

Structural reforms and small scale Drugs Industry in India (SSDI)

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Abstract

The Indian Pharmaceutical Industry, which enjoyed a favorable climate in yearly 1990, is being shifted by the major structural changes. The main issue of the study is structural changes had made any impact in pharmaceutical sector on the small-scale drug industry in terms of growth. The study is based on the primary data collected from the 200 samples on Rensis Likert Scale 1932. Out of the total 200 samples, 100 samples have been collected from the entrepreneurs of the small-scale drug industry in and around Tamil Nadu and Puducherry. In order to avoid bias, another 100 samples have been collected from the non-industrial respondents who are mostly connected with the drug industry and familiar with IPA-2005 & drug policies. The result shows both industrial and non industrial respondents have favored the abolition of industrial licensing, contract manufacturing and major structural reforms. All the above policies are favorable to SSDI for increased investment opportunities resulting increased employment opportunities in the rural areas.

Key Words: *Structural Changes, Globalisation, Leberalisation, New Industrial Policy, Industrial Respondents, Non-Industrial Respondents, Small Scale Drug Industry (SSDI).*

Introduction

As part of the globalization programme, India has become a signatory of the GATT (now know as the World Trade Organisation (WTO) since 1995) and hence a signatory to the TRIPS. Under the TRIPS agreement India was under compulsion to introduce the "Product Patent" in 2005. So the Indian Pharmaceutical Industry, which enjoyed a favorable climate due to the cost-advantages, is being affected by the

introduction of the product patent where the high cost-advantage is not possible.

The drugs price control order helped the Indian Pharmaceutical units to increase the market share from 10 percent in the year 1970 to 66.7 percent in the year 1991. Almost 90 percent of the drugs were under price control which safe guarded the local units. However in the year 1987, this was diluted and the number of drugs, which were under the price control, has declined to 142 only. It declined further to

76 drugs in the year 1995. Now this has still decreased and has also switched over from Control Regime to Monitoring Regime in 2002. As the DPCO shifted from Control Regime to Monitoring Regime, there is every chance that the MNCs will once again get back their lost market share.

Globalization also had an influence on the foreign direct investments in the pharmaceutical industry. As per the new system, the foreign direct investment through automatic route, which was 40 percent of the total capital in the pre globalization period, has increased to 51 percent after globalization. It has further increased to 74 percent in March 2000, and the limit for the same has been raised up to 100 percent, since March 2003. This shows that the conditions for the foreign investments into the Indian Pharmaceutical Industries have been totally lifted. This will give further boost to MNCs to increase their investments in India as before 1970, which will result in, increase in the market share of the MNCs. India as a signatory of WTO is committed to remove tariff restrictions subject to certain relaxation. As a result, the tariffs for importing bulk drugs and formulations have been reduced. Thus the MNCs are getting good opportunity to import less priced drugs from their parent companies, (in essence affecting the Indian manufacturers).

The drug and pharmaceutical industry in general and small scale drug industry in particular in the country today face new challenges on account of liberalization of the Indian economy, the globalization of

the world economy and on account of new obligations undertaken by India under the WTO agreements. These challenges require a change in emphasis in the current pharmaceutical policy and the need for new initiatives beyond those enumerated in the Drug Policy 1986, as modified in 1994, so that policy inputs are directed more towards promoting accelerated growth of the pharmaceutical industry and towards making it more internationally competitive.

In spite of the drawbacks as mentioned above, an important favorable factor is the industrial licensing policy. Industrial licensing for almost all bulk drugs has been abolished. It encourages all the Indian pharmaceutical companies to produce as much as they desired and export them freely. Thus the major obstacles to the growth of the Indian pharmaceutical companies have been removed. Under this situation, what is the condition of small scale drug industry in India.

