

DIAGNOSTIC STUDY OF BASIC/BULK DRUG CLUSTERS IN THANE-BELAPUR IN MAHARASHTRA

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1. SCOPE, OBJECTIVES AND APPROACH

Small Scale Industries contribute significantly in industrial production of the country. They produce a variety of products ranging from traditional to hi-tech. Although the volume of production from Small Scale Industries is quite large, the quality of the product, productivity, energy and environmental issues has always been a concern. All these concerns play a major role for the survival of the Small Scale Industries.

The Govt. Of India, Ministry of SSI has decided to start a large number of Cluster Development initiatives across the country under the UNIDO methodology for Cluster Development. UNIDO Focal Point Cluster Development Programme, New Delhi is actively assisting the Ministry in respect of designing the structure and contents of the programme. As many as 21 Cluster have been selected in July, 2003 for cluster development with a holistic approach by the O/o the DC (SSI). Bulk Drug cluster at Thane Belapur Belt in Maharashtra is one amongst the selected clusters. The following considerations have been kept in view while selecting the clusters:

- Distinct technology and product
- Status of basic infrastructure
- Presence of capable supporting Institutions
- Potential for Growth
- Local leadership and support within the Clusters
- Contribution to employment and exports etc.

The industries located in Thane Belapur Belt contribute to some extent as far as Bulk drugs are concerned. These industries come under the regulatory compliance by the Food and Drug Administration (FDA).

This study attempts to present and analyse the current position of the industry and also to understand its functional dynamics. The central concern of the study, however, relates to two important issues: (a) the nature and strength of current business and organizational linkages between the various cluster actors and (b) areas of intervention for development of the industry.

The information has been collected from both primary as well as secondary sources. The primary source mainly includes collecting facts and figures through survey and detailed discussion/interviews with a number of Large, Medium and Small Scale Bulk drug industries. Also, information has been collected through interactions with office bearers and members of industry associations, officials of the concerned state/central govt. offices, Technical Institutions, Pharmacy College and other knowledgeable and experienced persons in the field. The information has been collected from the institutions and organizations mentioned below:

Profile of Survey Respondents

Category	Perrsons/Organisations Interviewed
Large and Medium scale units	1
Small scale units	8
Financial Institutions	3
Public Testing Laboratory	1
Central/State Govt. Offices	4
Persons knowledgeable about the industry	2
Industry associations & Technical Institutions	4

Besides, useful insights and directions have been obtained from the faculties of UNIDO and NISIET, Hyderabad. In addition to the primary sources, information has also been obtained through government publications and also documents, papers and research reports of industry associations, research institutions and the press. Mostly the National and

International figures pertaining to the growth of Bulk Drugs and Formulations have been collected through internet source. In some of the areas figures for Basic/Bulk drugs are not separately available and hence Pharmaceutical sector as a whole has been indicated

2. INTERNATIONAL AND NATIONAL-PRIVATE SCENARIO OF BULK DRUG INDUSTRY

INTERNATIONAL SCENARIO

Bulk Drug Industry is the backbone of the self-reliant Pharma industry in India, playing a significant role in improving the health standards of the people. The industry consists of Large, Medium and many small-scale units providing tremendous employment opportunities. Today 90% of the domestic bulk drugs requirement is met by the Indian industry itself. United States is the largest contributor to world market with about 28% of market share followed by Japan with 21%. India's contribution to the world market is insignificant. The growth and achievement of the Indian Drug Industry during the last five decades has been phenomenal and has been rated as one of the highest among the developing countries. India's bulk drug and pharmaceutical industry today has grown into a highly sophisticated one, meeting the international standards of production, technology and quality control. R&D play a very important role in Drug and Pharmaceutical Sector. This sector has to fulfill the various regulatory norms right from the pre-production stage until the product reaches the final consumer.

Production

The Global pharmaceutical industry, presently valued at US\$ 305 billion, is projected to grow at 8% p.a. in the next 5 years. In 1998 market grew by 7% as against 6.6% in the previous year. The dominance of the developed countries, especially, the USA and Japan, and large multi national 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. 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, and 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.

Trade

The world exports of pharmaceuticals have been growing at a compound rate of about 13 per cent per annum and currently it is estimated to be about US \$ 50 billion. Over 90 per cent of the world exports and 70 per cent of imports are accounted for by developed countries. 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.

Research and Development

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&D. In the US, the ratio of R & 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 the market stage, a new drug has to go through a series of pre-clinical and clinical trials. It has been estimated that out 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.

THE NATIONAL SCENARIO

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. A highly organized sector, the Indian Pharma Industry is estimated to be worth US \$ 4.5 billion, growing at about 8 to 9 percent annually. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously.

Playing a key role in promoting and sustaining development in the vital field of medicines, Indian Pharma Industry boasts of quality producers and many units approved by regulatory authorities in USA and UK. International companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past 53 years and helped to put India on the pharmaceutical map of the world.

Following the de-licensing of the pharmaceutical industry, industrial licensing for most of the drugs and pharmaceutical products has been done away with. Manufacturers are free to produce any drug duly approved by the Drug Control Authority. Technologically strong and totally self-reliant, the pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade. The Pharmaceutical Industry, with its rich scientific talents and research capabilities, supported by Intellectual Property Protection regime is well set to take on the international market. The growth of this sector in terms of the Capital Investment, Production, Export, Import and R & D Expenditure are indicated below:

Growth Indicators (Rs. crores)

	1965-66	1999-00
Capital Investment	140	2,500
Production:		
Formulations	150	15,960
Bulk Drugs	18	3,777
Import	8.20	3,441
Export	3.05	6,631
R&D Expenditure	3	320

Source: www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/growth-indicators.html - dated 16/10/2003

Production:

The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles. There are about 250 large units (including 5 Central Public Sector Units) and about 8000 Small Scale Units engaged in direct manufacturing which form the core of the pharmaceutical industry in India. These units produce the complete range of pharmaceutical 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 pharmaceutical formulations. The production figures as regards Bulk Drugs and Formulation from 1980-81 onwards till 2000-01 are indicated below:

Production - Formulations

Years	(Rs. crores)
1980-81	1,200
1981-82	1,434
1982-83	1,660
1983-84	1,760
1984-85	1,827
1985-86	1,945
1986-87	2,140
1987-88	2,350
1988-89	3,150
1989-90	3,420
1990-91	3,840
1991-92	4,800
1992-93	6,000
1993-94	6,900
1994-95	7,935
1995-96	9,125
1996-97	10,494
1997-98	12,068
1998-99	13,878
1999-00	15,960
2000-01	18,354

Source: www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/pharmaceutical-formulations.html - dated 16/10/2003

Production - Bulk Drugs

Years	(Rs. crores)
1980-81	240
1981-82	289
1982-83	345
1983-84	355
1984-85	377
1985-86	416
1986-87	458
1987-88	480
1988-89	550
1989-90	640
1990-91	730
1991-92	900
1992-93	1,150
1993-94	1,320
1994-95	1,518
1995-96	1,822
1996-97	2,186
1997-98	2,623
1998-99	3,148
1999-00	3,777
2000-01	4,533

Source:www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/pharmaceutical-bulk-drugs.html - dated 16/10/2003

Number of Units:

The Indian Pharmaceutical sector is highly fragmented with more than 20,000 registered units engaged in direct and indirect manufacturing. It has expanded drastically in the last two decades. The leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share. It is an extremely fragmented market with severe price competition and government price control. The number of units under this sector is mentioned in the following table:

Years	Units
1969-70	2,257
1979-80	5,156
1989-90	16,000
1999-00	20,053

Source:www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/number-of-units.html - dated 16/10/2003

Investment:

The investment in this sector are indicated in the table mentioned below:

Years	(Rs. crores)
1973	225
1977	450
1979	500
1982	600
1985	650
1988	800
1993	1,060
1994	1,200
1995	1,380
1996	1,600
1997	1,840
1998	2,150
1999	2,500

Source:www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/investment.html - dated 16/10/2003

From the above table it is clear that between 1973 and 1977 there was a 100% increase in investment. Subsequently the investment increased by only 60% in subsequent period from 1979 to 1988. However, from 1993 to 1999 the investment increased substantially by 136%.

