

CHAPTER – I

1.0 Introduction

Creation of new Department

1.1 Cabinet Secretariat, vide Notification dated 1.7.2008 created a separate Department of Pharmaceuticals within the Ministry of Chemicals & Fertilizers in order to provide greater focus the pharmaceuticals industry.

1.2 The following work has been allocated to the newly constituted Department of Pharmaceuticals.

- 1) Drugs and Pharmaceuticals, excluding those specifically allotted to other departments.
- 2) Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceuticals sector.
- 3) Development of infrastructure, manpower and skills for the pharmaceuticals sector and management of related information.
- 4) Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- 5) Promotion of public – private – partnership in pharmaceutical related areas.
- 6) International cooperation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.
- 7) Inter-sectoral coordination including coordination between organizations and institutes under the Central and State Governments in areas related to the subjects entrusted to the Department.
- 8) Technical support for dealing with national hazards in pharmaceutical sector.
- 9) All matters relating to National Pharmaceuticals Pricing Authority including related functions of price control/monitoring.
- 10) All matters relating to National Institutes for Pharmacy Education and Research.
- 11) Planning, development and control of; and assistance to, all industries dealt with by the Department.
- 12) Bengal Chemicals and pharmaceuticals Limited.
- 13) Hindustan Antibiotics Limited.
- 14) Indian Drugs and pharmaceuticals Limited.
- 15) Karnataka Antibiotics and Pharmaceuticals limited.

16) Rajasthan Drugs and Pharmaceuticals Limited.

1.3 The work of the Department has been organized into three distinct divisions viz. Pharmaceuticals Industry, Public Sector Undertakings and NIPER and Research & Development. The Department has also National Pharmaceuticals Pricing Authority (NPPA), an attached office, which is entrusted with fixation/revision of prices of selected Pharmaceuticals products. Beside this, there are five PSUs viz Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Chemicals and pharmaceuticals Limited(.BCPL) Bengal Immunity Limited (BIL) and Smith Stanistreet Pharmaceuticals Limited (SSPL)

1.4 KAPL was a joint venture between HAL and state Government of Karnataka. Where as RDPL was a joint venture of IDPL and the State Government of Rajasthan. In order to sustain the growth & development of KAPL & RDPL, Government has approved de-linking of both these companies from HAL & IDPL respectively. The shares held by HAL & IDPL in these companies are being transferred to President of India. However, shareholding of respective States in these joint ventures would continue to remain unaffected.

1.5 National Institutes of Pharmaceuticals Education & Research (NIPER) are autonomous institutions under this Department.

1.6 Shri Ram Vilas Paswan assumed charge of the office of the Minister of Chemical and Fertilizers on 21.5.2004. Shri Bijoy Krishna Handique assumed charge of office of Minister of State for Chemical and Fertilizers on 31.1.2006. Shri Ashok Kumar has joined the newly created Department of Pharmaceuticals as Secretary on 7.7.2008.

CHAPTER - II

AN OVERVIEW of Pharmaceuticals Industry

2.1 The Indian pharmaceutical industry, now a \$19 billion industry, has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of products. It has established its presence and determination to flourish in the changing environment. The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies. Formulations in various dosage forms are being produced in GMP compliant facilities. Strong scientific and technical manpower and pioneering work done in process development have made this possible. The country now ranks 4th worldwide accounting for 8% of world's production by volume and 1.5% by value. It ranks 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe including highly regulated markets of US, Europe, Japan and Australia.

2.2 To enable Indian pharmaceuticals industry to play a leading role in the global market and to ensure abundant availability, at reasonable prices within the country, of good quality pharmaceuticals of mass consumption, Government has created, in July 2008, the Department of Pharmaceuticals, which shall deal with the allocated matters pertaining to drugs and pharmaceuticals. The Department is entrusted with the responsibility of policy, planning, development and regulation of Pharmaceuticals Industries.

2.3 The following attributes constitute the basis of the technological strengths of the Indian Pharmaceutical Industry: -

- i. Self-reliance displayed by the production of 70% of bulk drugs and almost the entire requirement of formulations within the country.
- ii. Low cost of production.
- iii. Low R&D costs.
- iv. Innovative Scientific manpower.
- v. Excellent and world-class national laboratories specializing in process development and development of cost effective technologies.
- vi. Increasing balance of trade in Pharma sector.

- vii. An efficient and cost effective source for procuring generic drugs especially the drugs going off patent in the next few years.
- viii. An excellent centre for clinical trials in view of the diversity in population.

Financial performance of the Drugs and Pharmaceutical Industry

2.4 The financial performance of the Drugs and Pharmaceutical industry for the year 2008-09 along with the respective figures for the previous year is given in Table below. The figures given in the Table are on quarterly basis showing the percentage increase/decrease with the same quarter of the previous year.

Drugs and Pharmaceuticals: Growth and Profitability (for the quarter ending)

Sl.No.	Particulars	June'07	Sept.'07	Dec.'07	March'08	June'08	Sept.'08	Dec.'08	March'09*
1	Income	15.5	18.5	18.1	13.9	18.5	14.4	9.0	11.8
2	Net Sales	12.2	20.8	19.5	15.7	22.1	15.2	10.6	14.0
3	Total Expenses	15.3	20.5	16.5	14.8	22.8	23.0	28.7	21.9
4	Raw Material	16.5	23.0	15.3	15.2	19.9	16.5	13.6	15.0
5	Salaries & wages	19.2	19.1	19.0	20.5	22.5	21.3	16.0	18.0
6	Power & fuel	62.2	17.4	7.2	0.0	-1.5	1.5	3.0	18.0
7	Depreciation	12.6	12.3	11.7	15.6	17.0	17.3	18.5	18.2
8	Interest Exp.	19.4	37.4	29.0	69.6	34.8	37.0	70.1	59.0
9	PBDIT	24.1	16.1	14.7	6.9	-3.7	-13.4	-52.4	-15.8
10	PAT	26.5	12.2	11.7	-2.1	-6.2	-27.6	-88.1	-49.8

* Forecasted figure

Source: Center for Monitoring Indian Economy (CMIE)

2.5 Despite global recession and financial crises, the Drugs and Pharmaceuticals sector could maintain its positive growth in sales volume. Aggregate income of the drugs and pharmaceuticals companies for the first quarter ending June,'08 of the financial year 2008-09 grew by 18.5 per cent backed by a healthy growth in sectoral sales of 22.1 per cent compared to 12.2 per cent recorded in a year ago quarter. Subsequently, the sectors incomes and sales growth slowed down for the quarters ending September 2008, December 2008 and March 2009.

2.6 The sector's profitability was affected with the expenses increasing at a faster pace as compared to income. The increase in expenditure was mainly on account of the increase in the raw material cost, wages and salaries, depreciation and interest expenses. The total expenses increased by 22.8 per cent, 23 per cent, 28.7 per cent and 21.9 percent (estimated) whereas the net

sales increased by only 22.1 per cent, 15.2 per cent and 10.6 per cent and 14%(estimated) during the quarters ending June 2008, September 2008 , December 2008 and March 2009 respectively.

2.7 The factors impacting the results were numerous and very few companies could escape these. The global economic environment turned negative with the key global financial institutions going bust. The credit markets choked up and interest rates soared. The economic turmoil resulted in a substantial reduction in consumption leading to decrease in production and trade. High base-year effect for some companies, delay in US FDA approvals, lower demand in the exports market, increase in the receivable days and high interest cost for companies in debt are likely to adversely affect companies' profits. Some respite is likely to come from the rupee depreciation of around 5% and easing off of raw material costs. With AS11 no longer mandatory, drug makers are not expected to report MTM loss on their foreign exchange borrowings.

2.8 While quarter ending December'08 saw a dip in sales growth trend, sales growth is estimated to have picked up during the quarter ending March'09 and continue its upward trend. As almost 40 per cent of the sector's sales are from exports, rupee depreciation vis-à-vis USD is expected to keep export sales buoyant. Although, a number of countries are in a recession, drugs being almost a necessity and Indian drug companies being generic manufacturers, export growth is unlikely to falter. Domestic growth is also expected to remain healthy and the Government's decision to open more Jan Aushadhis stores will support this trend.

PLAN SCHEMES

2.9 Keeping in view the promotional, facilitatory and regulatory role of the Department in the development of pharmaceutical sector, the public sector investment proposed through plan schemes is quite limited. In view of the Government policy adopted to ensure availability of quality life saving drugs at reasonable prices, various schemes in the Pharma Sector are proposed for the 11th Plan. Important amongst these are proposals for reviving Pharma PSUs for manufacturing critical bulk and formulation drugs, setting-up of more NIPER like institutes, Interest subsidy scheme for Schedule "M" Compliance etc. The Planning Commission approved the Budgetary Support of Rs.1960 crore for various Plan Schemes of the (undivided) Department of Chemicals and Petrochemicals during the 11th plan period, of which Rs. 1396 crore were for schemes of the pharmaceutical sector. For Annual Plan 2008-09 an expenditure of Rs 109.83 crore was incurred under schemes of the Pharma sector. The outlay proposed for Annual Plan 2009-10 as per the interim budget is Rs 155.25 crore. Scheme-wise outlays of schemes of the

Pharmaceutical sector for the 11th plan, annual plan 2008-09 (BE and actuals) and the outlay approved for 2009-10

are given below:-

<i>Rs. crore</i>					
Sr. No.	Name of the Scheme	XI Plan (2007-12) Outlay	AP (2008-09) (BE)	AP (2008-09) Exp.	AP (2009-10) Proposed
I	Project Based Support to PSUs	220.17	30.00	28.15	30.00
II	Support to Autonomous Institutions	100.00	26.50	69.10	8.60
1	National Institute of Pharmaceutical Education and Research(NIPER)	95.00	25.00	68.46	8.00
2	National Pharmaceutical Pricing Authority(NPPA)	5.00	1.50	0.64	0.60
III	Other Ongoing Schemes	8.00	1.25	2.02	2.50
1	Pharma Promotion & Development Scheme(PPDS)	7.50	1.00	1.81	2.00
2	IT/Secretariat	0.50	0.25	0.21	0.50
3	Provision for NE*			*	@
IV	New Schemes initiated in XI Plan	1068.00	97.50	10.50	114.15
1	New Schemes for NIPER, Mohali	69.00	15.00	#	15.00
2	New NIPER like Institutes	514.00	35.00	#	50.00
3	Interest Subsidy for Schedule M compliance	340.00	27.00	10.00	15.00
4	Strengthening of NPPA	60.00	10.00		1.65
5	Creation of IPR facilitation center at Pharmaexcil	5.00	0.50	0.50	1.00
6	ERP, R&D Parks	5.00	0.00		1.50
7	Critical assistance for WHO pre-qualification for pharma PSUs/R&D	75.00	10.00		10.00
8	New Schemes to be introduced in 2009-10				20.00
	Total	1396.17	155.25	109.83	155.25

* Included and incurred by the undivided D/o Chemicals & Petrochemicals from which D/o Pharmaceuticals was carved out in July 2008.

@ To be incurred from schemes of NIPER (item IV.2).

Included under item II.1 above.

PHARMACEUTICAL INDUSTRY:

2.10 The Indian pharmaceutical industry, has grown from a mere US \$ 0.3 Billion turnover in 1980 to about \$19 billion in 2008. The country now ranks 3rd in terms of volume of production (10% of global share) and 14th largest by value (1.5%). One reason for lower value share is the lower cost of drugs in India ranging from 5% to 50% less as compared to developed countries. Indian pharma industry growth has been fuelled by exports and its products are exported to more than 200 countries with a sizeable share in advanced regulated markets of US and Western Europe. The total employment is about 340,000 in the sector and an estimated 400,000 doctors and 300,000 chemists are serving an over 1 billion customers market.

2.11 The Pharmaceutical sector is one of the major export revenue earners of Indian economy. During 2007-08, Indian pharma exports were USD 7.24 billion, recording a growth of 8.34% in rupee terms and 21.91% in dollar terms compared with the previous year. During 2002-03 to 2007-08, Indian pharma exports have recorded a cumulative annual growth rate (CAGR) of 17.84% in rupee terms and 22.22% in dollar terms. India currently exports drug intermediates, APIs, Finished Dosage Formulations (FDFs), bio-pharmaceuticals, Clinical Services to various parts of the world. The top 5 destinations of Indian pharmaceutical products during the year 2007-08 are USA, Germany, Russia, UK and China.

2.12 India is a globally acknowledged source of high quality affordable generic medicine with rich vendor base. It is not only an API and formulation manufacturing base, the country is poised to become manufacturing hub for pharmaceutical industry of the world and an emerging hub for Contract research, Bio-technology, Clinical trials and Clinical data management. The country's pharmaceutical industry has shown tremendous progress in terms of infrastructure development, technology base creation and a wide range of production covering almost all therapeutic categories and dosage forms. The fact is firmly demonstrated by the trends in global exports of pharmaceuticals from India, the most significant is the number of product approvals received from various major regulatory authorities of the world. Other important features are; the cost advantage India offers in comparison with developed markets and the technical strengths of India in development and production of pharmaceuticals.

2.13 India, currently accounts for one out of every four Abbreviated New Drug Applications (ANDAs) (Generic products approvals) in the years 2007 & 2008, more than one fourth of total Drug Master Files (DMFs) with US FDA, the largest share in registrations granted in the world including USA. It also received 31% of all tentative approvals as at the end of December 2008. India has the highest number of USFDA approved plants outside USA.

2.14 India offers skilled scientists/ technicians/ management personnel at affordable cost. With low cost of innovation/ manufacturing/capex costs/ expenditure to run a GMP compliant facility, the cost of manufacturing in India is estimated to be half of that of western countries, the R&D costs and the cost of conducting clinical trials are also very less compared to the developed countries. India's entrepreneurial pharmaceutical manufacturers are now beginning to leverage benefits from the introduction of the nation's product patent system.

2.15 India is regarded as having the edge in terms of Qualified, English-speaking employees, Fair protection of intellectual property rights supported by well-developed judicial system. The scientific, technical and manufacturing skills, developed under the country's 35-year process patent system, perfectly matches the requirements of global

drug manufacturers who are increasingly seeking to offshore many manufacturing activities previously performed in-house. The country has well developed chemistry R & D and manufacturing infrastructure with proven track record in advanced chemistry capabilities, design of high-tech manufacturing facilities and regulatory compliance. It is known for its competency in API/Formulation intellectual property creation, facility design and maintenance, global regulatory affairs, legal acumen and managing international work force.

2.16 India has several opportunities opening in the global markets. An estimated US\$103 billion of generic products are at risk of losing patents by 2012. Even at a conservative estimate there is a huge opportunity for India. The global market for contract manufacturing of prescription drugs is estimated to increase from a value of \$26.2 billion to \$43.9 billion. India could potentially capture 20 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates. The country has very high skills in Phase II & Phase III Clinical trials, and has good to high skills in Preclinical trials and Phase I clinical trials.

2.17 Contract research in generic pharmaceuticals is also a significant opportunity. Established generic companies would like to outsource or buy services in formulation development, bioequivalence testing, stability studies centers, etc. Various surveys indicate that India has quite a number of resourceful firms in the field of Chemistry providing high quality output in timely schedules, allowing more leads to pursue. India is significantly ahead in chemistry services such as analog preparation, analytical chemistry, focus library, combinatorial chemistry, structural chemistry, structural drug design, computer aided drug design, high throughput screening and assay development.

2.18 There are opportunities such as licensing deals with MNCs for New Chemical Entities and New Drug Delivery Systems, marketing alliances for MNC products in domestic and international markets, Contract Manufacturing arrangements with MNCs. There is enormous potential for developing India as a centre for international clinical trials. The country can become a niche player in global pharmaceutical R&D and there are possibilities for expansion of Bio-similars and Bio-pharmaceuticals.

2.19 India exported US\$1.38 Billion worth drugs & Pharmaceutical to Asia (approx. 19% of India's total pharma exports) and ASEAN countries accounted for US\$497.73mn. (Approx 36%). The Pharma market in Thailand is fastest growing in Asia-Pacific region. It has a strong pharma Industry producing mostly generics. It depends on imports for patented drugs. The market is expected to be worth US \$1.82 bn by 2012.

2.20 The movement of the domestic Indian Pharmaceutical Market over the years is as under:

The Value of Total Indian Pharmaceutical Market for the last five years

(All figures are in Rs. Cr.)

	Nov''2004 MAT	Nov''2005 MAT	Nov''2006 MAT	Nov''2007 MAT	Nov''2008 MAT
Total domestic Indian Pharmaceutical Market	33,036	35,764	42,355	47,596	52,491

**the domestic Indian Pharmaceutical Market includes retail market at MRP, generic plus companies not tracked by ORG, hospital and institutional sales (except Government), direct doctor purchase, Pharma OTC products and diagnostics*

***Retail market at MRP calculated from retail market at PTR (SSA audit), rest all components are derived.*

The export figures of Pharmaceuticals over the years are as under:

Year	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
Exports (INR) in Crore	12826	15213	17857	22216	26895	30759	

2.21 The total Indian Pharmaceutical Market size taking into account the domestic market at MRP, exports, Government supplies and imports is approx. Rs. 81,000 crores.

IMPORTS: As per the D.G.C.I.S. statistics, imports of medicinal and pharmaceutical products for the last three years have been as under:

Year	Import of Medicinal & Pharmaceutical Products
2005-06	Rs. 4515.2 crores
2006-07	Rs. 5866.37crores
2007-08	Rs. 6699.15 crores (provisional)
2008-09	

2.22 There have been no reports of shortages of Drugs & Pharmaceuticals in recent years. The country is almost self-sufficient in case of formulations. The above figures of import essentially consist of some bulk drugs & intermediates and some formulations that are being imported on quality & economic considerations and not necessarily due to non availability from domestic sources. Manufacturers of Drugs & Pharmaceuticals are free to produce any drug approved by the Drug Control authorities. Import of drugs and Pharmaceuticals is freely allowed. However import of some bulk drugs & intermediates is still restricted under current Foreign Trade Policy. Import of most of such items is restricted basically due to applicability of the Narcotic and Psychotropic Substances Act to these due to common HS codes. Such items are imported against an import license issued by the DGFT. The requests of companies for import of items attracting import restrictions are received through DGFT which are examined in this Department and recommendations on the appropriateness of medicinal usage and Actual User status are sent to DGFT for their consideration of the application.

PRODUCT PATENT- Impact on medicine prices:

2.23 With the enactment of Patents (Amendment) Act 2005, the process of bringing Patents Act in line with the TRIPS Agreement has been completed. After the introduction of product patent w.e.f. 1.1.2005, 10 products have been granted product patent. This Department has also constituted a Committee on Price Negotiation on Patented Drugs. This Committee is now in the process of having another round of consultation with the stake holders. The new patent regime is not expected to have much impact on prices/availability of medicines for the following reasons:

- (a) At any given points of time, globally only 5-10 percent of the drugs would be under patent protection.
- (b) The price competition among different drugs in the same therapeutic group should keep the prices under control.
- (c) Since majority of the patients in India pay from their pocket, the limited purchasing power will act as a check on very high price.
- (d) Govt. continues to have powers to regulate the prices of medicines.
- (e) Safe-guards like compulsory licensing, parallel imports etc. exists.
- (f) The drugs covered in the list of Essential Medicines are not likely to be covered by patent - these would continue to be abundantly available at reasonable prices.

CREATION OF IPR FACILITATION CENTRES IN PHARMEXCIL:

2.24 The Working Group on Drugs and Pharmaceuticals for the 11th Five Year Plan (2007-2012) has recommended setting up of 3 IPR Facilitation Centres at 3 offices of Pharmexcil in order to disseminate information on IPRs and related issues to the Pharma Industry in an effective manner. For this purpose, a fund of Rs. 3.56 crores is available in the 11th Five Year Plan.

2.25 This scheme would greatly help the Pharma Industry to understand the patents/product status of various newly invented drugs/block busting drugs currently in the international market and to develop generic version for availing the opportunities in

international markets. Besides opening one centre at Hyderabad, the following progress in implementing the scheme has taken place.

- (i) Dr. Gopakumar Nair, a well known person in the industry for his knowledge and experience in the Pharma patents field has been appointed as Advisor for the Patents Facilitation Center. One Patents Analyst has been appointed who is working under advice from Dr. Nair.
- (ii) Patents Facilitation Center at Hyderabad is extending the following services to the members, either free of cost or at nominal charges, depending upon the query from the members;
 - a) General Information on Patents;
 - b) Patent status of pharmaceutical products in India and other countries;
 - c) Interpretation of search information;
 - d) Search based intellectual property related technology and prior art search;
 - e) Invention mining;
 - f) Patentability opinion;
 - g) Guidance and opinion of IM launch;
 - h) Infringement analysis and opinion;
 - i) Freedom to operate opinion.
- (iii) Periodical Analysis Reports on Patents are being circulated to the members for their information and reference;
- (iv) On the infrastructure front, they have procured computer systems, servers, printers, networking etc. They have also paid subscription for dialogue-pro, a paid site for Patent search;

DATA PROTECTION as per ARTICLE 39.3 OF TRIPS AGREEMENT :

2.26 The TRIPS Agreement expects WTO member countries to adopt minimum standards on the patent laws as stipulated therein. Article 39.3 of the TRIPs Agreement reads : “Members when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a

considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use". The data submitted while seeking marketing approval is proprietary information of the originator. Data Protection guarantees the 'non-reliance' of that data by any other company for unfair commercial use.