Contract Manufacturing (CM)

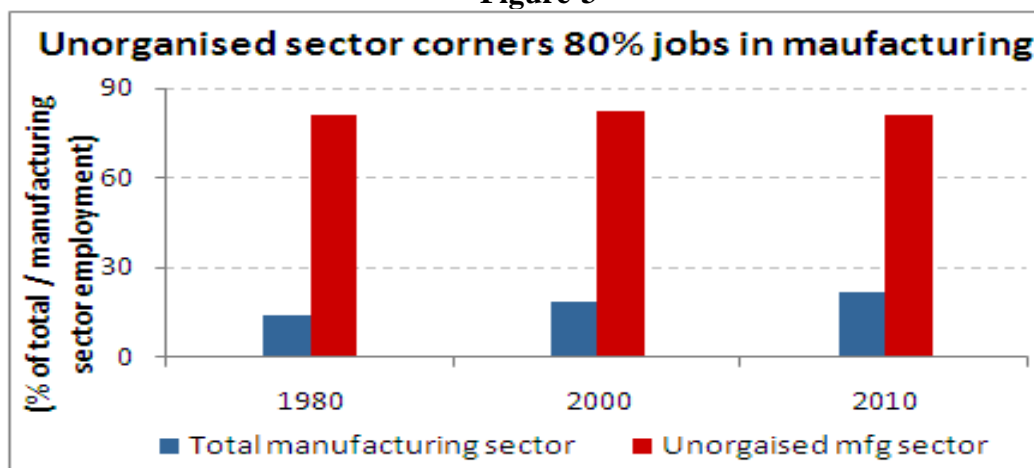
Contract research and manufacturing (CRAMS) market in India was valued at US\$ 800.4 million, of which contract manufacturing accounted for 84 per cent of the total market and the balance 16 percent became contract research, excluding clinical trials. Both contract research and manufacturing segments registered a robust growth of over 45 per cent in 2006-2007 and in 2010, the demand for contract manufacturing of formulations was around 300 million US\$. On the other hand, APIs and intermediate

demand was in the range of US\$ 600 to 700 million by 2010. This increase in contract manufacturing was because of rise in the confidence of global pharma, due to enforcement of product patent, large capital investment by Indian companies in building world class production facilities and increased service offerings by Indian players.

Figure-2
Primary source

Out of the total small scale drug industry in this study, 10 percent depend on only contract manufacturing, 12 percent on only loan licensing, 42 percent marketed by their own, 33 percent for all type of manufacturing and 3 percent for government supply. As a whole, in India 55 percent of the small scale drug industry depends on contract manufacturing.

Figure-3



Source: RBI, CSO

India's manufacturing may have already topped agriculture in terms of contribution to GDP. But its contribution to employment generation is not commensurate. Its contribution to employment is least impressive at 12% of total workforce. Archaic labor laws have hurt employment growth in the sector for decades. Even the most labor intensive sectors such as textile and jewelry making have halved their labor requirement. In fact as per data from **Central Statistics Office (CSO)** and **Reserve Bank of**

India (RBI), while the share of employment in manufacturing sector has grown from 13% to 21% over the past 2 decades, 80% of it has been in the unorganized segment. If this is the case for the small-scale industry as a whole in India, what about the contribution of the small scale drug industry in India? Is it increasing or decreasing over the years?

Aim of the Study

The study mainly focuses on abolition of industrial licensing for all drugs, contract manufacturing and investment

opportunity after structural reforms has created favorable effects or has caused harm to Small Scale Drug Industry (SSDI), and hence, based on this remedial measures can be suggested.. More specifically the objectives are 1) to analyze whether abolition industrial licensing for all drugs has improved the growth of SSDI. 2) Does contract manufacturing make good opportunities to SSDI after implementation of New Industrial Policy (NIP) and 3) evaluate the investment opportunity to SSDI after major structural reforms

The study primarily aims to analyse the attitudes, views, perceptions of small scale drug entrepreneurs towards implementation of New Industrial Licensing Policy in India and structural reforms during the study period 2005 to 2010. Small scale drug industry occupies a place of strategic importance in Indian economy in view of its considerable contribution to employment and rural upliftment. Therefore this type of study is more relevant.

