

*DIAGNOSTIC STUDY REPORT*  
*PHARMACEUTICAL CLUSTER AT INDORE (MADHYA PRADESH)*

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## CHAPTER - I

# PHARMACEUTICAL INDUSTRY INTERNATIONAL SCENARIO

The Pharma Industry the world over is fragmented given the vast array of therapeutic groups specially segmented markets, and alternative configurations of value chain for various dosage forms. The structure of market is oligopolistic at the level of therapeutics and highly competitive for Over the Counter (OTC) and generic categories. The pharmaceutical industry worldwide is expected to grow between 6 and 8 per cent per annum during this decade or so. While price increases are responsible for nearly 60 per cent of this growth, while volume increases explain 25 per cent and sale of new drugs (sold at higher prices) result in 15 per cent of the growth. The generic component of the world Pharma market is expected to experience a boom in the current decade, which could substantially increase the export prospects of developing countries like India.

### **1.1 PRODUCTION:**

The production of pharmaceuticals reached US\$ 296.4 billion in 1996. Of this, the OTC market accounted for US\$ 48 billion and generics US \$ 13.8 billion. The dominance of the developed countries, especially, the USA and Japan, and large multinational companies (MNCs) is quite striking in the global pharmaceutical production and trade. The USA is the largest producer of pharmaceuticals, accounting for nearly 28 per cent of the world pharmaceutical production. Japan accounts for about 18 per cent, Germany 8 per cent, France 7 per cent, the UK 3 per cent and Canada 2 per cent of the global production. India's share in world production is estimated at around one per cent.

The current value of world market for generics is estimated at US\$ 30 billion. Of this, the USA accounts for US\$ 12.3 billion, Western Europe US\$ 7.13 billion and Japan US\$ 5.1 billion. The remaining is accounted for by a large number of Asian and African countries. By 2003, the generic market is expected to reach US\$ 43 billion with Japan, Europe and USA being the major markets. Among the world's largest 200 odd Pharma firms, 50 are Japanese and 33 are of US origin. Further the largest 50 companies produce 60 per cent of world output of drugs and pharmaceuticals as also cater to about half of the drug needs of the developing world. Interestingly, over the past two years, mergers and acquisitions worth more than US\$ 1000 billion involving over 15 major companies have taken place worldwide.

### **1.2 TRADE:**

The world exports of pharmaceuticals have been growing at a compound rate of about 13 per cent per annum from US \$ 14.4 billion in 1983 to US \$ 35 billion in 1993 and to about US \$ 50 billion currently. Developed countries account for over 90 per cent of the world exports and 70 per cent of imports. The share of developing countries in

world exports is about 5 to 7 per cent. China, Hong Kong, Singapore, Republic of Korea and India are the major exporters among developing countries.

### **1.3 RESEARCH AND DEVELOPMENT :**

The industry is also substantially dependent on research and development (R and D) on a continuous basis. Pharma industry is a typical case where R and D and profitability are closely interrelated. Increasingly, R and D have come to “dictate profitability” and the profitability, in turn, will govern the scale and scope of R and D expenditure. The need for firms to recoup the huge and growing costs of research and drug development has made protection of intellectual property rights an impending issue in the nineties. During the present decade of the 21st century, the challenge is likely to intensify once much of the differences/ doubts over the issue of intellectual property rights (IPRs) are ironed out or clarified. The manifold widespread value chain and emerging possibilities in the spheres of production, marketing, distribution and R and D are opening up opportunities for firms to become specialised and focus on specific segments, molecules, dosage forms and areas of operation.

The pharmaceutical industry is a highly research and knowledge intensive industry mainly because of the need to sustain a pipeline of new drugs to replace old ones. On an average, large global companies in drugs and pharmaceuticals spend 12-15 per cent of their annual sales turnover on R and D. In the US, the ratio of R and D cost to sales turnover is estimated at 11.2 per cent, compared to 5 per cent for telecom, 4.2 per cent for automotive and an all industry composite of 3.8 per cent.

There has been a phenomenal increase in the cost of developing a new drug. In 1976 a new drug could be developed at the cost of about US\$ 54 million (including capital and other indirect costs). By the beginning of the nineties this had escalated to US\$ 359 million. From the concept to market a new drug has to go through a series of pre-clinical and clinical trials. It has been estimated that of the 5000 to 10000 substances screened, only 250 enter pre-clinical testing. From among these, approximately five enter the clinical testing phase and finally one drug gets approved. In order for the whole process to complete, it takes about 10 to 15 years.

The high investment and high risk involved in developing and commercialising a drug has posed major challenges to the pharmaceutical manufacturers who engage in basic research. This has led to the demand for strengthening intellectual property laws.

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CHAPTER - IIPHARMACEUTICAL INDUSTRY IN INDIA

The Indian Pharmaceutical Industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicines is now made in India. The organized sector of the pharmaceutical Industry has played a key role in promoting and sustaining development in this vital field.

The pharmaceutical industry is knowledge driven industry and is heavily dependent on Research and Development for new products and growth. However, basic research (discovering new molecules) is a time consuming and expensive process and is thus, dominated by large global multinationals, Indian companies have recently entered the area and initial results have been encouraging.

The Indian pharmaceutical industry is highly fragmented, but has grown rapidly due to the friendly patent regime and low cost manufacturing structure. Intense competition, high volumes and low prices characterize the Indian domestic market. Exports have been rising at around 30% compounded Annual Growth Rate (CAGR) over last five years. There is a shift in export profile towards value added formulations from low value bulk drugs.

In the domestic market, old and mature categories like anti-effective, vitamins, analgesics are degrowing or stagnating while new lifestyle categories like cardiovascular, CNS, anti diabetic are growing at double-digit rates. The growth of a company in the domestic market is thus critically dependent on its therapeutic presence. Pharmaceutical is a continuous growth industry, immune to economic recession and commodity cycles. With rising population, new incidence and resurgence of certain diseases, new practices in healthcare, the industry continues to grow. The growth rate has been around 15% for bulk drugs and 20% for formulations during nineties. The performance on the export front is also noteworthy, clocking a growth rate of more than 20% in 1997 - 98. Nevertheless, the scope to increase the volume of exports is tremendous.

**Table - 1. Growth Indicators** (Rs. Crores) :

	65 - 66	98 - 99
Capital Investment	140	2,150
Production:		
Formulations	150	13,878
Bulk Drugs	18	3,148
Import	8.20	3,128
Export	3.05	5,366
R & D Expenditure	3	260

(Source: Organization of Pharmaceuticals Producers of India-OPPI)

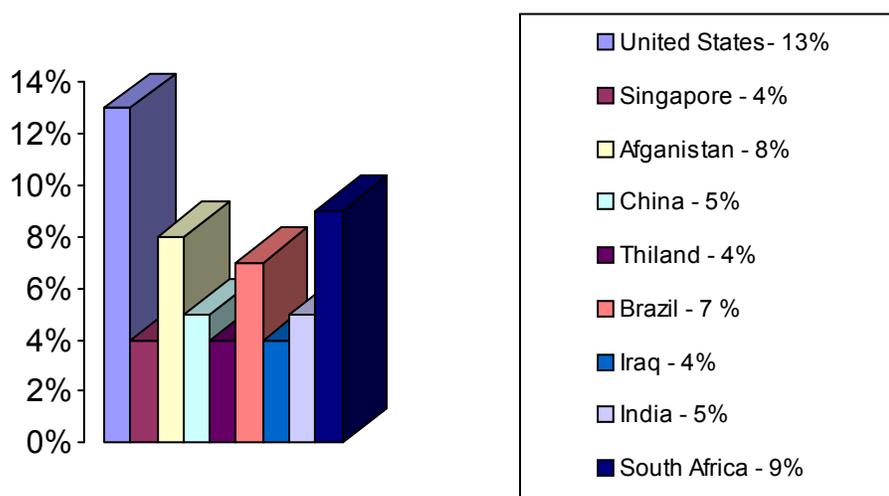
The Pharmaceutical Industry has shown tremendous progress in terms of infrastructure development, wide range of production and technology base creation, in the following basis of the technological strengths of the Indian Pharmaceutical Industry:

1. Self-reliance displayed by the production of 70% of bulk drugs and almost the entire requirement of formulations within the country.
2. Low cost of production
3. Low R & D costs.
4. Innovative Scientific manpower.
5. Strength of National Laboratories
6. Increasing balance of trade in pharma sector.

## 2.1 PRODUCTION:

There are about 260 large units and about 23000 small-scale units in operation, although the number cannot be authenticated, which form the core of the industry (including 5 central public sector units). These units produce the complete range of formulations i.e. medicines, ready for consumption by patients and about 350 bulk drugs i.e. chemicals having therapeutic value and used for production of formulations. Larger formulation players have a market share of less than 6%. Whereas, the top 10 players accounts for 26% of the formulation market.

### Expenditure on Health as percentage of GDP:



(Source: World Health Report - 2001)

India's drug and pharmaceutical production has risen from Rs.54 Crores in 1953 to around Rs. 20.000 crores in 1998 - 99. Indian drug and pharmaceuticals has made

tremendous growth since independence. In early fifties the country was completely dependent on imported chemicals. The production rise in bulk during 1970 -71 to 1997 - 98 is from 50 crores to 2632 crores and Rs. 250 crores to Rs. 12068 crores respectively. The growth of the pharmaceutical industry has played a key role in improving the health indicator of the country from 60-61 to 86-87 by following percentage:

**Table - 2. Improved Percentage Of Health Standard:**

S.NO.	PARTICULARS	PERCENTAGE
1.	Life Expectancy	42 %
2.	Infant Mortality	34 %
3.	Death rate	51 %
4.	Birth rate	22 %

The expected health indicator for the coming years is rising, which shows the further growth of Drugs and Pharmaceutical Industries in India. The value of production in bulk drugs and formulations from 1994 - 95 to 1998 - 99 is shown in the following table (in crores):

**Table - 3. Production:**

Year	Bulk Drugs	Formulations
1994 - 95	1518.00	7935.00
1995 - 96	1822.00	9125.00
1996 - 97	2186.00	10494.00
1997 - 98	2623.00	12068.00
1998 - 99	3148.00	13878.00

*(Source: Organization of Pharmaceuticals Producers of India-OPPI)*

The above data shows that the Drugs & Pharmaceuticals sector has continued to maintain steady growth in terms of production. Several proposals for foreign collaboration for joint ventures, research and developments, establishing new undertakings/ expansion of existing units (manufacturing new articles in the existing units) have been received. Following delicensing of the pharmaceuticals industry, a number of IEMs for manufacture of various bulk drugs/ drug intermediates/ formulations were received. The major items covered in IEM include various bulk drugs, intravenous fluids, formulations etc.

The following **drugs** are **reserved for exclusive manufacture by the Small Scale Units:**

- Niacinamide
- Paracetamol
- Glycerol Phosphates
- Nicotinic Acid.

## 2.2 INVESTMENT:

Over the period between mid sixties and mid nineties there was phenomenal increase in capital investment from 160 crores to 2150 crores.

**Table - 4. Investment In The Industry (in crores):**

S.No.	YEAR	INVESTMENT
1.	1965	160
2.	1973	225
3.	1979	500
4.	1985	650
5.	1988	1060
6.	1994	1200
7.	1996	1650
8.	1998	2150

(Source: OPPI 33<sup>rd</sup> Annual report 98 - 99)

There are three distinct phases discernible during this period. The growth rate during 65 - 73 was only 41%, during 73 - 85 it was 188% whereas during 86 - 98 the growth rate reduced to 102%. The Pharmaceutical industry has a Capital Investment of Rs. 2150 crores. It produced bulk drugs worth Rs. 3148 crores and formulations worth Rs. 13,878 crores. Imports stood at 3128 crores and Exports at Rs. 5366 crores. The R&D Expenditure was Rs. 260 crores in 1998-99. However, foreign investment in this sector is almost negligible. The total foreign investment was Rs. 8818 million against the total estimated commutative internal investment of Rs. 92300 million for the year 1993 to 1998.

## 2.3 EMPLOYMENT:

The pharmaceutical industry provides employment to approximately 28.6 lakh people. About 84 per cent of this employment is generated in the distribution trade and ancillary indorse, and only 16 per cent in the organised and small-scale sectors (OPPI, 1998-99).

**Table - 5. Employment (Estimated) In The Indian Pharma Industry:**

<b>Direct:</b>	
Organised Sector	290,000
Small Scale Units	170,000
<b>Total</b>	<b>460,000</b>
<b>Indirect</b>	
Distribution Trade	1,650,000
Ancillary Industry	750,000
<b>Total</b>	<b>2,400,000</b>
<b>Direct and Indirect</b>	<b>2,860,000</b>

## 2.4 DOMESTIC DEMAND :

The domestic Pharma Industry output exceeds Rs. 1250 crores of which around 83% is formulations and 17% is bulk drugs.

**2.4.1 Bulk Drugs:** Over 60% of India's bulk drug production is exported. The balance is sold locally to other formulators. However many of the MNCs affiliates/ subsidiaries in India import bulk drugs from the parent company and formulate it for local markets. Also local players exporting formulations avail of duty free imports of bulk drugs. Thus, there is a significant quantum of bulk drug imports, to the tune of Rs. 100 crores. Exports are mainly to developing countries in case of under patent drugs and to the developed nations in case of generics.

