EXECUTIVE SUMMARY

The Indian pharmaceutical Industry has witnessed a robust growth of around 14% since the beginning of the 11th Plan in 2007 from about Rs 71000 crores to over Rs1 lac crores in 2009-10 comprising some Rs62,055 crores of domestic market and exports of over Rs 42,154 crores. This also amounts to around 20% of total volume of global generics. However, the Industry is quite fragmented and comprises of nearly 10,500 units with majority of them in unorganized sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector with the top 10 manufacturers accounting for 36.5% of the market share. As regards the Bulk drugs component of the industry, the market is around Rs 42,000crores giving it a share of around 50% of the total domestic market. This gives the Indian Bulk Drug industry a share of about 9% of the global bulk drug market.

India is among the top 20 pharmaceutical exporting countries and the exports have grown very significantly at a CAGR of around 19% in the 11th plan period. Indian drugs are exported to around 200 countries in the world with highly regulated markets of USA, UK etc. The major therapeutic categories of export are anti infective, anti asthmatic and anti hypertensive.

The Department of Pharmaceuticals has a Vision for the development of the Indian Pharmaceutical Industry. This Vision is –

"To make India the Largest Global Provider of Quality Medicines at Reasonable Prices."

The Vision is to be achieved as per the following Mission:

- Develop Human Resources for Pharmaceutical Industry and Drug Research and Development
- Promote Public-Private Partnership for development of pharmaceuticals Industry
- Promote Pharma Brand India through International Cooperation
- Promote environmentally sustainable development of Pharmaceutical Industry
- Enable availability, accessibility and affordability of drugs

In order to realise the Mission, the Department has set the following Goals for 12th plan:

- Production size of US$60bn and export size of over US$25bn.
- Upgradation of SMEs to WHO-GMP and training of professionals therein.
- Establishment of Pharma Growth Clusters.
- Facilitate growth of Central pharma PSUs.
- Develop Pharma Infrastructure and Catalyze Drug Discovery and Innovation
- Develop Pharma Human Resources through increased M.Pharma and Ph.D programs in NIPERS
- Provide Infrastructure and staff for new NIPERs and strengthen NIPER Mohali
- Open 10 new NIPERs
- Jan Aushadi Campaign and implementation of Business Plan for setting up of 3000 Jan Aushadhi Stores (upto Subdivision level in the country)
- Incentivizing Private Sector for development of new Drugs for diseases endemic to India

For the achievement of these Goals, it is necessary for the Indian Pharmaceutical Industry to become globally competitive through world class manufacturing capabilities with quality and cost efficiency of production capacity and radical upgradation of research and development capabilities for new drugs and associated activities like clinical trials and contract manufacturing. There is need to develop world class support infrastructure both for production and research.

With this approach, the preparation of the 12th Plan involved a detailed SWOT analysis of the Indian Pharmaceuticals Industry. This analysis has revealed the following strengths: (a) Strong Low cost manufacturing sector (b) Significant breadth and depth of product expertise (c) Low cost of growing Human resources in the Pharma sector. The major weaknesses are – (a) High emphasis on generics both for domestic and international markets where filing and approval of ANDAs and DMFs have left little room for R&D on drugs development (b) Inadequate R&D Infrastructure (c) Poor Industry-Academia linkage (d) Lack of required high-end product development capable human resources (e) Lack of time driven regulatory infrastructure (f) Poor SME base for high-end manufacture. The major opportunities available are - (a) Global opportunity for increasing Generics and

bio-generics market both in developed and emerging countries due to pressure on budgetary limitations of these countries as well as emergent patent cliff due to off-patenting of major high-value drugs (c) Low cost good skill destination for contract research and manufacturing and resultant opportunities in drug discovery as well as clinical trials (d) High growth of domestic market attracting multi-nationals both for brown field and green field investments in production and capacity building. The threats to the industry are from - (a) Ever-greening strategy of MNCs for denying and limiting the patent cliff opportunities with debatable recourse to TRIPs and FTAs (b) Increasingly stringent regulatory and non-tariff barriers to generics markets in developed countries (c) Increased competition for generics and bio-generics production in terms of high capacity and production costs (d) High-entry barriers to enable market share in development of new drugs.

Based on the above SWOT analysis, recommendations have been made in the 12th Plan Document for –

1) **Development and growth of the Industry**
2) **Strengthening of R&D Capabilities**
3) **Strengthening of human resource base for Industry**
4) **Affordability and Access to Quality Drugs**

The major recommendations concerning support for Industry growth are - (a) Schemes for Upgradation of SMEs to WHO-GMP, USFDA/EDQM/TGA and other International Standards (b) Support for new generics and bio-generics through setting up of Formulation Development Centers and Manufacturing Standards Training Centers (c) Regional cluster-based Industry development through establishment and upgradation of 10 Pharma Growth Area Clusters (d) Industry support to International market access through capacity building and inter-governmental cooperation. The Medical Device Industry is also proposed to be supported through the development of a Medical Devices Park in Ahmedabad, Gujarat.

