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Deciphering the role and impact of India's pharmaceutical industries and its regulatory compliance

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Abstract

The pharmaceutical industry faces exceptionally high R&D costs, with the US research-based sector investing about 17% of sales into R&D. The cost of bringing a new compound to market was estimated at $802 million in 2001, up from $138 million in the 1970s and $318 million in the 1990s, necessitating stringent regulations. This study aims to determine the role and impact of India's pharmaceutical industry and its regulatory compliance. Personnel from organizations established between 1884 and 2004, with turnovers ranging from Rs. 25 crore (US $5.3 million) to Rs. 5500 crore (US $1.2 billion), were surveyed. Out of 150 companies approached, 73 responded, with 70 complete responses analyzed. Ongoing interactions with regulatory agencies helped companies better understand the regulatory system. Three key areas emerged as priorities: awareness of intellectual property rights (IPR) and patents, fostering a suitable environment for research and development, and implementing Good Manufacturing Practices (GMP), considered more critical than price control. The findings underscore the importance of regulatory compliance in promoting innovation and maintaining quality within the pharmaceutical industry, ensuring its competitiveness and ability to meet global standards.

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INTRODUCTION:

The regulatory framework in the Indian pharmaceutical sector is highly critical because of rapid and ongoing changes at the global level, mainly concerning good manufacturing practices (GMP), good clinical practices (GCP), and good laboratory practices [1]. The responsibility of the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the Indian masses also makes the regulatory framework critical. The Indian pharmaceutical industries are developing daily and becoming increasingly competitive, so regulatory agencies are

established to ensure drug safety, efficacy, quality accuracy, and appropriateness of the drug information available to the public [2]. Regulatory bodies provide strategic, tactical, and operational direction and support for working within regulations to accelerate developing and delivering safe and effective healthcare products to individuals nationwide [3].

ANALYSES OF DATA

Profile of Sample:

The respondents to the questionnaire for this research work were the personnel working in pharmaceutical industry/ organizations which were established from years 1884 to 2004 with turnovers ranging from Rs.25 crore (US $ 5.3 million) to Rs 5500 crore (US$ 1.2 Billion) [4]. A total of 150 pharmaceutical companies were approached to fill in the questionnaire; however, despite best efforts, only 73 respondents provided responses. Out of 73, 70 complete responses were used for the analysis, and three were rejected because of incomplete responses, regulations in the pre-development stage, post-marketing, pricing & patents, and the preferred Strategy [5].

Perceptions about the Pharmaceutical Regulatory System:

Purpose of Regulatory System

Table 1 Intention of Pharmaceutical Regulatory System

The intention of the Pharmaceutical Regulatory System	Average
Public authority to set and apply rules and standards	3.47
Set Procedures to conduct business	3.47
Protect consumers from business manipulations	4.07
Rationalisation of prices	3.42
Quality monitoring effort	4.07
Ensure access to medicines	3.77
Overall mean	3.71
Percentage	74.32

Significance of Regulations

Necessity of Regulations [6]

The respondents agree that regulations are essential. After the detailed data analysis, it was observed that regulations hinder innovation (Avg.score-3.48) and add to expenditure (Avg. score–3.45). This is depicted in Figure 2.

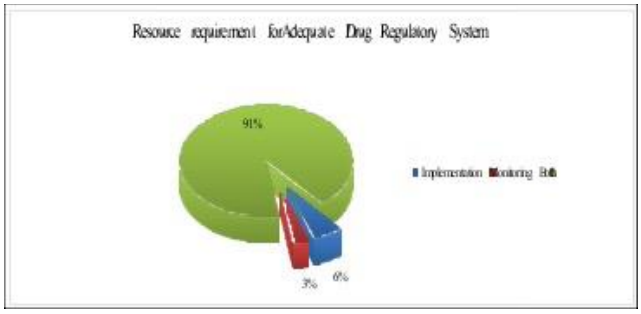

Figure 1 Resource Requirement for Adequate Drug Regulatory System

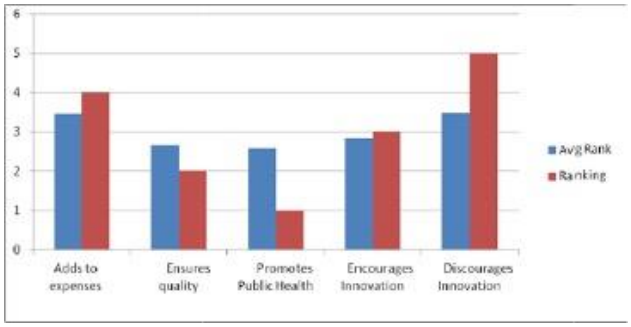

Figure 2 Ranking of features of the Pharmaceutical Regulatory System

Type of Regulatory System:

