



Third Round Up of Developments in the Pharmaceutical Sector July, 2009

From: Secretary (Pharmaceuticals)

Dear Readers

We had given our 2nd Round up in the month of April, 2009 on our website for the period upto March, 2009. I would like to keep you abreast of the further developments and initiatives taken by us and present a synoptic view of the sector through these round-ups. Let me now present our third round up, starting with the vision statement:

'To enable Indian pharmaceuticals industry to ensure abundant availability, at reasonable prices within the country, of good quality pharmaceuticals of mass consumption and to play a leading role in the global market'.

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 DoP² 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. DoP is also engaged in some of the newer areas of responsibilities pertaining to Pharma Research and Development (R&D), Education, training and capacity building in pharmaceuticals sector, related environment and hazard management, as well as promoting higher exports for greater share in the global market.

¹ *Active Pharmaceuticals Ingredients*

² *Department of Pharmaceuticals*

2. Structure of Indian Pharmaceutical Industry:

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 the advanced regulated markets of US and Western Europe. Indian pharma industry employs over 42 lakhs directly and indirectly. 40% of the world's bulk drug requirement is met by India.

3. Investments in the Pharmaceuticals Sector

3.1 Foreign Direct Investment (FDI)

The Pharmaceuticals sector has been able to attract FDI amounting to Rs.21409 million during the period from April, 2007 to April, 2009 including Rs. 43.42 million in the first month of the current year. Out of 36 countries which contributed to FDI in India, 5 countries, led by Mauritius (56.36%), Singapore (11.18%), USA (5.81%), UAE(4.73%) and Canada(4.00%), accounted for over 82% of FDI in Drugs & Pharmaceuticals(Table-1).

Table-1: FDI Inflows in Drugs & Pharmaceuticals during April, 2007 To April, 2009

(Rs. Million, %)

S.N.	Country	2007-08	2008-09	2009-10 (Apr-09)	Cumulative Total	% Share	Cumulative %
1	Mauritius	8497.96	3567.02	0.00	12064.98	56.36	56.36
2	Singapore	1020.16	1374.15	0.00	2394.31	11.18	67.54
3	U.S.A.	1202.75	40.11	0.00	1242.86	5.81	73.34
4	U.A.E.	6.80	971.95	34.55	1013.31	4.73	78.08
5	Canada	475.93	381.20	0.00	857.13	4.00	82.08
6	Others	2060.68	1766.73	8.87	3836.26	17.92	100.00
Grand Total		13264.28	8101.16	43.42	21408.85	100.00	