**2.4.2 Formulations:** More than 85% of the formulation production in the country is sold in the domestic market. India is largely self sufficient in case of formulations. Some life saving, new generation under-patent formulations continue to be imported specially by MNCs for marketing in India. Overall the size of the domestic formulations market is around 900 crores and it is growing at 15-16% P.A. formulation exports are largely to developing nations like China, South Africa, and CIS etc.

**2.4.3 Market Size: Major Therapeutic Segments:** The output of Indian pharmaceutical industry ranks 4<sup>th</sup> in terms volume and 13<sup>th</sup> in terms of value. In Financial Year 2002 the domestic Indian Pharma market was valued at \$ 4.5bn, representing 1.6% of the global market, and is growing at an annual rate of 8 to 9%. The industry produces about 60,000 finished medicines and roughly 400 bulkdrugs, which are used in formulations.

In financial year 2001 the total output of the Indian pharmaceutical industry was Rs.229 bn, which grew by 16% per year. In financial year 2002, it was above Rs.260 bn, of which bulk drugs accounted for Rs.54 bn (21%) and formulations Rs.210 bn (79%). The demand for the industry is mainly from urban areas (74%). Urban areas witnessed a 15% increase in sales in financial year 02 as against 13% in financial year 01. The industry grew at 2.6% per year during October 2002 and 9% during January to October 2002. In financial year 2003, the industry would have grown by 10-15% increase in sales, production and exports, despite adverse global conditions. The odd 400 bulk drugs make up 20% of total drug production. During financial year 91 to financial year 01 the production of bulk drugs increased at a Compounded Annual Growth Rate (CAGR) of 20%. On the other hand, formulations, which are the end product of the medicine manufacturing process, had a CAGR of 17% during financial year 91 to financial year 01. Most of the domestic demand for formulations is met by the domestic industry.

Segments that accounts for nearly 85% of the domestic formulation market are – Analgesics & Anti-pyretics, Antacids & Anti-ulcerants, Antibiotics, Anti-tuberculosis, Anti-parasitic & Anti-fungal, Cardiac Therapy, Corticosteroids, Anti-rheumatic, Respiratory System, Vitamins, and other Therapeutic Segments like Anti-anemic, Anti-diabetes, Anti-emetic, Ant-histamine, Anti-malarial, CNS & Psychiatric therapy, Gynecological, Nutrients & Mineral Supplements. The major group is psychiatric

products, which has a Rs.37 crores market, growing 11.5% per year. All other groups range between Rs. 10-20 crores in size.

**Table - 6. Market Size:**

Major Therapeutic Segments	Market Size (Rs. in crores)	Market Share (%)
Antibiotics	209	15.7%
Cardiac Therapy	93	6.9%
CNS & Psychiatric Therapy	88	6.5%
Vitamins	81	6.1%
NSAIDS & Anti-Rheumatism	80	6.0%
Respiratory Ailments	71	5.3%
Antacid & Anti-Ulserants	57	4.3%
Anti-Anaemic	34	2.8%
Anti-Diabetic	34	2.7%
Anti-Tuberculosis	33	2.5%

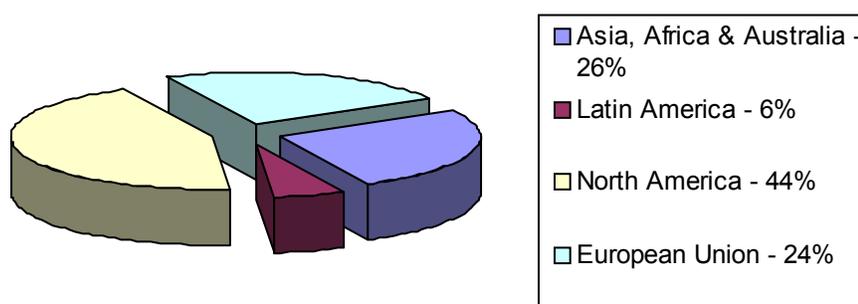
(Source: Indian Pharmaceutical Industry - Update April 2003)

## 2.5 TRADE:

### 2.5.1 Allopathic Medicines:

Over the years the drugs and pharmaceuticals sector has emerged as a net foreign exchange earner, a status it has maintained since 1988-89. The average annual growth rate of exports between 1980-81 and 1998-99 was about 33 per cent as against 22 per cent in the case of imports. The ratio of exports to imports rose from 0.61 to 2.15 between the early 1980s and the end of 1990s. Finished formulations dominate the export kitty, while bulk drugs and chemicals dominate the import basket.

**Region-wise breakup of Global Pharmaceutical Market (Global Size: \$363 bn.):**



(Source: Indian Pharmaceutical Industry - Update, April 2003.)

The Indian manufacturers are increasingly tapping the export market. Export revenues now contribute almost half the total revenues for the top 3-Pharma majors, viz, Dr.Reddy's, Ranbaxy and Cipla. In financial year 01, exports constituted 38% of the total production of pharmaceuticals in India. The industry exported drugs worth Rs.87 bn, of which formulations contributed nearly 55% and the rest was from the bulk drugs. During the year, exports grew by 21% per year. In financial year 03, the Indian Pharma market is estimated to have exported drug worth Rs. 110 bn. The comparative

advantage lies in the low cost of bulk drug manufacturers. In the past five years, the Pharma exports grew by 30% per annum. Formulation exports (i.e. finished products) are largely to developing nations in CIS, South East Asia, Africa and Latin America. In the last three years generic exports to developed countries have picked up. In the coming years, opening up of US generics market and anti-AIDS market in Africa would keep export growth high.

In financial year 01, India's pharmaceutical imports were approximately Rs.20.3bn. In the past five years, imports have registered a CAGR of only 2%. Imports of bulk drugs have slowed down because there is over capacity in the domestic market and the quality of bulk drugs manufactured by the domestic manufacturers has improved significantly.

Indian pharmaceutical exports are to the tune of Rs. 250 crores, of which nearly 50% are bulk drugs. It has been growing @ 20% per annum. The competitive pressure and DPCO has led the Pharma Industry to focus on export markets. In exports, domestic companies have a 3 - branched advantage over MNCs:

- Process Patents give freedom to make MNCs patented products, thus enabling wide therapeutic reach,
- Strong R&D and low manufacturing cost and
- No restrictions on export markets by patents' overseas ventures.

**Table - 7. Export and Import of Formulations and Bulk Drugs:**

Year	Exports (Rs. Crores)			Imports (Rs. Crores)		
	Formulations	Bulk Drugs	Total	Bulk Drugs	Formulations	Total
1994-95	1505.5	760.1	2265.6	811.4	173.0	984.5
1995-96	2044.8	1132.9	3177.7	1630.0	270.0	1900.0
1996-97	2509.2	1581.1	4090.3	1705.0	345.0	2050.0
1997-98	3343.2	1737.9	5081.1	1827.0	430.0	2257.0
1998-99	3038.5	2327.7	5366.2	1918.0	540.0	2458.0

*(Source: Organisation of Pharmaceutical Producers of India - OPPI)*

## 2.5.2 Ayurvedic Medicine:

Ayurved has been identified as the fastest growing with the organised market for Herbal medicine pegged at Rs.10bn. However, the total market including unorganised market is estimated to Rs.20bn. India is exporting about Rs.400 crores of Herbals extracts and Ayurvedic medicines, while on China's export is more than Rs.2000 crores in herbal medicines.

The global export market for herbal medicines is about \$5bn, and is projected to cross \$16 bn, in the next three years, which is just 25% of the total market for herbal medicines including health supplements and beauty products. The problem that the industry is facing is lack of standardization. Indian Government has understood the need for standardization and hence GMP has been introduced in this sector too. While

government is doing its bit, the corporate sector seems to tap the export market by building the brands on global map.

In a seminar on Indian systems of medicines the Prime Minister said, "*The Indian system of medicines need standardization and research. If the country could spend a fraction of money on modern health facilities for Indian medicines, the country could easily meet the challenges of **Health for All***". Indian SSI sector engaged in manufacturing Ayurvedic and Herbal products by updating their products and joining hands together for marketing can prove their capabilities in global market.

## **2.6 RESEARCH & DEVELOPMENT :**

Compared to the global pharmaceutical industry, Indian R&D expenditure is still minuscule, which could have a negative effect in the long run, especially if the product patent is enforced after 2005. The average R&D spends in India, though growing at a CAGR of 18% over last five years, is just 1.9% of sales, as against 9.10% spent by global pharmaceutical companies. A major problem that hampers the R&D thrust in India is that companies have to generate huge cash surplus for the basic research processes. This at the moment is not easy, due to the government's rigid price control administration (DOPC). The DOPC has been the millstone around the neck of Indian industry as it has severely restricted profitability and hence innovation. However government has been relaxing controls in a slow but progressive manner. The span of control of DOPC has come down from 90% in 1980s to 50% in 1995 and is likely to be further reduced as per the latest proposed changes. The recent budget proposal would reduce the current list of 74 drugs to considerably to 29 under DOPC

Thus, until the DOPC is revised or abolished and free pricing allowed, the companies would not be able to make sizable investments. However this has to be balanced by concerns about affordability of medicines. To overcome this problem, M&A activity is undertaken not only at the corporate level but various players are acquiring brands to re-align their portfolio and strengthen their presence in certain therapeutic segments. This is done either between Indian companies or between Indian and MNCs. To support the R&D investment, the Indian government is providing a range of concessions to encourage R&D. including a ten-year tax holiday on income arising from R&D. the aim is to double the domestic pharmaceutical industry's level of R&D expenditures by 2005. Companies like Ranbaxy and Dr. Reddy's Laboratories are the leaders in India though they are spending around Rs.20 crores only in R&D.

Research and Development, in Indian pharmaceutical industry, have mainly been in applied research for developing process technology for production, especially of synthetic bulk drugs. This was facilitated by the Indian Patent Act of 1970. In a number of cases there was no need to discover a new process as the inventor might not have filed an application in India, and even if they did, the patents would have expired in view of the short duration of validity under the 1970 Act. Patent play an important role in encouraging R&D. the new WTO rules imply that India will have to switch to a product patent regime post 2005 from its current process patent regime. This would

alter the scenario in the Indian market over the next 10 - 15 years. In the global pharmaceutical market, western markets are the largest and fastest growing due to introduction of newer molecules at high prices. A well-established reimbursement and insurance system implies that per capita drug expenditure is abnormally high in western countries as compared to the developing nations.

It has been observed that countries with weak patent protection systems spend much less on innovation. In India, the pharmaceutical industry's investment in the late 1990s was about Rs.220 crores, i.e., approximately 2 per cent of its total turnover.

**Table - 8. Trend in R and D Expenditure in India**

<b>Year</b>	<b>Expenditure (in crores)</b>
1994-95	140
1995-96	160
1996-97	185
1997-98	220
1998-99	260
R&D Expenditure on % of Sales	1.9%

*(Source: Organization of Pharmaceutical Producers of India)*

The total R&D expenditure in India today amounts to \$2.5 billion. It stands at a low 0.8% compared to 2.5% in USA and Japan. The total R&D expenditure in pharmaceutical sector is around \$52 million.

## **2.7 CURRENT ISSUES :**

Rigid administrative price control, weak Intellectual property rights regime, outdated and restricted labour law, high import tariffs & taxes and slow pace of economic reforms are the main growth barriers of pharmaceutical industry in India.

Currently, only process patents are recognized in India. However, by virtue of India being a member of World Trade Organization (WTO) and a signatory to General Agreement on Tariffs & Trades (GATT) it is bound to recognize product patents, latest by 2005. The Patent Amendment Bill, 1999 (Second Amendment) passed by the parliament, has made it Doha Declaration compliant. The bill has been accepted with all the safeguards to protect national interest and ensure easy availability of drugs at affordable prices. It gives government enough power to grant Compulsory Licenses for patented drugs in times of "National Emergency", "Extreme Urgency" and aims at safeguarding public interest, public health, protection of traditional knowledge and bio-reserve. The bill does not consider the introduction of product patent for which a third amendment bill would have to be brought before 1<sup>st</sup> January'2005.

## 2.8 OUTLOOK :

- During 1999 – 2005, drugs with annual sale of \$30 bn. would go off patent. The Indian pharma industry, with its reverse engineering skills and relatively low cost structure, is ideally placed to tap the generics market.
- Indian companies are climbing the value chain by moving to developed markets and from bulk drugs to formulation exports. As a result, Indian companies are expected to produce six of the top 10 drugs that are scheduled to lose patent protection over the next five years. Indian companies are targeting opportunities arising in the regulated and unregulated markets.
- Research focus of large companies has shifted towards discovery of New Chemical Entities in preparation of product patent era to commence from 1<sup>st</sup> Jan 2005. For large players, there is a possibility of increased financial risks, because of uncertainty in income flows.
- The financial results of the players post 2005 would depend on their ability to introduce new drugs.
- The big players will speed up the launch of new products and will look at brand acquisition from other relatively small players. The later will either close down or be taken over by larger players. Hence, the currently fragmented industry may consolidate further.
- Product patent regime will hamper India's drug exports, as countries will be forced to purchase from patent holders only.
- After the applicability of product patent, it may be predicted from the experience of other countries (like Pakistan, UK and USA) that the prices of drugs may go up significantly, and in some specific cases by as much as 5- 10 times.
- As more drugs are taken off the list, the DPCO will reduce its importance, but a system of government control to check against abuses of monopoly pricing will remain especially after 2005.