Methodology and Data:

Sampling Techniques:

The study is purely based on the primary data collected from the 200 samples from Tamil Nadu and Puducherry on Rensis Likert Scale 1932. Though respondents are only from Tamil Nadu and Puducherry, the main issue of the study is the impact of structural reforms on small scale drug industry in India. Hence the perception of the respondents is likely to be the same irrespective of the state chosen. Therefore

the study is undertaken in Tamil Nadu and Puducherry

To obtain the primary data, questionnaire method has been adopted. Out of the total 200 samples, 100 samples have been collected from the promoters of the small-scale drug entrepreneurs. In order to avoid the bias, another 100 samples has been collected from the non-industrial respondents who are mostly connected with the drug industry and familiar with IPA-2005 & drug policies. The non industrial respondents are further classified into four categories each representing 25 members. They are: (1) Industrial workers like production managers, Quality control managers, Quality assurance managers (2) Whole sale drug distributors (3) Industry association members and academicians and (4) Sales representative. The following two questions were placed before the small scale entrepreneurs and non industrial entrepreneurs and scoring technique was applied based on points on the Likert scale.

Data collection has been planned in such a way that all the 200 samples were collected from the respondents without fail. Hence, a structured interview method has been adopted in order to get the answered questionnaire from the respondents, so that it would result in a good response rate, accurate information, and possible in-depth questions and can be completed immediately. This type of data collection improves the observation skill & helps better understanding of the process, provides opportunities to learn through direct, concrete experience &

enhances the understanding that comes from the observation of the real world on the basis of the problems. Hypothesis has been formulated & this research methodology has been designed. This type of field work undertaken ultimately depends on the purpose of the activity; hence it is a deductive approach.

Period of the Study:

This study is mainly based on the primary data. Since the study is based on the aftermath of introduction of IPA-2005 and changes in drug policy, some of the

information relevant for this study is also collected from the secondary sources for the year 2005 to 2010. The period of the study is from 2005 to 2010.

Organising data:

Scaling Techniques: A five-point Likert scale has been used in the study. Letters to indicate choices, such as “SD”(Strongly Disagree), “D”(Disagree), “N”(Neutral), “A”(Agree), “SA”(Strongly Agree) rather than numbers will be used. Mean Scores have been computed after converting the choices into numerical values.

Scoring Rensis Likert Scale:

In order to avoid bias there were two statements used having the same concepts, one positive and another negative. The points given for each response depends on whether the statement is positive or negative. The person who ‘strongly agrees’ with a positive statement gets maximum points (5). One who ‘strongly disagrees’ with a positive statement gets the minimum points (1). For a five-point scale, the scoring would be as follows for

positive statement: SD=1, D=2, N=3, A=4, SA=5.

The person who ‘strongly agrees’ with a negative statement gets minimum points (1), while the one who ‘strongly disagrees’ with a negative statement gets the maximum points (5). For a five- point scale, the scoring would be as follows for a negative statement: SD=5, D=4, N=3, A=2, SA=1.

Statement	Positive Statement
S1	Abolition of Industrial licensing for all drugs has encouraged the growth of SSDI.
S2	Small Scale Drug Industry (SSDI) has good opportunities in terms of contract manufacturing after implementation of New Industrial Policy (NIP).
S3	The investment opportunity to SSDI has been increasing after major structural changes.

Frequency distribution

The following tables show the response of both industrial and non-industrial respondents of this study. It will give a clear idea about the implementation of

new Licensing Policy, contract manufacturing, investment opportunity, and impact of structural reforms on small scale drug Industry in India.