Import:

The country's import position as regards the bulk drugs, formulations, intermediates, chemicals, solvents and others are indicated in the following table:

Imports - Composition
(Rs. crores)

Years	Bulk Drugs	Formulations	Intermediates, Chemicals, Solvents & others	Total
1980-81	87.24	9.62	15.68	112.54
1981-82	105.06	1.93	29.34	136.33
1982-83	115.55	5.41	27.52	148.48
1983-84	123.06	3.43	36.85	163.34
1984-85	178.41	10.17	27.05	215.63
1985-86	208.13	15.82	43.44	267.39
1986-87	207.49	21.84	58.26	287.59
1987-88	234.13	21.44	93.87	349.44
1988-89	328.35	35.43	83.13	446.91
1989-90	425.64	55.09	171.39	652.12
1990-91	322.57	84.94	196.49	604.00
1991-92	458.51	96.12	252.75	807.38
1992-93	508.39	119.51	509.48	1,137.38
1993-94	612.74	138.33	415.46	1,166.53
1994-95	811.43	173.02	384.27	1,368.72
1995-96	1,630.00	270.00	505.00	2,405.00
1996-97	1,705.00	345.00	555.50	2,605.50
1997-98	1,827.00	430.00	611.00	2,868.00
1998-99	1,918.00	540.00	670.00	3,128.00
1999-00	2,025.00	680.00	736.00	3,441.00

Source: www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/imports.html - dated 16/10/2003

Export:

India is a net exporter of bulk drugs as over 50% of bulk drug production is exported. During the year 2000-01, the total value of bulk drugs and pharmaceuticals produced in India was worth US \$ 1230 million, out of which drugs worth US \$ 840 million were exported. The export of bulk drugs projected to be around US \$ 1350 million for the year 2003. The export figures as regards the Bulk Drugs and Formulations are indicated in the following table:

Exports
(Rs. crores)

Years	Finished Formulations	% of Total	Bulk Drugs Including Quinine Salts	% of Total	Total
1980-81	35.10	(76)	11.28	(24)	46.38
1981-82	69.34	(82)	15.45	(18)	84.79
1982-83	54.60	(83)	11.34	(17)	65.94
1983-84	61.46	(77)	18.46	(23)	79.92
1984-85	99.50	(77)	29.25	(23)	128.75
1985-86	106.59	(76)	33.36	(24)	139.95
1986-87	102.12	(54)	87.16	(46)	189.28
1987-88	88.25	(39)	139.71	(61)	227.96
1988-89	157.29	(39)	242.87	(61)	400.16
1989-90	314.20	(47)	350.50	(53)	664.70
1990-91	371.40	(47)	413.40	(53)	784.80

1991-92	558.50	(44)	722.60	(56)	1,281.10
1992-93	965.50	(70)	409.50	(30)	1,375.00
1993-94	1,310.80	(71)	530.80	(29)	1,841.60
1994-95	1,505.50	(66)	760.10	(34)	2,265.60
1995-96	2,044.80	(64)	1,132.90	(36)	3,177.70
1996-97	2,509.20	(61)	1,581.10	(39)	4,090.30
1997-98	3,180.00	(59)	2,173.00	(41)	5,353.00
1998-99	3,194.90	(54)	2,764.10	(46)	5,959.00
1999-00	-	-	-	-	6,631.00

Source: www.pharmaceutical-drug-manufacturers.com/pharma-industry-statistics/exports.html - dated 16/10/2003

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, and only 16 per cent in the organised and small scale sectors (OPPI, 1998-99).

Employment (Estimated) in the Indian Pharma Industry

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

Source: OPPI, 33rd Annual Report 1998-99.

Profitability:

The profitability (i.e., profit before tax as a percentage of sales) of the industry has steadily increased from 1 per cent in 1991-92 to 8 per cent in 1997-98.

Trend in Profitability

Year	Profitability
1991-92	1.0
1992-93	2.6
1993-94	4.4
1994-95	6.1
1995-96	6.5
1996-97	7.0
1997-98	8.0

Source : OPPI Surveys for 1991-92 to 1994-95 and OPPI estimates for the rest of the years.

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:

The Poisons Act, 1919

The Drugs and Cosmetics Act, 1940 (this was amended various by Drugs (Amendment) Acts in 1955, 1960, 1962, 1964, 1972, 1982 and 1986)

The Drugs and Cosmetics Rules, 1945

The Pharmacy Act, 1948

The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954

The Medicinal and Toilet Preparations (Excise Duties) Act, 1956

The Narcotic Drugs and Psychotropic Substances Act, 1985

The Drugs (Prices Control) Order, 1995

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

The Industries (Development and Regulation) Act, 1951

The Trade and Merchandise Mark Act, 1958

The Indian Patents and Design Act, 1970.

From among these the aforesaid legislations the following four play a critical role in the development of the industry as suggested by the interviewees. These are:

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

We shall briefly describe the major aspects of these legislations 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' will be made effective from 1/1/2005 and will be made mandatory for all the pharmaceutical industries. It 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)".

The 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.
- Air handling systems should be provided as per mentioned in Schedule 'M' to production and quality control area.
- Revised area mentioned is the minimum to be provided for production and quality control.

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 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.

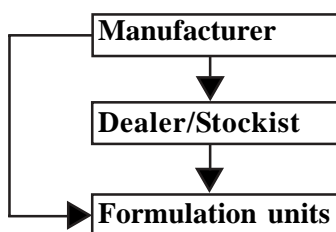
Pharmaceutical Policy:

The government has released Pharmaceutical Policy 2002 which aims to provide incentives to research-based pharmaceutical companies to encourage indigenous research and capability for cost effective quality production and exports by reducing barriers to trade. Further, the rigours of price control have been brought down substantially from the current level of 40%. The policy is aimed to promote new investments into pharmaceutical industry and encourages the introduction of new technologies and new drugs. It will also reorient the pricing system to enable the domestic industry to meet new challenges. The policy also lays stress on improvement of regulatory standards and strengthening of the quality control administration. The new policy provides for exempting drugs from falling under the Drug Price Control Order (DPCO) for a period of 15 years, provided the drug is developed through indigenous R & D and is patented under the Indian Patent Act, 1970.

Source: www.techno-preneur.net/timeis/technology/STechAugSep02/Pharma.html - dated 16/10/2003

Distribution Channel:

The Bulk/Basic drug i.e. chemicals having therapeutic value are used as raw materials by the Formulation units. Through discussion with the knowledgeable person it is revealed that the Bulk drug manufacturers sell their drugs directly to the Formulation units and in certain cases through dealer/Stockist. It is observed that some bulk drug manufacturers have their own formulation unit and as such they do not have the marketing problems. The distribution channel for bulk drug is given below:



Research and Development

R and D in Indian pharmaceutical industry has mainly been in applied research for developing process technology for production, especially of synthetic bulk drugs. It has been observed by some that countries with weak patent protection systems spend much less on innovation. In India, for instance, the pharmaceutical industry's investment on R&D for the year 1999-2000 was about Rs. 320 crores, i.e., approximately 1.6 per cent of its total turnover of Rs. 19,737 crores. (Refer Table Growth Indicators)

Why to choose India?

- Manufacturing costs are typically less than those in Europe or the US.
- More than 20 Indian manufacturers have been accredited by the USFDA
- India has become an attractive location for contract R&D as well as for contract manufacturing of pharmaceuticals. It offers several advantages: Lower costs combined with an abundance of trained scientific personnel, the common use of the English language in business and a robust legal system. India has around 7,00,000 postgraduates. It is estimated that 10% of researchers in pharma/biotech sectors in the US are of Indian origin.

- It is not just in old drugs and formulations that India offers far lower prices. Even in such frontier areas as genetically engineered vaccines, Indian companies have managed to slash prices by half.

Source: IDMA- Scaling new heights

3. CURRENT STATUS OF BULK DRUG INDUSTRY IN THANE BELAPUR BELT

History of the Cluster:

The survey of setting up of MIDC at Thane-Belapur was undertaken by S.G. Burve Committee in the year 1958. However, the proposal was approved and accordingly MIDC was set up in the year 1962. MIDC has admeasuring 2562 Hectares, along the Trans Thane Creek Area. Until now about 80% of the land has been developed and more than 3700 plots have been carved out, of which about 3300 plots have already been allotted. About 2300 different units are functioning at Thane-Belapur MIDC area. The infrastructural facilities like roads, drainage systems, water supply, street lights, telephone exchange, common facility centre building, police station, fire station, post offices etc. are available in this area. As a result of this a number of Industrialists have set up their unit in this area. The MIDC Area is also known as Trans Thane Creek (TTC) Industrial Area. The Bulk Drug Cluster at Thane-Belapur belt is an induced cluster and not a natural one. It is understood that the following reasons attributed for the development of this cluster at Thane-Belapur belt:

- Policy of Govt. of Maharashtra to decongest Mumbai, since the Mumbai city has been over saturated due to establishment of numerous units. The industrialist will find it easy to shift their units in Thane-Belapur MIDC since the area is nearer to Mumbai city.
- Due to Thane Creek, it was proposed that the hazardous wastages coming out of the Industries can be easily disposed off to the sea.
- CIDCO played a very important role in developing the MIDC by converting the nearby villages into cities. The problem of availability of skilled and unskilled labours was solved to a great extent.
- Proximity to Mumbai and Thane market.
- Proximity to Jawaharlal Nehru Port Trust and Bombay Port Trust.