The successful strategy for Indian companies in a post 2005 world will include: a) attain right product-mix, b) augment skills, c) use M&A option for either companies or products. The increasing importance of biotech industry, and its symbiotic relationship to pharma will also be very relevant in this strategy. Some Indian companies have also succeeded in the fast growing Over the Counter (OTC) Medication market, which is based on traditional Indian Medicine Systems.

## 2.9 THE INDIAN SYSTEM OF MEDICINES :

In recent years, there has been a growing recognition of the importance of drugs in the Indian System of Medicines (ISM), namely, *Ayurveda*, *Unani* and *Siddha* in recent years as substitutes for modern drugs. Also there has been a notable rise in the sales of large volumes of *Ayurvedic* 'nutraceuticals' in the market as drugs to make them eligible for excise duty concessions. Though *Ayurvedic* products are subject to standards prescribed in Schedule 1 of Drugs and Cosmetics Act, there is lack of clarity about the existing norms. It calls for a revamped ayurvedic pharmacopoeia and GMP standards. The GMP norms are radically different for the ISM due to -

1. Practical difficulties to quantitatively assess plant-based source materials; and
2. Preponderance of tiny units, which are unable to follow equipment standards requiring huge investments.

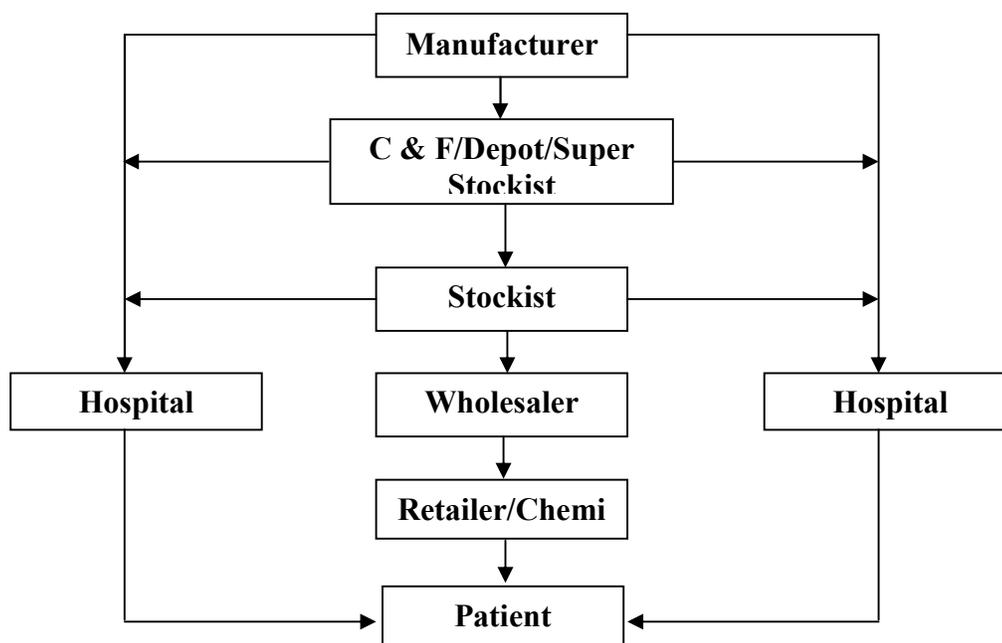
In the light of these concerns there is a need to have a comprehensive legislation on the lines of the Drugs and Cosmetics Act for exclusively regulating the manufacturing and marketing. Such legislation is now under the consideration of the government.

## 2.10 DISTRIBUTION CHANNEL :

In a geographically diverse and extremely competitive market where sales volumes are high, distribution plays a crucial role. Further, the common incidence of brand substitutions makes it imperative for a company to make available its brands at all times and at various levels of distribution.

The distribution channel for pharmaceutical products is as below:

### Channels of Distribution



It is estimated that there are 60000 stockists and more than 550000 retailers in the country, plus the population of dispensing doctors. These doctors account for roughly 10 per cent of the pharma market. During the seventies and early eighties, there were few but large distributors. As the pharma companies expanded their marketing operations, these distributors faced logistic problems while attempting to cater to emerging markets. As a result of this, many small players became stockists and wholesalers, making the sector fragmented, and hence, more localized. According to the Retail Druggists and Chemists Association, there were roughly 10000 distributors and 125000 retail chemists in India in 1978. The number of distributors has increased six-fold, and retail outlets five-fold during the last two decades.

Distribution margins in India are fixed as per provisions of the Drug Price Control Order. For controlled drugs, the stockists' margin is fixed at 8 per cent of the maximum retail price and for decontrolled drugs DPCO allows 10 per cent. For retail chemists, the margins offered are 16 per cent in the case of controlled formulations and 20 per cent for decontrolled formulations. Manufacturers also offer cash discounts of 5-10 per cent to stockists by issuing free packs. Stockists, in turn, provide a two per cent cash discount to retailers.

Drug distribution in India has been undergoing changes following liberalization. The changes have been initiated by pharma companies, which are increasingly replacing company owned depots and warehouses with Clearing and Forwarding (C and F) Agents. The aim is to curtail overheads. The C & F agents operate under contract on companies' behalf. An agent is paid a fee that depends on the turnover of products, and ranges from 4 per cent on a high turnover product to 10 per cent on a low turnover product. Because of extended transit time, companies can move seasonal product well in advance to C and F agents without incurring ex-factory excise costs.

Usually a stockist handles the business of six to eight companies. A few of them handle more than 50 companies. Traditionally, stockists have been non-competitive; with each handling a select group of retailers, and *vice versa*. However, the recent spate of mergers and acquisitions in the drug industry has put stockists in a quandary. When two companies merge, the number of stockists almost doubles. This creates complications for the stockists.

Competition at the stockist level is proving to be a bonanza for retailers, at least for the time being. But this sector has also begun to have its own share of worries as the retail sector is opened up for foreign investment and the concept of retail chain outlets is beginning to get tested in India for the first time. The first retail pharmacy chain was started by the Subiksha Retail Services Pvt. Ltd., which operates 19 retail outlets in Chennai. Similarly, The Medicine Shoppe, one of the largest retail drug store in the US, opened two retail outlets in Mumbai and has franchised three more in Mumbai, Calcutta and Vadodara. It is planning 100 such outlets in India. The drug retail market is very competitive and crowded. Together, they account for 80 per cent of the pharma market.

As far as public hospital supplies are concerned the tender procedures are compulsory for contracts. These contracts have to be published in the official newspapers/periodicals. Here, the supply is done directly without any intermediary.

### **2.11 MARKET FOR GENERICS:**

Generics represent a sound business opportunity for Indian manufacturers, as in any given year their number is more than new molecules that hit the market. Another opportunity is in the field of patent expired therapeutic equivalents of patented products. Another area where India has a distinct comparative advantage is export of bulk drugs. This market is growing rapidly in the US and Western Europe. A number of factors like availability of raw materials and new plants, emerging trend of green field export oriented projects; local enterprise, strong track record of generics etc. could act as strong facilitators.

However, many other crucial bottlenecks are to be overcome before India could exploit these opportunities. Some are mentioned below:

- Availability of finances at global rates of interest for fresh investments in production plants; access to international funds markets as also venture capital and equity financing markets;
- Creation of a 'quality image' in international markets;
- Use of state of the art and eco-friendly technologies;
- Encouraging international firms to bring Global Clinical Practices to India and initiate collaborative projects with Indian companies and institutes;
- Enhanced investments in R and D; and
- Development of superior marketing strengths.

### **2.12 NICHE MARKETING:**

Niche products have fewer competitors and hence margins tend to be higher and product life cycles longer. Some examples of niche products are advanced drug delivery systems, biotechnology, complex bulk chemistry and manufacturing of difficult formulations like sterile antibiotics and anti cancer drugs. Potential for specialising on these and many more such products needs to be explored.

### **2.13 ALLIANCE WITH GLOBAL MAJORS:**

There is an increasing trend towards alliances as the small firms are under the threat of extinction mainly due to an increase in research and marketing costs. Western pharma majors would be keen to partner with companies in countries like India, Poland, Italy or China, which are low cost manufacturing centres. Small companies and research institutions can focus on drug discovery and clinical trials, which are expensive functions for global majors. Their strength lies in distribution, marketing and

development, handling the regulatory and development procedures etc. Smaller units better handle the skill and focus required for discovery.

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CHAPTER - III

MAJOR LEGISLATIONS:

There are various legislations that govern the manufacture and sale of drugs and pharmaceuticals in India. There are also rules framed under the provisions of these laws. The following are the laws that are currently in operation in the country:

1. The Poisons Act, 1919
2. The Drugs and Cosmetics Act, 1940 (this was amended various by Drugs (Amendment) Acts in 1955, 1960, 1962, 1964, 1972, 1982 and 1986)
3. The Drugs and Cosmetics Rules, 1945
4. The Pharmacy Act, 1948
5. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954
6. The Medicinal and Toilet Preparations (Excise Duties) Act, 1956
7. The Narcotic Drugs and Psychotropic Substances Act, 1985
8. The Drugs (Prices Control) Order, 1995

General legislations that have a significant bearing on pharma industry in the country.

1. The Industries (Development and Regulation) Act, 1951
2. The Trade and Merchandise Mark Act, 1958
3. The Indian Patents and Design Act, 1970.

From among these legislations the following four play a critical role in the development of the industry:

- (a) Schedule 'M' of the Drugs and Cosmetic Act 1940
- (b) The Indian Patents and Designs Act, 1970
- (c) Patents (Amendment) Act, 1999
- (d) The Drugs (Price Control) order (DPCO), 1995

These legislations are briefly described so as to appreciate their likely impact on and response from the manufacturers and others concerned.

(a) Schedule 'M' of the Drugs and Cosmetics Act (1940)

The Schedule 'M' classifies the various statutory requirements mandatory for all drugs, pharmaceuticals and medical disposable industry relevant as per current good

manufacturing practices (CGMP). Schedule 'M' was last revised in 1986, when the concept of GMP was first introduced. The Central Government is now revising the Schedule 'M' to get it "harmonized with that of the various developed and developing countries and also to the level of the well established international organizations such as the World Health Organisation (WHO)".

**WHO guidelines on GMP for pharmaceutical products urge that:**

- All manufacturing processes are clearly defined, systematically reviewed, and shown to be capable of consistently manufacturing pharma products of the required quality that comply with their specifications;
- All necessary facilities are provided including qualified trained personnel, adequate premises and space, suitable equipment and services, correct materials, containers and labels, approved procedures and instructions, suitable storage and transport and adequate personnel, laboratories and equipments for in process controls;
- Instructions and procedures are written in clear and unambiguous language;
- Operators are trained to carry out procedures correctly;
- Records are made (manually and/or by recording instruments) during manufacture to show that all the steps required by the defined procedures and instructions have actually been taken and that the quantity and quality of the product are as expected and any significant deviation fully recorded and investigated;
- Records covering manufacture and distribution are retained in a comprehensive and accessible form;
- A system is available to recall any batch of product from sale or supply; and
- Complaints about marketed products are examined, the causes of quality defect investigated, and appropriate measures taken.

A special sub committee constituted by the Government of India has proposed revamping of the Schedule M, covering specifications such as general requirements in case of buildings and premises, personal sanitation and hygiene, training, production and operation controls, quality control and assurance, stability and validation studies, documentation, complaints and self-inspections; and special requirements for individual formulation categories. Among other things, the amendment calls for the following:

- To maintain a ratio of 1:2 between the constructed area and surrounding premises to prevent environmental pollution;

- To install a validated water system to aid monitoring and control of bio-burden levels;
- To have a good disposal system, in the absence of which to have arrangements to recycle rejects;
- To have proper environmental control, with emphasis on buildings, till the primary packaging is complete;
- To ensure supply of filtered air in all production areas to prevent environmental pollution;
- To have specifically designed areas for production, quality control, storage and ancillary areas;
- To take adequate precautions to segregate the manufacture of highly potent drugs to avoid cross contamination;
- To design adequate operational and process controls to ensure reproducible quality of drugs;
- To ensure total quality control from raw materials procurement till the retail counter;
- To undertake detailed stability studies to establish the quality of drugs in different climatic and storing conditions; and
- To evolve clear and realistic documentation procedures.

**(b) The Indian Patents and Designs Act, 1970**

This Act aims at protecting inventions. The term of patent granted is in respect of an invention claiming the method of process of manufacture of a substance. For a medicine or drug the protection is given for a period of five years from the sealing of the patent or seven years from the date of patent, whichever period is shorter. The Controller of Patents, Designs, and Trade Marks appointed under the Trade and Merchandise Act, 1958 is the Controller of Patents.

**(c) Patents (Amendment) Act, 1999**

After signing the GATT agreement, India needed to change its patent law from process patent regime to a product patent regime. Developing countries are given time till 2005 to change their patent legislation. Since January 1, 1995, India has begun to accept applications for product patents, which go into a black box. This box is to be

Pharmaceutical Cluster in Indore

opened in 2005 to establish right of priority before granting patent. From January 1, 1995 to October 31, 1999, 2994 product patents have been filed for pharmaceutical products. Meanwhile for each such patent application that has been accepted, exclusive marketing rights (EMR) have to be granted for a period of five years.

The Controller of Patents examines the applications to ascertain whether there is a violation of the relevant provisions of Patent Act. The government can not only fix the price of the product covered under EMR, but also reserve the rights to grant compulsory license or revocation of patent. Provision is made to ensure that EMRs are not granted for substances based on Indian System of Medicines where the products are already in public domain.