Source: Department of IPP, Ministry of Commerce & Industry

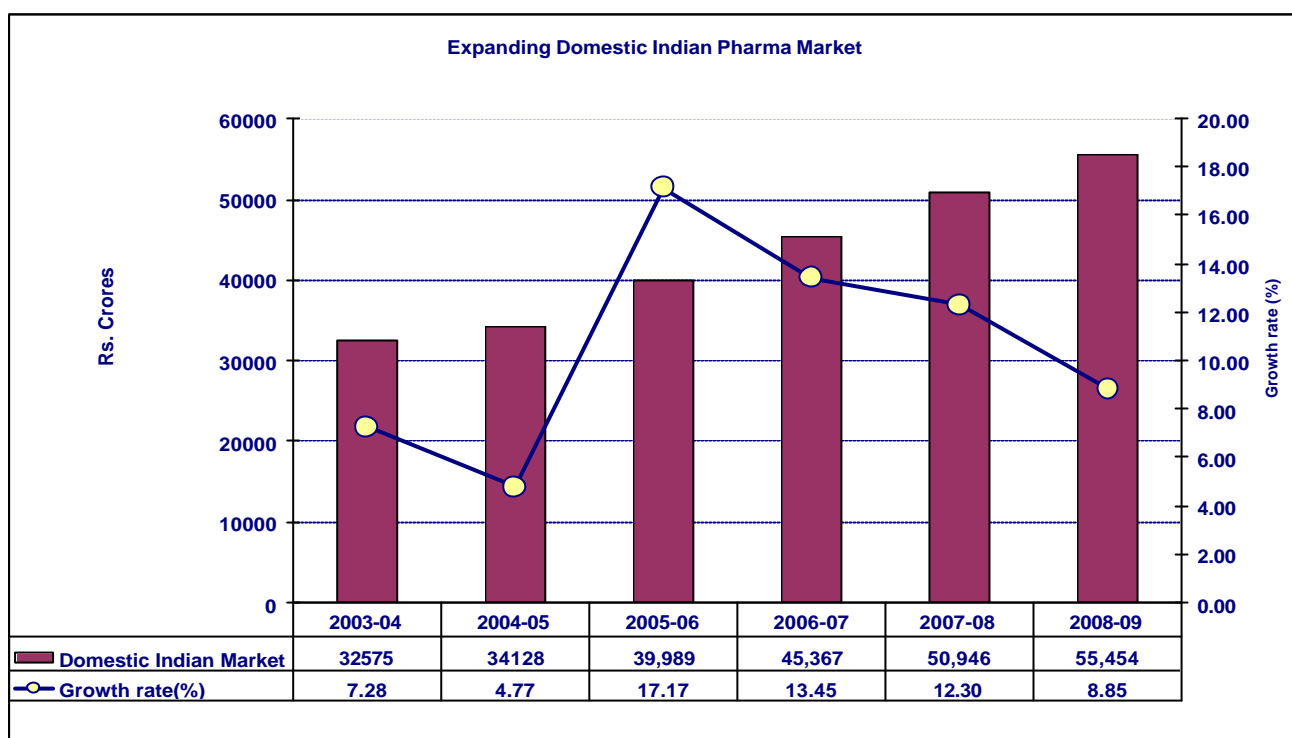
There were 208 foreign collaborators during the period April, 2007 to April, 2009 in so far as Drugs & Pharmaceuticals are concerned. Of these, top 10 foreign collaborators contributed 48.70% of FDI. Further, out of top 10 collaborators, 7 were from Mauritius and one each from Singapore, UAE and USA as may be seen from the Table-2.

Table-2 : Foreign Collaborator and Corresponding FDI inflows in Drugs & Pharmaceuticals during April, 2007 to April, 2009
(Rs. Million, %)

S.N.	Indian Company	Country	Foreign Collaborator	FDI	% Share	Cumulative %
1	Global Health Pvt Ltd	Mauritius	G L Asia Mauritius Ltd	2,246.66	10.49	10.49
2	Ravindranath Ge Medical Associates	Mauritius	Indivision India Partners	1,250.00	5.84	16.33
3	Bioplus Life Sciences Pvt. Ltd.	Mauritius	Aif Capital Iii Life Science Ltd.	1,174.18	5.48	21.82
4	Aptuit Laurus P. Ltd.	Singapore	Aptiuit (Singapore) P. Ltd.	1,020.00	4.76	26.58
5	Gland Pharma Ltd.	Mauritius	Eilsf Coinvest Illc	1,000.00	4.67	31.25
6	Peoples Intl And Services P Ltd	U.A.E.	Alliance Industries Ltd	956.33	4.47	35.72
7	M/S Sai Advantium Pahrma Ltd.	Mauritius	Mpm Investment Mauritius	803.54	3.75	39.47
8	Unimark Remedies Ltd	Mauritius	Cvcigp li Client Rosehilli	728.62	3.40	42.88
9	Care Stream Health Ind	U.S.A.	Care Stream Healthcare	647.59	3.02	45.90
10	Themis Laboratories Pvt Ltd	Mauritius	Nylim Jacob Ballas India Fund Iii Llc	600.00	2.80	48.70
	Others			10981.93	51.30	100.00
	Grand Total			21,408.85	100.00	

3.2 Domestic sector

The Domestic pharma sector had been monotonously expanding and has crossed Rs.55 thousand crores in 2008-09 from Rs. 32 thousand crores in 2003-04, as exhibited in the Chart.