Number of Units:

The concentration of Basic drugs and Formulation units has been observed in Mumbai, Pune, Raigad, Thane-Belapur belt and Tarapur. It is reported that there are about 37 Bulk Drug manufacturers in Thane Belapur belt. Out of these, 3 units are closed and about 11 units had diversified their product. Out of the remaining 23 units, 3 units are in the Large and Medium sector and 20 units are in the Small Scale Sector.

Every Bulk drug manufacturer is required to hold a license from the Food and Drug Administration (FDA), Government of Maharashtra. The licensees could be actual producers with own manufacturing facilities or loan licensees with a permit to manufacture, but not in possession of the facility. They use the facilities available with the actual units on a rate contract basis and produce and market drugs under their own brand name. Actual (own) licensees too can be loan licensees for those products for which they do not have any manufacturing facility. However, all the units located in this belt are the actual producers with own manufacturing facilities as intimated by the Food and Drug Administration Office.

Bulk Drugs Manufactured:

There are various drugs being manufactured at Thane-Belapur belt. The following are some of the Basic/Bulk drugs manufactured by the existing units as reported by them:

1. Aluminum Hydroxide Gel
2. Magnesium Hydroxide Paste
3. Metronidazole benzoate
4. Chlorozoxagone
5. Dicyclomine Hydrochloride
6. Phenobarbitone IP

7. Carbonil Iron
8. Vitamin B12 Zelin Trituarate
9. Iron Polymaltose
10. Nitrazepam
11. Alprazolam
12. Ciplomacin
13. Trioxsalen
14. Monobenzene
15. Fluconozol
16. Glibenclamide
17. Zlipizibe
18. Glipiride
19. Glizipdite
20. Vitamin B2 Phospate

Investment

The approximate total investment including fixed assets and current assets for Small scale units is less than One Crore per unit whereas for the Large and Medium scale unit is 10 Crores per unit. The estimated Investment figures for the Bulk Drug Cluster at Thane-Belapur belt is about 50 Crores. The total Capital Investment for both Bulk Drugs and Formulation units for the country as a whole is about 2500 Crores for 20,053 units for the year 1999-2000.

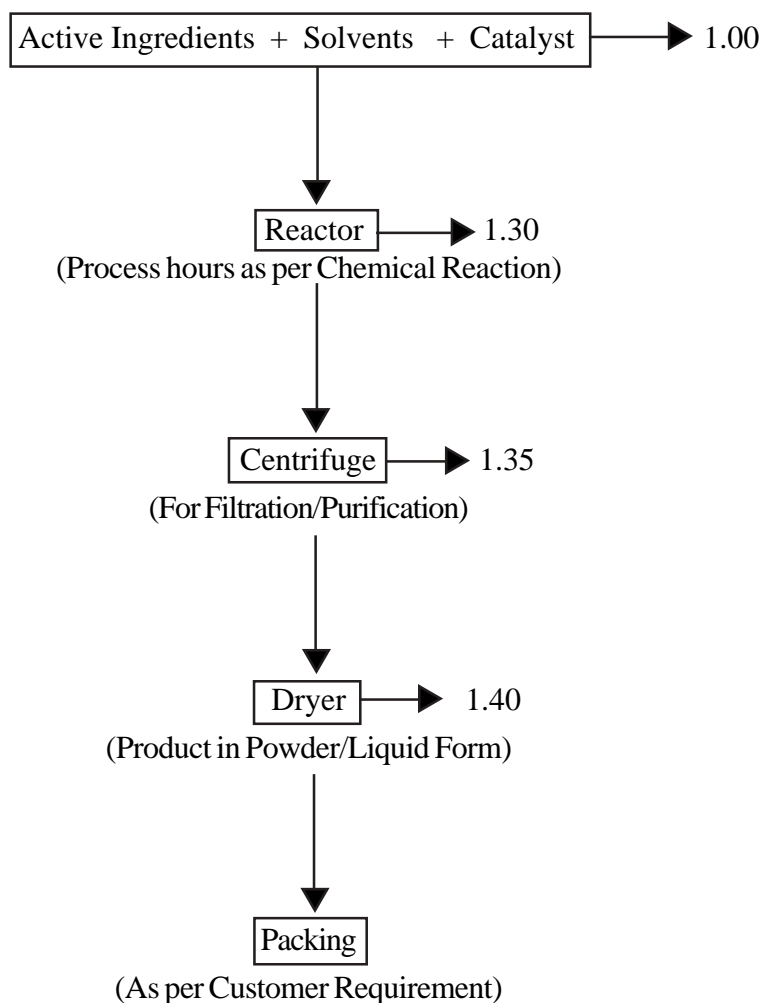
Turnover:

The estimated Annual Turnover per Small Scale unit comes to about Rs. 3.5 Crores whereas for the Large Scale unit is about 20 Crores. Based on this, the estimated annual turnover of the Bulk Drug Cluster is about 130 Crores. The total production of Bulk Drugs at National level is Rs. 4533 Crores for the year 2000-01. The bulk drug cluster of Thane-Belapur belt contributes to about 2.8 % of the total production of the country.

Production Process and Value addition:

The following chart indicates the production process of Bulk/Basic drug and value addition (ex-factory cost) that takes place during each stage of process. The exact value addition will vary from product to product. Generally, the Bulk drugs are in the powder/liquid form and are packed as per the customers need.

Bulk Drug



Market – Domestic as well Export:

In Maharashtra, the concentration of Bulk Drugs and Formulation units has been observed in places like Mumbai, Thane, Raigad, Pune, Tarapur etc. The Bulk Drug manufacturers in Thane-Belapur belt mostly caters to the needs of these formulation units. Some units do supply basic drugs to the formulation units situated in other states like Gujrat, Madhya Pradesh, Rajasthan etc. In this cluster, there are very few Small Scale units which export bulk drugs to the formulation units in abroad countries. These units export to the tune of 90 – 95% of their total turnover to the countries like Latin America, Mexico, Pakistan, Asian countries, South Africa etc. Some of the units have reported that they have their own formulation units in different states of the country and hence have given less importance for overseas market. Similarly, the Bulk Drug Manufacturers in large scale sector export about 50% of their production to overseas market.

India is a net exporter of bulk drugs as over 50% of bulk drug production is exported. During the year 2000-01, the total value of bulk drugs and pharmaceuticals produced in India was worth US\$ 1230 million, out of which drugs worth US\$ 840 million were exported.

Employment:

The estimated number of employees employed in a Small Scale unit is about 35 – 40 Nos., whereas for the Large & Medium Scale unit is about 250 – 300 Nos. It is estimated that the total employment generated through this cluster is about 1700 Nos. which includes Technical, Managerial, Administration and Workers (both Temporary as well as Permanent Staff).

In India, the Pharmaceutical industry provides employment to approx. 28.6 lakhs people. The percentage of employment generated through this cluster comes to about 0.06% as compare to the employment generated through this sector at National level.

4. BUSINESS LINKAGES OF BULK DRUG CLUSTERS IN THANE – BELAPUR BELT

Introduction

Usually, the cluster does not work in isolation. Working in cluster is all about collaborative working. Collaboration is possible in two ways i.e. Collaboration on backward linkages and on forward linkages. Working in isolation is the biggest obstacle for the development of the Small Scale firms unlike the present scenario of the Multinational companies amalgamating/merging in the large scale sector. The firms do not want to work in collaboration because they see market as limited. Further, they are overburden with their routine work. Working in collaboration will reduce the transaction costs, which directly benefits the units and in turn the consumers. The cluster can be developed through the help of the Industries Associations and by forming small consortia/networks. The developmental role can be undertaken by trade specific associations with a strong secretariat.

Business Linkages of Bulk Drug Cluster:

In this topic we will be listing out the various agencies, institutions and associations which are related to this cluster. The inclusion of an element does not imply that its linkage with the industry is strong. In fact, the industry's linkages with many of the element are rather weak. Also, the inter-firm linkages are not very strong.

Bulk Drug Manufacturers: The Core Cluster Actors:

As indicated earlier, out of the 37 bulk drug manufacturers at Thane-Belapur belt, 3 units are closed and about 11 units have diversified their products and gone into formulations and manufacturing of Chemical items. Some of the bulk drug manufacturers are doing well whereas some of the units are on the verge of closure. There are some units which are being managed by the second generations. The linkages amongst these Core Cluster Actors are very weak. It has been reported that they do not help each other in procuring inputs, lending machines/components, financial needs, providing labour during shortages etc. The units fear that working in collaboration will disclose their trade secrets.

Backward Industry Linkages:

The suppliers of raw material and capital goods form the most prominent backward linkages. It is important to note that the links between the industry and these suppliers spread beyond the geographical limits of the cluster. However, the industry is in no way dependent on import of either raw materials or machinery. The major input suppliers are as follows:

1. Active Ingredients:

Active Ingredients are generally available in domestic market mainly from the States of Gujarat, Rajasthan, Madhya Pradesh etc. The quality of the active ingredients is reported to be good and the supply is regular. Some of the active ingredients are also sourced through international market.