**(d) The Drugs (Prices Control) Order (DPCO), 1995**

The DPCO provides for ceiling prices for medicines, the lists of which are reviewed periodically. Over the years substantial changes have been made in the DPCO in terms of reduction in the number of drugs under price control and simplification of application procedures. The DPCO, 1995 allows for exemption from price control for new bulk drugs which have not been produced elsewhere and which are developed through indigenous R and D.

On the recommendation of the Hathi Committee (1973), the Government of India created a Drug Price Equalisation Account (DPEA) under the DPCO. This equalisation is done on the basis of a weighted price average determined by the government. Any company that sells the product at higher margins on account of cheaper sourcing of inputs is held liable to pay up the overcharged amount to the government.

**WTO Product patent regime 2005:**

From January 2005 product patent regime will come into existence replacing existing process patent regime because of that the companies cannot manufacture products, which have registered patent for a period of seven years. This makes Pharmaceutical manufacturers to invest money in R&D and develop their own drugs and patent them. SMEs who don't have R&D facilities will face problems and end up as jobbers to the big market players.

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## CHAPTER - IV

### INDUSTRIAL INDORE

Madhya Pradesh is known as the Heart of India as it is centrally placed. Till 31st October 2000, geographically it was the biggest Estate of India. After the formation of Chhattisgarh State on 1st November 2000 it became the 2nd largest state of the country. Over the years, tribal population has dominated the state traditionally. Industrialization took place in the state before independence but the growth rate was very slow. Industrialization in the state boomed after independence utilizing all available resources for sustained overall growth.

Indore is the industrial capital of Madhya Pradesh, with a long and chequered history, Indore has been a major Indian City right from the pre - independence days. Once, the seat of the great Holkar Dynasty, Indore has had the advantage of being centrally located in the country, such that most places in central, western and northern India are within reasonable reach. Added to this, the richness of resources in the central Indian plains has made Indore a fertile ground for industrialization. It has had a heady blend of old and new, with the bustling factories on one hand in Dewas, Pithampur and Sanwer Road and palace complexes on the other.

Indore is called the “Mini Mumbai” of India. A town that has seen rapid growth in the last 10 years, it is an important business and industrial center. Pithampur the third largest Industrial belt in Asia and Dewas house major factories of large companies. The importance of Indore can be judged by the fact that the country’s major domestic airlines have started flying to it.

One of the fastest developing cities of Central India, the state government has been pumping in a good deal of its finance into development here. It has also shown keen interest in the area of communication and information technology. In the last decade, Pithampur, Indore and Dewas have performed as the most dynamic Industrial zone of Madhya Pradesh. Pithampur, a well-developed industrial area 20 km from Indore, has 107 large and medium and 1,480 Small - Scale Industries. Companies of national and international repute are functioning in this area.

A large number of small-scale engineering ancillaries are also working in this prestigious industrial area. Globalisation and liberalisation policies of the Center and the industrial policy of the state government have opened new potentials of industrialization in each and every block (taluka). MP Audhyogik Kendra Vikas Nigam Ltd, Indore, has taken up various prestigious projects for infrastructure development in and around Indore of which Electronic Complex, Readymade Garments Complex, Software Complex, etc are some of the major ones. An “Herbal Park” near Betma is also proposed for infrastructure development for Ayurvedic medicines manufacturing units. The city is also known as one of the largest producer of pharmaceuticals in Asia.

Pharmaceutical industries started in Indore about 100 years back with the birth of "Wadnere Industries". The period up to the Independence pharmaceutical industry did not grow due to non-availability of infrastructure. Few units like Bombay Ideal Products and Pure Pharma were running in residential areas of Indore. After independence the first Industrial Estate at Pologround came up in 1954, which was a major milestone in the overall industrialization. During 60's another Industrial Estate at Laxmibai Nagar and in 70's Sanwer Road Industrial Area have been developed. Many units running in residential areas have shifted to these Industrial Estates. Government of Madhya Pradesh constructed multiple sheds with basic infrastructure that has attracted entrepreneurs to start their units in these areas.

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CHAPTER – VPHARMACEUTICAL INDUSTRIES IN INDORE

In the map of Asia Indore is known as one of the largest producer of pharmaceuticals like basic drug formulations, tableting, Capsulling etc. There are numerous small and big pharmaceutical units like, Plethico, Penjon, Ranbaxi, Syncom Formulations and Parental Drugs etc., located in and around Indore. Indore is an industrial city, where a big number of large medium and small-scale industries are located. Industrial Areas of Indore are:

- Pologround Industrial Estate.
- Laxmibai Nagar Industrial Area.
- Sanwer Road Industrial Area.
- Industrial Area, Pardesipura.
- Industrial Area Rau.

Other than these Industrial areas, Indore is surrounded by Ujjain, Dewas, Dhar, which are also having their Industrial areas. Pithampur Industrial area of Dhar district is nearer to Indore. Most of the firms having their works at Pithampur own their main / Administrative offices at Indore.

Main concentration of Pharmaceutical Industries is in Indore. However, some units are situated in nearby districts such as Dewas, Ujjain, Pithampur, District Dhar, etc. Major percentage of pharmaceutical units of Indore is in residential areas, only 32% units are working in Industrial areas.

Pharmaceutical units in Indore can be divided into two groups:

- **Allopathic formulations.**
- **Ayurvedic Formulations.**

At present about 350 pharmaceutical units in Indore are manufacturing following items:

- |  |   |  |
|--|---|--|
| <ul style="list-style-type: none"> <li>• Tablets</li> <li>• Liquids</li> <li>• Capsules</li> </ul>         | } | Both in Allopathy & Ayurvedic Formulations |
| <ul style="list-style-type: none"> <li>• I. V .Fluids</li> <li>• Eye Drops</li> <li>• Ointments</li> </ul> | } | Allopathic Formulations                    |

- Churna
  - Asava
  - Arishta
  - Avaleha
  - Malham
  - Snehalpa (Ghrta)
  - Vati and Gutika.
- } Ayurvedic Formulations

### 5.1 MAJOR FACTORS FOR THE GROWTH OF PHARMACEUTICALS IN INDORE :

Before independence, there were only a few Pharmaceutical Industries exist in Indore. After the independence, local governance of Madhya Pradesh developed Industrial Estates in Indore with basic infrastructure facilities that boomed the overall industrialization in Indore and its surroundings.

**The factors for the growth of pharmaceuticals in Indore:**

PERIOD	FACTORS
SEVENTIES	<p><b>ACTUAL BOOM OF PHARMACEUTICAL INDUSTRIES</b></p> <ul style="list-style-type: none"> <li>• Availability of basic infrastructure facilities.</li> <li>• Import policy of Raw Material.</li> <li>• Establishment of Industrial Area at "Sanwer Road."</li> <li>• Pro-active attitude of authorities.</li> <li>• Formation of pharma associations- MP Pharmaceutical Manufacturing Organization. MP Ayurvedic Manufacturing Association.</li> </ul>
EIGHTIES	<p><b>PERIOD OF CONSOLIDATION &amp; BIRTH OF PHARMACEUTICAL CLUSTER</b></p> <ul style="list-style-type: none"> <li>• Pharmaceutical Industries touched 100 marks.</li> <li>• Active involvement of MP Laghu Udyog Nigam in the area of marketing.</li> <li>• Around 60% of the total Turnover of 7 crores of pharma units marketed with Government Agency.</li> <li>• Man Power availability.</li> <li>• Availability of machinery and Raw Material Suppliers.</li> <li>• Availability of Good transportation facilities by Rail, Road and Air.</li> <li>• Advantage of well placed location, adjoining states- Maharashtra, Gujrat, Rajasthan,</li> <li>• Development of Pharma Industries at Gujrat had an advantage in the development of Indore Pharma units.</li> <li>• Proximity to the markets of adjoining states.</li> <li>• Establishment of testing laboratories both in private as well as Government sector (M.P.L.U.N.).</li> <li>• Availability of Educational Institutions - Medical collage, Pharmacy Collage, Ayurvedic Collage etc.</li> </ul>
NINTIES.	<b>GROWTH OF PHARMACEUTICAL INDUSTRIES.</b>

	<ul style="list-style-type: none"> <li>• Another industrial area nearer to Indore established at Pithampur district Dhar.</li> <li>• Establishment of Dry Port at Pithampur - Cargo facility.</li> <li>• Establishment of "Dawa Bazar", where around 200 wholesale dealers are available.</li> <li>• Availability of manufacturers/ suppliers of Basic Drugs.</li> <li>• Availability of suppliers of laboratory chemicals / equipment/ Excipients/ Preservatives/ Filters.</li> <li>• Availability of manufacturers/ suppliers of packing material-Aluminum Foil/ blisters/ pouches/ collapsible tubes.</li> <li>• Availability of manufacturers/ suppliers of Empty Gelatin Capsules/ Empty bottles/ Ampules/ Vials/ droppers/ cup products.</li> <li>• Availability of manufacturers/ suppliers of P.P.Caps/ Rubber Caps/ containers/ Poly bags/ Rubber Stereo.</li> <li>• Availability of manufacturers of corrugated boxes.</li> <li>• Availability of Offset printers/flexo-printers/designers/ scanners/ Box strapping.</li> <li>• Availability of Transporters.</li> </ul>
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## 5.2 POLICY RELATED FACTORS :

During late Fifties and Sixties, Drug Licenses issued by the authorities more Easily & Quickly. The pro-active attitude of the authorities during the initial periods of development of Pharmaceutical Industries has played a vital role. Particularly Mr. Agarwal, the then Drug Controller during sixties has motivated many entrepreneurs by issuing drug licenses. He could foresee the future of Pharma products in India, the development in the adjoining states in Pharma Sector and its potential in domestic market and export, which made him to be considerate for the development of this sector in Indore.

Raw material import quota was very high as compared to other states that made the raw material cheaper at Indore. Even today the cost of raw material is cheaper than other states. Raw material providers are directly connected with manufacturers and import brokers.

During the early sixties evolution period of industries in Indore, land was made available at cheap rates, the industrial estates were developed with basic infrastructure facilities, ample electricity was available at low cost and positive approach of the then officers of Industries Department have attracted the entrepreneurs of adjoining states to start their industrial units in Indore. Entrepreneurs from far off states of Haryana and Punjab have also come to Indore for their business in Pharmaceutical sectors. The scene that- till seventies there were hardly 50 pharmaceutical units that existed; the figure has raised upto more than 150 in Allopathic formulation, visualizes this fact. Similar is the case with Ayurvedic industries.

## 5.3 MARKET :

Connectivity of Indore to other states and wholesale market is a major advantage for the development of pharmaceutical units. As the city caters the need of almost all the categories of market segments throughout the State, being business capital of the state.

Presence of wholesale dealers of Pharmaceutical medicines and C & F agencies of big ventures of the country for distribution of Medicines in the state has been one of the major advantages in the development of pharmaceutical cluster in Indore. Dawa Bazar, where nearly 200 wholesale dealers, C & F Agents, Stockists operating and supplying the medicines, itself is acting as another cluster in marketing of drugs & formulations, fulfilling the requirement of local market demand in domestic sector and exports to some extent.

Dawa Bazar is a market place, where not only allopathic but Ayurvedic, Unani, Homeopathic medicines, and other players of the cluster like Raw material suppliers, basic drugs, chemicals, laboratory equipment, Herbal products, software service providers, etc. are available, Since it is centrally located in the city, transport facilities by road and rail are available within a span of one kilometer. The city is flooded with many other market places like Jawahar Marg, Siyaganj etc.

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**CHAPTER - VI****SKETCH OF PHARMACEUTICAL CLUSTER OF INDORE**

An Industrial Cluster is a concentration of manufacturing activities and services in similar and related spheres. Collaborative and collective actions of the cluster actors results scope for reduction in the production cost, thereby benefiting the manufacturers/ service providers directly and ultimately benefit the society. The growth of a cluster is dependent on the market demand and availability of supportive environment within the cluster. The cluster firms cannot operate in isolation, Related Industries and Service Providers together grow simultaneously. Thus the collective actions lead to the prosperity for the cluster firms, cluster actors, service providers and to the society as well.

**6.1 CORE FIRMS :**

At present in Indore, around 350 pharmaceutical units exist with an employment of approx. 20000 people engaged in manufacture of Ayurvedic, Allopathic and Homeopathic formulations. These units are scattered throughout Indore. Some units in the cluster are engaged in the manufacture of Both Allopathic and Ayurvedic formulations. Details of the cluster are given in tables below: -

**Table - 9. No Of Pharmaceutical Units In Indore:**

S.NO.	PARTICULARS	NO OF UNITS.
1.	Allopathic formulations own licensee	119
2.	Allopathic formulations loan licensee	52
3.	Ayurvedic formulations	177
4.	Homeopathic formulations	3
5.	Basic Drugs	31

(Source:- Pharma Directory-2000, MPSSDMA, Indore.)

**Table - 10. Location of pharmaceutical units in Indore:-**

S. NO.	NATURE OF UNIT	LOCATION			
		INDUSTRIAL AREA		RESIDENTIAL AREA	
		No. of Units	Percentage	No. of Units	Percentage
1	Allopathic Formulations	67	39.20	104	60.80
2	Ayurvedic Formulations	44	25.85	133	75.15
3	Homeopathic Formulations	01	33.33	002	66.67

(Source:- Pharma Directory-2000, MPSSDMA, Indore.)