In the area of R&D and human resource development the major recommendations concern (a) setting up of National Excellence Centres comprising three for Research and Development **in** Phyto-pharmaceuticals, Nano-Pharmaceuticals and Bio-Similars, one for setting up of National facilities for New Drugs Development along with another for End To End Large-Scale Animal House and setting up of a National Centre for R&D in APIs (b) Schemes for supporting R&D in Industry through assistance for setting up of GLP/GCP/Animal House Lab Schemes (c) Setting up of Pharma Venture Capital Fund to fund innovations in drug discovery including incubator driven translational research (d) Pharma Innovation and Infrastructure Development Initiative for R&D infrastructure development including funding of private sector initiatives in PPP mode. Emphasis on supporting extra mural research in development of new drugs and dosage forms for mass affliction diseases like JE, Chikungunya, TB (resistant strains), leishmeinasis, malaria, and the recent lifestyle diseases like diabetes and CVD, etc.

As regards strengthening of Human Resource base, it is estimated that direct employment in Pharmaceuticals Industry has increased from about 6.9 lacs people in 2006 to 8 lacs people in 2008 with 20% of this manpower being engaged in research and testing. The projected human resource requirement is around an estimated 21.5 lacs by 2020. Based on this it is proposed to fill the HR requirements through Schemes such as **(a) Expanding the student output at NIPER Mohali (b) Development of 6 New NIPERS already sanctioned in the 11th Plan and (c) Setting up of 10 New NIPERs etc.**

The 12th Plan Document highlights the vital role Drug price play in access to essential medicines across the world. While it is a fact that the drugs manufactured in India are considered to be amongst the lowest priced internationally, still, a vast section of Indian population is not in a position to access the needed health care as well as the medicines due to various reasons of access and affordability. Accordingly, the recommendations made by the Task Force under Dr. Pronab Sen made have been considered and a draft National Pharmaceuticals Pricing Policy has been formulated which seeks to control the prices of essential drugs as per the National List of Essential Medicines 2011 (NLEM-2011). Further to this, the Department would take up issues pertaining to prescription

and promotion of unbranded generic drugs with the Department of Health. Issues related to pricing of patented medicines would also be suitably considered in the light of need for promoting industry growth and research as well as development of new drugs along with affordability of new patented medicines for better therapeutic treatment of the masses, especially in diseases pertaining to cancer and HIV. Accordingly, it is proposed to continue schemes for strengthening of the **NPPA, for such functions as - (a) Strengthen Monitoring and Enforcement Work, (b) Building Consumer Awareness about pricing and availability and (c) Creation of NPPA Cells in States, etc.**

The present market size of Medical Devices and Equipments is around Rs 15,000 crores. The medical device Industry in India is very nascent and is largely import dependent. More than 65% of India's requirement of medical devices and equipments are met through imports with domestic production being largely restricted to low technology disposable equipments. The SWOT analysis of Medical Device Industry shows that its major strengths are – (a) Well developed Microelectronic, Telecommunication, Software and Precision Engineering Industry, (b) Ability to attract foreign investments and (c) Ability to handle low value large volume production as per global quality standards. The major weaknesses are – (a) Low per capita expenditure on health care & low health insurance, (b) Lack of adequate and trained manpower, (c) Lack of incubation and suitable ecosystem, (d) Lack of regulation/standards etc. The major opportunities are- (a) Huge market potential ,(b) Growing opportunities in export market, (c) Growing demand on account of changing demographic profile, increasing incidences of life style diseases like cancer, CNS and diabetics, etc. The major threats are – (a) Growing competition in export markets, (b) Increasing dependency on imports, (c) Unorganized market for medical disposables, (d) Lack of regulations in medical disposables and surgical items. **To give a boost to the Medical devices Sector, a number of schemes have been proposed such as for - (a) Setting up green-field Medical Devices Park and (b) Setting up National Center for R&D in Medical Devices at NIPER Ahmedabad**

The 11th Plan aimed at making the sick CPSUs financially viable through support for modernisation and rehabilitation as well as waiver of dues and payment of VRS packages.