Scores of Industrial and Non-Industrial Respondents in relation with Positive Statement

Respondents	Frequency					
	Industrial Respondents			Non-Industrial Respondents		
	S1	S2	S3	S1	S2	S3
Strongly Agree	33	46	42	48	61	42
Agree	52	34	46	32	32	48
No Comment	6	11	7	6	6	3
Disagree	6	7	2	10	1	7
Strongly Disagree	3	2	3	4	0	0
Mean Value	4.06	4.15	4.22	4.10	4.53	4.25
Std Deviation	0.95	1.01	0.89	1.142	0.658	0.821
Coefficient of vari	0.24	0.24	0.21	0.28	0.15	0.19
Range	100-500	100-500	100-500	100-500	100-500	100-500
Actual Score	406	415	422	410	455	425
Total Score		1243			1290	
		1500			1500	

IR = Industrial Respondents, Non-IR = Non Industrial Respondents

Data analysis

In the present study there are two types of statement– a positive and a negative and in each type there are three questions. Each question is valued on a five point Likert scale and scored. Each question's attitude score will range from 100 to 500, which is arrived by the formula Minimum score/maximum score \times number of respondents. For one question there were 100 respondents; so we get a low score of 100 (1×100) and a high score of 500 (5×100).

First we computed the total score of each question, and added all three statements to see the individual and overall perception of the industrial respondents. In the same way we arrived at the scores of the non-industrial respondents and finally both industrial and non-industrial respondents' scores were added for positive statements.

In the case of industrial respondents we arrived at an aggregate score of 406, 415, and 422 **points on this scale** (500 possible) for S1,S2,S3 respectively and for all three statements combined together the total

score added up to 1243 points (1500 points possible). On the other hand for non-industrial respondents score comes to 410,455, 425 **points on this scale** (500 possible) for S1,S2, S3 respectively and all the three statements put together the total points added up to 1290 points on this scale (maximum 1500 points

possible). By considering both industrial and non industrial respondents together the score comes to 2533 points out of 3000. This is exactly 84 percent of the score. This clearly indicates that both industrial and non industrial respondents have a positive attitude about the above statements.

Likert scale and scored.

	Negative Statements
1. Statement	India implemented controlled drug Licensing Policy hence it reduced the growth of SSDI.
2. Statement	Withdrawal of most of the favorable policies (price control, industrial licensing requirement, reservation of items, and preference in government procurement, etc.) has made the condition unfavorable to Small Scale Drug Industry (SSDI).
3. Statement	The large scale policy Liberalisation and globalization has created an unfavorable climate to Small Scale Drug Industry (SSDI)

Scores of Industrial and Non-Industrial Respondents in relation with Negative Statement

Respondents	Frequency					
	Industrial Respondents			Non-Industrial Respondents		
	S1	S2	S3	S1	S2	S3
Strongly Agree	11	10	11	10	1	3
Agree	11	17	10	22	12	9
No Comment	19	20	22	10	17	7
Disagree	34	32	28	34	39	31
Strongly Disagree	25	21	29	24	31	50
Mean Value	3.51	3.37	3.54	3.40	3.87	4.16
Std Deviation	1.28	1.27	1.31	1.33	1.02	1.09
Coefficient of vari	.37	.38	.37	.39	.26	.26
Range	100-500	100-500	100-500	100-500	100-500	100-500
Actual Score	351	337	354	340	387	422
Total Score	1042			1149		

	1500	1500
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In the case of non industrial respondents we arrived at an aggregate score of 351, 337, and 354 **points on this scale** (500 possible) for S1,S2,S3 respectively and all three statements combined together the total score added up to 1042 points out of 1500 points. On the other hand for non-industrial respondents we obtained 340,387, 422 **points on this scale** (500 possible) for S1,S2, S3 respectively and three statements put together the total points added up to 1149 points on this scale where the maximum points possible is 1500 points. By considering both industrial and non industrial respondents together the score comes to (1042+1149=2191 points out of 3000). This is almost 73 percent.

Taking positive and negative statements together the industrial respondents scored (1243+1042=2383) out of 3000 and the non industrial respondents scored (1290+1149=2439) out of 3000. By considering both industrial and non industrial respondents together, they secured (2383+2439)4822 points on this scale out of 6000 points. This clearly indicates both industrial and non industrial respondents have favored the abolition of industrial licensing, contract manufacturing and major structural reforms which are made available to SSDI for investment opportunities, and providing employment opportunities.