4. Exports Of Drugs & Pharmaceuticals

Exports of Drugs and Pharmaceuticals from 2002-03 to 2009-10 (May,09) are given in the Table-3:

Table-3 : Growth of Exports of Drugs and Pharmaceuticals

(Rs in Crores, %)

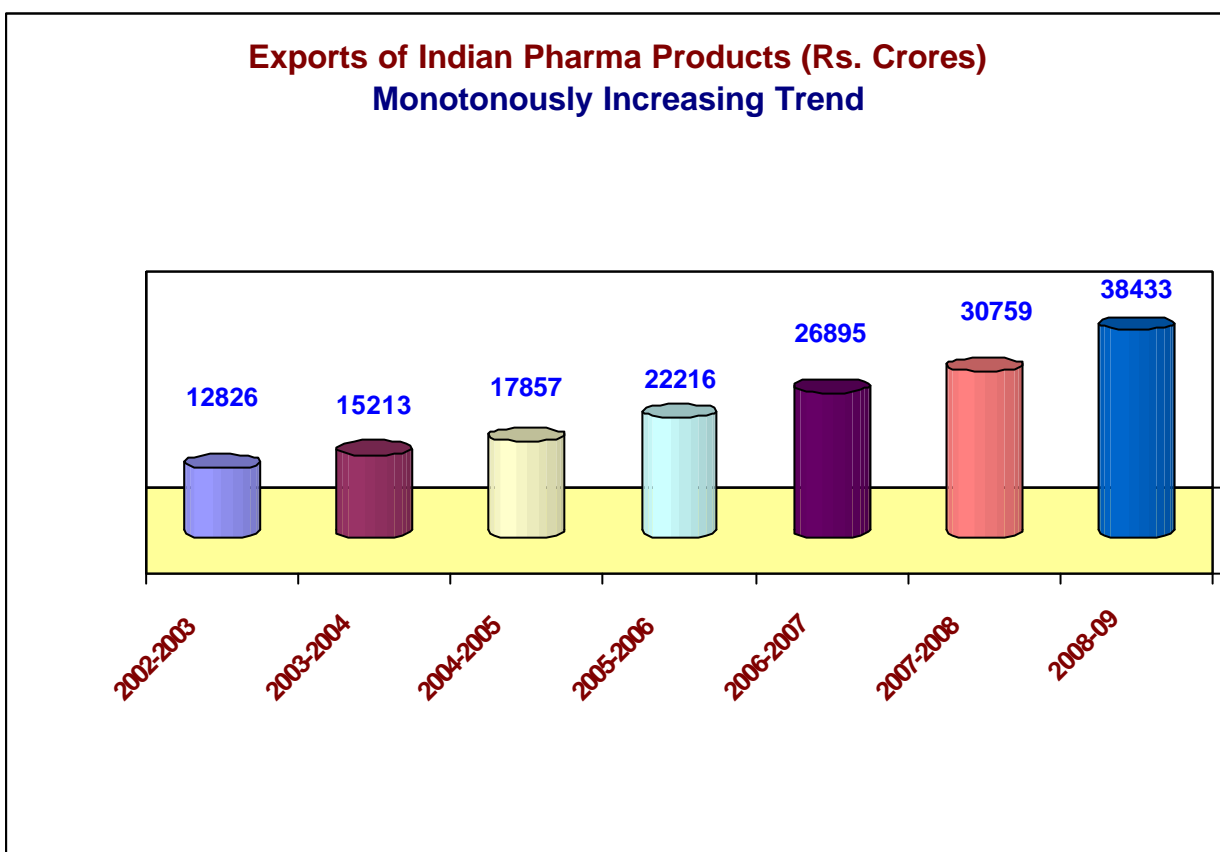
Year	Exports	Growth %
2002-03	12826	
2003-04	15213	18.61
2004-05	17857	17.38
2005-06	22216	24.41
2006-07	26895	21.06
2007-08	30760	14.37
2008-09	38433	24.94
April, 2009	3043	14.80
April-May, 2009	5775	2.50

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

- i. Exports of pharmaceuticals have been consistently outstripping the value of corresponding Imports in the period 1996-97 upto 2008-09. The

trade balance increased from Rs. 2157 crores in 1996-97 to Rs. 29881 crores in 2008-09.