2.27 On the request of Department of Commerce, the Department of Chemicals and Petrochemicals set up a high level Inter-Ministerial Consultative Committee in February 2004 under the Chairmanship of Secretary (C&PC) to examine whether the provisions applicable under common laws of India and existing IPR laws are adequate and sufficient to address the issues and concerns of Article 39.3 of TRIPs Agreement. The Committee submitted its report to the Department of Commerce on 31.5.2007. The same is also available on the Website of the Department of Chemicals and Petrochemicals (www.chemicals.gov.in). A meeting was convened by Department of Commerce on 6th August 2007 and decisions taken are as follows:

- (a) In order to follow-up on the recommendations made by the Committee in respect of Agro-Chemicals, the Department of Agriculture & Co-operation would draft necessary amendments to the Insecticides Act 1968 and process the matter further to obtain Cabinet approval;
- (b) As regards Traditional Medicines, AYUSH would process for acceptance of the recommendations of the Committee by the Government;
- (c) The Department of Health & Family Welfare would give wide publicity to the recommendations in the Report and carry out consultations with stakeholders before proposing appropriate amendments to Drugs & Cosmetics Act 1940 and its Rules.

2.28 This Department for the present has no further action to take in the implementation of the report. Ministry of Health and Family are consulting with the stake holders and Ministry of Agriculture & Cooperation is in the process of amending the Insecticides Act, 1968.

Sales promotional expenses

2.29 There were some reports in the newspapers in the recent past regarding promotional expenses being made by the Pharma Companies. The reports suggest that there are some unethical marketing practices being followed by certain pharma companies. Keeping in view the seriousness of the allegations made in the media reports, this Department felt the need to take up the matter in the interest of the consumers/patients as such promotional expenses being extended to doctors had direct implications on the pricing of drugs and its affordability. After discussing the issues with the Pharma Associations/Industry, this Department has been able to persuade most of the associations to have Code of ethics.

PRODUCTION

2.30 During 2008-09 some proposals for technology transfer including joint ventures, proposals for foreign direct investment, setting up of new undertakings/expansion of existing units (manufacture of new articles in the existing units) have been received and processed. Following the de-licensing of the pharmaceutical industry, fewer number of Industrial Entrepreneurial Memorandums (IEMs) for the manufacture of various bulk drugs/drug intermediates/formulations were received.

EXPORTS

2.31 Export of Drugs, Pharmaceuticals and fine Chemicals during the last five years has been as follows:

Year	Exports (Rs. In Crores)	Growth %
2003-04	15213	18.61
2004-05	17857	17.38
2005-06	22216	24.41
2006-07	26895.17	21.06
2007-08	30759.64	14.37
2008-09 Upto Sep., 2008	18021.16	

Source: Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata)

International cooperation/Export Promotion of Pharmaceuticals

2.32 An important focus area for the newly created Department of Pharmaceuticals is promotion of Indian pharma exports. The Department participated in the following International Cooperation events during the last year :-

- a. The Fourth meeting of the Indo-Tunisia Joint Working Group was held in Tunis on 6-7th October, 2008 which was co-chaired by Secretary, Department of Pharmaceuticals. Issues relating to Joint Ventures cooperation with NIPER etc. was discussed.
- b. During the year, third meeting of the India-EU Joint Working Group on Pharmaceuticals and Biotechnology was held in the month of June, 2008 at Brussels under the Co-chairmanship of Shri G.S.Sandhu, Joint Secretary(Pharma). During the meeting, issues relating to the problems being faced by the Indian Pharma Exporters were raised and the EU side was requested to find an early solution to these problems.
- c. Participation in the BIO 2008 which was held in June, 2008 in USA.
- d. Participation in the CPhI Worldwide held at Frankfurt Germany.
- e. Participation in Informex India 2009 held at Ahmedabad.
- f. Participation in India-Chem 2008 held at Mumbai.

PHARMA EXPORT PROMOTION COUNCIL (Pharmexcil)

2.33 The Department had played a pivotal role in the formation of Pharmexcil consequent to the recommendation from 9th Five Year Plan Working Group Report on Drugs and Pharmaceuticals. In the light of this, the Department constantly interacts with Pharmexcil in their work areas. The role of Pharmexcil is for facilitation of exports of Drugs, Pharmaceuticals, Biotechnology products, Herbal medicines and Diagnostics, to

name a few. It is authorised to issue Registration-cum-Membership Certificate (RCMC) which is one of the requirements for the importers and exporters of commodities. In addition to this, Pharmexcil is concerned with giving export thrust to the various products through visits of delegations to various markets abroad, organizing of seminars, workshops and exhibitions. As a major area of work, Pharmexcil also holds Buyers/Sellers meets and compiles detailed data base on pharma exports and problems in exporting pharma group products of pharmaceuticals. In India-Chem 2008 held on 20-22nd October, 2008 , Pharmexcil had organized a buyer-sellers meets. This meeting was attended by Secretary(Pharmaceuticals) and Joint Secretary(Pharma). The inauguration address was given by the Hon'ble Minister of Chemicals and Fertilizers and Steel. Buyers/Sellers meet was an important feature of this interaction towards boosting more exports. Another highlight was the participation of drug regulators who explained the regulatory procedures of their country for the benefit of India's exporters.

2.34 During the year the Department provided financial assistance for the following activities/events for promotion and development of the Pharma sector :

1. Organization of 40th Annual conference of Indian Pharmacological Society at NIPER, Mohali.
2. Organizing International Conference on Pharmaceutical Market Prognosis-2012 in collaboration with FICCI.
3. Organization of International Seminar on Pharmaceutical Pricing & Regulatory Framework for Affordable Medicines by NPPA
4. Study on "Assessment of number of Pharma SSI units requiring technological upgradation"
5. Work on conducting First Pharmaceutical Census of India.
6. Preparation of accurate data base of all Pharma exporters and making members directory by Pharmexcil.
7. Preparation of corporate film of Pharma Industry in India.
8. Procurement of International market Reports from reputed publishers and all Pharmacopoeias.
9. Organizing of International conference on Biotechnological approaches to Neuroimmunomodulation & Infectious Diseases.

10. Organization of “International conference on new developments in drug discovery from natural products and traditional medicines” by NIPER.
11. Participation in “Pride of India ISC Expo 2009 – 96th Indian Science Congress”.
12. Organization of Seminar on Environmental issues pertaining to Pharma industry.
13. Conducting study on the mechanism of price control of drugs in selected countries.
14. Organization of conference on Pharmaceuticals-“Pharmaceuticals 2014; will India leap forward” in collaboration with FICCI.
15. Conducting of Pre-feasibility study for development of a Green Field Project for Medical Devices cluster in Gujarat and a Brown Field Project for Bulk Drugs cluster in Andhra Pradesh.
16. Conducting of a study on Medical Devices – sub sector of Pharma by NIPER, Ahemdabad.

Pharmaceutical Advisory Forum

2.35 Through Drug policies announced from time to time, Government of India has been trying to ensure abundant availability of good quality essentials pharmaceuticals of mass consumption at reasonable prices. At the same time strengthening the indigenous capability for cost effective quality production of medicines has been an important objective. To help realize this and in order to provide a Forum for a meaningful dialogue amongst all the stakeholders on various issues concerning the drug, policy it was decided to constitute a Pharmaceuticals Advisory Forum in the Department of Chemicals & Petrochemicals.

2.36 A Pharmaceutical Advisory Forum has been constituted in July 2004 under the Chairmanship of Hon’ble Minister Chemicals & Fertilizers having Hon’ble Ministers of state for Chemicals & Fertilizers, Health Ministers of All States/UTs, Secretary, Department of Chemicals & Petrochemicals (now Department of Pharmaceuticals, Secretary (Health), Chairman, NPPA, Drugs Controller General of India, other concerned

senior Center and State Government Officers and representatives other stakeholders as its Members.

- (a) Generic-generic drugs to be allowed a reasonable MAPE so as to take care of market promotion expenses/and other profits etc. and 50% trade margin (15% Wholesaler – 35% Retailer).
- (b) State Governments to issue directions to doctors in Government Hospitals to prescribe only generic-generic medicines.
- (c) As a result of reduction in excise duty from 16% to 8%, all drug companies should reduce prices of their medicines by 4.58%.
- (d) Department to facilitate opening of Generic Drug Stores, initially one in each District through NGO's, Charitable bodies, Red Cross, Hospitals etc which are willing to work on 'not-on-profit' basis. Initially drugs from Pharma CPSUs to be supplied to them at low prices.
- (e) The Pharmaceutical Policy should be finalized & notified at the earliest.
- (f) Working Group on Branded-generic to be constituted – report in next meeting(*Working Group on Branded-generic has since been constituted. in August,2008.*)
- (g) During the next meeting, discussion would be focused on entry prices of new drugs including imported formulations and promotional/marketing strategies adopted by the pharmaceutical companies.

Environment Cell in the Department of Pharmaceuticals

2.37 The creation of the Department of Pharmaceuticals (DOP) under Ministry of Chemicals & Fertilizers, Government of India was notified by the Cabinet on 2nd July, 2008 and one of the subject items to be handled by the new department is “Technical support for dealing with national hazards in pharmaceutical sector”.

2.38 Indian Pharmaceutical industry has been making tremendous progress not only in the creation of excellent infrastructure but also attending to the global needs of the supply of APIs. The industry is also involved in introducing quality medicines in addition to entering into growing fields of contract research and manufacturing as well as clinical

trials. Like many chemical industries, the Pharma industry also has environment related issues, especially in the manufacturing of active pharmaceutical ingredients (APIs or bulk drugs).

2.39 The newly created Department, in its endeavor to familiarize the issue of environment in the Pharma industry, has created an Environment Cell November 2008 and it has since become operational. The main objectives of the Environment Cell is to collect and compile the data covering the latest technologies available for effluent treatment and hazard management and disseminate the information among the Pharmaceutical Industry.

The major functions of the Environment Cell are to:

1. Create awareness on environmental issues through holding of workshops, seminars etc. in coordination with Ministry of Environment & Forests and other stakeholders.
2. Collect and compile of data covering the latest technologies available for effluent treatment and disseminate this information among Pharma units.
3. Prepare a charter specifically for Pharma industry in consultation with the stakeholders.
4. Work closely with National Disaster Management Authority to formulate guidelines for disaster management specific to Pharma sector and Action Plan thereof.
5. Promote use of Green Technologies in manufacture of API's etc. so that the effluent load is reduced.

To initiate the activities of the Environment Cell a Seminar on the “Environment Management Issues pertaining to Pharmaceutical Industry” was organized in New Delhi on February 12, 2009. The seminar was attended by officials from State Pollution Control Boards, Ministry of Environment & Forests, Pharmaceuticals manufacturers, FICCI and various drug manufacturers’ Associations, UNIDO Centre for South-South Cooperation and eminent experts from NIPER, Andhra Pradesh Industrial Infrastructure Cooperation (APIIC), GTZ, IITs etc shared their experience on the environment issues.

2.40 The Environment Cell organized another Seminar in New Delhi on 27th March 2009 on “Hazards Management in Pharmaceutical Industry”. The objective of the seminar to underline the influence of technological advances in creating excellent infrastructure and attending to the global needs of the supply of bulk drugs as well as quality regulations vis-à-vis their obligation towards hazards or risk management issues. The seminar was attended by eminent scholars from Institute of Disaster Management,

Bhopal, NIPER, GTZ, FICCI, MHA, NDMA and other stakeholders besides representatives from Pharma Industry.

2.41 Based on the recommendations emanating from the proceedings from these seminars a Task Force under the Chairmanship of a Joint Secretary has been set up with members to be nominated from Pharma Industry, central & state government departments, APIIC, GTZ, Deloitte, DMI, Bhopal, NDMA and NGOs.

2.42 The Environment Cell also intend to organize two more seminars at Hyderabad & Ahmedabad respectively in association with FICCI and UNIDO Centre for South-South Cooperation during next few months.

Draft National pharmaceutical Policy-2006

2.43 The draft National Pharmaceutical Policy-2006 was prepared after extensive discussions with various stakeholders, in line with the declared objectives of the Government in the National Common Minimum Programme (NCMP). New Policy Initiatives proposed in New Pharma Policy includes enhancement if the exemption limit of small scale units to Rs. 5 Crore and introduction of Schemes for providing accessibility of drugs to the poor especially BPL families – National Health Insurance Scheme for BPL families, Drug Banks, Cancer Medicines Assistance Fund, Modification in the price Control regime, strengthening of NPPA etc.

2.44 This Policy was submitted before the Cabinet for its approval. The Cabinet considered the Policy in its meeting held on 11th January, 2007. It was decided that in the first instance the draft Policy be considered by a Group of Minister (GOM). The GOM has since been constituted with the following composition:-

- 1) Shri Sharad Pawar, Minister of Agriculture and Minister of Consumer Affairs, Food and Public Distribution.
- 2) Shri Ram Vilas Paswan, Minister of Chemicals & Fertilizers and Minister of Steel.
- 3) Shri Kamal Nath, Minister of Commerce & Industry.
- 4) Shri H.R. Bhardwaj, Minister of Law & Justice.

- 5) Dr. Anbumani Ramadoss, Minister of Health & Family Welfare.
- 6) Shri Kapil Sibal, Minister of Science & Technology and Minister of Earth Sciences.
- 7) Shri Montek Singh Ahluwalia, Deputy Chairman, Planning Commission.

2.45 The GOM has held four meetings since then on dates 10-4-2007, 12.9.2007, 30.1.2008 and 30.4.2008. The GOM is yet to make its recommendations to the Cabinet. No specific time frame can be indicated about the announcement of the Policy.

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

2.46 The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts, has been established on 29.08.1997 under the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals. The Authority is entrusted with the task of price fixation / revision and other related matters such as monitoring the prices of decontrolled drugs and formulations and to enforce and implement the provision of the Drug (Price Control) Order (DPCO), 1995.

2.47 The other functions of the National Pharmaceutical Pricing Authority (NPPA) are:

- (1) To implement and enforce the provisions of the Drugs (Price Control) Order (DPCO), 1995 in accordance with the power delegated to it.
- (2) To undertake and/or sponsor relevant studies in respect of pricing of drugs/formulations.
- (3) To monitor the availability of drugs, identify shortages, if any, and to take remedial steps.
- (4) To collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc. for bulk drugs and formulations.
- (5) To deal with all legal matters arising out of the decisions of the Authority

- (6) To render advice to the Central Government of changes/revisions in the drug policy.
- (7) To render assistance to the Central Government in parliamentary matters relating to drug pricing.

2.48 The organizational structure of NPPA is given in the chart at Annexure- -----

2.49 The performance of NPPA since its inception (up to 31.03.2009) is as under:

- The National Pharmaceutical Pricing Authority (NPPA) has fixed / revised the prices of scheduled bulk drug in 452 cases, which includes 290 bulk drugs and 162 derivatives of scheduled bulk drugs since its inception.
- Of these, the prices of 23 scheduled bulk drugs and 8 derivatives and 1577 formulations were fixed / revised during the period from 01.04.08 to 31.03.2009.
- The NPPA compiles the annual data on production of selected monitored bulk drugs. The data on production for the last three years 2005-2006, 2006-2007, 2007-08 and 2008-09 (upto Dec, 2008) is give in the Annexure - I.
- The price of scheduled bulk drugs fixed during the last four years & since inception are given in Annexure – II and summarized below:

BULK DRUGS PRICES

Particulars	2005-06	2006-07	2007-08	2008-09	Since inception of NPPA
No. of cases where Bulk Drugs Price Increased	8	8	9	22	108
No. of cases where Bulk Drugs Price decreased	68	42	50	9	325
No. of cases where Bulk Drugs price fixed for the first time	2	1	3	0	14
No cases where there was no change	0	0	3	0	5

in Price					
Total	78	51	65	31	452

FORMULATION PACKS

As on 31st March, 2009

Particulars	2005-06	2006-07	2007-08	2008-09	Since Inception of NPPA
No. of Packs Approved	1018	1020	2012	1577	8516
Price Increased	99	131	78	190	1125
Price Decreased	398	340	422	89	2849
Price fixed for first time	480	522	1429	1256	4297
No change in prices	41	27	83	42	245
Total	1018	1020	2012	1577	8516

2.50 The NPPA monitors and analyses month-wise price movements of non-scheduled formulations based on ORG-IMS reports. The prices of these formulations are fixed / determined by manufacturers themselves depending on various factors like the cost of production, market competition, company's profitability status etc. NPPA with very limited staff available to it, monitors the prices of non-scheduled formulations through various methods like (a) scrutiny of price lists submitted by manufacturers (b) analysis of monthly 'Stockiest Secondary Audit Reports' published by ORG-IMS, and (c) complaints / references received from official and non-official sources. Wherever substantial price increase is noticed, letters are sent to the manufacturers of such formulations to clarify the reasons for such price increases. The manufacturers are also invited to NPPA to attend a Personal Hearing before the competent authority wherever replies received are not satisfactory.

2.51 The manufacturers are impressed upon to bring down the prices voluntarily and to maintain the price level. So far 31 companies have reduced prices of 60 non-scheduled formulation packs voluntarily after intervention of NPPA. This is an on-going process and letters are sent to all manufacturers regularly. Further, NPPA has fixed the price of 27

non-scheduled formulations under para 10(b) of DPCO,1995. The price of 87 non-scheduled formulation packs have been reduced through the intervention of NPPA till 31st March,2009.

2.52 NPPA is holding regular Regional meetings with the Health Secretaries and State Drug Controllers, Trade and Industry representatives as well as representatives of Consumer Organisation and NGOs. Meeting for the North Eastern Region was held on 7th September,2006 and 6th November,2007 in Guwahati, meeting for Northern Region was held on 8th November,2006 in New Delhi and the regional meeting for Western Region was held on 18th June,2007 at Ahmedabad. Regional Meetings are being convened for other regions as well. In addition, State Level Workshops on Awareness on Drug Pricing, Affordability and Availability of Medicines and Related Issues was organized on **6th June,2008 at Bhubaneswar**,* Orissa. Further, the first NPPA-CIFG (Center for Information Facilitation and Grievances) was inaugurated by Sh. B.K. Handique, Hon'ble Minister of State of Chemicals and Fertilizers & Mines at **Chennai on 26th September,2008***, the second NPPA-CIFG was inaugurated by Sh. Ashok Kumar, Secretary, Department of Pharmaceuticals at **Mumbai on 15th December,2008*** and third NPPA-CIFG was inaugurated by Dr. A.K. Banerjee, Chairman, NPPA at Kolkata on 20th March,2009.

2.53 There are a total no. of 655 cases wherein demand notices have been issued (including cases suo-moto recovery) involving total overcharged amount of Rs. 1994.16 crores since inception of NPPA till March, 09. An amount of Rs. 156.04 crores has been recovered till 31.03.09 which also includes recovery through Court orders. During the year 2008-2009 Demand Notice for an amount of Rs. 435.62 crores have been issued and Rs. 51.41 crores has been recovered. As on 31.03.09 out of 41 cases referred to Collectors of various States for recovery under land and revenue arrears, 14 cases are under litigation and the balance 27 cases are pending for recovery with Collectors of various States. The recovery of the overcharged amount is affected due to various Court orders passed by various High Court and also Supreme Court in various cases filed by Pharmaceuticals Companies challenging the price fixation / notification issued by NPPA / Government and criminal complaints filed by various drug control authorities against Pharma companies

for not following the notified price. Inclusion of some bulk drugs under price control (scheduled 1 of DPCO'95) has also been challenged by the Pharma companies. NPPA / Government is defending such cases through SG, ASG's and Senior Government Counsels. Whenever necessary NPPA files urgent application in the Courts for vacation of interim orders and also for early hearing / disposal of the case.