**Table - 11. Breakup of small-scale units (Allopathic formulations) of the cluster in residential area:**

S.NO	RESIDENTIAL AREA	% OF UNITS
01	Shikshak Nagar	3
02	Palsikar Colony	5
03	Sudama Nagar	3
04	Usha Nagar	3
05	Kalani Nagar	3
06	Telephone Nagar	4
07	Palasia	4
08	Neema Nagar	2
09	Chandan Nagar	2
10	Lalaram Nagar	3
11	Tilak Nagar	3
12	Vijay Nagar	3
13	Rajandra Nagar	3
14	Deen Dayal Nagar	3
15	Vishnupuri	4
16	Other Residential Areas	20

*(The data has been collected during the second phase of training.)*

## 6.2 TURNOVER OF THE CLUSTER:

Indore Pharmaceutical cluster through its business/market channels has shown steady growth during the past years both in domestic & export market. The turnover of the cluster during the past two years is given below:-

**Table - 12 Turnover:**

Sales	2001 - 2002	2002 - 2003
Local Sales	185513 Lakhs	201508 Lakhs
Export	1732 Lakhs	1927 Lakhs
<b>Total Sales</b>	<b>187245 Lakhs</b>	<b>203435 Lakhs</b>

*(Source: District Trade and Industries Center, Indore)*

## 6.3 RELATED ENTERPRISES AND SUPPORT SERVICES:

Existence of pharmaceutical drug manufacturing industries in Indore has evolved many other related enterprises having direct business linkages with the core firms. The details of such enterprises are given in tables below:

**Table No. 13 Related Enterprises:**

S.NO.	ENTERPRISES	MANUFACTURERS	SUPPLIERS
1	Excipients/Preservatives/Filters	03	26
2	Empty Gelatin capsules	03	03
3	Basic Drugs	31	55
4	Laboratory Chemicals/Equipment	01	23
5	Flavors	-	10
6	Disinfectants	06	--
7	Surgical goods	05	--
8	P. P. Caps	05	03
9	P. V. C. Blisters	--	09
10	Aluminum foil/Blisters/Pouches/collapsible tubes.	--	08
11	Rubber stereo	--	03
12	Droppers/cup products	02	03
13	Empty Glass Bottles/ Ampoules/ vials	--	16
14	Ayurvedic Raw Material Suppliers	--	05

**Table No.14 Printing & Packing Material:**

S.NO	PARTICULARS	MANUFACTURERS	SUPPLIERS
1	Corrugated Boxes	25	--
2	Paper Board and paper	--	08
3	Flexo printers	10	--
4	Offset Printers	43	--
5	Designers	12	--
6	Scanners	07	--
7	Box strapping	08	--
8	Containers/ polybags	12	--

**Table No. 15 Support Services Providers:**

S.NO	SERVICE PROVIDERS	NUMBERS
1	Pharma machinery manufacturers	09
2	Die/Punchers/Tools	04
3	Transporters	86
4	Advertisers	19
5	Pest control	04
6	Consultants	24
7	Pharma book publishers	01
8	Govt. Approved Testing Laboratories	06

(Source: Pharma Directory 2000, MPSSDMA, Indore.)

#### **6.4 SUPPORTIVE ENVIRONMENT OF THE CLUSTER: -**

Pharmaceutical industries in Indore have grown up during the past 30 years, with so many support agencies of Government and Private support services providers. Among them, financial institutions, Technical/ Educational Institutes, Government departments, Marketing ventures have their own importance.

The various institutions playing a major role in the growth of the industry are:

- ❖ Central level institutions.
- ❖ State level institutions
- ❖ Global regulatory mechanisms.
- ❖ Private Sector networks: -- Industries associations
- ❖ Other support institutions.

#### **6.4.1 CENTRAL LEVEL INSTITUTIONS:**

- a) Drug control authority under Ministry of Health and family Welfare-controls introduction of New Drugs in India, GMP Norms.
- b) The Department of Chemical and Petrochemicals under Ministry of Chemicals and Fertilisers: Drug Price, Equilisation Account (DPEA).
- c) National Pharmaceutical Pricing Authority (NPPA): Implements Drug Policy of Govt. through Drug Price Control Order (DPCO).
- d) Small Industries Development Organisation under Ministry of Small Scale Industries - Development & Promotion of Small Scale Industries in the Country through its various schemes. Technology up-gradation, organising fairs etc.

#### **6.4.2 STATE LEVEL INSTITUTIONS:**

- a) Directorate of Industries: Development of industries and implementation of Government policies in the state, registration of units, providing assistance for subsidies etc.
- b) M.P. Audhyogik Kendra Vikas Nigam: Development of Industrial Estates, Providing basic infrastructure facilities.
- c) M.P. Constancy Organisations: Providing project constancy to entrepreneurs - Growth Catalyst.
- d) Center for Entrepreneurship Development Madhya Pradesh (CEDMAP) - Training facilities provider.
- e) Food and Drug Administration and Divisional Officer Ayurved.

#### **6.4.3 GLOBAL REGULATORY INSTITUTIONS:**

- a) World Trade Organisation
- b) World Health Organisation.

#### **6.4.4 PRIVATE SECTOR NETWORK -**

**6.4.4.1 Local Industries Associations:**

- a) Association of Industries Madhya Pradesh – State Level
- b) Madhya Pradesh Pharmaceutical Manufacturers Organisation, Indore.
- c) Foreign Trade Development Association of India, Indore.
- d) Madhya Pradesh Small Scale Drug Manufacturers Association, Indore.
- e) Madhya Pradesh Ayurvedic Manufacturing Association, Indore.

Associations publish their newsletters and coordinate with State, Local administration.

**6.4.4.2 National Level Associations:**

- Indian Drug Manufacturers Association (IDMA)
- Indian Pharmaceutical Association (IPA)
- Organisation of Pharmaceutical Producers of India (OPPI)
- Bulk Drug Manufacturers Association.(BDMA)
- All India Manufacturers Organisation (AIMO)
- All India Organisation for Chemists and Druggists (AIOCD)

**6.4.5 OTHER SUPPORT INSTITUTIONS: -****(i) Financial Institutions:**

All nationalized banks, Madhya Pradesh Financial Corporation, Corporate Banks and Cooperative Banks, providing credits to units have branches all over the city.

**Table No. 16 Credit to SSI Sector:**

S.NO	INSTITUTIONS	NUMBER OF BRANCHES	TOTAL CREDIT TO SSI SECTOR
1.	Nationalised Bank	45	Rs.1650 Lakhs
2.	Co-operative Bank	03	Rs.10 Lakhs
3.	Private Sector Bank	05	Rs.36 Lakhs

(Source: DIC, Indore)

(ii) **Small Industries development Bank of India (SIDBI)-** Providing financial Assistance for technology up-gradation, and other credit facilities for the cluster.

(iii) **Educational Institutions:**

- 1.Mahatma Gandhi Medical College, Indore.
- 2.Pharmacy College, Indore.
- 3.Ayurvedic Collage, Indore.
- 4.Devi Ahilya Vishwa Vidhyalaya, Indore.

(iv) **Marketing Support:**

1. M.P. Laghu Udyog Nigam, Indore- Government Purchase of Drugs.
2. National Small Industries Corporation \_ Government Single point purchase programs for market support, Assistance for machinery and Raw material purchase, Hire purchase scheme.
3. S.I.S.I., Indore - Marketing support through sub-contract exchange.

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CHAPTER – VII

**ANALYSIS OF BUSINESS OPERATIONS**  
**(BUSINESS LINKAGES OF PHARMACEUTICAL CLUSTER IN INDORE.)**

**7.1 MAPPING THE PHARMA CLUSTER IN INDORE –**

To understand the cluster in its originity, it is essential to map the core firms, related industries and support services along its supply and distributions chain. Indore Pharma cluster has grown up during the past 30 years with a yearly business of more then Rs.100 crores in Madhya Pradesh. The major elements of the cluster have already been detailed above in chapter 6. This chapter describes the linkage of all the elements of the cluster.

**7.2 CORE OF THE CLUSTER –**

Allopathic, Ayurvedic and Homeopathic formulation manufacturing units from the core of the cluster. Basic drug manufacturing units produce the inputs for formulators/ manufacturers, the end product producers. Allopathic formulators are broadly classified into two categories - Own licensees and loan licensees. Some units operate as own licensees and loan licensees as well. Overall majority of the industries are involved in manufacturing formulations.

Ayurvedic formulators are manufacturing medicines as per the Indian system of medicines, which has been practiced from the ancient years. It provides an integrated approach to the prevention and treatment of illness through a vide range of natural therapies and life style interventions. Homeopathic formulators are very few, only 3 in the cluster also manufacture medicines for the use in homeopathic therapy.

At the core, formulators can also be classified as - units having position to meet the GMP standard norms, units running in Industrial Areas and units running in Residential Areas. Some first generation small-scale units have now achieved the status of the medium scale industries, due to the proactive attitude of the then drug authorities and basic infrastructure facilities available at that time. However, most of the industries have grown to a great extent but are still in Small Scale. The cooperation among these units is only upto the level of tackling the matters pertaining to regulatory affairs with various Government departments.

**7.3 BACKWARD ENTERPRISES LINKAGE: –**

The suppliers of Raw material and other materials related to pharmaceutical industries having direct linkage with the core firms form this most prominent backward linkage. However, these suppliers are within the reach of core firms, within the

geographical limits of the cluster but the core firms have linkages with the suppliers beyond the geographical limits also. The suppliers of Maharashtra, Gujrat, North India have strong linkages, suppliers of Andhra-Pradesh, Tamilnadu also have linkages with the core firms. The industry is in no way dependent on import of Raw material and machinery.

- (a) **Basic Drugs:** - Basic drugs are available locally i.e., in Indore 86 basic drug suppliers exist. However, some big units procure bulk drugs from other places also.
- (b) **Excipients / preservatives/ filters:** - The suppliers of Excipients/preservatives/filters are available in Indore, which also cater the need of other Pharma units out side Indore.
- (c) **Empty Gelatin Capsules:** - Empty Gelatin Capsules are also available locally. There are manufacturers and suppliers, who supply the empty capsules to the core firms.
- (d) **Coating Material:** - Readymade coating materials are available locally.
- (e) **Empty Glass Bottles/Ampoules/Vials:** - The suppliers of these materials are available in Indore.
- (f) **Aluminum foils/Blisters/Pouches/Collapsible Tubes:** - Suppliers of these materials are also available in Indore.
- (g) **Ayurvedic Raw Material/Herbs Suppliers:** - Raw material suppliers for Ayurvedic medicines are also available in Indore. There are two major Raw Material suppliers - M/s Akhand Aushadhi Bhandar and M/s Gangaram Mohanlal, catering to maximum demand of the firms. Like Allopathic formulators, Ayurvedic formulators also leave linkages with the suppliers beyond the geographical limits of the clusters.
- (h) **Designers/Scanners/Printing and Packaging:** - There are specialised vendors for Pharma printing and packaging available locally. Packaging boxes (corrugated boxes) manufacturers are plenty in geographical limit.
- (i) **Machinery:** - Pharma machinery manufacturers are available locally. There are many Pharma machinery manufacturers available beyond the geographical limits, particularly in Maharashtra, Gujrat have direct linkages with the Industry.
- (j) **Advertisers:** - Advertisers in pharmaceutical products are available in Indore; however, Large and Medium Scale Industries have linkages with the advertisers in other parts of the country.

**(k) Human Resources: -**

**ENTREPRENEURS:** The pharmaceutical cluster is rich in knowledge and experience, as most of the entrepreneurs in the cluster are well qualified and experienced, some of them are even Doctors in Allopathy and Ayurved Ratnas; providing their services by Private Practices and social service to the public of Indore.

**LABOUR:** As compared to other states, labour in Indore is cheaper, hard working and calm. There is no problem of agitation from unions. However, the labour is not skilled enough at the time of recruitment, the entrepreneurs provide them in-house training. The docile attitude of labour helps the units run without any problem.

**(l) Transporters: -** Plenty of transporters available in Indore, connecting the cluster to the other parts of the country.**(m) Other Support Service Providers: -** Support services in the area of Pest control, Pharma book publishing, travel agents, consultants in various areas etc. are available locally.**7.4 NATURE OF BUSINESS LINKAGES: -**

The linkages between these elements are rather weak except for the basic drug manufacturers & suppliers and printing & packaging material suppliers. The subcontracting does not involve in the pharmaceutical production process. Neither does there is legal permission nor does the industry feel a need for subcontracting production. The only form of linkages between the units is with loan licensees. The loan licensees are basically traders utilising the excess manufacturing capacity of the unit. The products either passes through the normal distribution channel as explained in chapter 2 or go for institutional sale, some quantum of products are exported by few units directly. Small firms depend to a large extent on institutional sale due to the absence of brand names. Majority of the small firms depend on government orders through Madhya Pradesh Laghu Udyog Nigam, due to shortage of funds and as well as change in purchase policy of the Government, they are finding it difficult to get Government orders.

Some of the small units are using the ethical approach through their medical representatives and market channels. Only a few Pharma units of the cluster are exporting their products to countries like Bangladesh, Ghana, Shrilanka, Ginni, etc. The export formalities are on with other countries in Asia and Europe. Indore has a big trade house " Dawa Bazar" where Multi- National Companies and other big ventures have their marketing offices. Local Small manufacturers are scared of utilising the services of this trade house to price and quality competitiveness.