- ii. Exports of pharmaceuticals at Rs 38433 crores in FY 2008-09 registered a growth rate of 25% in 2008-09. This is quite impressive, given the growth in the country's total exports of all commodities was at 16.9% in the corresponding period.



- iii. India currently exports drug intermediates, APIs, Finished Dosage Formulations (FDFs), bio-Pharmaceuticals, Clinical Services to various parts of the world.
- iv. The top 5 destinations of Indian pharmaceutical products during the year 2007-08 are USA, Germany, Russia, UK and China .
- v. There was a sharp growth at 40% in exports to Brazil during April-Feb, 2009, according to CMIE.

- vi. 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 billion by 2012.

5. Pharma Export Promotion Council (Pharmexcil)

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 authorized 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.

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

- i. Organization of 40th Annual conference of Indian Pharmacological Society at NIPER, Mohali.
- ii. Organizing International Conference on Pharmaceutical Market Prognosis-2012 in collaboration with FICCI.
- iii. Organization of International Seminar on Pharmaceutical Pricing & Regulatory Framework for Affordable Medicines by NPPA
- iv. Study on "Assessment of number of Pharma SSI units requiring technological upgradation"

- v. Preparation of corporate film of Pharma Industry in India .
- vi. Procurement of International market Reports from reputed publishers and all Pharmacopoeias .
- vii. Organizing of International conference on Biotechnological approaches to Neuro immunomodulation & Infectious Diseases.
- viii. Organization of "International conference on new developments in drug discovery from natural products and traditional medicines" by NIPER.
- ix. Participation in "Pride of India ISC Expo 2009 – 96th Indian Science Congress".
- x. Organization of conference on Pharmaceuticals-"Pharmaceuticals 2014; will India leap forward" in collaboration with FICCI.
- xi. 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.
- xii. Conducting of a study on Medical Devices– sub sector of Pharma by NIPER, Ahemdabad .

6. Outlays & Expenditure of the Department of Pharmaceuticals

The plan outlays and expenditure of the Department of Pharmaceuticals is given in the Table-4:

Table-4 : Plan Outlay & Expenditure of The Department Of the Pharmaceuticals

(Rs. Crores)

S. N	Name of the Scheme	XI Plan (2007-12) Outlay	AP (2008-09) (BE)	AP (2008-09) Exp.	AP (2009-10)
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	95.00	25.00	68.46	8.00
2	National Pharmaceutical Pricing	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	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.

Against an outlay of Rs.155.25 crores for 2009-10, an expenditure of Rs.29.15 crores has been incurred upto June, 2009.