2. Solvents:

Mostly the solvents are available locally and are sourced through the various parts of the Maharashtra. Gujarat State, also, supplies solvents to these bulk drug manufacturers to some extent.

3. Catalyst:

Catalyst are generally available in the local market of Mumbai.

4. Machinery:

Machinery for bulk drug manufacturers are available in Mumbai market.

5. Human resources: This industry is basically run by technocrats. There is hardly any firm which is not owned and/or managed by a Pharmacy graduate or post-graduate or, a Chemical Engineer. This is true even for the small units. The availability of technical personnel is ensured by the steady supply of graduates/post-graduates in Pharmacy by the local pharmacy college. The villages around the industrial estates ensure supply of non-technical labour. The employment of women labour in bulk drug units is very less.

6. Transport:

The Transportation services are easily available which connects the clusters to the various states of the country.

Level of Cooperation and Competition at the firm level:

The survival and growth of the industries usually depends upon the nature and level of competition. Based on the information collected through survey, the bulk drug manufacturers are facing the competitions from all scales of enterprises namely small, medium and large, and across locations i.e. local, within the state, in India and abroad. The following are the main issues of competition:

- 1) Price
- 2) Brand name/ Company's image
- 3) Product Quality
- 4) Volume of output
- 5) Sales promotion (advertisement)
- 6) Prompt delivery

Similarly, the following Firm Level Competitive practices are generally observed, as reported by the units:

- 1) Wooing customers (by undesirable means)
- 2) Copying competitor's product
- 3) Imitating competitor's trade mark
- 4) Obtaining information through employees
- 5) Misinforming customers, traders and suppliers about products.

Members of Industries Associations:

On the basis of the response received from the units it is observed that most of the Bulk drug manufacturers are the member of Thane-Belapur Industries Association. Very few units have reported to be the members of Indian Drug Manufacturers Association, Chemexil, Indian Merchant Chamber etc. As reported by the units, the Industries Association helps in providing information on products through magazines and bulletins, helps in legal issues and also dealing with the Govt. policies and procedures.

Effect of Network on Long Term Competitiveness:

Even though the units feared that working in collaboration will affect their market, some units have shown keen interest in forming networks. According to them, working in networks will help them to improve their managerial skills, product quality and will induced them to invest in new equipments/methods of production.

INSTITUTIONS:

A number of institutions/bodies, both public and private, have been playing a major role in the growth of the industry. These include:

1. Central level institutions
2. State level institutions
3. Industries Associations and Other Support Technical Institutions.

1. Central Level institutions:

At the central level the Drug Control Authority of India under the Ministry of Health and Family Welfare controls the area of introduction of new drugs in India. The department also handles subjects related to GMP and its upgradation. The office of the Deputy Drug Controller (Western Zone) controls the issuance of the WHO-GMP certification.

Central Drug Testing Laboratory:

Central Drugs Testing Laboratory – Mumbai, a unit of Central Drug Standards Control Organisation coming under Directorate General of Health Services, Govt. Of India, was established in 1992 in an effort to cope better with testing of imported bulk drugs in this part of the country having greatest concentration of drug industries and also for appellate testing of contraceptive devices, besides extending greater support to Central Drug Standards Control Organisation (CDSCO) and some State Drugs Control Organizations in their surveillance efforts. The laboratory has sophisticated analytical instruments like FTIR, HPLC, UVVIS Spectrophotometers, Autotitrator and other equipment required for testing of bulk drugs and formulations. It has also established a microbiological section for testing of antibiotics and a small animal house to undertake biological tests. The laboratory is headed by a Director who is being helped by Administration, Pharmaceutical Chemistry, Microbiology and others. In the year 2002, CDTL has analysed and checked 2500 samples. The following types of samples are received by the laboratory:-

1. All the bulk drugs and formulations referred by DDC(I), ADCs and DI of west Zone.
2. Samples forwarded by State DIs.
3. Samples referred by Medical Stores Depots Organizations which include Copper T and Tubal Occlusion Rings.
4. Oral Contraceptive pills referred by Deptt. Of Family Welfare, Ministry of Health and Family Welfare, Govt. Of India.

2. State Level:

The Directorate of Industries, Government of Maharashtra:

The Directorate of Industries, Government of Maharashtra plays an important role for the development of Industries in Maharashtra. The office of the Directorate of Industries has 6 Regional Offices and District Industries Centre in each district in Maharashtra. These offices mainly provide the SSI Registration Certificate and implement the various Central/ State Govt. Schemes.

The Govt. of Maharashtra has announced its new Industrial Policy 2001, which will be operative from 1st April 2001 up to 31st March 2006. The objective of this new policy is to further accelerate the flow of investment in industry and infrastructure, promoting IT, high-tech, knowledge based and biotech industries, augmenting exports from the industrial units in the State and creating large scale employment opportunities duly ensuring environmental planning.

Highlights of the Industrial Policy 2001:

- Exemption from Electricity Duty.
- Waiver of Stamp Duty and Registration Fees.
- Refund of Octroi Duty.
- Special Capital Incentives for SSI units.
- Interest Subsidy to new textile, hosiery and knitwear SSI units.
- Development of non-conventional energy.
- Financing of capital incentives and refunds under the Package Scheme.
- Exemption from Sales Tax for Khadi & Village Industries.
- Sales Tax on IT products.
- Nursing of Sick SSI units.
- Stamp Duty on Corporate Restructuring.
- Establishment of IT/BT units on textile mill lands in Greater Mumbai.

- Floor Space Index (FSI) for IT units.
- Establishment of independent Industrial Townships.
- Establishment of Special Economic Zones.
- Development of Specialized Industrial Areas.
- Promotion of Education and Research Institutions.
- Permission of Captive Power Generation for industries throughout the State.
- Gas Cooperation Agreement.
- Review of Labour Laws and Procedures.
- Industry status to film sector.

Maharashtra Industrial Development Corporation:

Maharashtra Industrial Development Corporation (MIDC) is the primary industrial infrastructure development agency of the Maharashtra Government. Constituted under the Maharashtra Industrial Development Act, 1961, MIDC was established on 1st August 1962, with the basic objective of setting up industrial areas with a provision of industrial infrastructure all over the state for planned and systematic industrial development.

MIDC has played a vital role in the development of industrial infrastructure in the State of Maharashtra. Indeed, in the endeavour of the state to retain its prime position in the industrial sector, MIDC has played a pivotal role in the last 35 years. MIDC has developed more than 195 industrial estates (major and mini) across the state spread over 45,000 hectares of land.

The survey of setting up of MIDC at Thane-Belapur was surveyed and studied by S.G Burve Committee in the year 1958. However, the proposal was approved and accordingly MIDC was set up in the year 1961. MIDC has admeasuring 2562 Hectares, along the Trans Thane Creek Area. Until now about 80% of the land has been developed and more than 3700 plots have been carved out, of which about 3300 plots have already been allotted. About 2300 different units are functioning at Thane-Belapur MIDC area. The infrastructural facilities like roads, drainage systems, water supply, street lights, telephone exchange, common facility centre building, police station, fire station, post offices etc. are available in this area. As a result of this a number of Industrialist have set up their unit in this area. The MIDC Area is also known as Trans Thane Creek (TTC) Industrial Area.

Food and Drug Administration (FDA):

The Food and Drug Administration (FDA) based at Thane plays a critical and pivoted role for this cluster. This body issues drug licenses, monitors quality control, issues State GMP certificate, undertakes periodic inspection of units, and, overall, keeps a close watch over the industry, especially with respect to quality. At the level of officers, it has a commissioner, Joint commissioners, Assistant Commissioners, Public Relation Officers and Drug Inspectors.

3. Industries Associations and other Support Technical Institutions:

Indian Drug Manufacturers Association (IDMA):

IDMA has formed in the year 1961 and today acknowledged to be the voice of the National Sector. It has over 500 members, made up of large, medium and small national manufacturers spread across the length and breadth of the country. It has worked with the Govt. on the industry's development plans and various public matters. It has also represented the industry on such important issues as the Patents Act of 1970, a landmark piece of legislation that gave a huge impetus to the relatively nascent drug industry. It has, since then, played a crucial role in keeping opinion leaders, the Press and the public informed about the issues faced by the industry.

IDMA organises and takes part in national and international seminars/ workshops relating to key issues of the pharma and health care industries. It plays a very active role in policy consultations and dissemination of information to its members. It brings out two publications - one general and the other technical.