Accordingly, Hindustan Antibiotics Ltd (HAL) and Bengal Chemicals and Pharmaceuticals Ltd(BCPL) were given support of over Rs. 1000 crores in the 11th Plan period involving waiver, settlement and cash assistance for modernisation. Karnataka Antibiotics and Pharmaceuticals Ltd (KAPL) and Rajasthan Drugs and Pharmaceuticals Ltd(RDPL) were also given financial support following their delinking from HAL and IDPL respectively so as to make them individually more viable and independent in pursuing growth plans. As a result, the Pharma PSUs have been able to achieve a combined business of more than Rs. 600 crores. It is expected that they would grow in the 12th Plan for which Government support for marketing will be required. Accordingly, no major scheme has been proposed. **The** rehabilitation of Indian Drugs and Pharmaceuticals Ltd (IDPL) could be considered during the 12th Plan as per approval of the Cabinet.

As regards access to quality drugs at affordable prices, apart from the price control and monitoring initiative, the Government proposes to further expand the Jan Aushadhi Scheme started in the 11th Plan with the objective of making available unbranded generic medicines at affordable prices through the proposed 3000 dedicated outlets across the country. The 12th Plan document has supported the revised business plan of the Jan Aushadhi Scheme which has been prepared after a detailed analysis of shortfalls and possible solutions including special focus on supply chain management.

Finally, the Department of Pharmaceuticals has not been able to take up or launch any major new activity in line with its mandate even after three years of its existence. The main reason for this lies in lack of technical capability since its inception. Therefore there is an urgent need of strengthen the Department in terms of required human resources. For this, support of a technical cadre has been proposed.

It is expected that going forward in the 12th Plan, the Department would be able to play a vital catalytic role in spurring the growth of the pharmaceutical industry in the country and strengthen it to become a global leader in the comity of nations in the global economy.

SUMMARY OF SCHEMES

Sl No	Scheme	Brief description	Budget (Rs Crores)
1	**INDUSTRY PROMOTION & DEVELOPMENT**		
1.1	**Existing Schemes – Continued from 11th Plan**		
(i)	Pharma Promotion and Development Scheme (PPDS)	Grant assistance for Industry Studies, Workshops, Seminars, etc	10
(ii)	Intellectual Property Rights Facilitation Centers	Capacity building Grant assistance (capital and revenue) for setting up of IPR centres by Pharmaexcil, Industry bodies, etc to assist industry in IPR matters	26.5
1.2	**New Schemes**		
(i)	International Pharma Cooperation Initiative (IPCI)	Setting up of Joint testing and lab facilities for certification of Indian pharma products, development of locally sustainable formulations and drug delivery systems and other mutually beneficial schemes	50
(ii)	Upgradation of SMEs to WHO-GMP standards	Interest based subsidy scheme at the rate of about Rs 1 crs per unit of assistance to be implemented in partnership with IDBI / SIDBI for upgrading SMEs to WHO-GMP manufacturing standards to capitalize on the Generics Opportunity – about 1200 units out of about 10,563 SMEs in the country	1200
(iii)	Capacity building through training of 5000 Working Professionals in WHO-GMP	To provide manufacturing capability upgradation assistance for capital expenditure, skill development of personnel required for such upgradation and sustenance of supply of skilled personnel .	250
(iv)	Upgradation of SMEs to USFDA/EDQM/TGA and other International Standards	Specific assistance for standards higher than WHO-GMP to selected SMEs – 250 in nos to build **Competitiveness** of very high standards and second line of internationally capable industry for high value pharma products for strong regulated but high value markets	500
(v)	Setting up of one National and five Regional Formulation Development and Manufacturing standards training centres	Scheme to set up Formulation development centres to tap the patent cliff opportunity and become global leader in Generics and Bio-similars	160

(vi)	Establishment and upgradation of 10 Pharma Growth Clusters	Infrastructure building for pharma industry particularly for SMEs – building on strength of existing Clusters so as to provide infrastructure gaps for higher production including taking care of environment, power and labs testing, etc needs.	500
(vii)	Infrastructure support for Cold Chain for high end drugs for exports	In order to enhance exports capability for high end drugs requiring exact cold chain standards till the time they are exported from the country in light of stringent developed market requirements	50
(viii)	Scheme for environment standards compliance and required infrastructure support including capacity building	providing financial and technical assistance to improve financial sustainability of SMEs on one hand and also safeguard the environment from the hazards associated with the unplanned growth of the industry.	100
2	**R&D ,CAPACITY BUILDING AND EMPLOYMENT**		
2.1	**Continuing Schemes**		
2.1.1	**For NIPER Mohali**		
(i)	The continuation of the PG and the PhD education	The continuation of the PG and the PhD education at present strength levels would require budgetary support	100
(ii)	Capacity Enhancement for supporting required industry human resources and capacity building requirement by the Institute	a. Additional 1000 PGs and PhDs b. Training Industry and Regulatory personnel c. Public Health and Pharmacovigilance Trg. d. Infrastructure Upgradation	200 25 25 250
2.1.2	**For New NIPERs**		
(i)	Permanent establishment and operation of 6 New NIPERs		2000
2.1.3	**Other Schemes**		
(i)	Setting up of National Center for Phyto-pharma development	Major capital expenditure of about Rs 100 crs being met from DONER. Present allocation sought for initial years operation as per advice from DONER	20
(ii)	GLP/GCP/Animal House Lab Schemes	For setting up of GLP compliant Labs, GCP compliant Lab and a Animal House Lab on PPP basis is under implementation	50