General views collected from the entrepreneurs

Reasons why the entrepreneurs favor the New Industrial Policy

Abolition of drug licensing policy has benefitted the SSDI. Indirectly the SSDI are supporting the large scale industrial performance. It increases the growth of all kind of industries and the growth of the nation. Time to time SSDI has been renewing their license period subject to the same sort of rigorous inspections. It is good for the small scale industry because, it is leaving by the drug inspector and the inspector was giving suggestions to the industry owners if there is any problem or they were uncomfortable with the industry premises. Now in Tamil Nadu TANSTIA is providing the latest industrial data.

Nowadays the government wants to simplify the formalities to get new license and also renewal of existing license to encourage the SSDI. Most of the SSDI want the government to ensure licenses to every pharma unit, to make it more accountable and also monitor it periodically. They are not ready to tell about the policy details. Sometimes we are not aware of what are the new schemes announced by the Government from time to time, the incentives and subsidies. Every time they change the rules and regulation regarding the industrial premises structure.

The contract manufacturing is the main new source to SSDI for survival. More orders for the SSDI are getting through contract manufacturing. The numbers of the small scale drug industry are also increasing day by day due to simplified

licensing procedure in free zone areas, the man power and the raw material availability and contract manufacturing. At present the growth is good, but the future is full of competition with the multinational companies due to the Globalization. The government should take necessary step to safeguard the SSDI.

Reasons why the entrepreneurs do not favor to New Industrial Policy

Globalization and liberalization has created an unfavorable situation to the Small Scale Drug Industry because, of new entry of multinational firms. The local SSDI does not have much capacity to compete with large Domestic and Multi National Corporation (MNC). After globalization has taken place Indian economy has grown, but the government is not helping the SSDI. In Tamil Nadu there is a very low level of Government control over SSDI. We don't know where to go and where to ask for further details regarding the new licensing procedure. The administrative are violating the law and asking more amounts in the form of bribe. It starts from local municipal counselor, local rowdies, political party members, drug inspectors to tax evaluator. The government should control these activities otherwise the SSDI will suffer.

Positive Statement of Non-Industrial Respondents

Particularly the implementation of excise duty on drugs (from invoice to Maximum Retail Price (MRP) has increased the growth of Small Scale Drug Industry. Most of the industry owners welcome this

new method. Control is must in drug manufacturing, because it is directly related with the human life.

The actual license period for a drug is minimum three to five years. After the period ends, the SSDI should meet the drug inspector for getting no obligation certificate. The government officials are very helpful to all manufacturers to make a quick process. After 2005 most of the SSDI have implemented the Good Manufacturing Practices (GMP) in their building premises. Some industries have already entered under the GMP norms. Most of the industries are willing to establish additional infrastructure within their premises. It shows their involvement to make their industrial environment better. There was huge investment an opportunity increasing after major structural changes establishes by the government of India. It has directly reflected in the industrial performance as well as on the economic conditions.

Negative Statement of Non-Industrial Respondents

The latest information regarding new drug related scheme, incentives and subsidies are not known to all the pharmaceutical manufactures. Entrepreneurs who attend meetings in the state capital are only aware of this information. The government should at least conduct meeting in zonal places or district head quarters meet. Only then all pharmaceutical manufactures will be able to get the correct information.

State government license policy is different for each state. Every state

follows its own principle and policy. This license expense is included in the price of the product, and this price is directed on the consumer. The entrepreneurs spending huge amounts in the form of bribe, hence this bribing makes the variation in the drug price and this also falls on the common public. We don't know how to stop this unlawful activity. We don't know where to report against these unlawful officers. If we go against them, they will further give more pressure to manufacturing activities. During our visit, most of the manufacturers feel that the officers are not loyal to their duty.

After withdrawal of favorable policies like price control, industrial licensing requirement, reservation of items and preference in government procurement, the situation has been made unfavorable to the small scale drug industry. Most of the SSDI were affected and have closed down due to government of India's new policies. Suddenly the government changed its policies without considering the present position and condition of the SSDI.

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