IDMA has three state level bodies in Tamil Nadu, West Bengal and Ahmedabad. During the year, one more State Boards of IDMA was formed in Haryana. IDMA Secretariat has been fully computerized with every staff member provided with a

computer with uninterrupted access to internet. E-mails IDs have been provided section-wise. With a view to encourage Research and Development in the country, in 1981, IDMA instituted "Research Awards" for the best ORIGINAL RESEARCH ARTICLES published in the Association's scientific journal "INDIAN DRUGS" every year. IDMA has organized the following Seminars/Workshops during the year 2003:

1. IDMA-PEG Seminar on "Pharmaceutical Air Management"
2. IDMA-APA Seminar on "Filtration"
3. Post 2003-04 Budget update on Central Excise, Customs duty and Direct Taxation
4. IDMA-APA Seminar on "Pharmaceutical Microbial Controls"
5. Seminar on "Spurious Drugs, Its Magnitude and What Need's To Be Done"
6. IDMA-PEG Seminar on "Calibration"
7. IDMA-APA Seminar on "e-Record Keeping in Pharma Industry"
8. IDMA-TTA Seminar on "Role of Technology To Meet WTO Challenges"
9. IDMA-APAC 2003 on "European Pharmacopoeia Commission"
10. Colloquium on "Current Practice of Sampling of the Starting Materials"
11. IDMA-APA Seminar on "Stability Studies: What next?"

Thane Belapur Industries Association (TBIA):

Thane Belapur Industries Association, located in Ghansoli, Thane Belapur MIDC Area, Navi Mumbai, was established in the year 1978 as a Charitable Trust. The association is headed by the President. About 553 industries (Large = 90, Medium = 155 and Small = 308) are registered with this association. The total strength of the staff members are 12. The approximate annual revenue of this association is about 25 lacs. At present the association has a total assets of about 67 lacs.

In order to provide a proper treatment for hazardous waste and disposal of the same, meeting the environmental standards and to ensure ecological balance, TBIA has promoted a company called "Trans Thane Creek Waste Management Association" to implement Integrated Hazardous Waste Management in TTC Area i.e. Thane Belapur MIDC Area. It is actively supported with Financial Assistance from Ministry of Environment & Forests, Govt. of India, New Delhi, Maharashtra Industrial Development Corporation and Maharashtra Pollution Control Board. The work is under progress. Similarly, to tackle the industrial effluent, TBIA is successfully operating the Common Effluent Treatment Plant (CEPT) of 12 MLD capacity in TTC area since 1997. But, however, excess effluent is being generated in TTC Industrial Area than its handling and hence TBIA has planned to construct a second CEPT in TTC Area.

TBIA and its Member Industries alongwith Maharashtra Industrial Development Corporation (MIDC) and City & Industrial Development Corporation (CIDCO) since 1985 undertook a conscious campaign on Afforestation & Beautification of TTC area as a part of Clean and Green Navi Mumbai. Moreover, to prevent and mitigate any unwarranted fire, explosion and toxic gas release and support with Medical Response and Expert Group in case of Emergency, the Fire & Emergency Response Station has been set up in co-operation with MIDC. The Station works round the clock manned by 30 qualified staff including Firemen and Rescuers.

MPCB jointly with TBIA installed Automatic Ambient Air Quality Monitoring Station at TBIA Office at Rabale. This system function round the clock. The values of SO₂, NO_X, SPM are displayed at Toll Naka of Mulund-Airoli bridge on the main road to be viewed by general public. Also, it has planned to set up Cleaner Technology Centre jointly with South Indian Education Society – Indian Institute of Environment Management, Nerul in TTC area. The main object of this Centre is to adopt environmental friendly and economically/technically viable cleaner technology for waste minimisation, recycle and reuse.

The TBIA has conducted the following Seminars/Workshops/Training during the previous year:

1. Seminar on "Technologies in Energy Management & Environment Protection".
2. Seminar on "ISO 9000, ISO 9001 : 2000"
3. Seminar on "Stress Management".

4. Seminar on “Pollution – Restoring Harmony in Relation to Navi Mumbai” on the occasion of “World Environment Day”.
5. Seminar on “Energy Conservation”.
6. Workshop on “Total Productive Maintenance Fundamentals and Implementation”.
7. Workshop on “Umbrella Legislation For SSI”.
8. Workshop on “Marketing Strategy For Small & Medium Industries.”
9. With the help of Directorate of Industrial Safety & Health, TBIA has conducted Continuous Education Programme in TTC Area in order to promote Safety Awareness among the workers of small and medium industries, handling hazardous goods in their factory premises.

Integrated Hazardous Waste Management Facility at TTC Area:

In order to provide a proper treatment for hazardous waste and disposal of the same, meeting the environmental standards and to ensure ecological balance, TBIA has promoted a company called “Trans Thane Creek Waste Management Association” to implement Integrated Hazardous Waste Management in TTC Area i.e. Thane Belapur MIDC Area. It is actively supported with Financial Assistance from Ministry of Environment & Forests, Govt. of India, New Delhi, Maharashtra Industrial Development Corporation and Maharashtra Pollution Control Board.

An identified site in MIDC Area of TTC was selected for setting up a Sanitary Landfill Project for Solid Hazardous Waste Management. The said project site admeasure 7 Hectares. Techno Economic Feasibility Study and Environment Impact Assessment Study for the project has already been carried out by CHEMCONTROL, Denmark which has been approved by Ministry of Environment & Forests (MoE&F), Govt. of India, New Delhi who funded Rs. 55 towards the study of TEF & EIA. The project cost for the Phase I is Rs. 764 lakhs. The project is implemented in **Two Phases (Phase I : Landfill, Solidification + Physical Chemical Treatment (PCT): will be implemented by 2002 and Phase II : Incineration will be implemented later).**

Financial participation for the Project Cost:

Contributors	% Contribution to the Capital Cost
User’s contribution	20%
State Govt.: MIDC	20%
MPCB	5%
Central Govt.	25%
Loan from Financial Institution	30%

Common Effluent Treatment Plant (CETP):

To tackle the industrial effluent, TBIA is successfully operating the Common Effluent Treatment Plant (CEPT) of 12 MLD capacity in TTC area since 1997. The said project was designed and constructed by understanding the quantum of the effluent generated at that juncture. Treatment scheme comprises of Preliminary, Primary and Secondary Treatment Units. The effluent is being treated by Conventional Activated Sludge Process. The finally treated water is disposed off to Vashi Creek through a disposal line provided and maintained by MIDC. The capacity of disposal line is to carry 32 MLD treated effluent. But, however, excess effluent is being generated in TTC Industrial Area than its handling and hence TBIA has planned to construct a second CEPT in TTC Area.

Bulk Drug Manufacturers Association:

The Bulk Drug Manufacturers Association (India) was formed in 1991 with Hyderabad as its Head Quarters. This is an all India body representing all the Bulk Drug Manufacturers of India. The Association works for consolidation of the gains of the industry and serves as a catalyst between the government and the industry on the various issues for the growth of the industry. The Association sends representation to the Concerned Ministries and officials on various

problems faced by member industries, time to time. They send information on day to day matters through their newsletter and send circulars where in the industry's immediate attention is required. They conduct National Seminars periodically in different places on current technical topics.

The main objectives of the association are:

1. To promote the discussion, on all subjects effecting the Bulk Drug Industry in India, among all members and serve as a common forum for formulating their views on all matters including national, economic, financial, commercial and related policies concerning the growth of the Bulk Drug Industry in the country.
2. To create and encourage mutual help and cooperation among the members.
3. To assist and cooperate, in framing the legislative measures, with State/Central Governments or any such authorities on any matters directly or indirectly effecting the industry, and to represent the collective opinion of the industry in this regard.
4. To diffuse among its members information on all matters effecting the bulk drug industry and to print, publish, issue, circulate such papers, periodical books, circulars as may seem conducive to any other objectives of the Association.
5. To encourage the discovery and investigate and make known the nature and merits of inventions which may seem capable of being used by those engaged in Bulk Drug Industry.
6. To formulate methods for developing indigenous as well as export market for Bulk Drugs manufactured in India.
7. To establish or maintain laboratory for testing the quality standards of Bulk Drugs and other allied products and to establish or maintain Research & Development Centre for development of new drugs/improvement in existing drugs/processes etc., or any Hi-tech Research & Training Centre, in the interest of bulk drug industry and the country in general.

Bombay College of Pharmacy (BCP):

Bombay College of Pharmacy is a pioneering institution for pharmaceutical education in India. BCP was founded in 1957 by the Indian Pharmaceutical Association – Maharashtra State Branch, with financial assistance from the Govt. of Maharashtra and several pharmaceutical corporations. Since its inception as a college offering a Diploma in Pharmacy, the college has grown in stature and at present offers Bachelors, Masters, and Doctoral programs in Pharmaceutical Sciences. The Bachelors and Masters programs are recognized by the All India Council for Technical Education. The degree courses including Ph. D. program are recognized by the University of Mumbai.

The mission of BCP is to educate and train students in the basic knowledge of pharmaceutical sciences and to contribute to improvement of health of the society by means education and research programs.