7. Prices of Drugs & Pharmaceuticals

7.1 Price Movement

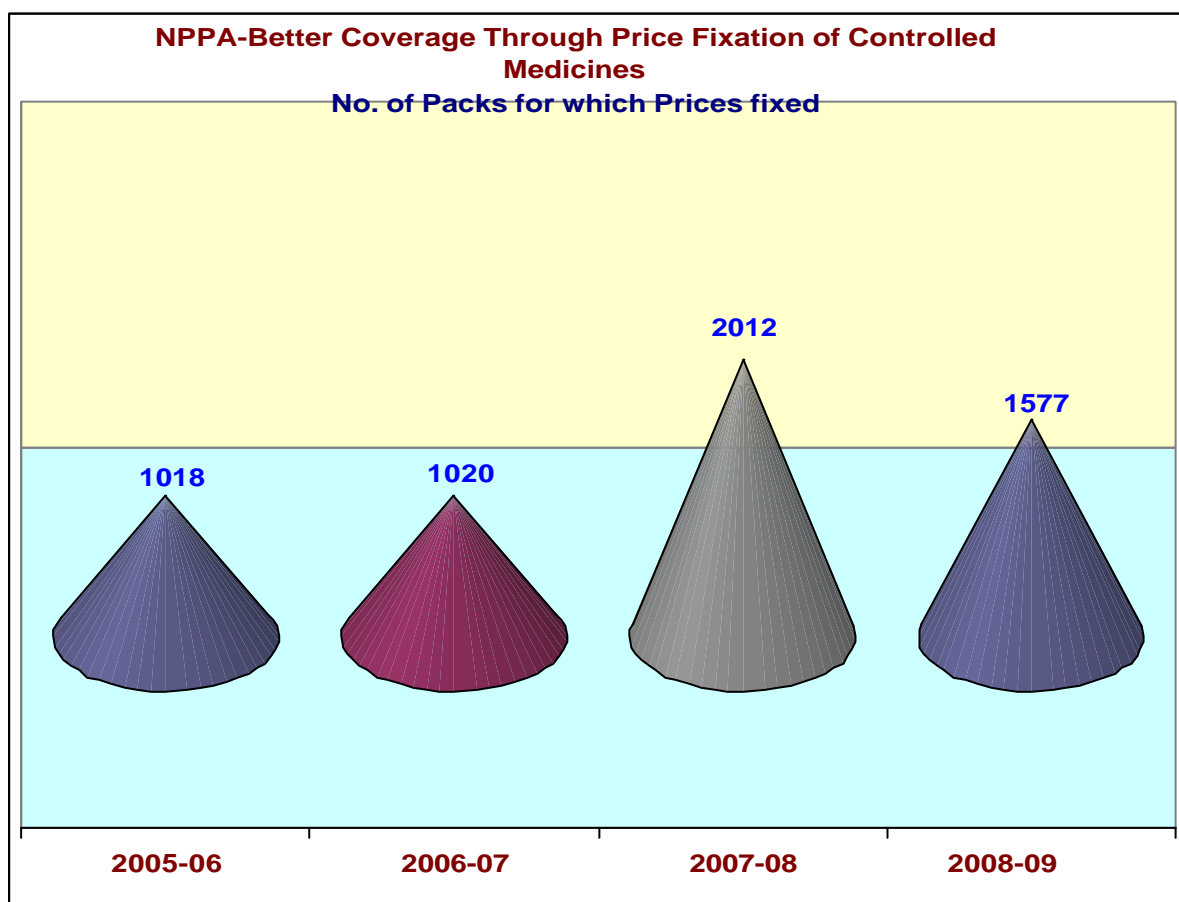
Based on ORG-IMS data for March,2009, NPPA tracks the prices of medicines. Of 57202 medicines (packs), prices of 84.59% packs have

remained unaltered, while prices of another 6.67% packs have declined and only 8.74% packs witnessed increase in their prices. This shows that prices of medicines have generally remained stable.

7.2 Price Fixation

The NPPA³, an attached office of this Department, has had a better coverage of controlled medicines through an instrument of price fixation as is exhibited in the following chart:

During 2008-09, NPPA has approved prices of 1577 scheduled formulation packs. Since its inception, the total number of scheduled formulation packs for which prices have been fixed till 31st March, 2009 are 8516 (Table-5, source: NPPA).



³ National Pharmaceutical Pricing Authority

Table-5 : Prices of Formulation Packs

Parameter	2005-06	2006-07	2007-08	2008-09	Total*
Total Number of Packs Approved, of Which	1018	1020	2012	1577	8516
i. Price Increased	99	131	78	190	1125
ii. Price Decreased	398	340	422	89	2849
iii. Price fixed for the first Time	480	522	1429	1256	4297
iv. No change in prices	41	27	83	42	245

* : Since inception of NPPA till 31st March,09.