**7.5 TECHNOLOGY & PRODUCTION: -**

Majority of the units is using old/ traditional manufacturing technology due to non-availability of sufficient space for expansion, since they are located in residential areas. The units running in such areas do not have earmarked well-defined areas for the production process, which is mandatory under WHO - GMP Norms. No well equipped in house laboratory/Research and Development facilities in such units force them to depend on Government approved laboratories as listed in Annexure - I. Loan licensing work of reputed Organisations is also becoming difficult, as these are not well equipped. This has led the entrepreneurs to reconsider the shifting of their works to any industrial area. The process flow of manufacturing Tablets, Capsules, Liquids, Powder, Ointment is given in Annexure-II, which remains same for both the formulation manufacturers i.e. Ayurvedic and Allopathic.

#### **7.6 FINANCE - TERM LOANS AND WORKING CAPITAL LOANS: -**

The term loan and working capital loans are available to the large/medium and some small-scale units, which are well organised in financial planning. The upto date financial controls and proper accounting help them obtain the term loan and working loan because they are able to provide the desired information, balance sheets and profit and loss accounts to the bankers. Majority of small scale units, working in residential areas face difficulty to avail term loan from the bankers, although Working Capital loan is obtained by them from their respective banks. The details of the credit given by various banks to SSI sector in the cluster are shown in Table 16 in Chapter 6.

#### **7.7 ASSOCIATIONS: -**

The Pharmaceutical cluster of Indore has links with Association of Industries Madhya Pradesh, a state level Association, its main work is to coordinate with state departments such as MPEB, Sales Tax, DIC, Labour Department, Pollution Control Board etc.

#### **Cluster has its own 3 Associations: -**

- *Madhya Pradesh Pharmaceutical Manufacturers Organisation (MPPMO):* Formed and registered under society act during 1977 with the prime objective of regulatory affairs presentation with various Government organisations like FDA, MPLUN, PCB etc. Normally the members of the Association meet as and when there is specific problem, otherwise the Executive Body meeting is held once in a month to discuss general issues. This association publishes fortnightly news latter, that focuses mainly on Government related matters only. During the year 2000, MPPMO organised a National Level Exposition "Pharma 2000" for the benefit of the Pharma units of Madhya Pradesh. MPPMO under the threat of WHO - GMP norms has proposed an Analytical and Research

center, a limited firm to be established as per the WHO - GMP norms. This center would work as Common Testing Facility and R & D Center on commercial basis for the benefit of cluster firms. The proposal is under consideration with Government of India for Grant - in - Aid approval.

- *Madhya Pradesh Small Scale Drugs Manufacturers Association (MPSSDMA)*: Due to the differences among the members, MPPMO paved for a split and this association came into existence in 1992. This Association also deals with the common problems related to Government departments and its members only.
- *Madhya Pradesh Ayurvedic Manufacturing Association (MPAMA)*: - Ayurvedic medicine manufacturers do have their own Association with same objectives and works as the above two. Recently due to the threat of WHO - GMP Norms, this association has approached state Government for providing a suitable land and infrastructure facilities for Ayurvedic medicine manufacturers working in residential area. Government of M.P. has identified an area of 167 acres near "*Betma*" at NH12, Indore - Ahamadabad Road. The area is to be developed as "**Herbal Park**".
- *Indore chemist Association and Basic Drug Dealers Association, Under All India Chemist & Druggists Association* also exist in the cluster.

#### **7.8 LINKAGES WITH OTHER INSTITUTIONS AND SUPPORT SERVICE PROVIDERS: -**

Pharmaceutical, being the knowledge driven Industry, it needs to have close links with Educational Institutions and R & D Centers for up-keeping the knowledge about the viable processes, technological developments and the latest trend of the products, quality etc. Since the research & Development is an expensive affair for the small scale due to financial constraints, it needs to have links with such centers. Educational institutes and R & D Centers are the major source of knowledge supply to Pharma industries. Another crucial linkage is with testing laboratories. In house laboratory as per WHO - GMP norms may not be possible for small-scale units to afford.

#### **7.9 CURRENT LEVEL OF COOPERATION AND COMPETITION AT FIRM LEVEL: -**

**Cooperation:** The core firms are cooperative at the level of legal difficulties and dealing with cumbersome government policy and procedural hurdles. Providing information through the publications in the cluster is yet to begin. The entrepreneurs felt useful to discuss their problems but bit reluctant to share their trade strategy. During the year 2000, a fair "Pharma 2000" was organised for sales

promotion and exposing the MP Pharma units to the other part of the country. A Pharma Directory was also published in 2000 with a view to improve interpersonal relations among the cluster and to provide the information of related service providers.

**Competition:** Cost and quality competitiveness is the main element among the firm level. Presence of MNC and big ventures, Dealers, C & F Agents are also a major factor. Change in Government purchase policy has led the small firms to explore the new areas of marketing which involve extensive sales network, publicity, and popularity of Brand Names Copying the competitor's product and technological standards etc. are the other elements of competition in the cluster. Small-scale units working in residential areas are unable to follow these standards. Moreover, majorities of Doctors prefer the product of MNCs; they have less faith on the quality of the drugs manufactured in Indore.

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## CHAPTER – VIII

### AREAS OF CONCERN

A century old Pharmaceutical Industry in Indore, over a period of more than 30 years had undergone phases of industrialization, development recession and realizing tremendous change in the overall scenario the world over. Industry in Indore must meet the requirements of present era for its development and existence. No doubt, it needs to make a lot of considerations, exercises and changes in the present working environment of Indore. The areas of concern and probable interventions are narrated below.

#### **8.1 IMPLEMENTATION OF SCHEDULE 'M' NORMS**

The major area of concern for the pharmaceutical industry is the compliance of Schedule 'M' norms. The large and medium firms have already graduated to the desired level of quality. Schedule 'M' guidelines cover comprehensive manufacturing process right from Raw Material inventory till the final product exit. It involves all the areas like documentation, personnel, material, infrastructure, management etc. The main objectives of Schedule 'M' are to prevent contamination and ensure the reproducibility of quality drug by controlling all the variables in supply chain and process. Schedule 'M' guidelines have already been mentioned in chapter III above. Primary affected group by these guidelines is the small-scale units running in residential area, for they do not have sufficient space for expansion, paucity of funds and other constraints.

Apart from regulatory compliance, tighter FDA regulations and global standardization, created a need to prove compliance with environmental standards. Demand from the market also emphasized on stricter quality compliance. Many MNCs and large Indian companies are entering the generic markets, as the generic sales do not require massive promotional expenses that can bring the prices down and provide challenges on the price front as well as on the quality, as large firms can have smoother entry because of their higher level of quality certification. But on the other hand small and medium firms are finding it difficult due to the huge investment involvement. At present, Schedule 'M' requirement would demand an investment of some Lakhs per unit in premises and installing sophisticated quality control measures. The entrepreneurs are comparing the cost and benefits of such a large investment, which may put them under tremendous pressure. Thus a significant support in the form of subsidized loan and other management support are to be envisaged.

Attaining the highest standard is a gradual and step-by-step procedure, initiation and motivation can be done through quality audit and training of work-force to update their knowledge with quality related information. The international quality norms related to export has four related dimensions:

1. Importing nations and bulk purchasers are demanding higher quality standards e.g. Schedule 'M'.
2. Importing nations have different registration procedure and documentation norms.

3. The quality of imports is not manageable by a single small firm, and
4. The small firms individually cannot afford to offer different formulations and dosage forms at internationally competitive prices because financial involvement by importing countries is high.

All these provide a good scope for co-operation within a group of firm since:

- (a) The documentation procedure varies for countries and products, but a majority of it is almost a repetition for a country. Thus joining hands can reduce cost.
- (b) Joint exploration of markets can reduce cost.
- (c) Joining hands can also help to specialize in products.
- (d) Jointly big orders can also be executed.

## 8.2 MARKET :

The market scenario for the Pharma industry world over is fast changing due to a variety of reasons. The emerging trends in marketing are:

- (a) The post- GATT environment has compelled manufacturers to place “**quality**” at the center of all business planning and strategy formulation exercise.
- (b) The generics market in the US and Europe is likely to witness a boom as large number of molecules is going off patent in a couple of years.
- (c) The generics market in the Indian countryside lies open to competition from MNCs and large Indian companies.
- (d) With the amendment of the patent law, the Pharma firms will have to commit massive investments to develop new drugs and to put in place an adequate and efficient sales force to successfully market them.
- (e) Other developing countries, especially China, will mount tough competition for Indian manufacturers in the coming years through its huge production capacities and an inherent strength to deliver large quantities at short notice. Of late, the Chinese manufacturers have also been rapidly upgrading their technology base.
- (f) Internationally, the Pharma industry is facing sluggish growth in sales and increasing R and D costs. The choices in front of Pharma leaders are only two:
  - (1) Make R & D more productive, or
  - (2) Make each of the drugs, a blockbuster.

The industry forecast states that the Pharma industry structure would change drastically by 2005 with only few producers reigning the market.

The scenario described above clearly suggests the challenges that the Indian pharmaceutical SMEs have to face in the years to come. At the same time, there are some potentially positive aspects on the market front. These include:

- (a) Expected boom in the generics market, which would open up both export opportunities and unexplored domestic segments for Indian firms. Generics market is a volume driven one, with promotion costs contained to a minimum.
- (b) Export destinations like Philippines and the CIS countries have good potential. A few big companies have already received sizeable export orders from the later and are expecting to have at least 70 per cent appreciation annually in their trade with these countries.
- (c) Another significant area for intervention and co-operation is in institutional sales. Small firms feel that they are not adequately conversant with the various formalities and working modalities of institutional sales. Moreover, huge orders by volume are also not possible for small firms to execute. A correct knowledge profile and co-operation between small firms are envisaged in this area.

### **8.3 RESEARCH AND DEVELOPMENT :**

The investment in R and D in India has been very low - only two per cent of sales. It is true that a shift over to a product regime would demand that basic capabilities of indigenous research be developed. The large firms have already begun thinking in the directions of upgrading their R & D capabilities. The small units take a detached view on R & D because of their lack of financial resources, untrained manpower, lack of affordable and accessible testing facilities etc. Co-operation on R & D is a very common phenomenon in the international scenario, where relatively small firms tie up with big ones to specialize in developing new molecules up to a certain stage and then transfer it to the mother firms. The government has recently taken some important positive steps in the direction of promoting Pharmaceutical R & D. These include a decision to exempt R & D expenditures from tax for ten years and a proposal to create a R & D fund of about Rs.1500 million. The government has invited expert opinions and ideas from various research institutions and has set up a group to formulate guidelines for the proposed Drug Development Promotion Foundation.

Small firms are finding it difficult to get right information, technological as well as regulatory. This problem is accentuated by the fact that local market pressure can dampen improvement in the technological sphere. It is essential to make available correct and relevant information to the small firms. Similarly, there is also a need to provide them with sources to proven technologies.

## **8.4 ISSUES RAISED BY THE ENTREPRENEURS DURING INTERVIEWS IN THE CLUSTER:**

### **8.4.1 Infrastructure:**

During the past recent years, with the implications of WHO - GMP Norms and India being the signatory of WTO agreement, Pharmaceutical Industries in Indore are scared of their existence particularly those running in residential areas. The compliance of norms by these units is not possible due to lack of scope of expansion in their existing premises. Having understood all the problems, the entrepreneurs of such units have to move to the industrial area, where basic infrastructure facilities and scope of expansion in future is available. An immediate attention to this is needed in the cluster.

Pharmaceutical units of Indore are mainly formulation units, does not pollute the environment, yet the Pollution Control Board is forcing to obtain No-Pollution Certificate to the units running in residential areas.

Existing formulation units are facing acute problem of clean water supply for medicinal purpose. The units presently having their individual boring for water and treatment plants, which makes the cost of medicines high.

### **8.4.2 Testing and Research & Development:**

At present the units either have their own testing laboratories or utilizing the service of other government approved laboratories in Indore, including laboratory run by Madhya Pradesh Laghu Udyog Nigam, Indore. (A government of MP enterprise.) These laboratories are setup long back and does not have facilities as per WHO -GMP norms. A fully modernize lab cum research and development center having all sophisticated instruments need to be established as Common Facility Center for the Pharma cluster keeping in mind the new specification/norms of the GMP. No Research and Development facilities are available in the cluster

### **8.4.3 Finance:**

Since the majority of the units in the cluster are dependent on Govt. supply, their payments are delayed for a long duration resulting huge shortage of funds. Arrangements for the additional funds need to be made. The criterion for working capital and term loan is also to be reconsidered in consultation with financial institutions in the cluster. Present criteria for working capital need to be revised on the basis of actual requirement Programmes on various schemes offered by other agencies under which unit or the group of units can be facilitated to be organized.

Small Scale units of the cluster need to shift from residential area to industrial area due to the implementation of WHO - GMP norms, which involve huge investment. Provision for arranging the fund be made in consultation with financial institutions of Indore.

#### **8.4.4 Export:**

Many units of the cluster are exporting their formulations to various countries directly or indirectly; most of the units are dependent on the local or domestic market. Emphasis needs to be given to the small-scale units for marketing their product in export market. Programmes on export marketing to be organized. Services of Foreign Trade Development Association of India, Indore need to be enhanced to facilitate the export by the units through it.