BCP has produced more than 1500 pharmacists and 200 M. Pharm and Ph. D. graduates. Several faculty members have received teaching and research awards from AICTE, UGC, CSIR, ICMR, DST and corporate sectors. It has well equipped laboratories, a bioavailability study centre, Dr. M.K. Rangnekar drug testing laboratory, state of art equipments, instruments, internet facilities and an excellent library for the benefit of students. BCP encourages and undertakes industrial collaborative projects. More than 200 industry-sponsored projects have been completed. BCP has planned several new facilities including a pilot-plant for drug synthesis and scale-up, new drug delivery systems laboratory, drug metabolism research centre, drug information service centre, library networking, state of the art auditorium and industry-institute interaction cell.

Dr. M.K. Rangnekar Drug Testing and Training Laboratory:

The Dr. M.K. Rangnekar Drug Testing and Training Laboratory was founded in 1988 by the Bombay College of Pharmacy to provide specialized analytical and related services to the pharmaceutical industry. The laboratory is recognized by FDA, Maharashtra State. It has sophisticated instruments like FT-IR, HPLC's, GLC, DSC, particulate matter counter, particle size analyzer etc.

University Institute of Chemical Technology (UICCT):

The Pharmaceutical Technology and Pharmacy Division in UICCT has achieved excellence both in teaching and research activities. The division has expertise in new drug discovery, computer-aided molecular design, synthesis of novel drugs and intermediates, bulk drug technology, asymmetric organic synthesis, development of novel drug delivery systems, development of pharmaceutical analytical methods, pharmacological assay methods and standardization of medicinal plants and herbal drugs. The faculty members have several research grants and consultancies from various pharmaceutical industries. A large number of research papers have been published. This division has received recognition by UGC under its special Assistance Programmes. The B.Pharm.Sc. courses are approved by Pharmacy Council of India and AICTE. The division has Ph.D.(Tech) and Ph.D.(Sci) programmes in various disciplines of Pharmaceutical Science & Technology. The current strength of Masters students is 65 and Doctorate is 49.

Organisation of Pharmaceutical Producers of India (OPPI):

OPPI is an organisation of pharma manufacturers established in 1965, four years after IDMA was launched. Currently, it has a membership of about 67. This includes 59 members from the drugs and pharmaceutical sector. Around 66 per cent of them are companies of foreign origin.

The Organisation takes initiative in organising seminars and workshops to discuss the key issues in the area. It brings out technical publications including Quality Assurance Guide and Safety, Health and Environmental Guide. OPPI is an active member of International Federation of Pharmaceutical Manufacturers (IFPMA) and has developed operational guidelines for interpretation and implementation of IFPMA code of Ethical Marketing Practices.

OPPI has been lobbying vigorously for the amendment of the Indian Patent Law to make it TRIPs compliant. It has been actively advocating rationalisation of duty structure and a revision of drug pricing policy. Efforts have been made by this body to make suppliers (of bulk drugs, excipients, packaging materials, equipments that go in for manufacturing these etc.) more responsive to the needs of the pharmaceutical industry in terms of quality, price stability and delivery schedules.

Public Testing Laboratories:

There are 7 approved public testing laboratories in Thane district approved by the office of Food and Drug Administration. They do various statutory tests for bulk drugs and formulations. The Bulk Drug Manufacturers at Thane-Belapur belt can have a direct commercial linkages with these laboratories. A list of Public Testing Laboratories (Konkan Division) is as follows:

1. M/s. Ratpacos Brett Trust Laboratories,
Pokharan Road, Thane.
2. M/s. S.G.S. Industries Ltd.,
A-177, Road No. 16, Wagle Estate, Thane.
3. M/s. Invochem Laboratories,
220, 226A-3, Gouri Ambika Commercial Complex,
Station Road, Vasai (E), Thane.
4. M/s. Omega Analyticals Laboratories,
106, 107, Manisha Indl. Estate, Navghar Village,
Vasai (E), Thane.
5. M/s. Amol Test Laboratories,
B-3, Matruchhaya, Boisar,
Palghar, Thane.

6. M/s. M.J. Laboratories,
Plot No. 60, Village Khaniwali,
Tal. Wada., Thane.

7. M/s. Padmaja Aero Biological Pvt. Ltd.,
Plot No. 36/3 & 4, Sector 24,
Turbhe, Navi Mumbai.

Source: Food & Drugs Administration Office, Thane

5. ISSUES OF CONCERN

Introduction

The Bulk Drug manufacturers have to satisfy the rigid conditions of various regulatory norms. As a result of globalization and liberalization, the SSI sector has to face stiff competition from overseas suppliers like Japan, China, South Korea etc. In this situation, the survival of small firms would depend on how well and quickly they adapt to the new business scenario and evolve appropriate strategies. Even the relatively larger firms are also not free from these compulsions. The following problems of this sector have been revealed through discussions with the Bulk Drug Manufacturers, concerned Industries Association and through the various reports of the concerned Industries Association.

Need for easy Finance to meet Revised GMP standards and increase exports:

To achieve and maintain the standards required to capture the overseas markets and to statutorily observe the Good Manufacturing Practices (GMP) as contained in the revised Schedule "M" of the Drugs & Cosmetics Rules, the SSI units in this sector will be required to make huge investments in plant, machinery and equipment. Also, due to globalization the units are required to compete with the units from countries like Japan, South Korea etc. who reportedly enjoy finance at lower rate of interest ranging from nil to 2%. Most of the units are on the verge of closure due to dumping of materials by China and Korea. It is, therefore, necessary to make finance available to SSI units from this sector at lower rate of interest with longer repayment terms.

Role of Banking Sector:

It has been pointed that whenever a SSI account is categorized as Non-Performing Asset (NPA), the unit is immediately threatened to be put in DRT (Debt Recovery Tribunal). It is, therefore, recommended by the industries associations that the bank should implement the OTS (One Time Settlement) system for payment.

Investment limit for SSI sector:

The investment limit for plant and machinery in the small scale sector has been reduced from Rs. 3 crores to Rs. 1 crore. The Govt. has, however, recently raised the investment limit only in case of those units which are manufacturing 13 specified bulk drugs. To restrict it only to 13 drugs would be an injustice to the Industry which produces a number of bulk drugs and formulations which have tremendous export potential the world over. To achieve and maintain the standard required to capture the export market of medicines and even to observe the new GMP standards prescribed by the Govt., the SSI units in this sector will be required to make huge investment in plant, machinery and equipments. However, with the present limit of Rs. One core no bulk drug/formulation unit in the SSI sector will be in a position to adopt the new GMP standards.

Maintaining WHO-GMP standards:

Issues relating to WHO-GMP compliance have been a relatively major area of concern for the industry as a whole. Here the primary affected groups are the small firms. The large firms and majority of the medium firms have already graduated to the "desired" level of quality. The emerging regulatory trend is a movement towards stricter quality norms. The GMP guidelines cover comprehensively the entire process right from manufacturing till the product reaches the final consumer. Interestingly,

apart from regulatory compliance, the industry feels that this is also gradually becoming a demand from the market. However, the small scale firms are finding it difficult, especially because of their unpreparedness to invest huge amounts. In order to fulfill the norms of WHO-GMP, the unit will require to make huge capital investment. At present, the entrepreneurs are weighing the costs and benefits of undertaking such huge additional investment. Most old units have plant designs unsuitable for WHO-GMP specifications and have no alternative but to go for entirely new plants. Considering that the profit margins of small firms have gone down over the past few years, such additional investments may put them under tremendous pressure. Moreover, at the current level, the feeling is that there is no guarantee that as soon as a firm qualifies for WHO-GMP, business will be guaranteed. Thus a significant support is envisaged in this front in the form of subsidized loan and other management support.

International Quality Norms:

The international quality norms especially those related to exports is also a major area of concern. This has four related dimensions (a) Importing nations and bulk purchasers are gradually demanding higher quality standards, e.g. WHO-GMP. (b) Secondly, importing nations have different registration procedure and documenting norms for import. (c) Thirdly the quantity of imports is not always manageable by a single small firm. (d) Fourthly, the small firms individually cannot afford to offer a basket of drugs at internationally competitive prices.

All these however provide good scope for co-operation within a group of firms, since:

- (a) The documentation procedure though 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

Low investment in R&D:

As India is following the process patent law, it has harmed the India's basic research capabilities. Moreover, the investment in R&D in India has been very low. However, with shift-over to a product patent regime would lead to the development of India's basic research capabilities. The small scale firms prefer to invest less for Research and Development because of their lack of financial resources, trained manpower, lack of affordable and accessible testing facilities etc. However, this problem can be overcome by having a common R&D facility centre wherein a group of small firms would develop a new drug.

Non-availability of Skilled manpower:

The units are facing the problem of availability of skilled manpower at a reasonable cost. This problem is in fact acute for small firms since they cannot afford highly qualified persons. Even larger units find it difficult to get people who are well trained in regulatory and technical aspects. It is expected that job opportunities in the shop floor would be reduced with automation, whereas those in marketing, product management, formulation development, production planning and inventory control, quality control and quality audit will expand. The current education policy needs to contribute more in the new environment.