*photographs from NPPA are available of these occasions

The Status of cases of overcharging since inception till March 2009

SI No.	Particulars	No. of Cases	Demand Raised	Amount Realised	Amount Outstanding
			(Amount in Rs. Crores)	(Amount in Rs. Crores)	
1	Total Demand since inception	655	1994.16	156.04	1838.12
2	Cases Closed	261	17.53	16.49	1.04
3	Balance Cases (1-2)	394	1976.63	139.55	1837.08
4	Amount in Litigation	76	1795.6	94.25	1701.35
5	Recovery cases under Litigation	14	96.14	33.86	62.28
6	Total cases under Litigation (4+5)	90	1891.74	128.11	1763.63
7	Balance Cases (3-6)	304	84.89	11.44	73.45
8	Balance Recovery cases	27	34.99	0.66	34.33
9	Balance Cases (7-8)	277	49.9	10.78	39.12
10	Cases Under BIFR of Official Liquidator	6	4.36	0	4.36
11	Balance Cases (9-10)	271	45.54	10.78	34.76
12	Pending Demand Cases including 56 SUO-MOTO deposit cases	271	45.54	10.78	34.76

YEAR WISE BREAK UP OF OVERCHARGED AMOUNT FROM 2005-2006 TO 2008- 2009

S No.	Year	During The Year		Cumulative (Total since inception)		Amount Recovered	
		No. of cases	Estimated overcharged amount including interest (Rs. in crores)	No. of cases	(Rs.in Crores)	(Rs. in crores)	(Rs. in crores)
1	2005-06	50	29.59	335	700.22	11.80	99.16
2	2006-07	67	38.01	402	738.23	0.96	100.12
3	2007-08	118	820.31	520	1558.54	4.51	104.63
4	2008-09	135	435.62	655	1994.16	51.41	156.04
		370				68.68	

AVAILABILITY OF MEDICINES

2.54 NPPA also monitors the availability of medicines to the common people in the country. In the month of October-2008, a report was received from the Department of Pharmaceuticals about shortage of certain medicines in the valley region of J & K. The NPPA co-ordinated with the State Drug Controller of J & K and held several meetings with industry associations and manufacturers to ease the supply of medicines in the valley and to restore the supply of medicines. The supply situation of medicines in J & K was monitored by NPPA until the medicines supply became regular and normal. NPPA has been monitoring the availability of drugs in the country regularly and taking remedial steps to make drugs available in the country.

2.55 This responsibility is carried out mainly thoroughly monthly field reports received from the State Drug Controller and other available sources of information.

2.56 In the last 5 years, NPPA has received occasional reports about sporadic shortage of certain brands in states like T.N., Punjab, Gujarat, Goa, J & K, Daman & Diu, Rajasthan wherever reports for shortage of a particular drugs in any state is received, the company concerned is asked to rush the stock and to make the drugs available. Generally shortages are brand specific where alternate brands are available.

RECENT INITIATIVE TAKEN BY NPPA

1. NPPA was granted ISO 9001: 2000 certification by The Bureau of India Standards on 11th January 2008.
2. NPPA has redesigned its website www.nppaindia.nic.in to make it more user friendly and interactive. It is available in both English and Hindi and provides more information on all Pharma and related issues.
3. NPPA has started online filing of complaints and will initiate action within 30 days of the receipt of such complaints.
4. NPPA has initiated online filing by manufacturers of applications for fixation/revision of formulation prices in form III/form IV of DPCO's 1995 and submission of price list in form V to NPPA.

5. NPPA has issued the fifth edition of the compendium of prices fixed/revised in Hindi and English.
6. NPPA has prepared a directory of Pharmaceutical Manufacturers state wise both for bulk drugs & formulations.
7. NPPA has been interacting with various Health Secretaries, State Drug Controllers, representatives of trade industry, consumers and NGO's on issues relating to pricing, overcharging, problems of state drug control administration etc.
8. NPPA created a separate enforcement division for suo-moto detection of violation of DPCO, 1995.
9. NPPA has initiated computerization with assistance of NIC for creating a reliable centralized database to be shared by all divisions, strengthening monitoring of drugs etc.
10. NPPA has initiated efforts for Consumer Awareness through advertisements in newspapers, coverage through television and dissemination of information through website.

Pharmaceutical Industry Census – NPPA has commenced the First Pharmaceutical Census 2008-09.

NPPA granted ISO 9001 : 2000 - The grant of ISO 9001-2000 certification to NPPA is an important achievement for the price regulator, thereby acknowledging the transparency of working of NPPA and consistent of procedures and practices followed by NPPA.

Grievance Redressal Cell - NPPA has recently set up a Grievance redressal cell and facility under the Right to information Act to redress grievances from the general public. A senior officer of the NPPA has been designated at CPIO and applications under Right to Information Act are being disposed off as per the provisions of RTI Act. The CPIO hears grievances from the General Public at the NPPA office on first Tuesday of every month between 11 am to 12 noon. The complaints can also be sent through Email / mail. For this purpose NPPA has prepared proforma for making complaint and the same is available on the website of NPPA – www.nppaindia.nic.in. The name of the nodal officer for complaints is Sh. A.K. Singhal, Adviser (Pricing), NPPA, 5th Floor, YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi – 110 001. Tel : 011 – 23746933, Fax : 011 – 23354119, Email : dir_bdnppa.nic.in

Consumer Awareness – Efforts are being made to create consumer awareness through advertisement in leading newspapers (English and Hindi) coverage through television and dissemination of information through website. NPPA is in discussion with Department of Consumer Affairs to start joint consumer awareness campaign in 2008-09.

Implementation of Rajbhasha – In order to encourage and motivate the use of Hindi in official work, a Hindi fortnight was organized in NPPA from 12th September,2008 to 26th September,2008. A number of books such as Compendium of Prices, booklets on latest progress and overview of NPPA, on consumer Awareness and Protection have been published in Hindi during the year. A Hindi website of NPPA has also been launched. A workshop in Hindi was organized by NPPA on 12th August,200

CHAPTER.III

DRUG PRICES EQUALISATION ACCOUNT (DPEA)

3.1 Drug Prices Equalisation Account (DPEA) has been maintained by Government under the provision of Drugs (Prices Control) order, 1979. Under the Drugs (Prices Control) order, 1979(DPCO, 1979), there were 345 bulk drugs under price control. The Department computed tentative liabilities in respect of 47 bulk drugs only on suo-motu basis covering 172 cases till the Interim stay dated 30.6.1997 was granted by the Hon'ble Bombay High Court in the writ petition No. 2368/1996 filed by the Indian Drugs Manufacturers' Association (IDMA) and Organization of Pharmaceutical Producers of India (OPPI) restraining the Department and its committees etc., from issuing fresh notices to the drug companies calling for information required for determining liabilities. Out of these 172 cases where the liabilities have already been determined tentatively and communicated to the companies, only 72 such cases during the period 1994-97 could be referred to the Drugs Prices Liabilities Review committee (DPLRC) constituted on 21.3.1994 under the Chairmanship of a judge of Hon'ble Delhi High Court (retired in October, 1994) alongwith two members to review / determine the liability in such cases. Out of these 72 cases, the Committee after deliberation in each case and giving adequate opportunity of hearing to the drug companies to present their point of view, gave reports in 47 cases. In view of the stay granted by the Hon'ble Bombay High Court the committee had not taken up the other 25 cases and also any fresh case. On the basis of the recommendations of the DPLRC, Department issued demand notices in 45 cases (no liability in one cases and one case inked with another case). Most of these companies filed writ petition in the different High Courts against the demand notices. The total amount of liability on the basis of the recommendation of the DPLRC is to the tune of Rs. 228.47 crore appx).

3.2 Since, no new case could be taken up by DPLRC for determination of the DPEA liability because of the stay granted by the Hon'ble Bombay High court, there was no work with the DPLRC. Hence a conscious decision has been taken by the Government to keep the DPLRC under suspended animation w.e.f. 31st December, 2005 vide Resolution dated 16th December, 2005. At that time 25 cases were pending with the DPLRC because of stay, where no quantification could be done till the vacation of the stay. In addition to these 25 cases, there may be a large number of DPEA liability cases in respect of 298 bulk drugs where information from the companies concerned are to be gathered for determination of the **DPEA liability.ts in National TV network and Regional Kendras on prices of medicines.**

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

3.3 Keeping in view the difficulties experienced by the manufacturer especially belonging to the small and medium enterprises in the pharmaceutical sector in respect of the additional financial burden in implementing the measures under the Schedule 'M' to the Drugs and Cosmetics Rules, 1945, WHO GMP and other international norms relating to Good Manufacturing Practices and requirements of premises /equipments etc. for pharmaceutical products, a Pharmaceutical Technology Upgradation Assistance Scheme for technological upgradation of their manufacturing facilities has been proposed. The scheme provides for interest subsidy in respect of 5% of the loan taken by the small and medium enterprises for implementing Schedule 'M' etc. The Department is in the process of seeking necessary approvals for this scheme.

CHAPTER.IV

Pharmaceutical Units and concession available in select States.

4.1 There was no authentic consolidated list of manufacturers of pharmaceutical units in the country until recently. To bridge this data gap, the first “**Directory of Pharmaceutical Manufacturing Units in India,**” has been brought out. This Directory contains state-wise addresses of pharmaceutical manufacturers (both for bulk drugs and formulations) in alphabetical order, their telephone numbers, e-mail, websites, wherever available, of **10563** pharmaceutical manufacturers across the country. These manufacturing units have been dichotomized into two broad camps viz. ‘Formulation’ and ‘Bulk Drugs’.

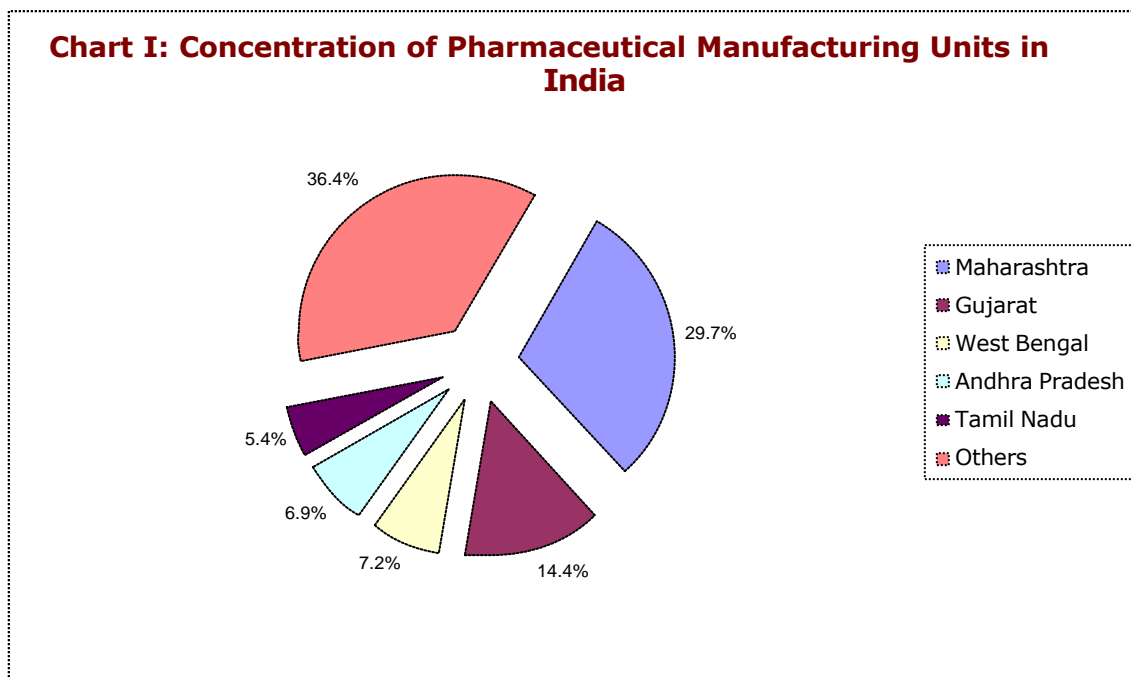
4.2 The shares of the first five States in terms of number of pharmaceutical manufacturing units, are presented in the Exhibit-I. It is noted that each of these five states account for more than 5% of total number of pharmaceutical manufacturers in the country.

Exhibit-I : State-wise Number of Manufacturers of Pharmaceutical Units in India

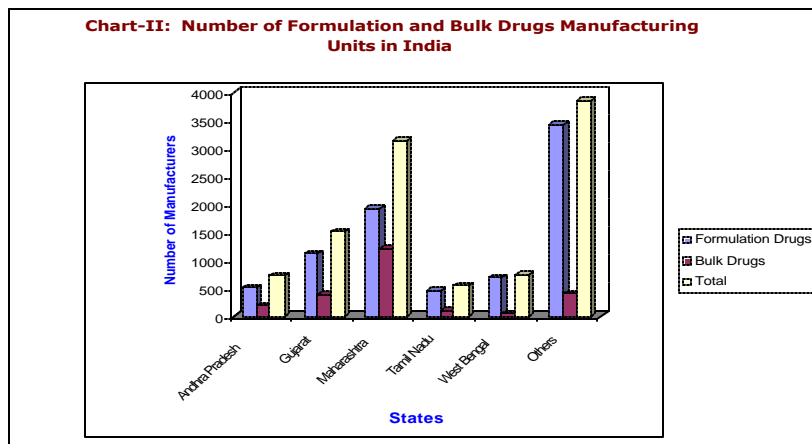
S.N	State	Number of Manufacturing Units			% Share	Cumulative % Share
		Formulation	Bulk Drugs	Total		
1	Maharashtra	1928	1211	3139	29.7	29.7
2	Gujarat	1129	397	1526	14.4	44.2
3	West Bengal	694	62	756	7.2	51.3
4	Andhra Pradesh	528	199	727	6.9	58.2
5	Tamil Nadu	472	98	570	5.4	63.6
6	Others	3423	422	3845	36.4	100.0
	Total	8174	2389	10563	100.0	

Note: States have been arranged in descending order of number of manufacturing units.

4.3 The concentration of pharmaceutical manufacturers in various states has been depicted in the Chart-I.



4.4 Out of total 10563 pharmaceutical manufacturers in the country, 8174 or 77.4% manufacture ‘formulation’ drugs and remaining 22.6% are engaged in manufacturing of bulk drugs. The state-wise distribution of number of formulation and bulk drugs manufacturers is depicted in Chart-II. It is noted that while five states of Maharashtra (29.7%), Gujarat (14.4%), West Bengal (7.2%), Andhra Pradesh (6.9%) and Tamil Nadu (5.4%) account for about two-third of the total number of manufacturers, another twenty-two states/UTs account for a little over one-third of the pharmaceutical manufacturers in the country.



First Pharmaceutical Census of India (FPCI)

4.5 The emergence of a highly competitive environment, both at the national and global levels, has increased the imperatives of ensuring the availability of adequate and reliable statistics. To respond to this, the First Pharmaceutical Census of India (**FPCI**) has been launched alongwith the Fourth All-India Census of Micro, Small and Medium Enterprises (MSMEs). The **FPCI** is a path-breaking exercise which seeks to create robust and responsive database of allopathic pharmaceutical manufacturing units in India.

Main Objectives of the FPCI

- To provide insights into the structural composition of Pharmaceutical manufacturing units, their products across the country.
- To provide data on investment, R&D, employment generated etc. to provide reliable & effective inputs for policy purposes.
- To assess the level of employment generated in the country by the pharmaceutical sector, by class of industry, state-wise and district-wise and also by type of units.
- To provide a sampling frame for future surveys and studies.

Pharmaceutical Scenario in Selected States

4.6 The Indian pharma industry has made significant progress in creation of required infrastructure, meeting global needs for supply of quality medicines and APIs¹. One of central objectives of this Department is to enable Indian pharmaceuticals industry to play a leading role in the global market and to ensure availability of quality medicines and pharmaceutical products at reasonable prices for all. Accordingly, DoP formulates policies and implements programmes for achieving growth and development of the domestic Pharmaceutical sector in the country along with ensuring adequate availability of medicines at reasonable prices to the consumers. To deepen the understanding of functioning of pharmaceutical manufacturers and also to capture ground realities obtaining in the pharmaceutical manufacturing units, a team of officers of this Department led by Deputy Director General was drafted to selected states namely Assam,

Himachal Pradesh, Orissa and Uttarakhand for undertaking sample surveys. The findings of the sample surveys so undertaken are presented below:

Pharmaceutical Scenario in Assam

4.7 Out of 23 districts in the state of Assam, only 4 districts namely Kamrup², Dibrugarh, Jorhat, and Kokrajhar have the presence of pharmaceutical manufacturers. Of the total number of 18 pharmaceutical manufacturing units in the state, 14 are located in the district of Kamrup, 2 in the district of Kokrajhar and one each in Jorhat and Dibrugarh. Thus, 78% of the pharmaceutical manufacturing units are concentrated in the district of Kamrup.

Package of Incentives

4.8 With a view to create an enabling environment for industrial development, generation of employment, improve availability of capital and increase market access to provide a fillip to the private investment in the state, the Government has approved a package of fiscal incentives and other concessions for the North East Region namely the 'North East Industrial and Investment Promotion Policy (NEIIPP), 2007', effective from 1.4.2007, which, inter-alia, envisages the following:

i. Income Tax Exemption

100% Income Tax exemption continues under NEIIPP, 2007 as was available under NEIP, 1997.

ii. Excise Duty Exemption

100% Excise Duty exemption continues, on finished products made in the North Eastern region under NEIIPP, 2007 as was available under NEIP, 1997.

iii. Capital Investment Subsidy

4.9 Capital Investment Subsidy has been enhanced from 15% of the investment in plant and machinery to 30% and the limit for automatic approval of subsidy at this rate will be Rs. 1.5 crores per unit, as against Rs. 30 lakhs under NEIP, 1997. For grant of capital investment subsidy higher than Rs. 1.5 crore but upto a maximum of Rs. 30.00 crores, an Empowered Committee Chaired by the Secretary (IPP) considers the proposals. Proposals which are eligible for a

¹ *Active Pharmaceuticals Ingredients*

² *Guwahati & Dispur are part of Kamrup district.*

subsidy higher than Rs. 30 crores, are to be placed by Department of Industrial Policy and Promotion before the Union Cabinet for its consideration and approval.

iv. Interest Subsidy

Interest Subsidy is admissible @ 3% on working capital loan under NEIIPP, 2007 as was available under NEIP, 1997.

v. Comprehensive Insurance

New Industrial units as well as the existing units on their substantial expansion are entitled for reimbursement of 100% insurance premium.

vi. Substantial Expansion

Incentives on substantial expansion is given to units effecting 'an increase by not less than 25% in the value of fixed capital investment in plant and machinery for the purpose of expansion of capacity/modernization and diversification', as against an increase by 33.5 % prescribed in NEIP, 1997.

vii. Duration of Incentives

All new units as well as existing units which go in for substantial expansion, unless otherwise specified and which commence commercial production within 10 years period from the date of notification of NEIIPP, 2007 are eligible for incentives for a period of ten years from the date of commencement of commercial production.

viii. Neutrality of Location

Incentives are available to all industrial units, new as well as the existing units on their substantial expansion, located **anywhere** in the North Eastern Region. Consequently, the **distinction** between 'thrust' and 'non-thrust' industries made in NEIP, 1997 has been **discontinued** from 1.4.2007.

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4.10 Based on field visit to the state and the discussions held with *randomly* selected sample of pharmaceutical manufacturers in the state, the following important points emerged:

- i. Based on the units visited, an **average investment of Rs. 119.24 lakhs** per pharmaceutical unit has been made in the state which has led to an **average turn over of Rs. 561.37 lakhs** per unit per annum. While the investment varied in the

range of Rs.18 lakhs to Rs.400 lakhs, **spectrum of turnover was fairly wide in the range of Rs. 8.00 lakhs and 4000.00 lakhs .**

- ii. On an average, **31 person** per unit have been **employed** by the units visited, generating employment for **279 person** by these units. However, the number of person employed by various units varied a great deal from the lowest of 8 to the highest of 100 persons.
- iii. On an average, generation of employment for one person required an investment of Rs 4.00 lakhs in the pharmaceutical sector in the state.
- iv. All the pharmaceutical units visited had their 'own' licenses and there was no 'loan' licensee.
- v. Most of the units were manufacturing multiple formulations and their capacity utilization varied between 10% and 80%.
- vi. All the pharmaceutical manufacturing units get most of raw materials and also packaging materials from Kolkata, Mumbai or Delhi.
- vii. Most of manufacturing units have employed over 90% of the total workforce from within the State.
- viii. There exists unmet demand for raw / packaging material in the state, with the result that all manufacturers get their demand met from outside the state. Government or some lead Organization may establish Small Scale Depot, on the lines of SISI³, to make raw / packaging material available at competitive prices in the state. There are some success stories of SISI run by SIDO in some states.