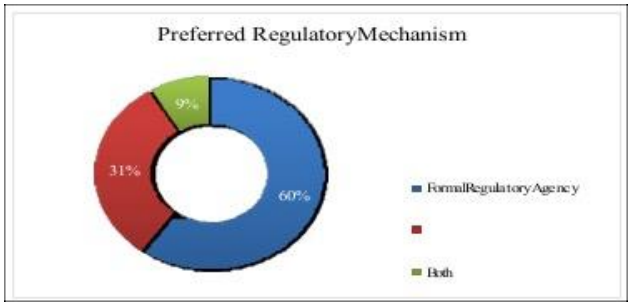

Figure 3 Preferred Regulatory Mechanism

Objectives of Regulatory System–Formal and Self-Regulatory System

As per the responses received and carrying out top 2 boxes analysis and assigning percentages to the top 2 boxes (those who selected 4 & 5 on a five-point rating scale), [7] the objectives of the formal regulatory agencies are listed below:

The advantages associated with self-regulation were also analyzed based on top2boxes for responses received on a five-point scale; promotion of good quality practices remained top

of the heap with an 82.3% score, and other factors such as promotion of good manufacturing practices, imposition of lower compliance cost on business were ranked as per the table hereunder.

Table 2 Objectives of the Formal Regulatory Agencies

Objectives of the formal regulatory agencies	Top2 Boxes	Top 2 Boxes Score %
Set Precise Rules	51	72.8
Monitor the Rules	32	45.7
Penalise for noncompliance	30	42.8
Give incentives for compliance	23	32.8

Table 3 Advantages associated with Self-regulation

Advantages associated with Self-regulation	Top 2 Boxes	Top 2 Boxes Score%
Promote good quality practices	56	82.3
Promote good manufacturing practices	52	76.4
Impose lower compliance costs on business	46	69.6
Offer quick, low-cost dispute solution procedures	46	69.6
Serve as product differentiator in the Market	40	64.5
Target specific problems within the industry	40	58.8

Comparison of different regulatory agencies

The respondents were further asked to compare the Indian regulatory system with other stringently regulated systems, such as the United States and the European Union. The findings were plotted on a radar plot to reveal the subtle differences in perceptions. All the points with more than 0.5-point difference are significant differences [8].

Approaches used for clinical trials

The regulatory agencies worldwide use different approaches such as – 1) trials by comparison to existing, 2) using a placebo comparator, and 3) trials on a target audience; the participant respondents felt that the trials by comparison to existing treatment are the best way to conduct the clinical trials [9].

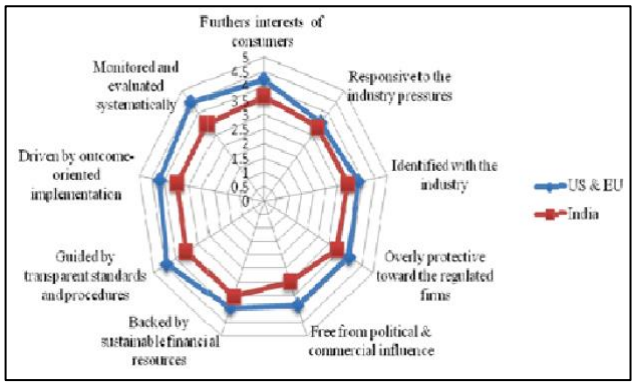

Figure 4 Comparison of different Regulatory agencies

The comparison of the suitability of clinical trial approaches adopted by Various is shown below:

