopt green chemistry and address the critical issue of waste, chemicals, and energy.

3. ISM METHODOLOGY

Interpretive Structural Modelling is a tool that helps identify and understand the interrelationship existing between qualitatively defined variables and create a structured model. It is based on the group's brainstorming session on how the variables are interrelated, creating a digraph [3]. The current research tries to demonstrate the interrelationship amongst the enablers of the green pharmaceutical industry. Following are the steps for ISM methodology.

3.1 ISM Model Formation

Interpretive structural modelling is a process that transforms a low model system in to visible models which was useful for pharmaceutical purposes. ISM is found to be a prominent modelling approach for analysing the interrelationship and bring into consideration a system of directly and indirectly related elements, which narrates the complex organisational issues. This makes ISM a more natural approach to the pharmaceutical approaches [28].

Ten enablers are identified by exploring the extensive literature and consultation with the industry experts and academics. The identified variables are further examined for their contextual relationships amongst themselves [27]. Various matrixes are formed regarding this, and a model is developed towards the end.

- Structural Self Interaction Matrices (SSIM)
- Reachability Matrix and Transitivity Principle
- Partitioning of Final Reachability Matrix
- Conical Matrix development
- Diagraph development

3.2 Structural Self-Interaction Matrix (SSIF)

After identifying the significant enablers, a brainstorming session between the experts was

conducted to determine the comparison between each pair of enablers. ‘i' and 'j' symbols to portray the relationship between these variable pairs, i.e., total enablers in rows and columns.

- V - the variable i will help achieve variable j
- A - the variable j will help achieve variable i
- X -variable i and j will help achieve each other
- no relationship between the variables.

The matrix formed from these 10 enablers, based on the contextual relationship can be seen in Table 1.

3.3 Reachability Matrix

SSIM is developing the Initial Reachability Matrix, which depicts the binary relationship within variables. The symbol V, A, X, O, which shows various relationships, is now replaced with 0 and 1, shown in Table 2. The substitution is done as follows:

1. In SSIM –> if (i, j) entry is V, then in the reachability matrix, the (i, j) entry becomes one, and entry (j, i) becomes 0
2. In SSIM-> if (i, j) entry is A, then in the reachability matrix, the (i, j) entry becomes 0, and entry (j, i) becomes 1
3. In SSIM-> if (i, j) entry is X, then in the reachability matrix, the (i, j) entry becomes 1, and entry (j, i) becomes 1
4. In SSIM-> if (i, j) entry is O, then in the reachability matrix, the (i, j) entry becomes 0, and entry (j, i) becomes 0

Further, transitivity is integrated to derive the Final Reachability Matrix. Transitivity is explained as; if variable X enablers variable Y and variable Y further enables variable Z, then variable X enables Z. Transitivity is shown as 1*in Table 3 and Table 2 shows the Initial Reachability Matrix.

Table 1. Structural self-interaction matrices

ENABLERS			J								
			10	**9**	**8**	**7**	**6**	**5**	**4**	**3**	**2**	**1**
i	**1**	Top management commitment	A	V	X	V	V	V	V	V	V	-
	2	Product Stewardship	A	V	A	A	A	O	A	A	-	-
	3	Education and awareness- internal stakeholders	A	X	A	V	O	V	A	-	-	-
	4	Organizational capabilities	O	V	A	X	V	X	-	-	-	-
	5	Cost Savings	O	O	A	A	X	-	-	-	-	-
	6	Supplier Involvement	A	X	A	A	-	-	-	-	-	-
	7	Technological enablers	A	V	A	-	-	-	-	-	-	-
	8	Regulation	O	O	-	-	-	-	-	-	-	-
	9	Reputation	A	-	-	-	-	-	-	-	-	-
	10	Pressure from the customers	-	-	-	-	-	-	-	-	-	-

Table 2. Initial reachability matrix

ENABLERS	1	2	3	4	5	6	7	8	9	10	Driving power
1	1	1	1	1	1	1	1	1	1	0	9
2	0	1	0	0	0	0	0	0	1	0	2
3	0	1	1	0	1	0	1	0	1	0	5
4	0	1	1	1	1	1	1	0	1	0	7
5	0	0	0	1	1	1	0	0	0	0	3
6	0	1	0	0	1	1	0	0	1	0	4
7	0	1	0	1	1	1	1	0	1	0	6
8	1	1	1	1	1	1	1	1	0	0	8
9	0	0	1	0	0	1	0	0	1	0	3
10	1	1	1	0	0	1	1	0	1	1	7
Dependence power	3	8	6	5	7	8	6	2	8	1	