Pharmaceutical Scenario in Himachal Pradesh

4.11 Out of 12 districts in the state, Solan district (Baddi P.O., Parwanoo and Nalagarh tehsil in particular) is the most significant district from the point of view of number of pharmaceutical manufacturers it has been able to attract in recent past. The district has disproportionate population⁴ of 8.2% of the state's total population on 3.5% of its area. On the basis of *random*

³ *Small Industry Service Institute*

⁴ *According to Population Census of India, 2001.*

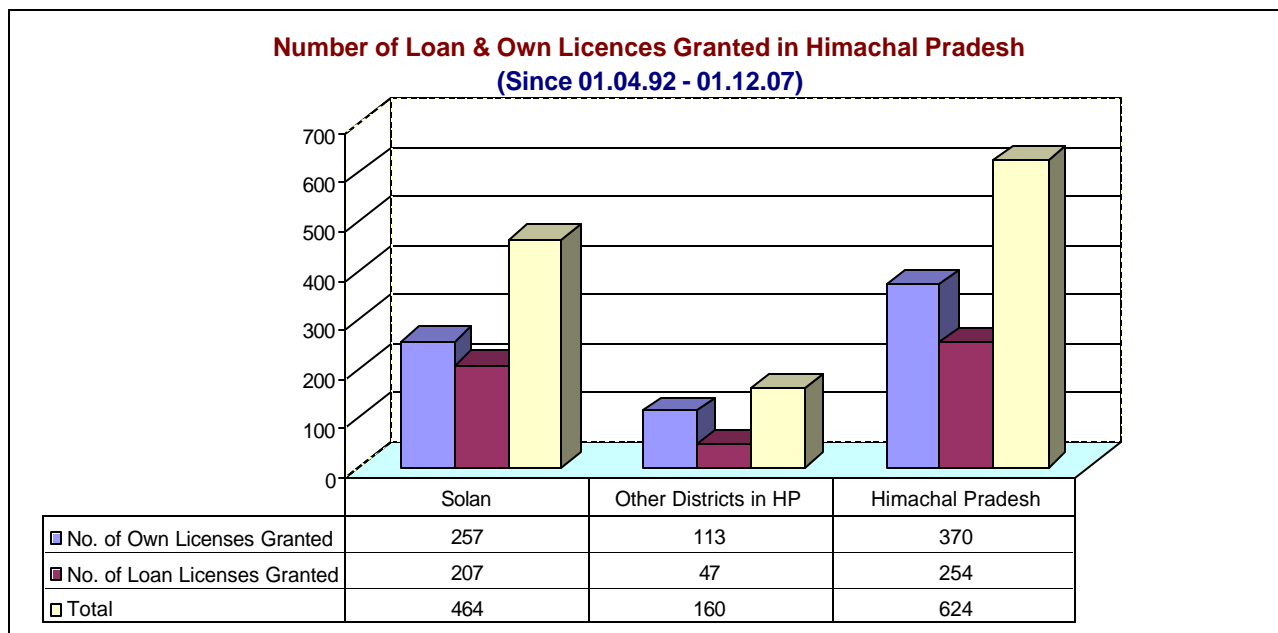
sample survey of pharmaceutical manufacturers undertaken in the state and detailed discussions held with concerned state Government functionaries, the following points emerged:

- i. The state Government of Himachal Pradesh has granted 370 'own' licenses and 254 'Loan' licenses to pharmaceutical manufacturers during the period 1991-92 to 2007-08 (upto 01.12.07). The year-wise details of licenses granted by the state government are given in the table-1:

Table-1: Year-wise Number of 'Own' / Loan Licenses Granted in Himachal Pradesh

Year	No. of Own Licenses Granted		% of Solan to the total Own Licenses	No. of Loan Licenses Granted		% of Solan to the total Loan Licenses
	In the entire State	Of which in Solan		In the entire State	Of which in Solan	
As on 31.03.1992	6	4	66.7	0	0	0.0
During VIII Five Year Plan (1992-1997)	34	20	58.8	0	0	0.0
During IX Five Year Plan (1997-2002)	60	33	55.0	0	0	0.0
2002-03	5	3	60.0	4	4	100.0
2003-04	14	8	57.1	1	1	100.0
2004-05	5	4	80.0	6	6	100.0
2005-06	95	83	87.4	83	74	89.2
2006-07	118	77	65.3	100	87	87.0
2007-08*	33	25	75.8	60	35	58.3
Total	370	257	69.5	254	207	81.5

*: Upto 01.12.07



On perusal of the Table-1 and other auxiliary information gathered, the following important points emerge:

- ii. A preponderance proportion of licenses, 70% of 'own' and 82% of 'loan' licenses, have been sanctioned to manufacturers in Solan district which is mainly due to its proximity to an important city of Chandigarh.

- iii. There was clearly a sharp surge in the interest of manufacturers in the pharmaceutical sector in the state, mainly due to package of certain incentives such as location specific exemption in excise duty, income tax exemption and one time subsidy at 15% of investment in P &M⁵ subject to an outer limit of Rs. 30.00 lakhs, offered to the manufacturers.

- iv. Of all 'own' licenses granted ever since 1991-92, 66% were issued during 2005-06 to 2007-08 (upto 01.12.07). Likewise, 96% of total 'loan' licenses were issued during the aforesaid period. This could be attributed to the response to special area-specific package of incentives.

- v. Of the total licenses of 489 in number (both own and loan) granted by the State Government during last three years (upto 01.12.07), 243 or 50% are accounted for by loan licenses. Thus, there exists a sizeable chunk of loan licensees in the State.

⁵ Plant and Machinery

Though this segment may not be directly contributing to the development of the state, it does stimulate the demand which in turn propel the development.

- vi. Factories for labeling/ packaging material have been set up recently in Baddi to cater to newly emerged hub of the pharmaceutical units in the state. It is expected that most packaging/ labeling needs would be met locally instead of turning to Mumbai and Ahemdabad for their labeling needs.
- vii. Most of the units manufacture multiple formulations and their capacity utilization has varied between 25% and 95%.
- viii. Capacity utilization is generally higher by about 20% during peak season (April to September) than that during lean season (October to March). This is probably so because a large number of people fall sick due to more outbreak of common diseases during summer months of 'peak season'.
- ix. Due to environment considerations, State Government no longer permits manufacturing of bulk drugs in the state.
- x. Most of loan licensees registered for production contain many common formulations.
- xi. Most of manufacturing units have employed 70% of the total workforce from within the State.
- xii. Those manufacturers who imported their P & M have done so either from south Korea or from Germany. Besides efficiency consideration, less dependence on human resource has been a factor behind automation of plants.

Pharmaceutical Scenario in Orissa

4.12 Out of 30 districts in the state of Orissa, only 5 districts namely Balangir, Cuttack, Ganjim, Puri and Sambalpur have the presence of pharmaceutical manufacturers. Of the total number of 74 pharmaceutical manufacturing units in the state, 70 are located in the district of Cuttack and 1 each in other 4 districts. Thus, 95% of the pharmaceutical manufacturing units are concentrated in the district of Cuttack. On the basis of *random* sample survey of pharmaceutical

manufacturers undertaken in the state and detailed discussions held with concerned state Government functionaries, the following points emerged:

- i. Based on the units visited, an average investment of Rs. 45.8 lakhs per pharmaceutical unit has been made in the state which has led to an average turn over of Rs. 185 lakhs per unit per annum. While the investment varied in the range of Rs.5 lakhs to Rs.132 lakhs, spectrum of turnover was fairly wide in the range of Rs. 21 lakhs and 600 lakhs.
- ii. On an average, 38 person per unit have been employed by the units visited, generating employment for 376 person by these units. However, the number of person employed by various units varied a great deal from the lowest of 15 to the highest of 80 persons.
- iii. On an average, generation of employment for one person required an investment of Rs 1.22 lakhs in the pharmaceutical sector in the state.
- iv. Most of the units manufacture multiple formulations and their capacity utilization has varied between 6% and 80%.
- v. All the pharmaceutical manufacturing units get most of raw materials and also packaging materials from Kolkata, Mumbai or Delhi.
- vi. Most of manufacturing units have employed over 90% of the total work force from within the State.
- vii. As GMP⁶ compliance has become mandatory, almost all pharmaceutical manufacturers surveyed have taken loan for this specific purpose to meet the requirement.
- viii. Most of pharmaceutical manufacturers in the state buy raw / packaging material from suppliers outside the state, mainly from Maharashtra and West Bengal.
- ix. There exists unmet demand for raw / packaging material in the state, with the result that all manufacturers get their demand met from outside the state.

⁶ *Good Manufacturing Practices.*

Pharmaceutical Scenario in Uttarakhand

4.13 Out of 13 districts of the state, two districts namely Dehradun and Hardwar are the most significant ones from the point of view of number of pharmaceutical manufacturers it has been able to attract in recent past. On the basis of *random* sample survey of pharmaceutical manufacturers undertaken in the state and detailed discussions held with concerned state Government functionaries, the following points emerged:

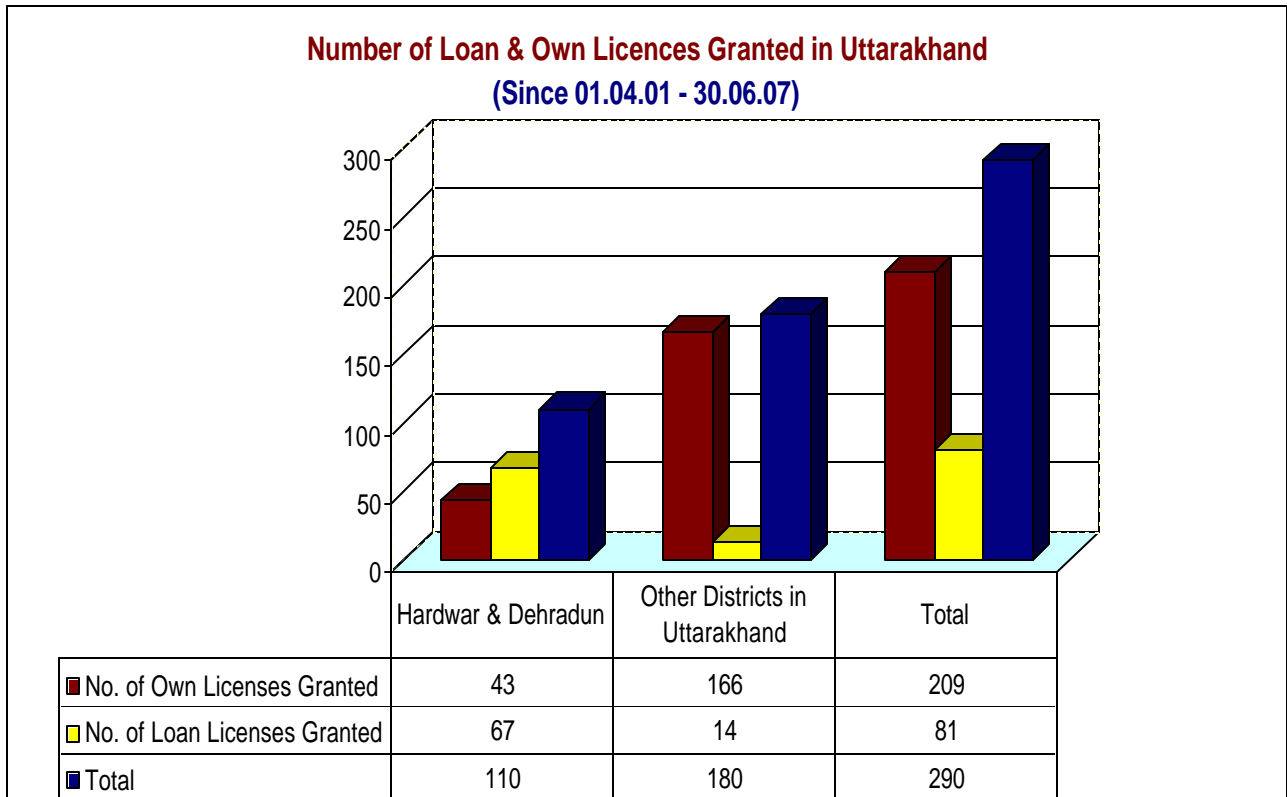
- i. The state Government has granted 209 'own' licenses and 81 'Loan' licenses to pharmaceutical manufacturers during the period 2001 to 2007 (upto June 2007). The year-wise details of licenses granted by the state government are given in the table-2:

Table-2: Year-wise Number of 'Own' / Loan Licenses Granted in Uttarakhand

Year	No. of Own Licenses Granted		% of to col. (3) to col. (2)	No. of Loan Licenses Granted		% col. (6) to col. (5)
	In the entire State	Of which in districts of Dehradun and Hardwar		In the entire State	Of which in districts of Dehradun and Hardwar	
(1)	(2)	(3)	(4)	(5)	(6)	(7)
2001	8	6	75.0%	0	0	0.0%
2002	5	4	80.0%	1	1	100.0%
2003	5	4	80.0%	4	4	100.0%
2004	23	14	60.9%	6	6	100.0%
2005	23	19	82.6%	18	17	94.4%
2006	80	68	85.0%	31	25	80.6%
2007 (upto June)	65	51	78.5%	21	14	66.7%
Total	209	166	79.4%	81	67	82.7%

- ii. A preponderance proportion of licenses, 79% of 'own' and 83% of 'loan' licenses, have been sanctioned to manufacturers in the districts of Dehradun and Hardwar which is mainly due to its proximity /easy connectivity to State capital and Delhi.
- iii. Of all the licenses granted ever since the state came into being, 82% have been issued during last two and half years viz. 2005 onwards. Thus, there is clearly a sharp surge in the interest of manufacturers in the pharmaceutical sector in the state after 2005. The contribution of this 'pull' factor in accelerating influx of pharmaceutical

manufacturers towards area-specific exemption package in Uttarakhand/ Himachal Pradesh can not be undermined.



- iv. Of the total licenses of 290 in number (both own and loan) granted by the State Government so far, 81 or 28% are accounted for by loan licenses. Thus, there exists a sizeable chunk of loan licensees in the State. Though this segment may not be directly contributing to the development of the state in terms of investment, employment generation, they do stimulate the demand which in turn propel the development.

4.14 The Government had announced special package of incentives for ensuring area-specific development in select states such as Himachal Pradesh and Uttarakhand. This package was a kind of an instrument to compensate against difficulties faced by them in terms of economic costs of underdevelopment, high cost of construction, transportation and others. With reduction in excise duty on pharmaceutical manufacturers from 16% to 8% and further to 4%, difference between the total cost of production to manufacturers in excise exempted states and non-exempted states has narrowed down. It is perceived that this difference is not large enough to attract orders from 'outside states' as was happening earlier

CHAPTER V

R&D Initiatives

5.1 Background: Based on the demands of the Indian Pharmaceutical industry and the unique requirements/projections of the pharmaceutical industry in the global economic scenario, the Government of India notified the establishment of the Department of Pharmaceuticals under the aegis of the Ministry of Chemicals and Fertilizers in July, 2008. The vision of this new Department is to inspire innovation in pharmaceutical sciences and to enable the Indian pharmaceutical industry to play a leading role in the global market and to ensure abundant availability, at reasonable prices within the country, of good quality pharmaceuticals of mass consumption.

5.2 Under Business of Allocation rules the works allocated to Department of Pharmaceuticals in respect of R&D in pharmaceuticals sector are as under:

- (1) Promotion and co-ordination of basic, applied and other research in areas related to the pharmaceutical sector.
- (2) Development of infrastructure, manpower and skills for the pharmaceutical sector and management of related information.
- (3) Education and training including high end research and grant of fellowships in India and abroad, exchange of information and technical guidance on all matters relating to pharmaceutical sector.
- (4) International co-operation in pharmaceutical research, including work related to international conferences in related areas in India and abroad.

5.3 One of the proclaimed aims of this Department is to promote research and development in the pharmaceutical sector. To achieve this, the Department proposes to increase the capacity building in the areas of drugs and pharmaceuticals. Quality and safety of the drugs and pharmaceuticals manufactured in the country for domestic consumption as well as for the export is an essential requirement. The goal of this initiative is to build up national facilities which can

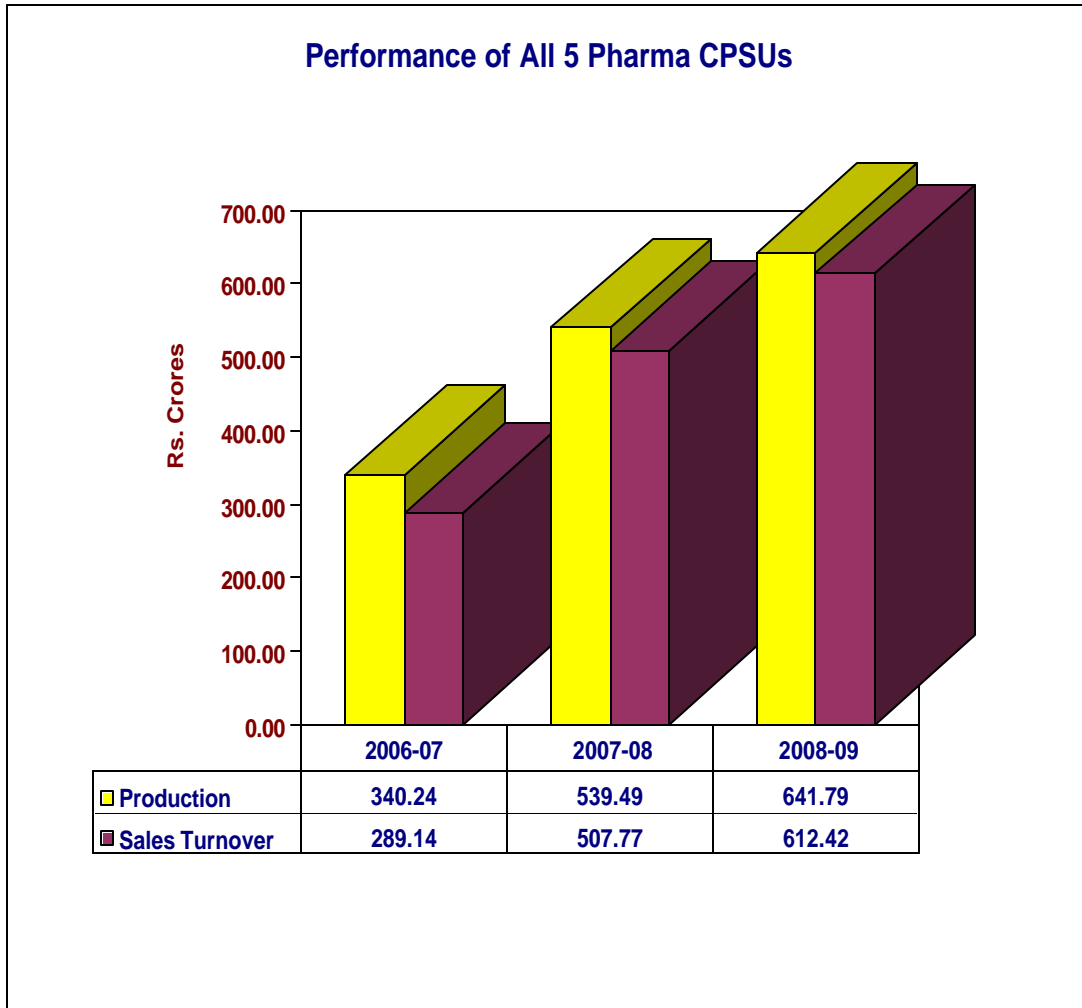
meet national as well as international regulatory requirements to test the quality and safety of the pharmaceutical. The drugs and pharmaceuticals and NCEs need to undergo toxicological and safety pharmacological testing before released in to the market or submitted to IND committee for Phase I approval, respectively. These facilities require apart from bioanalytical testing facilities animal testing facilities and animal breeding facilities. The testing facilities need to follow Good Laboratory Practices (GLP) , which is a mandatory requirement as per national and international requirements. GLP monitoring authority of India is with Department of Science and Technology, GOI. Further, FDA also issued GLP guidelines and all the Pharmaceutical companies need to follow from Sept 2010. The Department would make an all out effort in consultation with Ministry of Science & Technology, Ministry of Health & Family welfare to build up basic support system so that R&D initiative can be taken in a free & comfortable atmosphere.