Lack of Information:

Small firms are finding it difficult to avail right information as regards market, finance, technical, Govt. procedures etc. 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 of proven technologies.

Specialization:

The Bulk Drug manufacturers, especially small scale firms, are finding it difficult to stay in the market may be because of rising quality expectations or low profit business. In order to earn more profit and to stay in the market, the units have

started manufacturing no. of products as per the demand in the market. With such diverse product profile, it is not easy to go for WHO-GMP or have a good resource management. It is found that, unlike entrepreneurs in the past who wanted to “do something worthwhile”, those of the present generation want to “make a quick buck” even if they have to compromise on quality.

Management Practices – Not given much importance:

The Small Scale units does not pay much more attention in improving their managerial skills, especially in areas like financial management, inventory management, material handling, personnel management etc. Often, working capital is used for investing in capital equipment. They are not aware of the modern concepts and practices of management.

Burden of Taxes:

Medicines bear a heavy burden of taxes. Today, almost every pharmaceutical product is being taxed to the extent of 30-35 % through custom duty, excise duty, sales tax, octroi and other taxes. The burden of taxes keeps on increasing year by year. In a way, the tax on medicine is a tax on sickness. At the same time the units have to face the cut-throat competition from abroad countries, especially from China, which has the capacity of producing and delivering huge quantities at a shorter period of time.

Lack of knowledge of Govt. rules and regulations:

It has been reported that most of the units are not fully aware of the Govt. rules and regulations, especially in case of Schedule ‘M’ of the Drug and Cosmetic Act as well as the import and export procedures. They find it difficult to deal with the Govt. bureaucracy. As most of the units are one man show, they cannot give much attention to the production and promotion related matters and have to run after fulfilling the Govt. procedures.

Need for Common Testing Laboratory:

At present the units either have their own testing laboratories or are utilizing the service of government approved public testing laboratories. Every small scale unit does not afford to have a modernize testing laboratory having all advanced testing instruments. Hence, a fully modernize common laboratory center having all sophisticated instruments need to be established in the cluster keeping in mind the new specification/norms of the GMP

Export:

In Maharashtra, the concentration of Bulk Drugs and Formulation units has been observed in places like Mumbai, Thane, Raigad, Pune, Tarapur etc. The Bulk Drug manufacturers in Thane-Belapur belt mostly caters to the needs of these formulation units. Some units do supply basic drugs to the formulation units situated in other states like Gujarat, Madhya Pradesh, Rajasthan etc. In this cluster, there are very few Small Scale units which export bulk drugs to the formulation units in abroad countries. Emphasis needs to be given to the small-scale units for marketing their product in export market. Programmes on export marketing needs to be organized.

Food and Drug Administration:

The development of pharmaceutical sector is dependent on the support of Food & Drug Administration. 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 will lead the industry with accurate information and guidance to excel in the upcoming era of enhanced competition.

6. SWOT ANALYSIS:

Strengths:

- Large untapped domestic market
- Low cost manufacturing
- Availability of Trained Scientific Personnel
- Raw material available in sufficient quantity
- Existence of Technical Institutes
- Well developed Infrastructural facilities
- Presence of number of Financial Institutions, Banks etc.

Weakness:

- Characterised by low margins
- Low investment in R & D
- Imports started coming in
- Finance available at high rate of interest
- Trust level very low
- Poor testing facilities
- Poor coordination with Govt. bodies and other related Organisations

Opportunities:

- Possibility of establishing Common Testing Laboratory
- Globalisation can ensure tremendous market potential
- Enterprise can join hands together for overseas market, brand building and participation in trade fairs.
- New Drug Price Control Order – exempting drugs from falling under DPCO for a period of 15 years, provided the drug is developed through indigenous R & D and is patented under the Indian Patent Act, 1970.

Threats:

- China threat – capacity to deliver huge quantity at low price
- Competition is increasing
- Investment in Plant & Machinery will increase in order to fulfill the norms of 'Schedule M' of Drugs and Cosmetic Act irrespective of assured market
- Burden of Taxes increasing day by day
- Product Patent Law will be made compulsory

7. ACTION PLAN:

The development of cluster will mostly depend upon the level of trust being built amongst the core cluster actors and the stake holders. Also, the core cluster actors and the stakeholders are required to devote a lot of time for its development. Small consortiums/networks are to be formed. The business linkages are to be strengthened. Based on the needs and interest shown by the Bulk Drug Manufacturers located at Thane Belapur belt the following action may be taken up for the development of the cluster:

A) Training programmers to be organized:

- 1) Personnel Management
- 2) Financial Management
- 3) Marketing Management

- 4) Export Management
- 5) Advertising and Sales promotion

B) Seminars/Workshop to be organized:

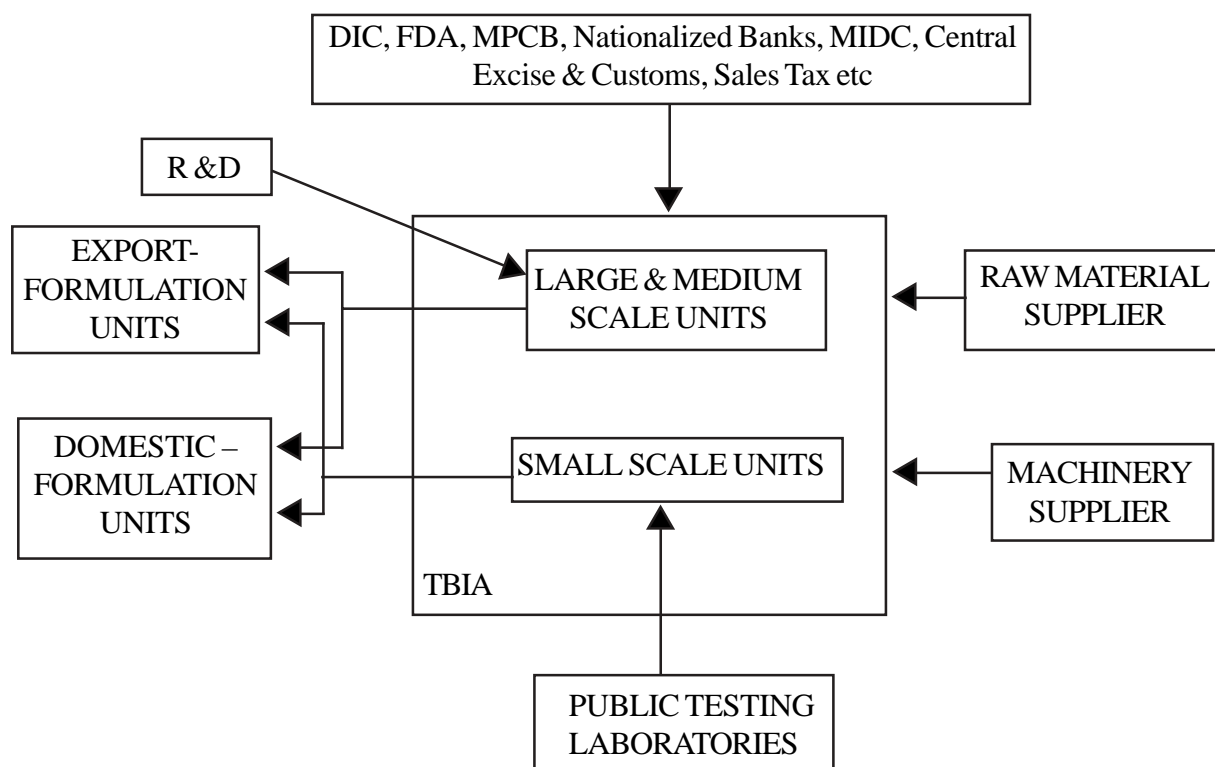
- 1) Schedule 'M' of Drugs and Cosmetic Act
- 2) Modernization and Technology Up gradation
- 3) Pollution Control
- 4) Financial assistance provided by SIDBI, NSIC, Banks etc.
- 5) Export/Import procedures