Table 3. Final reachability matrix

ENABLERS	1	2	3	4	5	6	7	8	9	10	SUM	RANK
1	1	1	1	1	1	1	1	1	1	0	9	2
2	0	1	1*	0	0	1*	0	0	1	0	4	5
3	0	1	1	1*	1	1*	1	0	1	0	7	3
4	0	1	1	1	1	1	1	0	1	0	7	3
5	0	1*	1*	1	1	1	1*	0	1*	0	7	3
6	0	1	1*	1*	1	1	0	0	1	0	6	4
7	0	1	1*	1	1	1	1	0	1	0	7	3
8	1	1	1	1	1	1	1	1	1*	0	9	2
9	0	1*	1	0	1*	1	1*	0	1	0	6	4
10	1	1	1	1*	1*	1	1	1*	1	1	10	1
SUM	3	10	10	8	9	10	8	3	10	1		
RANK	4	1	1	3	2	1	3	4	1	5		

3.4 Partitioning of Final Reachability Matrix

Level partitions are developed concerning the final matrix to determine the hierarchical placing of the variables. Both antecedent sets and reachability sets are developed from the final matrix. It contains the variable itself and all variables influenced by it, and antecedent includes the variable itself and all variables it influences. It is repeated till each variable is placed in levels. The summary of these levels is demonstrated in Table 4.

3.5 Conical Matrix

After Level partitioning of reachability matrix, a conical matrix is made where variables are rearranged as per their levels. This is exhibited in Table 5. The final digraph is composed by aggregating variables in the same level together.

Table 4. Summary of partitioning the final reachability matrix

ENABLERS	Antecedent set	Reachability set	Intersection set	Level
1	1,8,10	1,2,3,4,5,6,7,8,9	1,8	3
2	1,2,3,4,5,6,7,8,9,10	2,3,6,9	2,3,6,9	1
3	1,2,3,4,5,6,7,8,9,10	2,3,4,5,6,7,9	2,3,4,5,6,7,9	1
4	1,3,4,5,6,7,8,10	2,3,4,5,6,7,9	3,4,5,6,7	2
5	1,3,4,5,6,7,8,9,10	2,3,4,5,6,7,9	3,4,5,6,7,9	2
6	1,2,3,4,5,6,7,8,9,10	2,3,4,5,6,9	2,3,4,5,6,9	1
7	1,3,4,5,7,8,9,10	2,3,4,5,6,7,9	3,4,5,7,9	2
8	1,8,10	1,2,3,4,5,6,7,8,9	1,8	3
9	1,2,3,4,5,6,7,8,9,10	2,3,5,6,7,9	2,3,5,6,7,9	1
10	10	1,2,3,4,5,6,7,8,9,10	10	4

Table 5. Conical matrix

ENABLERS	2	3	6	9	4	5	7	1	8	10
Product Stewardship	1	1	1	1	0	0	0	0	0	0
Education and awareness- internal stakeholders	1	1	1	1	1	1	1	0	0	0
Supplier Involvement	1	1	1	1	1	1	0	0	0	0
Reputation	1	1	1	1	0	1	1	0	0	0
Organizational capabilities	1	1	1	1	1	1	1	0	0	0
Cost Savings	1	1	1	1	1	1	1	0	0	0
Technological enablers	1	1	1	1	1	1	1	0	0	0
Top management commitment	1	1	1	1	1	1	1	1	1	0
Regulation	1	1	1	1	1	1	1	1	1	0
Pressure from the customers	1	1	1	1	1	1	1	1	1	1

3.6 Developing a Diagraph

Concerning the Conical Matrix, a digraph is developed with a significant transitivity link. The indirect links have not been considered. All variables identified at level 1 are placed at the top, followed by level 2 variables, and so on. The arrows signify the hierarchical interrelationship between the variables.

Fig. 1 exhibits the developed digraph, which represents the level-wise relationship between the ten enablers. A four-level model is obtained where the enabler, i.e., pressure from the customers at the fourth level, is most significant. It further leads to top management commitment and regulation. These enablers lead to the organizational capabilities, Cost savings, and Technological enablers, which have more to do with the organization's internal orientation. Product stewardship, supplier involvement, education and awareness of the internal stakeholders, and Reputation are enablers that form the first level where stakeholders at the internal and external end have to be responsible for improving the operations and the environment. Fig. 1 shows the Hierarch of Enablers developed using Interpretive Structural Modeling (ISM).

4. RESULTS AND DISCUSSION

MICMAC studies the driving and dependency power of the variables. Along with confirming the important role of certain variables, MICMAC also helps reveal the importance of indirect variables. The initial reachability matrix is used in deriving the overall driving and dependence power. MICMAC further classifies quadrants into autonomous, dependent, linkage, and independent.