R & D PROPOSALS DEVELOPED BY THE DEPARTMENT

- a. Proposal for assistance in setting up of GMP Complied Biological/Bio Pharmaceutical Testing Lab (2 Lab/year @ 1.5 crore, total Rs. 9 crore for 3 years).
- b. Proposal for setting up of GLP Complied Chemical Lab (one Lab/year @ RS. 4 crore, total Rs. 12 crores for 3 years).
- c. Proposal for setting up of GLP Complied Large Animal Facility (One facility/year @Rs. 5 crore, total Rs. 15 Crore for 3 years).
- d. Proposal for conducting Educational Programme for Drug Regulatory/Industry/Lab representatives (560 persons/ years) at NIPERs (80 lakhs/years, total 2.4 crore for 3 years).
- e. Proposal for assistance to public funded institutions for extra Mural research in Pharmaceutical Sciences (Budget requirement Rs. 20.00 crores for next three years).
- f. Proposal for National Award for innovation and Research in Pharmaceuticals (30 lakhs per year, 90 lakhs for 3 years).
- g. Proposal on development of Pharma incubation/clusters (being developed).
- h. Capacity building programme by IDFC.
- i. Project Proposal For Venture Finance and Incubation Fund for Innovative R & D in Pharmaceuticals (total budget requirement is Rs. 50 crores)

Public Sector Undertakings

6.1 There has been noticeable improvement in the total production and sales of five Pharma Central Public Sector Undertakings (CPSUs) under the control of this Department as would appear from the graph below:- Graph



INDIAN DRUGS & PHARMACEUTICALS LIMITED (IDPL)

6.2 Indian Drugs & Pharmaceuticals Limited (IDPL) was incorporated on the 5th April, 1961 with the primary objective of creating self sufficiency in essential life saving drugs and medicines. The company has presently three manufacturing plants, one each at Rishikesh (Uttarkhand), Hyderabad (Andhra Pradesh) and Gurgaon (Haryana). IDPL has two wholly owned subsidiaries, namely, IDPL (Tamil Nadu) Ltd., Chennai (Tamil Nadu) and Bihar Drugs & Organic Chemicals Ltd. at Muzaffarpur (Bihar). In addition, IDPL has two joint sector undertakings, promoted in collaboration with the respective State Governments. These are Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL), Jaipur, and Orissa Drugs & Chemicals Ltd. (ODCL), Bhubaneshwar.

6.3 IDPL was formally declared sick by the Board for Industrial & Financial Reconstruction (BIFR) on the 12th August, 1992. A revival package for the company was formulated and approved by BIFR on the 10th February, 1994. However, after taking into account the performance of the company which fell short of the targets, the BIFR on 23.1.1996 treated the sanctioned package as failure.

6.4 BIFR in its meeting held on 4.12.2003 confirmed its prima-facie opinion about winding up of IDPL in terms of Section 20(1) of the Sick Industrial Companies (Special Provisions) Act, 1985.

6.5 Department of Chemicals & Petrochemicals filed an appeal against the order of BIFR in Appellate Authority for Industrial & Financial Reconstruction (AAIFR) on 10.2.2004.. Hon'ble AAIFR at its hearing on 13.9.2005 set aside the impugned order of BIFR dated 4.12.2003 and remanded the matter back to BIFR for taking further action for rehabilitation of IDPL.

6.6 An Expert Committee was appointed in September, 2004, to study the techno-financial feasibility of rehabilitating IDPL. A technical audit of various plants of IDPL was also assigned to National Institute of Pharmaceutical Education and Research (NIPER). NIPER in its report submitted to the Department on 31.8.2005, recommended revival of all plants of IDPL and its

subsidiaries in phases for production of existing and new products. IDBI supported the recommendations for revival of IDPL subject to certain conditions.

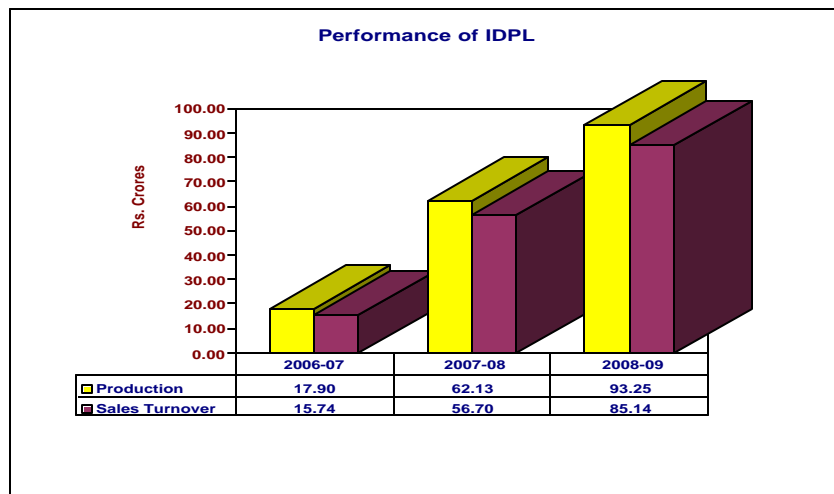
6.7 In a meeting held under the chairmanship of Minister (C&F&S) it was decided to revive all the five units of IDPL in a phased manner.

6.8 Having considered the Draft Rehabilitation Scheme for revival of Indian Drugs & Pharmaceuticals Limited (IDPL) at its meeting held on 9.3.2007, the Board for Reconstruction of Public Sector Enterprises (BRPSE) recommended the scheme for approval of the Government.

6.9 The scheme was placed before the Cabinet for approval. Cabinet considered the proposal at its meeting held on 17.5.2007 and referred it to GoM for consideration at the first instance. GoM has been constituted on 1.6.2007. The first meeting of the GoM was held on 11.10.2007 and a further meeting is to follow. The recommendations of the GoM when finalised would be placed before the Cabinet. Since Elections to the Lok Sabha have been announced, it has been decided to place the matter before the new Government.

6.10 The company has signed MoU with the Government for the year 2008-09.

6.11 There has been very noticeable improvement in the performance of the company in the last 3 years. Details of Production & Sales figures (unaudited) of IDPL from 2006-07 onwards are as under:



INAUGURATION OF NEW CEPHALOSPORIN PLANT IN GURGAON

6.12 IDPL is engaged in setting up a new Cephalosporin plant at an estimated cost of Rs 13.00 crore at its premises in Gurgaon. The plant was inaugurated by the Minister (C&F&S) on 20th February, 2009. This will help the company in further growth of production and sales.

6.13 For Muzzafarpur (Bihar) and Hyderabad (Andhra Pradesh), fresh initiatives have been taken for re-starting these Plants and also to generate revenue from the non performing assets (NPAs). Development of plant/ area through Joint Venture/ Public Private Partnership mode is also being explored.

HINDUSTAN ANTIBIOTICS LIMITED (HAL)

6.14 Hindustan Antibiotics Ltd. (HAL), Pimpri, Pune was incorporated on 30th March, 1954. This was the first Public Sector Company in drugs and pharmaceuticals. HAL has its plant located at Pimpri. The company produces a wide range of Pharmaceutical formulations including agro-vet products. There are three joint sector units promoted by HAL in collaboration with the respective State Governments. These are Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL), Bangalore (Karnataka), Maharashtra Antibiotics & Pharmaceuticals Ltd. (MAPL) at Nagpur (Maharashtra-since closed) and Manipur State Drugs & Pharmaceuticals Ltd. (MSDPL) at Imphal (Manipur-since closed). In addition there was a joint venture, namely, HMGB, with a private sector company Max GB-since discontinued.

6.15 As the company had been incurring continuous loss since 1993-94, it was referred to the BIFR in January, 1997. BIFR declared the company formally sick on 31.3.1997. BIFR appointed the Industrial Development Bank of India (IDBI), Mumbai as the Operating Agency for a techno-economic viability study and report. The first rehabilitation scheme prepared by HAL was revised on the directions of the BIFR and the Government.

6.16 In the Budget speech 2004-05, the Finance Minister announced financial support for restructuring HAL. On 9.3.2006, Government approved the rehabilitation Scheme of the company. The rehabilitation Scheme inter alia involved the following:-

S. No.	Particulars	Amount(Rs. in crores)	
1.	Cash infusion	137.59*	
2.	Write off/exemptions from Government of India	267.57	
3.	Sacrifices by Banks, financial institutions and PSUs	103.34	
	Total	508.50	

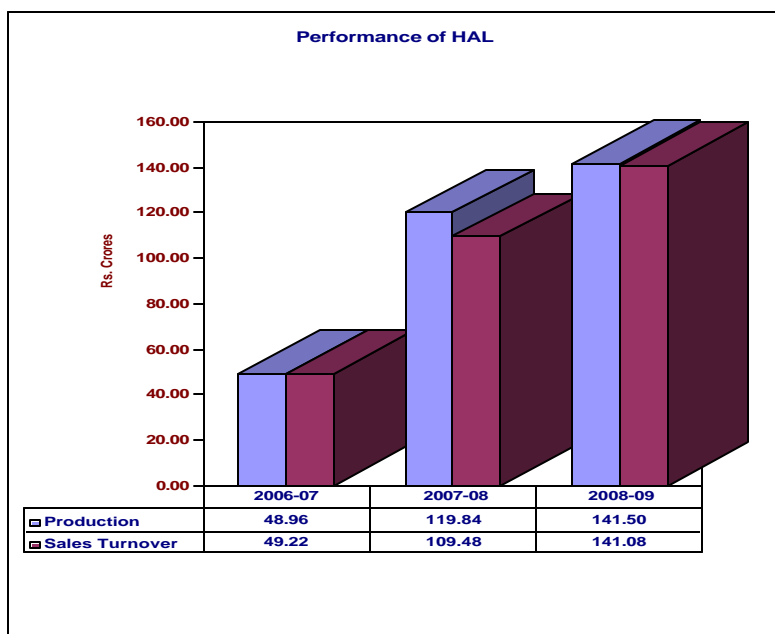
* This includes interest free loan of Rs. 56.96 crores to be repaid by HAL. by sale of land within a period of two years.

6.17 The entire cash infusion of Rs. 137.59 crores has been released to the company. Parliament has approved writing off of loan and waiver of interest to the extent of Rs. 259.43 crores. BIFR has also sanctioned the Rehabilitation Scheme vide its order dated 5th June 2007 and issued guidelines for constitution of Assets Sale Committee. Action has been initiated by HAL for sale of land.

6.18 Government has approved the proposal received from HAL for setting up new powder injectable facilities for Cephalosporin and upgradation of existing vialling facilities for Betalactum (Penicillin) Antibiotics complying to WHO-GMP standards at an estimated cost of Rs. 20.17 crores.

6.19 The entire amount of Rs. 20.17 crores has been released to HAL. HAL has completed the work on Cephalosporin in record time of 9 months. It is likely to commence commercial production in February, 2009. Work relating to upgradation of existing vialling facilities for Betalactum Antibiotics is likely to be completed by March 2009.

6.20 It has improved its production and sales during 2007-08 (unaudited information) onwards vis-à-vis 2006-07. Details of Production & Sales of HAL from 2006-07 onwards are as under:-



6.21 The company has signed MoU with the Government for the year 2008-09.

6.22 Government has sanctioned Rs. 10.00 crore during the year 2008-09 to this company to undertake WHO-GMP compliance of its plants. This is planned for giving a boost to exports of products manufactured by HAL for which substantial potential exists.

BENGAL CHEMICALS & PHARMACEUTICALS LIMITED (BCPL)

6.23 BCPL was a sick company in the private sector in the name and style of Bengal Chemicals & Pharmaceuticals Works. It was nationalized on 15th December, 1980. A new public sector company in the name and style of Bengal Chemicals & Pharmaceuticals Limited (BCPL) was incorporated on the 17th March, 1981.

6.24 The company has four manufacturing units one each at Maniktala at Kolkata, Panihati at North 24 Parganas (West Bengal), one at Mumbai (Maharashtra) and at Kanpur (UP). The company manufactures and markets a wide a range of industrial chemicals, a large number of drugs and pharmaceuticals besides cosmetics and home products. In the home products, the well known products include Cantharidine Hair Oil and Lamp Brand Phenol.

6.25 The company was formally declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on the 14th January, 1993. A revival package was approved by the BIFR on the 4th April, 1995.

6.26 The package was reviewed by BIFR from time to time. As a result, BIFR sanctioned a Modified Revised Rehabilitation Scheme on 14.1.2004 for the revival of BCPL. This envisages a number of reliefs and concessions from the Government and other agencies.

6.27 The Modified Revised Rehabilitation Scheme sanctioned by BIFR was further modified by the Company keeping in view its requirements for modernization of plants & machinery and placed before BRPSE for its recommendations. The Board for Reconstruction of Public Sector Enterprises (BRPSE) at its meeting held on 25.8.2006 recommended the modified revival plans for approval.

6.28 On 21.12.2006, Cabinet Committee on Economic Affairs (CCEA) approved the revival scheme of BCPL, as under:

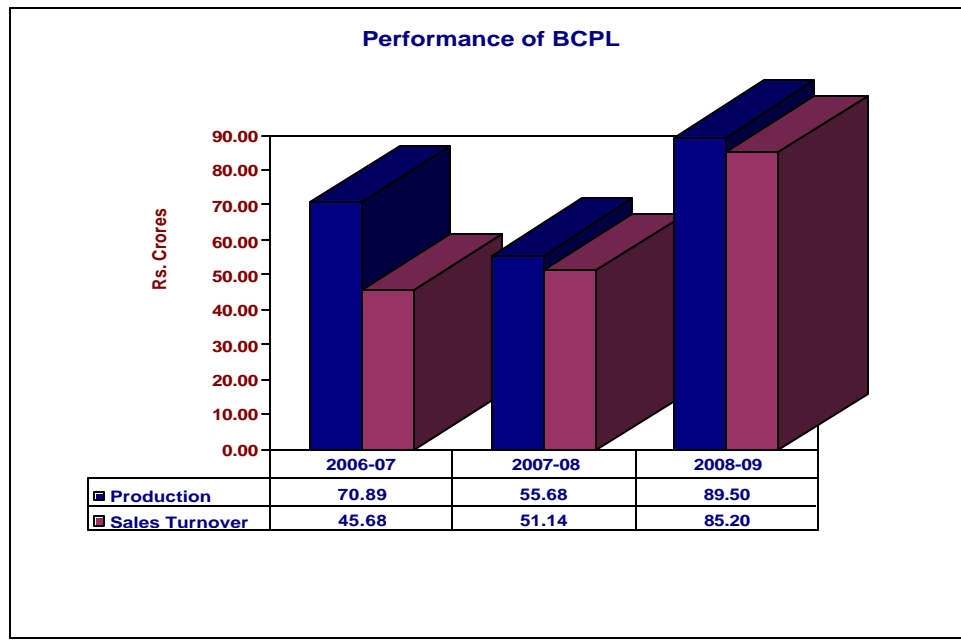
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|--|---------------------|
| (i) Cash infusion by GOI | - Rs. 207.19 crores |
| (ii) Write off/Waiver of Loans/Interest(As on 31.3.2005) | - Rs. 233.41 crores |
| (iii)Waiver of Loan/Interest by the GOI not - | Not quantified |
- to be treated as income in terms of Income Tax Act.

6.29 Out of Cash infusion of Rs. 207.19 crores, Rs. 117.19 crores has since been released to BCPL and an interest free loan of Rs. 90.00 crores would be provided during 11th Five Year Plan. Of this, Rs. 20.00 crores has been released in 2007-08 and Rs. 20.00 crores has been released in 2008-09.

6.30 Parliament has approved writing off of GOI loans & interest of Rs. 233.41 crores. The company has appointed a Consultant for undertaking the work of upgradation & modernization of plant & machinery including compliance with Schedule 'M', WHO GMP standard. The work has since commenced at Maniktala, Panihati & Kanpur. It will take 18-24 months to complete the work. Impact of upgradation/modernization work will be visible in 2009-10.

6.31 The company has entered into MoU with the Government during the year 2008-09.

6.32 Details of Production & Sales of BCPL from 2006-07 onwards (unaudited information) are as under:



BENGAL IMMUNITY LIMITED (BIL)

6.34 BIL was a sick company in the private sector in the name and style of Bengal Immunity Company Limited. The management of the company was taken over by the Central Government with effect from the 18th May, 1978. It was nationalized w.e.f. 1st October, 1984 and a new public sector company in the name and style of Bengal Immunity Limited was incorporated on the 1st October, 1984. The company has two manufacturing units, one each at Baranagar at Kolkata (West Bengal) and at Dehradun (Uttarakhand).

6.35 The Board for Industrial and Financial Reconstruction (BIFR) formally declared the company sick on 9th March, 1993. BIFR heard the case from time to time. In the hearing held on 13th September, 2002, BIFR formed its prima-facie opinion to wind up the company. The opinion was confirmed by BIFR in the hearing held on 25th February, 2003. With the approval of the Cabinet, VSS was introduced in the company. The company has since relieved all employees under VSS as on 30th September, 2003.

6.36 The company is closed. The Official Liquidator has already been appointed by the Kolkata High Court. However, the appointment of Liquidator in respect of BIL has been stayed on a Writ Petition filed by the BIL Employees Union and thereafter this Department on the ground that a Committee has been set-up to look into the issue of revival of BIL looking to the order passed by AAIFR.

6.37 The Committee, constituted to explore the possibility of revival of Bengal Immunity Limited (BIL), recommended revival of BIL through public private partnership mode.

A meeting was held under the Chairpersonship of Secretary(C&PC) on 20.2.2007 to hear the private companies. As a result of the meeting held on 20.2.2007, a Technical Committee was constituted to examine technical & financial capabilities of short listed companies. The Committee submitted its report on 12.7.2007. The Committee while reflecting the technical capabilities of the short listed companies, recommended financial due diligence & assessment by a reputed financial consultant.

6.38 The constitution of the Committee was by reason of the order passed by the Appellate Authority for Industrial & Financial Reconstruction (AAIFR). As such, AAIFR also heard short listed companies. Subsequently, AAIFR called all five companies who met the eligibility criteria. For the purpose hearing was held in AAIFR on 6.11.2007. AAIFR passed orders in this regard on 3.3.2008.

6.39 AAIFR, inter alia, asked the Government to consider & evaluate proposals from 5 short listed companies mentioned in the Report of the Committee. SBI Caps have been appointed for evaluation of proposals of 5 short listed companies as per the order dated 3.3.08 passed by AAIFR.

SMITH STANISTREET PHARMACEUTICALS LIMITED (SSPL)

6.40 It was a sick company in the private sector in the name and style of Smith Stanistreet Company Limited set up in 1821 and its management was taken over by the Government of India with effect from 4th May, 1972. The company was nationalized on 1st October, 1977, and a new public sector company in the name and style of Smith Stanistreet Pharmaceuticals Limited (SSPL) was incorporated on 19th July, 1978. The company has its registered office at 18, Convent Road, Kolkata (West Bengal)

6.41 The company was formally declared sick by the Board for Industrial and Financial Reconstruction (BIFR) on the 21st December, 1992. The BIFR approved a revival package for the company on the 31st August, 1994. The revival package was for a period of ten years beginning from 1994-95. The same was declared as having failed during the hearing on October, 17, 2000.

6.42 The BIFR heard the case on the 3rd December, 2001 and confirmed its prima facie opinion that it was just, equitable and in public interest that the company should be wound up. With the approval of the Cabinet, VSS was introduced in the company. The company has since relieved all the employees under VSS as on 30th September, 2003. The company is closed.

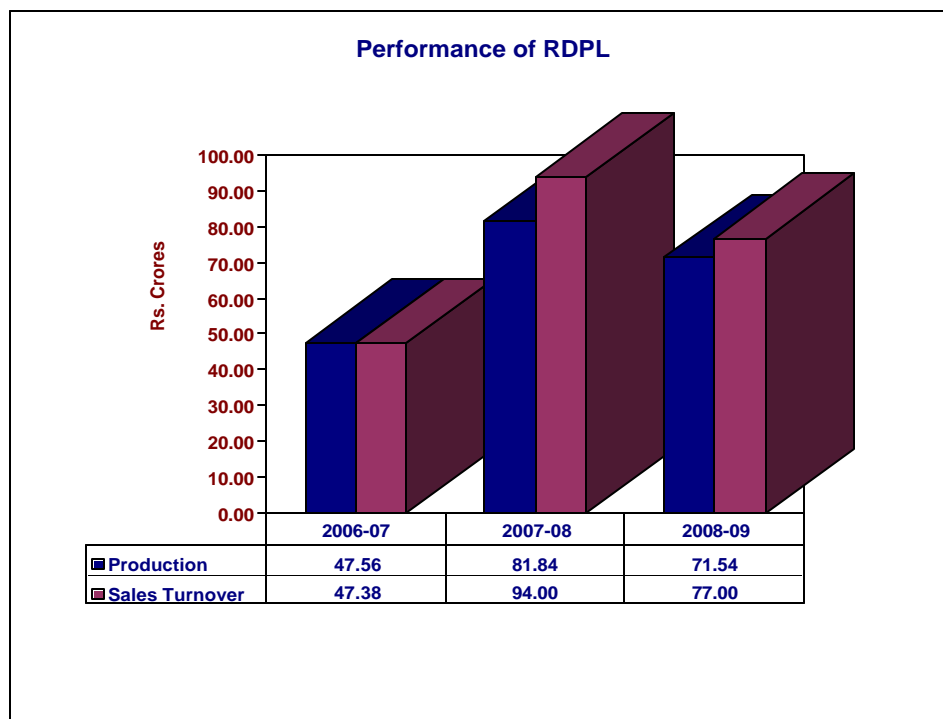
6.43 The Official Liquidator has been appointed by the Hon'ble High Court of Calcutta vides Order dated 12.1.2006. The Registered Office, Plant & machinery and other assets have since been taken over by the Official Liquidator.