#### **8.4.5 Food and Drug Administration:**

The development of pharmaceutical units is dependent on the support of FDA & Drug Controller Authorities. It requires more proactive and supportive role and proper communication between the cluster firms and authorities on the matters pertaining to the betterment of the quality, training etc. The proper communication leads the industry with accurate information and guidance to excel in the upcoming era of enhanced competition.

Power to be delegated to the office of Food & Drug Administration Authorities at Indore for issue of licenses in order to prompt disposal of work.

#### **8.4.6 Technology, process & Production:**

Since the quality of the product have been improved during the past years, the traditional method of manufacturing Ayurvedic medicine has to be modernized and proper facilities to be made available for analysis of strength of active ingredients in medicines as well as in raw material. Hygienic conditions for storing raw materials, process, packing has to be maintained by the suppliers and manufacturers. Facilities available in the analytical laboratories in Indore need to be improved including Government Laboratory - MPLUN, Indore in the wake of WHO - GMP norms and quality requirements. The laboratories to be properly equipped to meet out these requirements.

#### **8.4.7 Policy:**

Policy for pharmaceutical industries has to be reviewed considering limitations of small-scale industries. Most of the norms are made keeping MSI /MNCs in view, which are not possible to follow by the small scale due to the restrictions of fund, staff, space etc. As such no pollutants are thrown by Pharma units thus interference of Pollution Control Board is unnecessary.

In case of Ayurvedic formulation, precious raw materials like *Kasturi*, *Prawal*, *Barasingha* etc. are restricted by government and other items have been suggested for use which ultimately degrade the quality of the medicine. These materials are made available on licenses; the quantity in the license is very less in comparison to the requirement that

has to be reconsidered. Many of the raw materials are such that they lose their weight after drying and accountability of this loss rests with the manufacturer, hence the manufacturer refrain themselves to use such materials at the cost of quality of the medicine. Similarly many items have been considered as poison as per government rules though these are essential ingredients of various life saving medicines, efforts are to be made for availability of such materials under strict supervision and control for exclusive use in medicines. Tree bark of some trees like *Peepal*, *Neem* etc. are another kind of raw material in Ayurvedic preparation but peeling off bark has been restricted by the Conservators of forest and other government agencies that has also degraded the quality of herbal medicines. For effectiveness and quality competitiveness of the medicines this policy needs to be reconsideration.

Most affected units are Ayurvedic medicines formulation industries due to the imposition of WHO - GMP norms; Indore is the only city in India where around 165 units are engaged in Ayurvedic formulations. Certain norms of WHO - GMP force a large number of existing units to get away business as at present they are working in residential areas with minimum work place and much less quality control methods.

Obtaining licenses, no objection certificates etc. is a troublesome job for the units, government should work out the provision of all such documents through single window.

Analytical personals are to be made aware of quality of the medicine and Good Manufacturing Processes; short-term courses to upgrade their knowledge on latest technology, process, GMP, etc. need to be organized.

## **8.5 FOCUSED AREAS FOR DEVELOPMENT:**

The cluster development programme envisages cooperation between related units to solve common problems and explore common opportunities to enhance business. The programme aims towards sustainable development that can lead towards continuity of such business development services. The process for sustainable development and continuity in business development service lie necessarily in the empowerment of organizations and strengthening linkages between the various complimentary organizational forces. The business linkages provide the clues to grouping and the necessary trust level for joint actions. Following activities are suggested for the development of pharmaceutical cluster in Indore:

### **8.5.1 Workshops/ Seminars/ Training Programmes:**

- Seminar on WHO - GMP
- Seminar on Factory Audit
- Seminar on Quality Upgradation, Technology Upgradation
- Sensitization programme on Quality Aspect
- Orientation programme on Export - Opportunities, Procedure, Export Credit Guarantee Scheme etc.

- Seminar on IPR/ WTO
- Seminar on latest and effective methods of Sales Promotion & Advertising, Institutional Sales/ Purchase and other market techniques
- Workshop on Inventory Management, Wastage and Effluent Management
- Coordination seminar for Doctors and Pharma entrepreneurs for better understanding the quality of product and other related queries.

#### 8.5.2 Training Programmes on -

- Technology Upgradation
- Raw Material Management
- Inventory Management
- Process Management
- Financial Management
- Equipment Management
- Personnel Management
- Quality Control
- Cost Reduction & Value Addition in process

#### 8.5.3 Support Services:

- ◇ Awareness programme on various schemes of financial institutions like soft loan, hire purchase, raw material purchase etc.
- ◇ Educational programme for supervisory and other staff and workers to maintain hygienic conditions in the work place and good manufacturing practices
- ◇ Linkages between educational and technical institutions with the cluster
- ◇ Information center/ Library that can provide right and timely information on all aspects of techno - commercial matters concerning to market, government procedures, technical information, export, reference standards etc.
- ◇ Introduction of other BDS providers and enhancing linkages with the existing BDS providers
- ◇ Enhancing linkages between the associations and trust level in the cluster - All the three associations should join hands together for the development of cluster, their own area of work, to deal efficiently with various agencies. The proactive role of associations can boost the status of cluster to a high level
- ◇ Develop linkages with another associations of the cluster working in the field of sales & marketing of pharmaceutical products i.e. Indore Chemist & Druggist Association and Basic Drug Suppliers Association in order to reduce the gap, if any, between manufacturers and traders and to ensure effective utilization of existing trade house "Dawa Bazar" for sale and market promotion in domestic market as well as exploration of export market.

#### 8.6 INTERVENTIONS :

- Small Industries Service Institute Indore has intervened and held detailed discussions with Pharmaceutical Associations for establishing a Common Facility Center for Testing and Research Development. The outcome of this

has resulted the formation of a limited firm namely MPPMO Analytical and Research Center Ltd., Indore registered under companies act. The proposal made by MP Pharmaceutical Manufacturers Organisation, Indore has been forwarded through Directorate of Industries, Bhopal to Development Commissioner (SSI) for consideration under govt.-aid-scheme. The objective of this Center is to facilitate Allopathic as well as Ayurvedic industries on commercial basis. The facilities provided in this laboratory would be of ISO 17025 and NABL Standards.

- Small Industries Service Institute, Indore also held a number of meetings with Associations and various departments of infrastructure development, Govt. of Madhya Pradesh. A land with an area of 167 acres has been identified near **Betma** at Indore – Ahmedabad, NH-12, to be developed as “**Herbal Park**” for Ayurvedic and herbal products manufacturing units. The development of the infrastructure is under progress with Government of Madhya Pradesh.
- Similar, intervention is needed for the allopathic formulation units presently running in residential areas. A land is to be identified for development as an industrial zone for allopathic medicines manufacturing units.
- Joint efforts to explore the export market are to be done by forming a consortium of units.
- A network of firms can setup a Common Water Treatment Plant and supply of clean water for medicinal purposes can be made available at reasonable rate to the Pharma Industries.

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## TERMS USED IN THE REPORT

Dosage form is the nature of end product of-the medicine that a patient consumes. The principal dosage forms are tablets, capsules and liquids also known as oral dosage form and injectables, also known as parenteral dosage form.

Molecules are the bulk drugs, which are the active component in any Pharma product.

OTC (over the counter) products are sold without prescription

Generics products are those that have run out of patent. It is an important item for firms in developing countries, which do not require much basic R and D related to development and patenting of new molecules.

Direct manufacturers, or own licensees, manufacture products in their own units for direct distribution in their own brand names. Indirect manufacturers are loan licensees who get products manufactured in some other units and then market it under their own brand names. Both own and loan licensees need to obtain licenses from the FDCA.

Whenever a new drug is introduced in India the first three firms have to go for phase II clinical trials. The next 7 firms who plan to introduce the drug have to go for bioavailability and bio-equivalence study. The next 15 firms have to only produce the basic drug data for getting permission to introduce such products. Firms can reduce their cost if they go for registration jointly as part of the 3 or 7 firms.

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*CHAPTER - IX*  
**SWOT ANALYSIS**

**9.1 STRENGTHS OF THE CLUSTER:**

- Well-qualified and established entrepreneurs.
- Easy and cheap workforce availability.
- Locational Advantage – Strategically well placed, connected to other states by road, rail and air.
- Availability of number of Financial Institutions, Banks etc.
- Industrial City and Commercial Capital of Madhya Pradesh.
- Availability of Trade House – Dawa Bazar, having more than 200 traders under one roof.
- Easy availability of Raw material and other related material manufacturers/suppliers/service providers.
- Availability of Educational/Technical Institutions/Collages/University.
- Availability of central and state Government Institutions.
- Presence of Special Economy Zone

**9.2. WEAKNESSES :**

- Trust level in the cluster is very low
- Old and Traditional Technology / manufacturing processes in most of the units affecting productivity.
- Poor Testing & almost nil R& D facilities.
- Untrained work forces – No qualified Ayurvedic person in majority of the units.
- Under utilisation of financial facilities.
- Poor coordination with Government bodies and other related Organisations.
- Maximum number of units running in Residential Areas.
- No scope for expansion in Residential Areas.
- Unable to follow WHO – GMP Norma.
- Food and Drug Administrative office at Bhopal.
- Government purchase agency MPLUN at Bhopal.
- Presence of Number of Associations.
- Poor infrastructure facilities.
- Non-availability of clean water for medicinal purposes, water supply by AKVN is costly.

**9.3. OPPORTUNITIES :**

- Having good number of Hospitals and Doctors, opening avenues for direct supply.
- Dry Port at Pithampur – Good scope for Export.
- Better utilisation of Trade House Dawa Bazar for domestic market.
- Availability of MNCs – Good opportunity for loan licensees.

#### 9.4 THREATS :

- Implementation of WHO – GMP norms.
- Stiff competition due to WTO norms and arrival of MNCs.
- Commencement of Product Patent law in near future.
- Dependency on Government Supply.
- Shortage of water and electricity.
- Capturing market by other countries at low cost with good quality.

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## Chapter - X

### ACTION PLAN

In order to build strong relations with higher level of trust, it is suggested to constitute a committee for Pharmaceutical Cluster Development comprising members from each association and officers of various organizations related to the cluster. The Chairman of the committee would be the Director, SISI, Indore, head of intervening agency at Indore. This committee would monitor and coordinate the actions for the development of Pharmaceutical cluster in Indore.

Action for setting up of Herbal Park at Betma is under process; follow up actions for prompt development of industrial area with required infrastructure facilities like roads, power, water etc. will be undertaken.

Another proposal for setting up an analytical laboratory has been moved and is under consideration under Govt. - aid - scheme with DC (SSI); follow up is to be done for an early sanction and establishment. The need for such an establishment is badly felt in the wake of implementation of WHO - GMP norms.

A piece of land, which can be developed as an industrial park for Allopathic formulation units, similar to that of Herbal Park, is to be identified in and around Indore. Small Scale Allopathic formulation unit working in residential areas would be shifted to this place in order to comply with the proviso of WHO - GMP norms.

Seminars/ workshops/ programmes on the various aspects narrated in the previous chapter would be organized for the development of cluster. Most importantly, meeting of formulation associations and those in marketing need be organized for promotion of sales in domestic market and export market exploration.

Meetings with government approved laboratories in Indore and cluster firms associations would be organized so as to equip these labs in line with the WHO - GMP norms.

Common Water Treatment Plant and Effluent Treatment Plants are also the areas of immediate concern; steps would be taken to form consortia for these facilities in the cluster with the help of consultants/ BDS providers.

Follow up with Food and Drug Administration Authorities for delegation of powers for issue of licenses and other powers to their Indore office so that the FDA at Indore can function properly for the development of Pharmaceutical units in Indore.