8. R&D Initiatives

One of the proclaimed aims of DoP is to promote research and development in the pharmaceutical sector. To achieve this, the Department proposes to increase capacity building in the area of drugs and Pharmaceuticals. Quality and safety of drugs and Pharmaceuticals manufactured in the country for domestic consumption as well as for 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 pharmaceutical. The testing facilities need to follow Good Laboratory Practices (GLP), which is a mandatory requirement as per national and international requirements. I am glad to inform that NIPER, Mohali has been granted a GLP Compliant accreditation Certificate on 23.06.09.

Further, FDA has also issued GLP guidelines and all Pharmaceutical companies need to follow from Sept 2010. DoP would make an all out effort in consultation with Ministry of Science & Technology, Ministry of Health & Family Welfare to build up basic support systems so that R&D initiatives can be taken in a free & enabling atmosphere.

The Indian Pharma Industry with its leadership in generics now needs to be equally strong in drug discovery and innovation. For this purpose, it is essential to create world-class infrastructure for R&D, upgrade human resource for pharmaceutical drug discovery innovation, improve capabilities and competence in Bio Pharma as well as set up mechanisms for funding of

R&D in the public-private-partnership. The Department aims to do this as a part of the vision that has been proposed with the ultimate objective of catapulting India as a leader in drug discovery and innovation and make India one of the most competitive destinations for pharma drug discovery and innovation through substantial cost advantage of R&D as well as availability of infrastructure and international-class pharma researchers, scientists and technicians. The programme would have to be led in the public-private-partnership mode with significant presence of industry. The objective would be to upscale Indian pharma drug discovery and innovation for this purpose, enlarge the scope and extent of clinical research in India. Substantial cost advantages for such R&D make India an attractive location for foreign companies also to locate their R&D projects in India. Apart from significant addition to the GDP of the country, it will also significantly boost direct and indirect employment, production and exports in the pharma sector.

Another major initiative taken by the Department relates to Medical Devices. A Report on Medical Devices commissioned by the Department through NIPER, Ahmedabad, will shortly be released. It is planned to hold the first National Conference on Medical Devices in September–October, 2009. NIPER, Ahmedabad is being contemplated to be a National centre for core competence in medical devices and also for pilot plant and incubator facilities for this purpose. A pre-feasibility report for a green field Medical Devices Development Project has also been commissioned by the DOP.

The Department is contemplating to set up Pharma City at Hyderabad, Pharma Clusters, Educational Campus and R&D Hubs in various parts of the country which may include Gurgaon, Hyderabad, Pune, Mumbai, Kolkata, Chennai, Rishikesh, Dehradun and Mohali (Chandigarh). The project profiles are being finalized to explore viability of such projects at specific locations.

Some of other R & D proposals planned by DoP are:

- i. Innovative drug discovery with clinical trials is underway in 34 molecules- CT market has grown from US\$ 470 million in 2005 to US \$ 800 million in 2007.

- ii. Proposal for assistance in setting up of GMP Compliant Biological / Bio Pharmaceutical testing Lab.
- iii. Proposal for setting up of GLP Compliant Chemical Lab
- iv. Proposal for setting up of GLP Compliant Large Animal House Facility
- v. Proposal for conducting Educational Programme for capacity building for Drug Regulators, Industry/ & Labs.
- vi. Proposal for assistance to public funded institutions for extra Mural research in Pharmaceutical Sciences
- vii. Proposal for National Award for innovation and Research in Pharmaceuticals
- viii. Proposal on development of Pharma incubators.
- ix. Capacity building programme.
- x. Project Proposal For Venture Finance and Incubation Fund for Innovative R & D in Pharmaceuticals.