JOINT SECTOR UNDERTAKINGS

RAJASTHAN DRUGS & PHARMACEUTICALS LIMITED (RDPL).

6.44 This is a profit making joint sector undertaking promoted by Indian Drugs & Pharmaceuticals (IDPL) and the Rajasthan Industrial Development and Investment Corporation (RIICO). IDPL holds 51% of the equity shares and the rest is with RIICO. The company was incorporated in 1978 and the commercial production was commissioned in April, 1981. The company has its manufacturing unit and the registered office located at V.K.I. Industrial Area, Jaipur (Rajasthan). This is a formulation unit engaged in the production of Tablets, Capsules, Liquid Orals and Injectables. It is an MOU signing company. RDPL has been continuously generating profits for the last 10 years and the performance of RDPL has further improved and gone up especially on account of Purchase Preference Policy announced by the Department.

Details of Production & Sales of RDPL:



Delinking and funding sanctioned by Government for Schedule 'M' and WHO-GMP

Compliance and capacity enhancement in RDPL.

6.45 In the interest of continued growth and development of the company, Government has decided to delink RDPL from IDPL and transfer the shareholding of IDPL in RDPL to Government of India. Government of India has also invested Rs. 2.00 crore in RDPL to enable it to upgrade, modernize and enhance capacity of its plants and to make them Schedule 'M' and WHO-GMP compliant. Rajasthan Industrial Development Investment Corporation (RIICO), other joint venture partner would bring in additional investment of Rs. 1.90 crore in RDPL.

ORISSA DRUGS & CHEMICALS LIMITED (ODCL)

6.46 This is a profit making Joint Sector Undertaking promoted by Indian Drugs & Pharmaceuticals Limited (IDPL) and the Industrial Promotion and Investment Corporation of Orissa (IPICOL). IDPL holds 51% of the equity shares and the rest is with IPICOL. The company was incorporated in 1979 and commissioned fully for production from September, 1983. The company has its manufacturing unit and its registered Office in Mancheshwar Industrial Area, Bhubaneshwar in the State of Orissa. The company is engaged in the manufacture of Pharmaceutical formulations in the form of Tablets, Capsules, Powders, and Ointments etc.

6.47 ODCL was formally declared sick by the Board of Industrial and Financial Reconstruction (BIFR) on the 26th October, 1992. On the basis of the report of the Operating Agency, appointed by the BIFR and the support extended by the promoters, the BIFR approved a revival package for ODCL on the 18th August, 1994. BIFR heard the case from time to time.

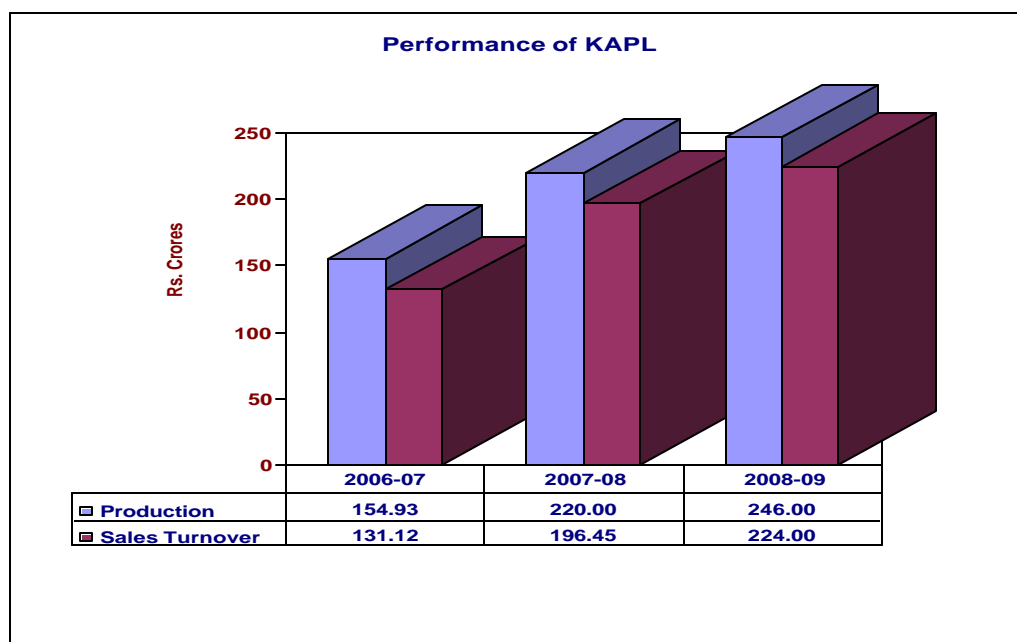
6.48 The BIFR in the hearing on 18.12.2000, declared this scheme as failure. The BIFR issued a show cause notice for winding up of the company in the absence of a fully tied up proposal for revival. In the hearing held on 8.7.2002, the BIFR, inter-alia, directed the O.A. to issue advertisement inviting offers for sale of the assets of the company under Section 18(2) (i) without any liability or under Section 18(ii). The advertisement was issued by the OA (IDBI) and then a joint meeting was held on November 13, 2002.

6.49 BIFR in its order dated 8th April, 2003 passed orders for winding up of the company under the provisions of Sick Industrial Companies (Special Provisions) Act, 1985. The appeal filed by ODCL employees against the winding up order of BIFR has been dismissed by the AAIFR vide its order dated 23.6.2005. High Court of Orissa had appointed a provisional Liquidator. This has since been stayed by the High Court.

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED (KAPL).

6.50 This is a profit making Joint Sector Undertaking promoted by Hindustan Antibiotics Limited (HAL) in collaboration with Karnataka State Industrial and Investment Development Corporation (KSIIDC). HAL holds 59% of the equity shares and the rest is with KSIIDC. The Company was incorporated on 13th March, 1981 and the commercial production started from August, 1984. the manufacturing units and the registered office of the company is located at Bangalore(Karnataka). The main products are pharmaceuticals formulations like tablets, capsules, injectables, etc. It is an MOU signing company. It has been continuously generating profits for the last 10 years and the performance of the company has further improved and gone up especially on account of Purchase Preference Policy announced by the Department.

Details of Production & Sales of KAPL:



Delinking and funds sanctioned by Government for upgrading manufacturing facilities and setting up new Cephalosporin plant in KAPL.

6.51 In the interest of continued growth and development of the company, Government has decided to delink KAPL from HAL and transfer the shareholding of HAL in KAPL to Government of India. Government of India has also invested Rs. 7.10 crore in KAPL for upgrading its manufacturing facilities conforming to WHO-GMP standards and setting up a new WHO-GMP compliant Cephalosporin plant. Other joint venture partner, viz. Karnataka State Industrial & Investment Development Corporation (KSIIDC) would bring in additional investment of Rs. 4.90 crore in KAPL.

MAHARASHTRA ANTIBIOTICS & PHARMACEUTICALS LTD (MAPL)

6.52 This is a Joint Sector Undertaking promoted by Hindustan Antibiotics Limited (HAL) and State Industrial & Investment Corporation of Maharashtra (SIICOM). HAL holds 52% of the equity shares, 38% is with SICOM and 10% with IDBI. The company was incorporated in November, 1979, and the commercial production started in May, 1981. The registered office and the factory of the company is located at Nagpur, (Maharashtra).

6.53 The BIFR formally declared MAPL as sick on 14.1.1997. BIFR heard the case from time to time. In the hearing held on 04.07.2000, BIFR formed opinion for winding up of the company under Section 20(1) of the SICA, 1985. Appeals filed in AAIFR were also dismissed. How ever writ petitions have been filed in the Nagpur Bench of the Mumbai High Court against the liquidation proceedings of MAPL. At present, the company is closed and is before the High Court for appointing a Liquidator.

6.54 In accordance with the direction of the Nagpur Bench of the High Court of Mumbai, Government introduced VSS in MAPL. Accordingly all employees were released under VSS.

MANIPUR STATE DRUGS & PHARMACEUTICALS LIMITED (MSDPL)

6.55 This is a joint sector undertaking promoted by Hindustan Antibiotics Limited (HAL) in collaboration with Manipur Industrial Development Corporation (MANIDO). HAL holds 51% of the equity shares and the rest is with MANIDO. The company was incorporated on the 18th July, 1989. The manufacturing unit and the registered office is at Imphal (Manipur).

6.56 Due to time and cost overruns, the project was not completed by 1991. In 1993, the cost of the project was estimated at Rs. 395.00 lakhs. But it was not approved. In August, 1997, a professional consultant, M/s. Business Horizon Private Ltd. was engaged to examine viability of the project. The consultant estimated cost of completion of the project at Rs. 859.50 lakhs.

6.57 The matter was referred to the Government of Manipur for their comments on the report of the consultant. Based on the comments of the State Govt. of Manipur, closure of MSDPL was proposed after separation of employees with retrenchment benefits under the Industrial disputes Act/Workmen's compensation Act. At present, the company is closed.

WHOLLY OWNED SUBSIDIARIES:

IDPL (TAMIL NADU) LIMITED, CHENNAI.

6.58 In terms of the revival package approved by BIFR in 1994 in the case of IDPL, the Surgical and Formulation Unit of IDPL at Chennai was converted into a wholly owned subsidiary in the name and style of IDPL (Tamil Nadu) Limited, Chennai with effect from the 1st April, 1994. IDPL holds the entire equity capital of this unit. At present, it is engaged in the manufacture of pharmaceutical formulations.

BIHAR DRUGS & ORGANIC CHEMICALS LIMITED, MUZAFFARPUR.

6.59 In terms of the revival package approved by the Board for Industrial & Financial Reconstruction (BIFR), the Organic Chemicals and Drug Manufacturing unit of IDPL at Muzaffarpur (Bihar), was converted into a wholly owned subsidiary in the name and style of Bihar Drugs & Organic Chemicals Limited, Muzaffarpur with effect from the 1st April, 1994. IDPL holds the entire equity capital of this Unit. The past long-term liabilities amounting to Rs.36 crore as on 31.3.1994 were taken over by IDPL. At present there is no production activity in the unit. However, IDPL has taken a new initiative to commence work relating to production of clarithromycin, Roxithromycin and Azithromycin bulk at this plant.

JAN AUSHADHI (GENERIC DRUGS STORES)

6.60 The concept of launching Generic Drugs Campaign by opening Generic Drug Stores was mooted during the Fourth Pharma Advisory Forum meeting chaired by Hon'ble Minister of Chemicals and Fertilizers and Steel on 23rd April, 2008 at Vigyan Bhawan, New Delhi.

6.61 As part of the Generic Drug Campaign started by this Department and Pharma CPSUs, first Generic Drug Store by the name of Jan Aushadhi 24x7 Generic Drug Store (JAGDS) was inaugurated in the Civil Hospital, Amritsar on 25.11.2008 with the support and cooperation of Government of Punjab. Additional stores have since been opened in 2008-09 one each at Bhatinda, Mohali, Gurgaon, Punchkula, Jaipur and Shastri Bhavan, New Delhi.

6.62 Consultations are also going on with the States, including Andhra Pradesh and Assam etc. for opening Jan Aushadhi Generic Drug Stores in these States.

6.63 The Bureau of Pharma CPSUs set up recently is also involved in promotion of the unbranded generic drugs and the Generic Drug Campaign.

CHAPTER-VII

NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH, (NIPER)

7.1 National Institute of Pharmaceutical Education & Research (NIPER). SAS Nagar, Mohali, Punjab Is set-up as a “Institute of National Importance” under the Act of Parliament on 26th June 1998. It is an Autonomous institution under the aegis of Department of Pharmaceutical, Ministry of Chemicals & Fertilizers, and government of India.

7.2 The main objective of the Institute is to nurture and promote quality and excellence in pharmaceutical education & research. NIPER is a member of Association of Indian Universities and Association of Commonwealth Universities.

There are 23 members on the Board of Governors under the Chairmanship of Dr. T. Ramasami, Secretary, DST, as on date.

7.3 NIPER is offering four Masters level programmes and the PhD programme in the following 14 streams and is catering to the needs of pharmaceutical industry:

- | | |
|--------------------------------|--|
| (1). Medicinal Chemistry | (2). Pharmaceutics |
| (3). Natural Products | (4). Pharmacology & Toxicology |
| (5). Pharmaceutical Analysis | (6). Biotechnology |
| (7). Pharmaceutical Technology | (8). Pharmacy Practice (Formulations) |
| (9). Pharmaceutical Management | (10) Pharmaceutical Technology (Bulk
Drugs) |
| (11). Pharmacoinformatics | (12). Pharmaceutical Technology
(Biotechnology) |
| (13). Traditional Medicine | (14). Regulatory Toxicology |

7.4 The NIPER laboratories are fully equipped with modern equipments that are equivalent to the other laboratories set up in the world. All the available facilities are of international level and standards. Technology Development Centre has been set up in the NIPER SAS Nagar.

7.5 The WHO accredited National Bioavailability Centre established with support of Department Of Science & Technology, Government of India, is one of the two centers to

conduct bio-availability studies. The Institute has also set up the Good Laboratory Practices Compliance National Toxicology Centre, National Centre of Pharminformatics, National Centre for Safety Pharmacology and Centre for Nanotechnology with the support of Deptt. of Science & Technology.

7.6 A new facility named, "System Biology: Genome to Drug Initiative" laboratory was setup this year. The following central facilities provide support to the research groups within the Institute as well as from outside:

- (1).Central Instrumentation Laboratory
- (2).Computer Centre
- (3).Library and Information Centre
- (4).Central Animal facility
- (5).National Toxicology Centre (GLP compliance)
- (6).Technology Development Centre
- (7)..National Bio- availability Centre (WHO accredited)
- (8).Impurity profiling & stability testing laboratory
- (9).Pharmacological & Toxicological Screening Facilities (GLP compliance)

7.7 NIPER also conducts regular continuation education programs for academia and industry in various disciplines and helps the Indian Pharmaceutical Industry in solving their R&D related problems. NIPER has upgraded facilities for achieving highest level of efficiency in importing education and events as under:

- NIPER laboratories are fully equipped with modern instruments and are equivalent to the other similar laboratories elsewhere in the world. All the available facilities are of international level and standards. The classrooms were made state-of-art with installation of TV panels and laptop systems.
- In addition, there was significant improvement in research infrastructure. Several high value sophisticated instruments were added, that helped in increased thrust in R&D activities.
- The Institute entered into several International collaborations and a number of visitors from abroad and within the country converged at the Institute, thus highlighting the ever-rising status of the Institute.
- The success of NIPER has facilitated the setting up of six more similar Institutes, which have already started functioning at Ahemdabad, Hyderabad, Gauhati, Hajipur, Rae Bareilly and Kolkata. The Institute played its mother role to all new NIPERs started in different parts of the country, by helping them in variety of ways including centralized admissions.

- Impressed by the dedication of the faculty and the diligence of the students, Sh. Ram Vilas Paswan, Hon'ble Union Minister of Chemicals & Fertilizers and Steel, has announced a hike in the fellowship received by the Masters' students as per with IITs during his visit to the Institute for inauguration of SMPIC.
- To maintain the momentum, the Quality Policy for academic activities initiated. The Institute has been declared as an Institute with Zero tolerance towards ragging.
- Institute celebrated its Foundation Day on 15 Feb. 2009. Dr. A.V. Rama Rao, Chairman & Managing Director, Avra Laboratories Pvt. Ltd., Hyderabad delivered the Foundation Day lecture.
- The fourth convocation was organized. Prof. C.N.R. Rao, FRS, Linus Pauling Research Professor and Founder President, JNCASR, Bangaluru and Chairman, Scientific Advisory Committee to Prime Minister (SAC- PM) delivered the Convocation address. Dr. T. Ramasami, Chairman, BoG, NIPER, S.A.S. Nagar & Secretary, Dept. of Science & Technology, Govt. of India was the Guest of Honour. 240 Students were awarded the degrees.
- Sh. Ram Vilas Paswan, Hon'ble Union Minister of Chemicals & Fertilizers and Steel inaugurated the Small and Medium Pharmaceutical Industries Centre (SMPIC) in the presence of Prof. Laxmi Kanta Chawla, Hon'ble Minister of Health, Govt. Of Punjab and Sh. Ashok Kumar, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Govt. of India at the Institute. NIPER started conducting training programs at newly established SMPIC for Small and Medium Pharmaceuticals industry on the aspects of Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP), Instrumental analysis and manufacturing of APIs and Formulations. The centre will also provide a focal point to industry academia interaction.
- Prof. V.L. Chopra, Member, Planning Commission inaugurated the Natural Products Field Laboratory (NPFL) at the Institute. Laboratory will act as a base for physical resources and related research work conducted in the study of Natural Products.
- The Institute became host to its first Fulbright Scholar Dr. Anil Gulati from the United States. Anil Gulati, MD, PhD is also the first faculty member from Midwestern University to be named a Fulbright Scholar Dr. Gulati taught students, organized and participated in several symposiums and workshops.
- A two weeks intensive course on 'Advanced Analytical Techniques: Basic Principles & Application for Quality Assessment of Drugs and Pharmaceuticals for Export' was organized at the Institute . The course was sponsored by Govt. of

India, Ministry of External Affairs under the Indian Technical and Economic Cooperation (ITEC) and Special Commonwealth African Assistance Plan (SCAAP) programs and was attended by 19 delegates from countries like Sudan, Iraq, Sri Lanka, Ethiopia, Laos, Mauritius, Tanzania, Belarus, Uzbekistan, Nigeria and Afghanistan.

- The Institute has been selected as a nodal agency in the Capacity Building Project funded by the World Bank under the Government of India, Ministry of Health and Family Welfare for providing training to drug regulatory personnel, analytical staff and personnel from small scale industries, which concluded in 2008. 53 programmes were held over a span of four and a half years. 2603 professionals were trained against the target of 2275, which also include drug regulatory personnel from SAARC member-states.
- MoUs have been signed with University of Hertfordshire, UK, and Chicago College of Pharmacy, USA, in selected fields of pharmaceutical sciences. Apart from above, MoU has been signed with IDPL for providing Project Management Consultancy for reengineering and implementation to restart their Hyderabad and Muzaffarpur plants.
- MoU was signed between NIPER, S.A.S. Nagar & Indian Drugs Pharmaceutical Limited (IDPL) for transfer of the technology of Zinc dispersible tablets for the management of diarrhoea in children.
- Institute is advisor on designing and implementation of green field projects at BCPL and HAL.
- Apart from international delegations, more than 100 foreign visitors visited the Institute during this period for developing collaborations and for scientific deliberations.
- Successful completion of North East Natural Products Project for the survey of Traditional Medicine and herbs.
- Renewal of agreement at enhanced rate, i.e. Rs. 14.85 lacs per month for Technology Development Centre (TDC) with the upgrading of its facilities for meeting the GMP requirements.
- Financial sanction of dosage form plant to cater the needs of Scale facilities for capsules, tablets etc. and training on Schedule M to SMEs, students, etc.
- Award for Best performance in the Hindi from Ministry of Chem. & Fertilizers and TOLIC, Chandigarh -2008. Several Faculty of the Institute received various prestigious scientific awards and honours.

- Institute participated in INDIA CHEM-2008 exhibition organized by Ministry of Chemicals & Fertilizers, in association with FICCI at Mumbai and in Indian Science Congress Expo-2008 organized at Shillong to showcase its potential.
- In this period, the Institute has published 186 articles in journals of repute. As on date NIPER has filed 78 patents, out of these 13 patents have been granted.
- During 2008-09, applications have been filed for nine patents, out of which two patents have been granted.
- Since the inception of academic programmes, 523 Masters, 78 Doctoral students and 134 Master scholars in MBA in Pharmaceutical Management have graduated till date. They have since been placed very well. A total of 165 Masters' [including M.B.A. (Pharm.)] and 21 Ph.D. students were admitted this year.
- Apart from the financial aid received from our parent ministry, NIPER also received grants from various national and international funding agencies.

New initiative taken by NIPER SAS Nagar recently are:

1. New Scheme of Strengthening some good institution in different states into "Star Pharma College" for strengthening of Pharmaceutical Education & Research at undergraduate level.
2. Partial tuition fee waiver for students belonging to economically weaker sections of society in the National Institute of Pharmaceutical Education & Research (NIPERs) at Masters level.
3. Extra Mural Research Funding at NIPER.
4. Start National Pharmaceutical Sciences Eligibility Test (NALPET) for post graduate level Pharmaceutical Research scholars in line with CSIR.