C) Other Activities

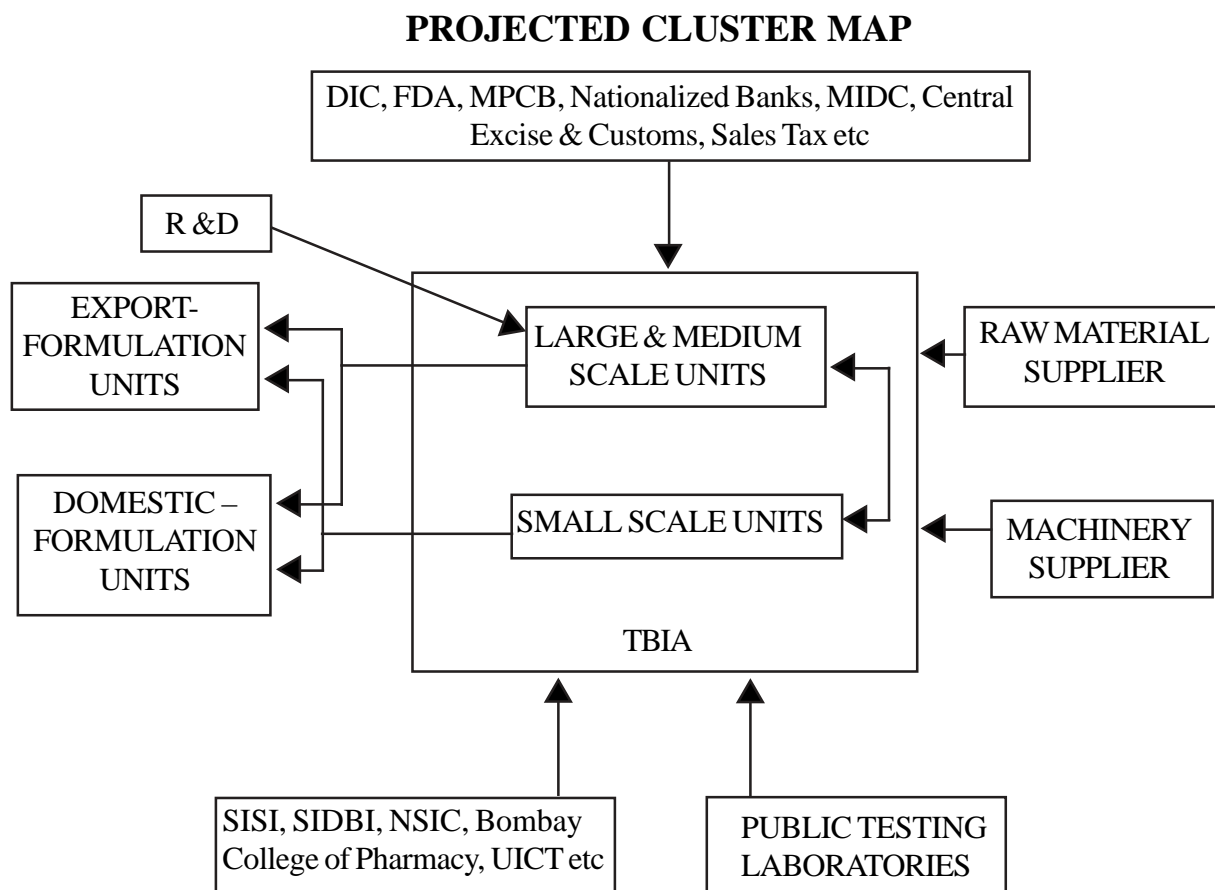
- 1) Developing a Common Facility Centre (CFC) which can provide the right and timely information as regards change in rules and regulations, market potential, Govt. procedures etc.
- 2) Appointing local BDS providers for common factory audits, common ISO-9000 consultant, common export agent etc.
- 3) Forming consortiums/networks for:
 - a) Common raw material procurement
 - b) Common marketing brochures
 - c) Common Advanced Testing Laboratory facility
 - d) Common R & D Centre
- 4) Buyers and Sellers meet
- 5) Linking Educational and Technical Institutions with the cluster
- 6) Most of the units in the cluster are not the members of Associations like IDMA, BDMA, OPPI etc. Hence, this cluster should linked up with these associations.

Annex 1

CLUSTER MAP PRIOR TO INTERVENTION



Annex 2



Annex 3

LIST OF REFERENCES:

- 1) Maharashtra Industrial Development Corporation – Knowledge Corridor Mumbai-Pune
- 2) IDMA – Scaling new heights
- 3) IDMA – 42nd Annual Report 2002-03
- 4) Thane Belapur Industries Association – 24th Annual Report
- 5) Dr. Tamal Sarkar's Diagnostic Study Report of Drugs and Pharmaceutical Clusters in Ahmedabad and Vadodara.
- 6) IDMA – Comprehensive Memorandum submitted to Sub-Committee-II for Ministry of Small Scale Industries of Department Related Parliamentary Standing Committee on Industry to Mumbai from July 6th to July 9th, 2002.

BUDGETARY ESTIMATES BASED ON SUGGESTED ACTION PLAN

Year	Activity	Budget Estimates			Total	Remarks
		DC(SSD)/ Resource center	Units	Support Instt./ Assons.		
2004-05	Seminars on cluster development	10,000/-			10,000/-	It is taken for granted that Min. 20 units will participate
2004-05 & 2005-06	Two Awareness Seminar on Schedule 'M'	30,000/-	500/- per unit		50,000/-	It is taken for granted that Min. 20 units will participate
2006-07	Buyers-Sellers meet	15,000/-	1000/- per unit		35,000/-	It is taken for granted that Min. 20 units will participate
2006-07	Participation in International Trade Fair	2,50,000/ (CDE's expenses only)			2,50,000/-	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.
2005-06	Seminar on Quality Up gradation	15,000/-	1000/- per unit		35,000/-	It is taken for granted that Min. 20 units will participate
2005-06	Workshop on Technology Up-gradation	25,000/-	1000/- per unit		45,000/-	It is taken for granted that Min. 20 units will participate
2005-06	Workshop on Pollution Control	25,000/-	1000/- per unit		45,000/-	It is taken for granted that Min. 20 units will participate
2004-05	Seminar on Financial Assistance	15,000/-			15,000/-	It is taken for granted that Min. 20 units will participate
2006-07	Training Programme on Export Management	50,000/-	1000/- per unit		70,000/-	It is taken for granted that Min. 20 units will participate
2004-05, 2005-06 & 2006-07	Creation of Common Testing facility	4800000/-(*)	1200000(*)		6000000/-(*)	

Note:

Common Testing facility:

There are two options as follows:

1. (*) M/s. Padmaja Lab. (approved by FDA) is already existing in the cluster. However, it needs to be further up-graded by having advanced Lab instrument like GC, Polari Meter, Atomic Absorption, Environmental Oven with Temperature, Humidity control etc. As per the preliminary discussion, M/s. Padmaja Lab will tie up with cluster units, for which the said Lab have agreed in principle. It is estimated that an amount of Rs. 60,00,000/- will be required for purchasing these advanced lab instrument. Out of these, Rs. 12,00,000/- approx. will be borne by the cluster units. The exact modality of working is yet to be finalized. **OR**

2. The cluster units can utilized the services of the Drug Testing Laboratory run by the Bombay College of Pharmacy, Kalina or Central Drug Testing Laboratory, Thane, for getting their samples tested. A brief write up of these support institutions is already mentioned in Chapter no. 4.

CONSOLIDATED BUDGETARY ESTIMATES FOR THE ACTIVITIES AS SUGGESTED IN THE ACTION PLAN.

Sl.No.	Activity	2004-05	2005-06	2006-07	TOTAL
1.	Awareness seminars on cluster development	10000			10000
2.	Awareness Seminar on Schedule M	15000	15000		30000
3.	Buyers – sellers meet			25000	25000
4.	Participation in International Trade Fairs			250000	250000
5.	Seminars on Quality Upgradation		15000		15000
6.	Creation of Common Testing Facility	1600000	1600000	1600000	4800000
7.	Workshop on Technology Upgradation		25000		25000
8.	Workshops on Pollution Control		25000		25000
9.	Seminar on Financial Assistance provided by SIDBI, NSIC, Banks etc.	15000			15000
10.	Training Programme on Export Management			50000	50000
	TOTAL	1640000	1680000	1925000	5245000

For the convenience and smooth functioning of CDE the following are required at SISI, Mumbai for exclusive use for cluster programmers for the year 2004-05

Sl.No.	Item	Amount	Remarks
1.	Computer with Printer	1,00,000/-	
2.	O.E.	15,000/-	
3.	T.E. Expenses	15,000/-	
4.	Misc. Expenses	15,000/-	
	Total	1,45,000/-	

TIME SCHEDULE OF ACTIVITIES QUARTER WISE

SL. No.	Activity	2004-05				2005-06				2006-07			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1.	Awareness Seminars on Cluster Development	✓											
2.	Two Awareness seminar on Schedule M		✓			✓							
3.	Buyers – Sellers meet									✓			
4.	Participation in International Trade Fairs											✓	
5.	Workshops on Quality Upgradation						✓						
6.	Creation of Common Testing Facility			✓	✓	✓	✓	✓	✓	✓	✓	✓	
7.	Workshops on Technology Upgradation						✓						
8.	Workshops on Pollution Control							✓					
9.	Seminar on Financial Assistance provided by SIDBI, NSIC, Banks etc.		✓										
10.	Training Programme on Export Management										✓		

Diagnostic Study Report
of
Basic / Bulk Drug Cluster
in
Thane-Belapur area
in
Maharashtra



Small Industries Service Institute

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