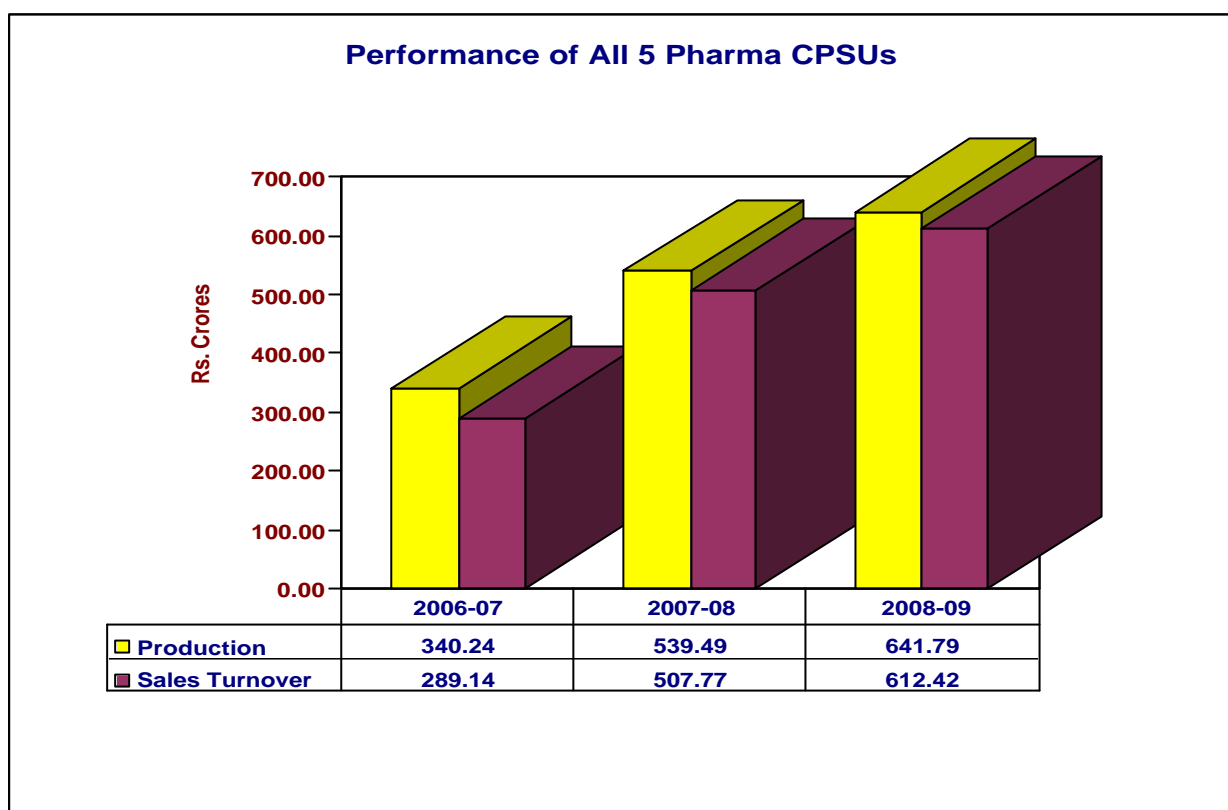
9. Public Sector Undertakings

The foundation stone of a new Cephalosporin plant with WHO GMP at Indian Drugs & Pharmaceuticals Limited (IDPL), one of five important Pharmaceutical Central Public Sector Undertakings/joint sector undertakings under the DoP, was laid by former Hon'ble Minister of Chemicals & Fertilisers.

The five Pharmaceutical CPSUs are:

- Indian Drugs & Pharmaceuticals Limited (IDPL)
- Hindustan Antibiotics Limited (HAL)
- Bengal Chemicals & Pharmaceuticals Limited (BCPL)
- Rajasthan Drugs and Pharmaceuticals Ltd. (RDPL)
- Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)

Under various rehabilitation programmes, the CPSUs have made remarkable progress as may be seen in the Chart below:



10. Jan Aushadhi

In a campaign to ensure access to quality medicines for all at affordable prices of this Department, the first Generic Drug Store 'Jan Aushadhi' 24x7 generic drug was opened on 25th November 2008 at Amritsar with the full support and assistance of the Govt. of Punjab. Encouraged by success and feedback received, more such generic drug stores have been set up in Panchkula, Gurgaon, Bhatinda, Mohali, Jaipur (two), Alwar, Ludhiana, Jalandhar, Faridkot and Moga, besides one in New Delhi. Some more locations are being planned for such stores in Haryana, Punjab and Rajasthan in collaboration with concerned State Governments by October, 2009. DoP is also exploring to set up Generic Drug Stores in premier hospitals of the country.