SIX NEW NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPERs)

7.8 The Union Cabinet has given in principle approval for setting up of six National Institutes of Pharmaceutical Education and Research (NIPER) at Ahmedabad (Gujarat), Hyderabad (Andhra Pradesh), Hajipur (Bihar), Kolkata (West Bengal), Rae Bareli (U.P.) and Guwahati (Assam), in August 2007. With this the Government has fulfilled the demand of pharmaceutical industry to meet its long drawn demand of highly skilled trained manpower. This would also help in providing better healthcare to people in the long run. With the opening of six more NIPERs there would be seven NIPERs in the country. These NIPERs

would award Masters & Doctoral Degrees in different streams of pharmaceutical sciences and would give more emphasis on R&D activities of pharmaceutical industry. NIPERs would be equipped with R&D infrastructure of International standards and having various specializations suited to the needs of the Industry. The students would be exposed to cutting edge technology to meet the newer challenges of the industry. The intake of students in various NIPERs would be about 200-250 each and after all the seven NIPERs become functional about 1500 highly skilled trained manpower would be available for pharma industry annually.

7.9 Four new NIPERs at Ahmedabad, Hyderabad, Kolkata and Hajipur started working with the help of Mentor Institutes at these places and classes were started from the academic session 2007-08. NIPER, Guwahati & NIPER Rae Bareli have been started through Mentor Institutes in 2008-09. The student are being selected through common admission test connected by NIPER S.A.S Nagar in association with these new NIPERs.

7.10 An Apex Committee under the Chairmanship of Secretary (Pharma) has been formed to oversee the smooth functioning of new NIPERs till the Board of Governors of each new NIPER is formed. Likewise, State Level Coordination Committee under the Chairmanship of an Officer of the level of Principal Secretary of the concerned State Government have been formed for each NIPER to oversee the functioning of these new NIPERs.

7.11 Meanwhile, consultants M/s. Deloitte Touche Tohmatsu Pvt. Ltd., have been appointed by the Department for preparation of Detailed Project Report for each new NIPER incorporating the element of Public Private Partnership (PPP) wherever possible and to suggest the areas of specialization. The Consultants have submitted the Report, which has been accepted by the Government. The estimated cost on each NIPER as worked by consultant would be approximately Rs.330 crores including PPP element. In addition, about 100 acres of land are required for the project which is to be provided by the concerned State Governments free of cost. Each of these NIPERs would take about 4-5 years time to be fully established. Based on the detailed project report submitted by the consultant approval would be taken from Expenditure Finance Committee/ CCEA.

Present status of activities in six new NIPERS:

Following are the Mentor Institutes of the six new NIPERS:

NIPER – Ahmedabad	B.V. Patel Pharmaceutical Education & Research Development (PERD) Centre
NIPER – Guwahati	Gauhati Medical College & Hospital (GMCH), Guwahati
NIPER – Hajipur	Rajendra Memorial Research Institute of Medical Science (RMRIMS), Agamkuan, Patna (ICMR)
NIPER – Hyderabad	Indian Institute of Chemical Technology, Hyderabad (CSIR)
NIPER – Kolkata	Indian Institute of Chemical Biology, Kolkata (CSIR)
NIPER – Rae Bareli	Central Drug Research Institute (CDRI), Lucknow (CSIR)

7.12 MOUs between the Department of Pharmaceuticals and Mentor Institutes have been signed on 5th November 2008.

NIPER-AHMEDABAD

Objectives

1. To innovate in pharmaceutical education and research.
2. To impart state of art practical training in the various filed of pharmacy
3. To develop new formulations and drug delivery systems.
4. To understand nitty-gritty of biopharmaceuticals, their application and pharmacogenomics.
5. To investigate the potential of medicines from natural origin in various therapeutic areas.

7.13 National Institute of Pharmaceutical Education and Research at Ahmedabad with B.V. Patel Pharmaceutical Education Research and Development (PERD) Centre as its mentor Institute came into existence from 2007.

7.14 Gujarat government and PERD Centre were forthcoming in setting up of this Institute in Gujarat, with PERD accepting to be the mentor institute and Gujarat government in giving the 60 acres of land for the institute near Gandhinagar.

7.15 NIPER-Ahmedabad started with three courses in Pharmaceutics, Natural Products and Biotechnology with 10 seats in each discipline. PERD Centre as one of the leading Institute itself in Pharmaceutical Research and Development in Gujarat was already on a similar path of the concept of NIPER.

7.16 PERD Centre actually took the position of the mentor institute seriously and the courses were completed for the first batch on time with 98% teaching course completed. The existing faculty at PERD, the newly appointed NIPER faculty on contractual basis for NIPER and the overwhelming response from the visiting faculty made this happen.

7.17 PERD Centre metamorphosed from a Research and Development Institute to an academic institute with new class rooms, new labs, latest equipment, new canteen for students, a computer room and internet connection for its students. Within no time NIPER-Ahmedabad was functioning par excellence with mentorship of PERD Centre.

Present Scenario

7.18 NIPER-Ahmedabad would award Masters Degrees in different streams of pharmaceutical sciences such as Pharmaceutics, Biotechnology, Natural Products and would give more emphasis on R&D activities of pharmaceutical industry. NIPER-Ahmedabad would be equipped with R&D infrastructure of International standards and having various specializations suited to the needs of the Industry. The students would be exposed to cutting edge technology to meet the newer challenges of the industry. Focus area of research at NIPER-Ahmedabad will be Biotechnology, Medical Devices and Pharmaceutical Technology (Formulations).

- 1st semester for these students started from 1st October 2007 and their mid term examination was held from 19th November 2007.
- The final examination for semester 1 was from 14th January 2008 and 2nd semester was initiated from 28th January 2007.
- The 3rd and 4th semester which mainly comprises of the project work was initiated from 1st June 2008.

7.19 Project work of these students was planned and designed in such a way that the students get good exposure in their respective discipline.

7.20 In Biotechnology the projects focuses on the phenotypic changes which might have a genetic background. Thus, study the phenotype-genotype correlation in our Indian population.

One of the projects is to detect the Multidrug resistant 1 (MDR1) gene polymorphism by studying its correlation with P-Glycoprotein expression in peripheral blood mononuclear cells (PBMCs). Another project on the similar lines is to study the mutations of Fat mass and obesity associated (FTO) gene and to correlate where these mutation have a role to play in the development of obesity also expression of human erythropoietin in *Dictyostelium discoideum* and optimization of the expression of the same for more commercial value. Another interesting thing is we are trying to figure out the leading cause of pathogenesis by performing a comparative genome analysis of pathogenic and non-pathogenic strain of *Mycobacterium tuberculosis* using bioinformatics tools. One of the project deals with IL2 toxicity in two different dosage regimen.

7.21 In Natural products, students are primarily working in interdisciplinary area including phytochemistry, chemistry, pharmacology and analytical chemistry. The majority of the projects are basically bioactivity guided fractionation and activity of the crude extracts and the active fraction by *in vitro* or *in vivo* assays. The basic research is presently focused on Asthma, Diabetes, Hypertension and Cancer. Apart from search for novel molecules from medicinal plants, projects also focus on determining the bioavailability of herbal molecules, extract and formulations along with the development of comparative data on bioavailability upon administration of the isolated single compound and the compound present in the extract to check for synergism mediating bioavailability. Some of the projects are for stability studies for single molecules and detoxification of poisonous plants.

7.22 In Pharmaceutics the students are working with two major approaches:

1. To develop novel drug delivery systems like nano particles, microspheres, mouth dissolving films, controlled release tablets, microemulsions, pulsating drug delivery, controlled release pellets.
2. Alternative routes other than classical oral and parenteral routes for drug delivery mainly in transdermal and intranasal.

7.23 Some of the students in Pharmaceutics and biotechnology are working on Industry projects sponsored by INTAS Biopharma, Century Pharma and Themis Medicare. Some of the students participated in conferences and seminars held in Gujarat or at different parts of the country and presented their project work. Two of these students received prizes for their presentation

7.24 The second batch of NIPER Ahmedabad who was counseled on 15th July 2008 started their classes from 28th July 2008. These students completed their first semester in December 2008 and the second semester is in progress for which the mid term examination got over on March 21st 2009. These students will be completing their 2nd semester by 30th May 2009 and will initiate their project (semester 3) work from 6th July 2009.

Facilities Created

1. Air-conditioned class rooms with LCD monitors for teaching.
2. Air-conditioned seminar room for in-house seminars, symposia and conferences.
3. Several lectures from national and international visiting scientists have been organized for benefit of these students.
4. A two day 8th International Symposium of Controlled Release Society on “Advances in Technology and Business Potential of New Drug Delivery Systems” was organized on 26th and 27th February 2008.
5. Several equipment have been purchased for NIPER students like:
 - Three HPLC's (apart from 9 of PERD Centre)
 - GC with head space (GC with ECD detector of PERD Centre)
 - Fully automated clinical biochemistry analyzer
 - Non invasive blood pressure monitor.
 - Digital plythsmometer
 - Preparative HPLC
 - 24 hours internet connection for all the computers in computer room and Wi fi connection in the entire Centre and Library.
- Canteen for students

Future Plans

7.25 Apart from the routine teaching and project work of the students. NIPER-Ahmedabad is committed to start 2-3 diploma courses and offer the Medical Disposable Industry a helping hand to meet their demands in R & D and other sensitive areas. NIPER-Ahmedabad also would like to start Ph.D program from 2009-2010 batch. PERD Centre has proposed is to create an “INCUBATOR” on the premises of PERD Centre which is a mentor institute where NIPER-Ahmedabad is housed since 2007. PERD has ‘nurtured’ several such start-up companies in the recent past but the limited space constrains have limited its role as an Incubator. As done in the past, PERD will make its investment in terms of its existing infrastructure and equipment

NIPER-GUWAHATI

7.26 Classes in NIPER Guwahati has been started with two stream of master programme on Pharmacology & Toxicology and Pharmacy Practice during the session 2008-09 with the help of Gauhati Medical College and Hospital (GMCH) in the premises of GMCH Guwahati. The faculty support is being provided by GMCH, ITI Gauhati, Guwahati University & through guest faculty through similar institutions.

7.27 Land of 100 Acres has been provided by the State Govt. near CIPET, other institution of this Ministry near ITI, Guwahati. Preliminary work at the site has been undertaken through CIPET. Deptt. In pursing with the State Govt. to provide approach road to this site from National Highway.

NIPER -HAJIPUR

OBJECTIVES AND MANDATE

- Provide leadership in pharmaceutical sciences
- World-class research in novel and emerging areas
- National/International collaborative research
- Human resources development
- Study of sociological aspects of drug use
- Development of germplasm depository for plants of medicinal importance.
- Centre for relevant technology transfer to local population.

7.28 The Institute is running at the Campus provided by the State Government at EPIP Complex Hajipur. Small Laboratory facilities and Hostel facilities have been provided at the Campus. However major Laboratory facilities are being provided by the Mentor Institute (RMRIMS) at Patna. The Institutes and the Mentor Institute are located at opposite Bank of the river Ganga and these are not far of. Presently three courses of master programme are being run at NIPER Hajipur. The faculty is being provided by RMRIS, some of the faculty have been engaged on contractual basis and some guest faculties are being hired from BHU, BIT Mesra

and other places. One Coordinator from NIPER S.A.S Nagar has been appointed to over see the functioning of the Institute so that academic excellence and standard are maintained.

7.29 Presently Government of Bihar has already provided around 12 acres of land and some buildings. Process of allotting 100 acres of land has been under taken by the State Government, which is being pursued by the Department.

ACADEMIC PROGRAMMES

7.30 The institute has started M.S (Pharm) and M. Pharm courses in Pharmacy Practice, Pharmaco-informatics and Biotechnology with a promise of further expansion in the disciplines as soon as the infrastructure and skilled manpower increases. A central library and core computer facility has already been created for supporting the students and faculties within the institute to conduct the courses efficiently. Besides the facilities created at NIPER, Hajipur, the mentor institute RMRIMS, Patna provides all other required technical infrastructure, laboratory, equipments and expertise.

RESEARCH ACTIVITIES (STUDENT PROJECTS)

7.31 The research and development activities are currently centered at the mentor institute RMRIMS, Patna. Students of the first batch are pursuing their project work not only at the mentor institute but also at other leading institutions of Patna under the supervision of selected experts in the field.

7.32 We have established research collaborations with the leading local centers of learning, such as Mahavir Cancer Sansthan, Patna Medical College & Hospital, Nalanda Medical College & Hospital and Indira Gandhi Institute of Medical Sciences (IGIMS).

Board of Research Studios (BRS) has been established.

NIPER Hyderabad

7.33 The first batch (**2007-08**) students of NIPER-Hyderabad are at the fag end of their research projects and are about to submit their thesis. The second batch students (**2008-09**) are also about to complete the second semester Classes in NIPER, Hyderabad has been started in 2007-08 in three disciplines namely Medicinal Chemistry, Pharmaceutical Analysis, Pharmacology and toxicology.

7.34 NIPER Hyderabad has been started in the R&D Centre of IDPL, Hyderabad. The land of around 150 acres has been provided by IDPL with the consent of State Govt. In addition, some buildings of R&D Centre, old hostel & some residential complex/Guest house of IDPL have been provided by IDPL some of the buildings have been renovated with the help of APPIC.

7.35 At NIPER-Hyderabad, students are trained for their soft skills, subjects concern to the specialization, practical exposure to sophisticated instruments and also personality development. Numerous people from academia and industry from India and abroad contributed to NIPER-Hyderabad by delivering extension lectures and shared their experiences. Further, the students are encouraged to present their new ideas in the form of seminars and conferences which will enable them to interact with the scientists, dignitaries and other participants from across the world. Moreover, students are allowed to participate in scientific symposiums, plenary lectures

7.36 NIPER-Hyderabad also involved in conducting several symposia in the campus of NIPER. M/s Jai Research foundation and Royal Society of Chemistry Deccan branch conducted a day symposia during September 2008 and February 2009 at NIPER- Hyderabad

7.37 Recently, the Secretary of Dept. of Pharmaceuticals, Ministry of Chemicals and fertilizers, Shri Ashok Kumar inaugurated modern molecular modeling laboratory of NIPER-Hyderabad. This facility will enable to obtain the insight in this area of new techniques involving lead identification and optimizations, for the rational drug discovery programs. In this event, Secretary released first NIPER- Hyderabad magazine VEDEM-2009. This comprises the efforts made by the contribution of students, staffs and guest faculties of NIPER Hyderabad highlighting even the extracurricular activities of this institute

NIPER-Kolkata:

7.38 The Institute is presently housed at the Indian Institute of Chemical Biology (IICB) – a premier Institute of the Council of Scientific & Industrial Research (CSIR), India. IICB was established in 1935 as the first non-official centre in India for biomedical research and was included within the aegis of CSIR in 1956.

Objectives: The main objectives of NIPER-Kolkata are:

- To tone up the level of pharmaceutical education and research.
- To produce leaders in the field and provide opportunities for training of future teachers and research scientists for the industry and the profession. To be a centre for innovation in pharmaceutical sciences and technology. To encourage research and studies in new

and emerging areas like discovery of pharmacologically active molecules, cellular and molecular biology, immunology and immunodiagnosics, recombinant DNA technology and monoclonal antibody technology, novel drug delivery systems, chemical and biochemical process technology, etc. To provide scientific footing to traditional medicines.

Academic status:

Classes have been started in discipline of Master Programme:

1. Medicinal Chemistry
 2. Natural Products
 3. Pharmacoinformatics
- **Session 2007-2009 (First batch):** 1st Semester, 2nd Semester and 3rd Semester classes and examinations have been completed. The 4th Semester project work is in progress. The 4th Semester Examination is scheduled to be held in July, 2009.
 - **Session 2008-2010 (Second batch):** 1st Semester classes and examination has been completed. 2nd Semester classes are underway and the examination is scheduled to be held in July, 2009.
 - The Institute has organised some lectures by eminent academicians both from Universities and Industries.
 - **The Faculty:** The faculty selected for teaching various courses of NIPER-Kolkata comprises eminent teachers and scientists belonging to IICB and Universities such as Calcutta University, Jadavpur University and West Bengal State University at Barasat, Research Institutes such as Indian Association for the Cultivation of Science, Bose Institute, Saha Institute of Nuclear Physics, and Central Research Institute (Ay) at Salt Lake, and Industries such as TCG Life Sciences at Salt Lake and Chem biotech. The first batch of students at the 4th Semester are carrying out their project work at well known centres of research like IICB, Jadavpur University, Bose Institute, Saha Institute of Nuclear Physics, Chembiotek and TCG Life Sciences.
 - **Placement Cell:** In order to implement the job prospects of the M. S. (Pharm.) students, the Placement Cell for these students has been set up with Dr. J.R. Vedosiromoni as the Placement Cell Coordinator and the cell has already started functioning.
 - **Future Plan:** The Government of West Bengal has agreed to provide 35 acres of land for NIPER- Kolkata in the Institutional area at Baruipur R & D Hub. This would include 25 acres for NIPER and 10 acres for common facilities to be anchored by NIPER. The

common facilities, which include convention centre, library, guest house/hotel, etc., shall be constructed by NIPER but would serve all institutions.

NIPER, Rae Bareli.

7.39 NIPER, Rae Bareli started functioning with the starting of classes in two streams viz. Medicinal Chemistry and Pharmaceutical in 2008-09 at the rental building provided by ITI, Rae Bareli. The Mentor Institute, the CDRI, Lucknow in providing full support in the form of faculty & laboratories, the CDRI, Lucknow has massive Lab Machines will state of the art technologies, which have been provided for NIPER, students for their lab work. The small labs have been set up at Rae Bareli and students are taken to CDRI for major Lab works during weekend/occasionally. Some faculty on contractual basis have been engaged and some guest faculty are being called also. NIPER Rae Bareli in collaboration with CDRI Lucknow has organized the first “CDRI-NIPER (RBL) Symposium” focusing on Medicinal Chemistry & Pharmaceutics during 24th-26th March 2009 and has seen strong participation of M Pharma students. Lectures on Topics of current interest were delivered by advances researchers of the country.

7.40 The issues of land to be provided by the State Govt. is being pursued but nothing lazgible has been resolved. The Deptt. is pursing with the State Govt. & also with ITI Rae Bareli to provide required is atleast necessary land for further development.

New initiative in six new NIPERS:

A. Short Term Courses

- **NIPER Hyderabad has started the following 3 courses:**
 - i. Clinical Research
 - ii. Advanced Instrumental Methods in Pharmaceutical Analysis
 - iii. Pharmaceutical Export Management
- **NIPER Hajipur: - 6 months courses in i. Bio Informatics ii. Clinical Research and iii. Lesimaniasis are being started**
- **NIPER Ahmadabad:- Short term courses in i. clinical Research ii. Operational Excellence & IT iii. Medical devices being started.**
- **NIPER Guwahati:- Short term courses on herbal medicine is being started.**
-

B. Incubator Facility

- Incubator facility started at NIPER Ahmedabad. Budget requirement is Rs. 2.50 crores.
- Proposal to create Incubator facilities at Hyderabad is being firmed up.
- Incubator facility at NIPER, Mohali already underway with system Biology worldwide.

CHAPTER VIII

General Administration

ORGANISATION SET UP

8.1 The main activities of the Department are policy making, sectoral planning promotion and development of pharmaceutical industries, R&D, International Co-operation in Pharmaceuticals. The administrative and managerial control of the public sector undertakings engaged in the manufacture of various pharmaceuticals and some other organizations is another major function of the Department.

8.2 The Department is headed by Secretary to the Government of India who is assisted by two Joint Secretaries, one Economic Adviser and one Deputy Director General.

8.3 There is an attached office namely “National Pharmaceutical Pricing Authority” which looks after Price fixation/revision of pharmaceuticals and other related matters. It also monitors the prices of decontrolled drugs and formulation and oversees the implementation of the provisions of the Drug (Price Control) Order. In addition, there are 5 public sector undertakings and 7 other organizations under the administrative control of the Department. The names of these are given in Annexure .

EMPLOYMENT OF SCHEDULED CASTES/SCHEDULED TRIBES/PHYSICALLY HANDICAPPED IN THE MAIN SECRETARIAT OF THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS

8.4 The status of employment of Scheduled Castes/Scheduled Tribes/Physically handicapped in the main Secretariat of the Department of Pharmaceuticals as on 31.1.2008 is as under:

Group	Total No. of posts	Scheduled Castes	Scheduled Tribes	Physically Handicapped
A				
B				

C				
D				
TOTAL				

8.5 Officers in Group A include officers belonging to Central Secretariat Service besides officers on deputation from All India Services, Central Services and other Departments/ Undertakings. Appointment to posts in Group B and C is mostly done on the basis of nominations made by the Department of Personnel & Training.

8.6 The Department also monitors the progress of filling up of the posts reserved for Scheduled Castes, Scheduled Tribes and other Backward Classes in the Public Sector Undertakings under its administrative control .