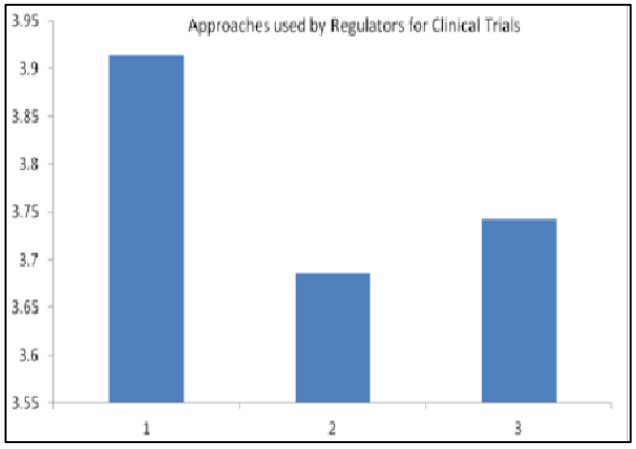

Figure 5 Approaches Used by Regulators for Clinical Trials

Table 4 Approaches used for clinical trials

Component No	Initial Eigenvalues		
	Total	% of Variance	Cumulative %
1	2.684	22.363	22.363
2	1.803	15.027	37.390
3	1.577	13.145	50.535
4	1.538	12.818	63.353
5	1.096	9.131	72.484
6	0.929	7.739	80.224
7	0.679	5.657	85.881
8	0.484	4.033	89.914
9	0.432	3.598	93.513
10	0.351	2.923	96.436
11	0.261	2.174	98.610
12	0.167	1.390	100.000

Table 5 Rotated component matrix

	Component				
	Production Centric	Marketing Centric	Collaboration Centric	M&A Centric	Capacity Centric
Integration (Forward & backward)	.771	.028	-.092	-.176	.085
Co-marketing alliances	.799	.194	.069	-.046	-.138
Being a major source of supply	.599	-.285	.382	-.036	.389
Entering into marketing alliances abroad	.464	.782	-.044	.071	-.038
Focus on alternative medicines (Herbal, Biotech, Genetic)	.189	-.798	-.148	.192	-.194
Collaboration	-.465	.207	-.508	-.059	.174
In-licensing and out-licensing alliances	.267	.079	-.649	.202	.344
International acquisitions	.154	.276	.741	.058	.234
Collaboration with Regulatory bodies	.031	.526	.583	.011	.088
Mergers & Acquisitions	.020	.043	.129	-.853	-.212
Expanding into niche formulations	-.192	-.058	.101	.881	-.194
Setting up production facilities	-.050	.145	-.005	.015	.889
Eigenvalue	2.684	1.803	1.577	1.538	1.096
% variance	22.363	15.027			
Standardized beta co eff.					

CONCLUSION

Indian pharmaceutical businesses have developed excellent chemical, regulatory, and manufacturing capabilities. The Indian pharmaceutical sector is subject to audits by purchasers as well as audits by regulators (both domestic and foreign). These businesses export both drug goods and medication ingredients. The industry's ongoing interactions with regulatory agencies helped them understand the regulatory system. Creating awareness about IPR/ patent, providing a suitable environment for research & development, implementing Good Manufacturing Practices, and compelling price control are the first three areas considered as more important by the industry as compared to price control, i.e., price control is not on a high on priority for the respondents for the growth of Pharmaceutical Industry in this country.

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REFERENCES

[1] Chatterjee B, Dash B, Shrestha B, and Bhuyan NR. Current Scenarios on Regulatory Landscape of Indian Pharmaceutical Industries. International Journal of Pharmaceutical Science and Research, 12:5642-5651, 2021.

[2] Chataway J, Tait J, and Wield D. Frameworks for pharmaceutical innovation in developing countries—the case of Indian pharma. Technology Analysis & Strategic Management, 19(5):697-708, 2007.

[3] Agrawal M and Thakkar Nimish. Surviving patent expiration strategies for marketing pharmaceutical products. Journal of

Product and Brand Management, 6(5):1061-0421, 1997.

[4] Dow Jones Irwin, Illinois Athreye S, Kale D, and Ramani SV. Experimentation with Strategy and the Evolution of Dynamic Capability in the Indian Pharmaceutical Sector. Industrial and Corporate Change, 18(4):729-759, 2009.

[5] Ernst R Berndt, Ashoke Bhattacharjya, David N Mishol, Almudena Arcelus, and Thomas Lasky. An analysis of the diffusion of new antidepressants: variety, quality and marketing efforts. Journal of Mental Health Policy and Economics, 5(1):3-19, 2002.

[6] Santiago G Moreno, and Joshua A Ray. The value of innovation under value-based pricing. Journal of Market Assessment and Health Policy, 4:10, 2016.

[7] N Kalant. Re: AP Boulet, G Tessier. Reference-based pricing in British Columbia: implications for cardiologists--an analysis. Canadian Journal of Cardiology, 13(1):46-51, 1997.

[8] Charles I. Jones and John C. Williams. Measuring the Social Return to R&D. The Quarterly Journal of Economics, 113(4):1119-1135, 1998.

[9] Pradeep K. Chintagunta, and Ramarao Desiraju. Strategic Pricing and Detailing Behavior in International Markets. Marketing Science, 24(1):67-80, 2005.