The Jan Aushadhi store is for providing quality unbranded generic medicines at very reasonable prices. This can be seen below in the comparative prices in the illustrative list of some of the medicines in Table-5, which are on sale at the Jan Aushadhi store at Amritsar.

Table-5 : Illustrative Prices of Branded Medicines vis-à-vis Generic Prices at Jan Aushadhi Generic Store

Prices of pack size 10 (Rs.)

Medicines	Market Prices of Branded Medicines	Price of Generic Medicines at Jan Aushadhi Generic Store, Amritsar	Average Higher Prices of Branded Medicines (%)
Tab. Ciprofloxacin 500 mg	97.00	20.10	383
Tab. Diclofenac 100 mg	36.70	3.10	1084
Tab. Cetirazine 10 mg	27.00	2.50	980
Tab. Nimesulide 100 mg	32.00	2.50	1180
Cap. Cephalexin 500 mg	155.00	29.40	427

11. Promising Future : Way Ahead

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 a manufacturing hub for pharmaceutical industry of the world and an emerging hub for Contract research, Bio- technology Clinical trials and Clinical data management. Indian pharma industry has demonstrated its resilience in 2008-09 when exports registered a growth rate of nearly 25% despite global economic melt down. The country's pharmaceutical industry has shown very significant 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 include the cost advantage India offers in comparison with developed markets and the technical strengths of India in development and production of pharmaceuticals.

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 exists a huge opportunity for India. The global market for contract manufacturing of

prescription drugs is estimated to increase from a value of US\$ 26.2 billion to US\$ 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 .

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. India is significantly ahead in chemistry services such as analog preparation, analytical chemistry, combinatorial chemistry, structural chemistry, structural drug design, computer aided drug design, high throughput screening and assay development .

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 .

The pharma industry is expected to increase to USD 30 bn by 2020⁴. Going forward, the Indian pharma industry is taking leaping strides in innovative drug discovery with clinical trials underway in 34 molecules. Consequently, the Indian drug discovery market has grown from USD 470 millions in 2005 to USD 800 millions in 2007. The market is growing at about 30% annually spurred by the high cost advantage of upto 50% for clinical trials as compared to those in western countries.⁵

The industry growth is being driven by six important factors, namely:

- doubling of disposable incomes and the number of middle class households;

⁴ ORG-IMS

⁵ IMS Health, Mckinsey, ABLE

- large future potential due to low penetration level (30%) coupled with a large population base and rising prevalence of chronic diseases;
- large increase in the rural markets from a base of low per capita expenditure on drugs of about USD 5 in India as compared to USD 436 in the US and USD 375 in Japan⁶;
- increasing public health expenditure and rise of private hospital care facilities including corporate hospital chains and rising Health Insurance sector;
- adoption of product patent regime in 2005 at the right time with a large number of projected expiry of globally patented drugs in 2010; and
- growth of emerging markets and its aggressive penetration by relatively smaller companies.

With these drivers, the industry has a bright future growth promise and potential. The right mix of policies and programs of the Department of Pharmaceuticals will be an enabling, empowering and ensuring factor in its realization. The pharma industry is fully geared up for promising future.

12. Feedback

We have tried to collate information from various sources for this round-up. If there are any corrections required or more data and information available with you, please send it to us for our future round-up. In addition, if there are any suggestions or comments, please email to us at js-pharma@nic.in or write to Joint Secretary (Pharma), Department of Pharmaceuticals, Ministry of Chemicals and Fertilisers, Shastri Bhawan, New Delhi-110001, Tele : 011-23385131.

⁶ Yes Bank Study on Pharmaceuticals Industry in India