Record Management

8.7 The Parliament had enacted “The Public Records Act 1993” to regulate the management, administration and reservation of Public Records of the Central Government, Union Territory Administrations, Public Sector Undertakings, statutory bodies and corporations etc. The Central Government has also made the rules to carry out the provisions of the Act. In terms of the provisions and terms contained in Section 5(1) of the Act, the Under Secretary Incharge of General Administration has been nominated as Records Officer in the Department. The requisite reports and returns are being sent to National Archives of India (NAI) regularly.

Information Technology (IT Plan)

8.8 In the Budget estimates 2008-09 under IT Expenses (Plan) head, there was a budget provision of Rs. 50.00 lac for implementation of IT Plan of the Department. The Administrative Division procured various hardware and software for the implementation of IT Plan in the Department. As part of e-Goverence, the Office Procedure Automation (OPA) System, Comprehensive DDO Package (for pay bill ,GFP etc. and Public Grievances Redress and monitoring system(PGRAMS) have been fully implemented in the Department. The Department has been provided with local area network (LAN) facility. In compliance with the Government of India’s order relating to e-Procurement. All the Tender inviting Notices issued by the Department were uploaded on the website of the Department.

Information Technology Initiative

8.9 Internet portal for the department is operational to provide various information to employees like monthly pay slip. A web based application is also operational for intra document sharing. Department website is also operational in Hindi & English. It is regularly updated.

8.10 A web based “Production Monitoring System” is also implemented for the Monitoring Division to generate various reports and queries on production, Import/Export data from the chemicals and petrochemical sector.

8.11 The department has been provided with LAN facility with Internet network on fibre backbone upto L2 switch level.

USE OF HINDI IN OFFICIAL WORK

8.12 The Department of Pharmaceuticals has come into existence on the 1st July, 2008. Compliance of statutory provisions and Presidential Orders on the Official Language policy of the Government in the Department and also in its’ attached and subordinate offices is ensured.

8.13 All documents like Annual Report, outcome Budget, Demand for grants, Parliament Questions & Assurances, material for Standing committee, C& AG Reports, Cabinet notes, updation of Departmental website etc. and the documents falling under Section 3 (3) of the Official Language Act, 1963 were issued in bilingual form. All letters received in Hindi were replied to in Hindi as per Rule 5 of the Official Language Rules, 1976. Efforts were made to progressively increase the use of Hindi in day to day official work as set out in the Annual Programme formulated by the Department of Official Language.

8.14 Hindi Fortnight was organized in the Department from 01st to 15th September, 2008. During this period, seven competitions in Hindi Essay, Noting and Drafting, Translation, Debate, Slogan writing and Typing were held. A competition on Hindi dictation and text writing

exclusively for Group 'D' employees was also held. Separate prizes were earmarked for non-Hindi speaking officers and staff. The meritorious participants were given cash prizes by Secy C&PC) in a formal function held on 4th November, 2008. Secretary (Pharma) and senior officers of both the Departments.

OFFICIAL LANGUAGE IMPLEMENTATION COMMITTEE

8.16 The Department has an Official language Implementation Committee under the chairmanship of Joint Secretary and its' meetings were held regularly. The progress made in the use of Hindi was reviewed and suggestions for further improvement were adopted for compliance.

HINDI SALAHAKAR SAMITI

8.17 A Joint Hindi Salahkar Samiti of the Ministry under the chairmanship of the Hon'ble Minister has been reconstituted by the Deptt. of Fertilizers. Two meetings of the Samiti was held on 5th April, 2008 and 10th February,2009 respectively.

FOLLOW UP ACTION ON THE MINUTES OF THE CENTRAL OLIC

8.18 33rd meeting of the Central Official Language Implementation Committee was convened by the Department of Official Language under the Chairmanship of Secretary (OL) on 22nd September, 2008 which was attended by an officer of the Department. Follow up action on the minutes of the meeting has been initiated in the Department. All offices under the Department have also been instructed to take necessary action in this regard.

QUARTERLY PROGRESS REPORTS/ANNUAL ASSESSMENT REPORT

8.19 Quarterly progress Reports for each quarter during the year were compiled on the basis of inputs received from different sections of the Department and sent to the Department of Official language for inclusion in the data base. Reports received from attached and subordinate offices were reviewed and deficiencies found therein were suggested for rectification. Follow up action on the observations of the Department of Official Language on the Annual Assessment Report

was initiated in the Department and necessary instructions were imparted to the attached office, institutes and PSUs.

TRAINING UNDER HINDI TEACHING SCHEME

8.20 In order to impart proficiency/working knowledge of Hindi, officers and employees not possessing such knowledge, are sent for in-service training as per the programme formulated by the Hindi Teaching Scheme, Department of Official Language. Staff members are also sent for Hindi stenography and typing training under the same scheme. On successful completion of such training, they are given advance annual increments and cash awards depending on their performance ratings.

CASH AWARD SCHEME

8.21 There is an annual cash award scheme under which officers/employees doing their official work in Hindi are required to maintain their daily work sheet for the entire year and submit it for evaluation by the screening committee constituted in the Department.

INSPECTION BY THE COMMITTEE OF PARLIAMENT ON OFFICIAL LANGUAGE

8.22 The first sub-committee of the Committee of Parliament on Official Language visited Hindustan Antibiotics Limited(HAL), Pune and Bengal Chemicals & Pharmaceuticals Limited(BCPL), Kolkata during the year 2008-09 to make assessment of official work in Hindi in these offices. Follow-up action reports on assurances given to the sub-committee by different offices inspected during the previous year were sent to the Committee office after review by the Department.

INSPECTION OF OFFICES BY THE DEPARTMENT

8.23 Efforts are made to carry out inspections in at least 25 per cent offices during a financial year. At the same time, as and when inspection of an office is planned by the Parliamentary Committee, the departmental officers visiting that office also carry out inspection of that office for bringing in improvement in the implementation of provisions of Official Language. The

officers have also been advised to assess the progress of Hindi in official work whenever they go on tour to the offices under the administrative control of the Department.

Grievances Cell.

8.24 As per instructions from Hon'ble Minister of Chemicals & Fertilizers. Grievance cell was established in the Office of Minister Chemicals and Fertilizers, Department of Chemicals & Petrochemicals in the month of July, 2004.

8.25 This Cell is monitoring grievances related to all Chemicals, Petrochemicals and pharmaceuticals viz. Their Availability, Quality, Pricing, Policy Matters etc. One of the main objective for opening of this cell was to make available medicines to common man at affordable prices.

8.26 Publicity about the setting up of this Grievances Cell was given through the National daily newspapers of Hindi and English. The on line Grievance Redressal Mechanism, Public Grievances Redressal and Monitoring System (PGRAMS) has been brought into operation w.e.f. 1st August, 2005. Recently an online Centralized Public Grievance Redressal and Monitoring System (CPGRAMS) has also been introduced by Department of Administrative Reforms and Public Grievances (DARPG).

8.27 Under Ministry of Chemicals & Fertilizers, Department of Pharmaceuticals has been created in July 2008. The grievances pertaining to the Department of Pharmaceuticals are also been taken care by this grievance cell functioning under the office of Minister Chemicals & Fertilizers. For giving wide publicity to the Grievance Cell, information has been uploaded on the websites of Department of Chemicals & Petrochemicals and Department of Pharmaceuticals and also on the websites of the Institutions/Organizations falling under their purview. Links are given with the home pages of Department of Chemicals and Petrochemicals and Department of Pharmaceuticals to access CPGRAMS with the websites of the Institutions/Organizations under Department of Chemicals & Petrochemicals and Department of Pharmaceuticals. Grievance Cell plays a vital role in the redressal of grievances of common man.

Data of Production of selected Bulk Drugs based on the Production Return received from the companies for the year 2005-06 and 2006-07 and 2007-08.

S.No	Name of the Therapeutic Group and Bulk Drugs	Unit	2005-06	2006-07	2007-08
I	ANAESTHETICS				
1	Lignocaine / Xylocaine / Lidocaine	MT	78.291	78.453	69.590
2	Procaine	MT	N.A.	N.A.	N.A.
II	ANALGESICS & ANTIPYRETIC				
	E				
3	Analgin / Metamizole (s)	MT	231.412	353.357	240.882
4	Aspirins (s)	MT	1213.693	1072.271	921.378
5	Ibuprofen (s)	MT	5406.590	1083.511	5986.000
6	Oxyphenylbutazone	MT	N.A.	N.A	N.A
7	Paracetamol	MT	N.A.	5185.428	N.A
8	Pethidine	MT	0.197	0.232	N.A
9	Phenylbutazone	MT	N.A.	N.A.	N.A
10	Piroxicam	MT	0.420	N.A.	N.A
III	ANTI-ASTHAMATICS				
11	Aminophylline (s)	MT	8.445	10.933	5.695
12	Ephedrine (s)	MT	190.039	380.363	241.310
13	Salbutamol (s)	MT	4.837	8.017	9.591
14	Terbutaline	MT	0.137	1.046	0.599
15	Theophylline (s)	MT	62.000	208.364	N.A
IV	ANTI-BIOTICS				
16	Amoxicilline	MT	1100.290	621.088	1034.485
17	Ampicilline	MT	89.940	101.330	23.990

18	Cephalexin	MT	708.652	914.617	949.831
19	Chloramphenicol Palmitate	MT	30.655	N.A	N.A
20	Chloramphenicol Powder	MT	44.024	12.180	5.241
21	Cloxacillin (s)	MT	62.990	57.510	1.198
22	Doxycycline (s)	MT	1.281	7.259	1.350
23	Erythromycin (s)	MT	166.241	297.596	156.628
24	Framycetin (s)	MT	N.A.	N.A.	N.A.
25	Gentamycin (s)	MT	N.A.	N.A.	N.A.
26	Griseofulvin (s)	MT	N.A.	N.A.	N.A.
27	Oxytetracycline (s)	MT	N.A.	N.A.	N.A.
28	Penicillin (s)				
	a. Penicillin G 1st Crystal	MMU	2012.266	1002.74	1595.421
	b. Penicillin G Procaine	MMU	69.194	0.000	N.A.
	c. Penicillin G Sodium	MMU	48.929	0.000	N.A.
	d. Penicillin G Benzathine	MMU	3.470	3.910	23.210
29	Rifampicin (s)	MT	383.567	317.690	399.271
30	Streptomycin (s)	MT	0.100	0.100	N.A.
31	Tetracycline (s)	MT	N.A.	N.A	N.A.
V ANTI-DIABETICS					
32	Chlorpropamide (s)	MT	9.260	11.351	4.300
33	Glibenclamide	MT	6.813	14.891	5.155
34	Insulin (s)	KG	89.662	N.A	120.75
35	Tolbutamide	MT	19.801	17.726	10.551
VI ANTI-DYSENTRY DRUGS					
36	Diloxanide Furoate	MT	N.A.	N.A	N.A
37	Iodo Chloro Hydroxy Quinoline (s)	MT	165.252	120.852	129.390
38	Metronidazole (s)	MT	2993.492	1886.168	1956.828
39	Tinidazole	MT	510.688	600.779	654.085
VII ANTI-FILARIALS					
40	Diethyl Carbamazine (DEC Citrate)	MT	0.000	N.A	40.974

VIII	ANTI-HELMENTICS				
41	Mebandazole	MT	N.A.	N.A	N.A
42	Piperazine and Salts	MT	40.650	N.A	N.A
43	Pyrantel Pamoate (s)	MT	N.A.	N.A	N.A
44	Tetramisole / Levamisole	MT	N.A.	N.A	N.A
IX	ANTI-HISTAMINS				
45	Diphenhydramine	MT	N.A.	N.A	53.122
46	Pheniramine Maleate (s)	MT	52.095	65.104	56.119
X	ANTI-LEPROTICS				
47	Clofuzamine	MT	N.A.	N.A	N.A
48	Dapsone	MT	N.A.	N.A	N.A
XI	ANTI-MALARIALS				
49	Amodiaquin (s)	MT	0.000	N.A	3.871
50	Chloroquine (s)	MT	374.702	302.894	287.521
XII	ANTI-T.B. DRUGS				
51	Ethambutol	MT	722.287	1092.450	932.522
52	INH	MT	N.A.	N.A	N.A
53	Pas & its Salts	MT	N.A.	N.A	19.145
54	Pyrazinamide	MT	184.400	178.100	182.400
55	Thiacetazone	MT	0.000	0.000	N.A
XIII	CARDIOVASCULAR DRUGS				
56	Digoxin	MT	N.A.	N.A	N.A
57	Methyl Dopa (s)	MT	N.A.	N.A	N.A
58	Propranolol	MT	0.100	0.200	N.A
59	Xanthinol Nicotinate	MT	2.721	0.000	N.A
XIV	CNS STIMULANTS				
60	Caffeine	MT	N.A.	N.A.	N.A
61	Nikethamide	MT	N.A.	N.A	N.A

XV CORTICOSTEROIDS

62	Betamethasone (s)	MT	2.147	3.971	4.311
63	Dexamethasone (s)	MT	N.A.	N.A	N.A
64	Hydrocortisone	MT	0.181	N.A	N.A
65	Prednisolone (s)	MT	6.840	N.A	N.A

XVI DIURETICS

66	Acetazolamide	MT	N.A.	N.A	N.A
67	Furosemide (s)	MT	N.A.	N.A	N.A
68	Hydrochlorothiazide	MT	36.300	43.198	43.363
69	Spironolactone	MT	N.A.	1.391	N.A.

XVII GASTRO INTESTINAL

70	Ranitidine (s)	MT	836.241	925.309	931.123
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XVIII OTHER ANTI-BACTERIALS

71	Nalidixic Acid (s)	MT	12.005	N.A	N.A
72	Trimethoprim (s)	MT	312.797	395.912	239.918

XIX Sulpha Drugs

73	Sulphacetamide	MT	N.A.	N.A	N.A
74	Sulphadiazine (s)	MT	N.A.	N.A	N.A
75	Sulphadimidine (s)	MT	N.A.	N.A	N.A
76	Sulphaguanidine	MT	N.A.	N.A	N.A
77	Sulphamethoxazole (s)	MT	N.A.	N.A	N.A
78	Sulphamoxole (s)	MT	N.A.	N.A	N.A
79	Sulphaphenazole	MT	N.A.	N.A	N.A
80	Sulphasomidine	MT	N.A.	N.A	N.A

XX TRANQUILIZERS & SEDATIVES

81	Diazepam	MT	N.A.	5.620	5.356
82	Imipramine	MT	N.A.	3.893	N.A.
83	Nitrazepam	MT	0.382	0.610	0.391
84	Phenobarbitone	MT	6.250	19.005	24.711

85	Trifluoperazine	MT	N.A.	N.A	N.A
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XXI VITAMINS

86	Folic Acid	MT	N.A.	N.A	N.A
87	Nicotinamide	MT	600.498	450.08	502.787
88	Nicotinic Acid	MT	174.559	203.350	205.060
89	Vitamin A (s)	MT	81.315	30.87	36.721
90	Vitamin B1 / Thiamine (s)	MT	N.A.	N.A	N.A
91	Vitamin B12	MT	N.A.	N.A	N.A
92	Vitamin B2 (s)	MT	N.A.	N.A	N.A
93	Vitamin B6	MT	N.A.	N.A	N.A
94	Vitamin C / Ascorbic Acid (s)	MT	422.029	N.A	143.625
95	Vitamin D3	MT	N.A.	N.A	N.A
96	Vitamin E (s)	MT	241,648	266.645	269.785

NA : Not Available / not reported.

(s) : Scheduled Bulk Drugs out of 74 bulk drugs specified in the DPCO, 1995.

Source: monthly production submitted by selected companies

2008-09								Annexure-II
PRICES OF SCHEDULED BULK DRUG/DERIVATIVES FIXED /REVISED BY NPPA								
SINCE ITS INCEPTION								
S.No.	NAME OF THE DRUG		Existing		Revised		%	Remarks
1	Analgin	1385(E)	459.00	29.09.06	503.00	05.06.08	9.59	Increase
2	Nalidixic Acid	1386(E)	1591.00	20.03.08	1749.00	05.06.08	9.93	Increase
3	Spironolactone	1387(E)	25667.00	24.03.05	29601.00	05.06.08	15.33	Increase
4	Frusemide	1388(E)	1442.00	21.03.07	1225.00	05.06.08	-15.05	Decrease
5	Vitamin E Acetate	1942(E)	754.00	20.03.08	768.00	04.08.08	1.86	Increase
6	PCMX	1943(E)	248.00	20.03.08	273.00	04.08.08	10.08	Increase
7	Metronidazole	1944(E)	471.00	07.02.06	526.00	04.08.08	11.68	Increase
8	Metronidazole Benzoate	1944(E)	401.00	07.02.06	447.00	04.08.08	11.47	Increase
9	Ranitidine Hcl	1945(E)	615.00	20.03.08	691.00	04.08.08	12.36	Increase
10	Cefotaxime Sodium (Sterile)	1946(E)	6673.00	20.03.08	6805.00	04.08.08	1.98	Increase
11	Sulphamethoxazole	2269(E)	361.00	20.03.08	397.00	25.09.08	9.97	Increase
12	Potassium penicillin G	2270(E)	1106.00	20.08.01	629.00	25.09.08	-43.13	Decrease
13	Potassium penicillin V	2270(E)	1001.00	20.08.01	569.00	25.09.08	-43.16	Decrease
14	Benzathine Penicillin G	2271(E)	2670.00	01.06.07	3319.00	25.09.08	24.31	Increase
15	Salbutamol Sulphate	2272(E)	4748.00	20.03.08	4478.00	25.09.08	-5.69	Decrease
16	Human Insulin	2273(E)	3105620.00	20.03.08	3396087.00	25.09.08	9.35	Increase
17	Vitamin C (Plain)	2729(E)	366.00	27.07.07	544.00	25.11.08	48.63	Increase
18	Vitamin C (Coated)	2729(E)	353.00	27.07.07	533.00	25.11.08	50.99	Increase
19	Sodium Ascorbate	2729(E)	381.00	27.07.07	575.00	25.11.08	50.92	Increase
20	Chloroquine Phosphate	2730(E)	717.00	20.03.08	874.00	25.11.08	21.90	Increase
21	Chloroquine Sulphate	2731(E)	1692.00	18.12.92	1248.00	25.11.08	-26.24	Decrease
22	Ibuprofen	2732(E)	442.00	20.03.08	486.00	25.11.08	9.95	Increase
23	Analgin	2733(E)	503.00	05.06.08	553.00	25.11.08	9.94	Increase
24	Chloroquine Phosphate	2865(E)	874.00	25.11.08	871.00	11.12.08	-0.34	Decrease
25	Chloroquine Sulphate	2866(E)	1248.00	25.11.08	1244.00	11.12.08	-0.32	Decrease
26	Theophylline	252(E)	438.00	29.11.07	512.00	22.01.09	16.89	Increase
27	Hydroxy Ethyl Theophylline	252(E)	504.00	29.11.07	534.00	22.01.09	5.95	Increase
28	Vitamine E Acetate	253(E)	768.00	04.08.08	1156.00	22.01.09	50.52	Increase
29	Chloroquine Phosphate	637(E)	871.00	11.12.08	861.00	06.03.09	-1.15	Decrease
30	Chloroquine Sulphate	638(E)	1244.00	11.12.08	1230.00	06.03.09	-1.13	Decrease
31	Famotidine	639(E)	1042.00	29.11.07	1218.00	06.03.09	16.89	Increase
	First Time		14	cases*				Since Inception of NPPA
	No Change		5	cases				Bulk Drug - 290
	Increases		108	cases				Derivative -162
	Decreases		325	cases				Total - 452
			452	cases				

List of Public Sector Undertaking and Other Organization under the Administrative Control of the Department of Pharmaceuticals.

ATTACHED OFFICE

NATIONAL PHARMACEUTICAL PRICING AUTHORITY (NPPA)

PUBLIC SECTOR UNDERTAKINGS

1. Bengal Chemicals and pharmaceuticals Limited, Kolkata, West Bengal.
2. Hindustan Antibiotics Limited. Pimpri, Pune, Maharashtra.
3. Indian Drugs and pharmaceuticals Limited, Dundaheera Industrial Complex, Dundaheera, Gurgaon, Haryana.
4. Karnataka Antibiotics and Pharmaceuticals limited,
5. Rajasthan Drugs and Pharmaceuticals Limited.

OTHER ORGANISATIONS

**NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION & RESEARCH, (NIPER),
SAS NAGAR, MOHALI, PUNJAB**

SIX NEW NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH (NIPERs) are as under:-

1. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH, Ahmedabad (Gujrat).
2. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH Hyderabad (Andhra Pradesh).
3. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH Hajipur (Bihar).
4. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH Kolkata (West Bengal).
5. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH
6. Rae Bareilly (U.P.).
7. NATIONAL INSTITUTES OF PHARMACEUTICAL EDUCATION & RESEARCH Guwahati (Assam).