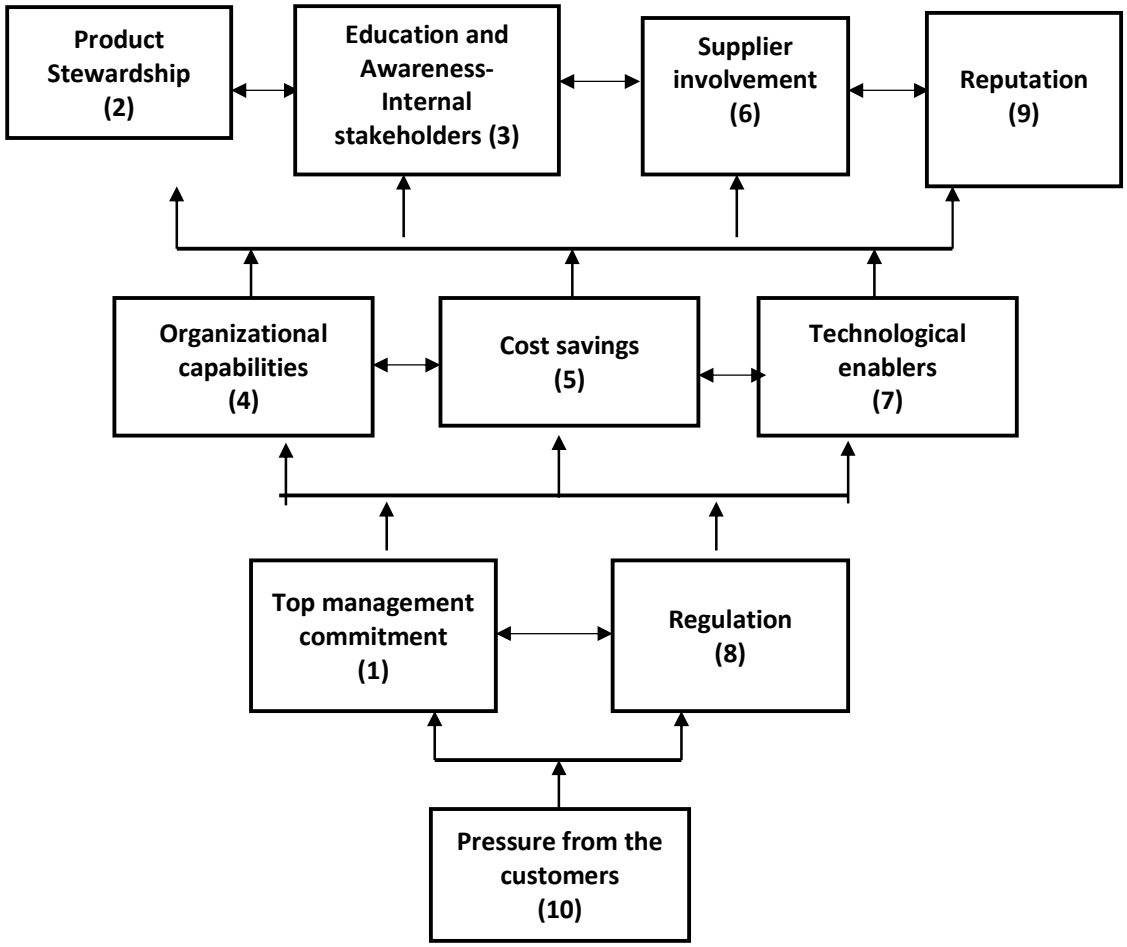

Fig. 1. Hierarch of enablers developed using interpretive structural modeling (ISM)

Table 6. Micmac classification of the enablers

Driving power									
		4. Independent factors				**3. Linkage factors**			
	9			1					
	8		8						
	7	10				4			
	6						7		
	5						3		
	4								6
	3							5	9
	2								2
	1								
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
		1. Autonomous factors				**2. Dependent factors**			

Dependence power

These four quadrants are classified in Table 6. Top management commitment, Regulation, and Pressure from the customers (i.e., enablers 1, 8, and 10), are major driving enablers because of high driving power. The enablers which provide linkage between dependent and independent variables are education and awareness of internal stakeholders, Organizational capabilities, and Technological enablers (i.e., enabler 3, 4, and 7). Product stewardship, Cost savings, Supplier involvement, and reputation (i.e., 2, 5, 6, and 9) are on the higher side of dependence power. MICMAC assists in visualizing the significance of the variables. Table 6 shows the MICMAC classification of the Enablers.

5. CONCLUSION

Pharmaceutical firms worldwide are constantly adopting new and sustainable approaches to gain a competitive advantage. Integrating sustainable practices are a way of getting closer to economic, operational, and environmental objectives. This ISM study aims to provide assistance to pharmaceutical drugs manufacturers by identifying the enablers' hierarchy to be implemented. It enables the practitioners to understand the significance of enablers through relationship links and a structured model. Amongst all the enablers, Pressure from the customers is the most dominant enabler, followed by Regulation and Top management commitment. These variables with high driving power should be given significant consideration. The pressure from customers and regulators is shown here to drive organizations to adopt green, sustainable processes. The external variables put pressure on the pharmaceutical firms to adopt environmentally benign products through clean processes. The top management has a significant role in integrating green initiatives and sustainability at all organizational levels. These enablers further lead to organizational capabilities, cost savings, and technological enablers. They are responsible for driving the green process through the organization, adopting clean and innovative technology, and providing economic and operational benefits in the long run.. All the stakeholders involved in the life-cycle are critical in mitigating the environment's negative effects. Reputation enhances the relationship with these stakeholders. The study in all has identified enablers and provided a model for integrating green practices in the pharmaceutical industry.

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CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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