## 9.1 ACTION PLAN AND BUDGETARY ESTIMATES

### 9.1.1 OBJECTIVE: Cluster Development Programme Awareness

**Output:** Creating awareness among the Cluster Actors on the Cluster Development Programme.

**Subject:** Creating awareness among the cluster actors for better cooperation for the Cluster Development Programme.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSI)/ Resource center	Units	Support Instt./ Assons.		
1	Two Seminars on cluster development	20,000/-			20,000/-	
	<b>Total</b>	<b>20,000/-</b>			<b>20,000/-</b>	

### 9.1.2 OBJECTIVE: Implementation of Schedule 'M'

**Output:** Making the units competent to comply with Schedule 'M' practices

**Subject:** Govt. of India is going to implement Schedule 'M' practices from Jan'2004 and all units have to comply with this. The existing manufacturing process should be revamp as per schedule 'M'.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSI)/ Resource Center	Units	Support Instt./ Assons.		
1	Two Awareness seminar on schedule 'M'	25,000/-	500/- per unit	25,000/-	75,000/-	It was randomly taken that min. of 25 units will participate in each seminar
	Interface with BDS for implementation of Schedule 'M'	15,000/-		10,000/-	25,000/-	
	<b>Total</b>	<b>40,000/-</b>	<b>25,000/-</b>	<b>35,000/-</b>	<b>1,00,000/-</b>	

### 9.1.3 OBJECTIVE: Trust building

**Output:** Creating the trust among the Cluster Actors on the Cluster Development Programme.

**Subject:** Building strong relations with higher level of trust among the cluster actors for effective implementation of Cluster Development Programme.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSl)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three Seminars on trust building	20,000/-		10,000/-	30,000/-	It was randomly taken that min. of 25 units will participate in each seminar
	<b>Total</b>	<b>20,000/-</b>		<b>10,000/-</b>	<b>30,000/-</b>	

### 9.1.4 OBJECTIVE: Implementation of GMP

**Output:** Attaining Cost Effective and High Quality and Safety Manufacturing Process

**Subject:** To attain cost effective and safety manufacturing processes which reduces risk hazards and cost of production, increases quality of the product.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSl)/ Resource center	Units	Support Instt./ Assons.		
1,2	Conducting four Seminars on GMP by Relevant and Experienced BDS	25,000/-	1000/- per unit	20,000/-	1,45,000/-	It was randomly taken that min. of 25 units will participate in each seminar
	<b>Total</b>	<b>25,000/-</b>	<b>1,00,000/-</b>	<b>20,000/-</b>	<b>1,45,000/-</b>	

### 9.1.5 OBJECTIVE: Conducting Buyers – Sellers Meet

**Output:** To create a cost effective supply chain.

**Subject:** Buyers – Sellers meet will be organised for mutual business interactions at reasonably competitive prices.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSJ)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Conducting three Buyers – Sellers meet	45,000/-		15,000/-	60,000/-	It was randomly taken that min. of 25 units will participate in each seminar
	<b>Total</b>	<b>45,000/-</b>		<b>15,000/-</b>	<b>60,000/-</b>	

### 9.1.6 OBJECTIVE: Exposure visits to Implemented cluster.

**Out put:** The cluster actors will get better understanding on the cluster development

**Subject:** The cluster units after seeing the developments of the clusters like Ahmedabad. They will know the development activity and the benefits of the Cluster Development.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSJ)/ Resource center	Units	Support Instt./ Assons.		
1	Conducting exposure visits to the Association Members.	25,000/-	1000/- per unit		75,000/-	It was randomly taken that min. of 50 units will be visiting.
	<b>Total</b>	<b>25,000/-</b>	<b>50,000/-</b>		<b>75,000/-</b>	

**9.1.7 OBJECTIVE: International Marketing/ Export marketing visits.**

**Output:** Reach will be created for international marketing.

**Subject:** Units will be taken abroad for various marketing meets to develop network for Export marketing.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSl)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Conducting three visits abroad.	3,00,000/- ( CDE Expenses Only)			3,00,000/-	Coordination will be done for getting subsidy from NSIC for Stall Rent and for reimbursement of expenses of the trip through MDA Scheme. However initially the expenses will be borne by participating units.
	<b>Total</b>	<b>25,000/-</b>	<b>1,00,000/-</b>	<b>20,000/-</b>	<b>1,45,000/-</b>	

### 9.1.8 OBJECTIVE: Value Chain Analysis

**Out put:** To reduce the working capital

**Subject:** The cluster units will be exposed to the latest developments in value chain analysis and resource planning so that they can reduce their working capital by reducing their raw material stocks, material in process and finished goods.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSI)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three seminars will be conducted on supply chain management and resource planning by experienced ERPs	25,000/-	1000/- per unit	15000/-	115000/-	It is envisaged that 25 units are going to participate in each seminar.
	<b>Total</b>	<b>25000/-</b>	<b>75000/-</b>	<b>15000/-</b>	<b>115000/-</b>	

### 9.1.9 OBJECTIVE: Quality Upgradation.

**Out put:** The cluster actors will get awareness on quality production.

**Subject:** To upgrade the quality of production and care to be taken for quality upgradation at various phases of manufacturing processes.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSI)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three workshops will be organised on quality management over a period of three years.	25,000/-	1000/- per unit	15000/-	115000/-	It is envisaged that 25 units are going to participate in each seminar.
	<b>Total</b>	<b>25000/-</b>	<b>75000/-</b>	<b>15000/-</b>	<b>115000/-</b>	

**9.1.10 OBJECTIVE: Implementation of safety measures.**

**Out put:** The cluster actors will be made aware of the safety measures to be taken for safeguarding the workforce and establishment..

**Subject:** To upgrade the knowledge of workforce about the safety-working environment.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSJ)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three workshops will be organised on safety measures over a period of three years.	25,000/-	1000/- per unit	15000/-	115000/-	It is envisaged that 25 units are going to participate in each seminar.
	<b>Total</b>	<b>25000/-</b>	<b>75000/-</b>	<b>15000/-</b>	<b>115000/-</b>	

**9.1.11 OBJECTIVE: Development of portal for e-commerce.**

**Out put:** Export marketing reach will be created through e-commerce

**Subject:** A web site will be developed on association domain or consortium domain for better reach of international market.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSJ)/ Resource center	Units	Support Instt./ Assons.		
2	Development of portal	25000/-		75000/-	100000/-	
	<b>Total</b>	<b>25000/-</b>		<b>75000/-</b>	<b>100000/-</b>	

**9.1.12 OBJECTIVE: Creation of common testing facilities.**

**Out put:** A common testing facility will be created both for testing and R&D

**Subject:** A common testing facility for the benefit of units will be created in association with existing MPLN Lab which reduces the cost of infrastructure. A consortium of Pharma associations, MPLUN, SISI, INDORE will be formed for maintenance of lab. However, the variable expenses of lab will be met from the nominal charges collected from units seeking the facility.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSSI)/ Resource center	MP State Govt.	Support Instt./ Assons.		
2	Formation of consortium and coordinating with state govt. for setting up advanced testing and R&D facilities in their existing common testing facility which will be managed by the consortium.	1000000/-	1000000/-	1000000/-	3000000/-	MPLUN Lab is already having testing facilities for RM, Chem. Analysis for most of the drugs manufactured in the cluster. However, it need to be upgraded for compression testing and some advanced chemical analysis. It is also required to upgrade the lab for chemical structuring which helps in R&D in post Product patent regime. Funds may be granted by DC(SSSI) from the relevant existing scheme.
	<b>Total</b>	<b>1000000/-</b>	<b>1000000/-</b>	<b>1000000/-</b>	<b>3000000/-</b>	

**9.1.13 OBJECTIVE: Technology Upgradation**

**Out put:** Awareness will be created on latest technological upgradation in the Pharmaceutical Industry in accordance with international standards.

**Subject:** Experts in the field of Pharmaceutical will conduct workshops for creating awareness amongst cluster actors and to upgrade themselves accordingly.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SS)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three workshops will be conducted on technology upgradation over a period of three years.	50000/-	500/- per unit.	50000/-	137500/-	It is envisaged that 25 units are going to participate in each seminar.
	<b>Total</b>	<b>50000/-</b>	<b>37500/-</b>	<b>50000/-</b>	<b>137500/0-</b>	

**9.1.14 OBJECTIVE: Creating Consortium for marketing and Raw Material procurement.**

**Out put:** A collective marketing network will be formed through consortium for better marketing benefits and cost effective raw material procurement.

**Subject:** Marketing and RM consortium will be created for the benefit of cluster actors to have a better reach in marketing and cost effective RM procurement.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SS)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three seminars on the benefits of consortium approach.	75000/-			75000/-	
	<b>Total</b>	<b>75000/-</b>			<b>75000/-</b>	

**9.1.15 OBJECTIVE: Creating awareness on Pollution norms and controlling pollution.**

**Out put:** Cluster will be equipped with better Effluent Treatment in controlling the Pollution.

**Subject:** Awareness will be created in the cluster on effluent treatment and upgrade their pollution control practices.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSI)/ Resource center	Units	Support Instt./ Assons.		
1,2,3	Three workshops on pollution control	30000/-	500/- per unit		67500/-	It is envisaged that 25 units are going to participate in each seminar.
2	Creation of Common Effluent Treatment Plant	400000/-		400000/-	800000/-	A consortium of SISI, INDORE, PCB, Financial Instt., and Pharma Associations will be formed to set up and maintain this CETP.
	<b>Total</b>	<b>430000/-</b>	<b>37500/-</b>	<b>400000/-</b>	<b>867500/-</b>	Note: It is envisaged that Land for CETP will be provided State Govt.

**9.1.16 OBJECTIVE: Strengthening Association.**

**Out put:** Strong networking among the association members will be formed for co-optition.

**Subject:** Association will be strengthen for better networking and collective efforts. A separate secretariat for the association will be formed for day-to-day activities. The secretariat will take care of getting information on international marketing through Internet and disseminate the same amongst its members and maintenance of association portal. The secretariat will also maintain the information on various government schemes, which benefit the cluster firms.

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSl)/ Resource center	Units	Support Instt./ Assons.		
1	Two seminars on strengthening associations will be organized	30000/-			30000/-	
	Infrastructure facilities for Asson. Secretariat	25000/-		100000/-	125000/-	To motivate the Associations for having the secretariat a token assistance will be given for infrastructure like computers, internet etc.
	<b>Total</b>	<b>55000/-</b>		<b>100000/-</b>	<b>155000/-</b>	

**9.1.17 Note: For the convenience and smooth functioning of CDE the following are required at SISI, Indore for exclusive use for cluster programmes.**

Sl.No.	Item	Amount	Remarks
1.	Laptop and LCD Projector for making presentation during the seminars, workshops and training programmes.	<b>1,00,000/-</b>	Computer system and a laser printer in the instt. May be spared for use of cluster development.
2.	Stationery	<b>10000/-</b>	
	<b>T O T A L</b>	<b>1,10,000/-</b>	

## 9.2 TIME SCHEDULE OF ACTIVITIES QUARTER WISE

SL. No.	Activity	Year - 1				Year - 2				Year - 3			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
1.	Two Awareness Seminars on Cluster Development	√	√										
2.	Two Seminars on Strengthening the Associations	√		√									
3.	Two Awareness seminar on Schedule M		√		√								
4.	Interface with BDS for implementation of Schedule .M		√		√								
5.	Three Seminars on Trust Building	√				√				√			
6.	Four Seminars on GMP			√	√		√		√				
7.	Three Buyers - Sellers meet				√				√			√	
8.	Exposure visits to clusters			√									
9.	Participation in International Trade Fairs (Three Visits)				√				√			√	
10.	Three Seminar on Value Chain Analysis			√				√			√		
11.	Three Workshops on Quality Upgradation		√			√				√			
12.	Three Workshops on Safety				√		√				√		
13.	Development of Portal for Associations							√	√	√	√	√	
14.	Creation of Common Testing Facility			√	√	√	√	√	√	√	√	√	
15.	Three Workshops on Technology Upgradation			√			√				√		
16.	Three seminars on Consortium			√			√			√			
17.	Three Workshops on Pollution Control				√			√				√	
18.	Creation of COMMON Effluent Treatment Plant (CETP)		√	√	√	√	√	√	√	√	√	√	

**NOTE:** The activities start period is taken as 01.04.2004, as the CDE will undergo phase three training at **nisiet**, Hyderabad upto 28.01.2004.

**9.3 CONSOLIDATED BUDGETARY ESTIMATES YEAR WISE TO BE FUNDED BY O/o DC (SSI), New Delhi AS PER THE ABOVE ACTION PLAN.**

Sl. No.	Activity	Upto 31 <sup>st</sup> March'05	Upto 31 <sup>st</sup> March'06	Upto 31 <sup>st</sup> March'07	TOTAL
1.	Awareness seminars on cluster development	20000			20000
2.	Seminars on strengthening associations	30000			30000
3.	Infrastructural assistance for association	25000			25000
4.	Awareness Seminar on Schedule M	25000			25000
5.	Interface with BDS for implementation of Schedule M	15000			15000
6.	Seminar on Trust Building	7000	7000	6000	20000
7.	Seminars on GMP	12500	12500		25000
8.	Buyers - sellers meet	15000	15000	15000	45000
9.	Exposure visits to clusters	25000			25000
10.	Participation in International Trade Fairs	100000	100000	100000	300000
11.	Seminars on Value Chain Analysis	8000	8000	9000	25000
12.	Seminars on Quality Upgradation	8000	8000	9000	25000
13.	Workshops on Safety	8000	8000	9000	25000
14.	Development of Portal	9000	8000	8000	25000
15.	Creation of Common Testing Facility	400000	400000	200000	1000000
16.	Workshop on Technology Upgradation	18000	18000	14000	50000
17.	Seminars on forming Consortium	25000	25000	25000	75000
18.	Workshops on Pollution Control	10000	10000	10000	30000
19.	Creation of Effluent Treatment Plant	200000	200000	100000	500000
	<b>T O T A L</b>	<b>960500</b>	<b>819500</b>	<b>505000</b>	<b>2285000</b>

## Annexure - I

**APPROVED TESTING LABORATORIES :**

<b>S.NO.</b>	<b>NAME &amp; ADDRESS</b>	<b>CONTACT PERSON</b>	<b>PHONE NO.</b>
1.	Alpa Laboratories 103 /104, Usha Nagar, INDORE (M.P.)	Mr. Patel	2481711/ 2481712
2.	Anusandhan Anlytical Lab. 435, M.G. Road, INDORE. (M.P.)	Mr. Arvind	2534167/ 2531482
3.	Chokse Analytical Service Ltd 6/3. Manoramaganj, INDORE (M.P.)	Mr. Chokse	2490592/ 2493593/ 2493352
4.	M.P.P. Analytical Lab. 7, Pipalyapala Road, INDORE. (M.P.)	--	2366196/ 2365468
5.	M.P. Laghu Udyog Nigam Ltd. Pologround INDORE. (M.P.)	Dr. Heda	2421003
6.	Standard Analytical & Research Labs. 35 - A/A, Laxmibai Nagar, Industrial Area, INDORE (M.P.)	Dr. Pramod Jain	2412818

### CLUSTER MAP – PRIOR TO INTERVENTION