(iii)	Continuing R&D Schemes For Niper Mohali	Niper Mohali is presently implementing a number of projects in R&D for various pharma areas like neglected diseases, infectious diseases, vector borne diseases, etc. In addition a number of projects are being implemented for Public health, PHarmacovigilance, Regulatory capacity building for academia and industry, etc.	50
(iv)	Continuing scheme at New Nipers	Joint development of Tuberculosis related drugs at Niper Ahmedabad and AIIMS, Delhi	1
2.2	**New Schemes**		
(i)	Establishment of New New NIPERs	Inorder to meet the gap of a very low graduate to postgraduate pharma education seats capacity of 1:10 (51000 graduate seats vs 5100 PG seats in the entire country)there is need to set up further new Nipers apart from the 6 approved in the 11th plan. It is proposed to set up 10 New new NIPERs	3000
(ii)	New Schemes at Niper Mohali	R&D Centre for Biologicals and NCEs R&D Centre for NDDS , Setting up 20 New Incubators , Incentive Scheme for CROs Devpt for New ,Drug Discovery Partnership with International Centres of Excellence	825
(iii)	Pharma Venture Capital Fund	To consider investment of identified funds into a newly created specialised private equity / venture capital fund that undertakes R&D investments into companies in the pharmaceutical industry	500
(iv)	Pharma Innovation and Infrastructure Development Initiative (PIIDI)	Develop technical and innovation capacity of Indian pharma for manufacturing quality affordable medicines ,develop International competitiveness of the Indian Pharma so as to be the largest producer of generic medicines in the world, To make India a preferred destination for global initiatives in curing the world's ailments specially the developing world in a value based manner	2000
(v)	At NIPER Hyderabad : Setting up National Center for R&D in Bulk Drugs at NIPER Hyderabad	Build competitiveness through Innovation and Productivity efficiencies in the API industry. Also tap Generics opportunity and meet competition of China, etc.	56

(vi)	At NIPER Kolkatta National Pharmaceutical Nanotechnology Center	To be set up at NIPER Kolkatta for development of Nano-materials from inorganic substrates for innovative drugs and drug delivery systems	50
(vii)	Setting up National and Regional Biosimilar Expertise Centers	To provide expert advice and assistance to industry on regulatory issues pertaining to Clinical Trials, Testing and Approval process for Biosimilars – One national centre at Bangalore and 3 regional centres at Chandigarh, Hyderabad and Ahmedabad	60
(viii)	Setting up of a Industry focused Animal House	End to end services from Primates to small animals for pre-clinical drug development	100
(ix)	Support to Academia, Research Institutions and private sector for Extra Mural Research	For funding both academia individually, as an institution and private companies for targeted drug development including assistance for clinical trials.	100
(x)	Support to Academia, Research Institutions and private sector for Extra Labs upgradation	For funding upgradation of labs in the private and government sector with sharing basis on 50-50 pattern for the lab upgradation for equipments deployed for drug development under specifically identifiable projects	10
(xi)	All NIPERs : International cooperation in R&D	To promote R&D in CIS and developing countries for mutual advantages	25
3	**Pricing**		
3.1	**Continuing schemes**		
(i)	Monitoring and Enforcement Work	Strengthening the Existing Monitoring and Enforcement Work	2
(ii)	Awareness and Publicity t	Consumer Awareness and Publicity through Print, Electronic and other Medium	20
3.2	**New Schemes**		
(i)	Creation of NPPA-State Government Coordination Cells in States	Scheme originally proposed in 11th Plan but not approved by Planning Commission. Hence proposed for 12th Plan. Will help in strengthening the Monitoring Objective of drugs prices.	25
(ii)	Scheme for Interaction with States	Scheme originally proposed in 11th Plan but not approved by Planning Commission. Hence proposed for 12th Plan. Will help in strengthening the Monitoring Objective of drugs prices.	2

4	**Medical Devices industry development**		
(i)	Setting up green-field medical devices and equipment parks.	Tapping the opportunity US $ 200 Bn global industry	300
(ii)	Setting up National Center for Medical Devices at NIPER Ahmedabad.	Promoting indigenous R&D in Medical devices sector	50
5	**CPSUs and Jan Aushadhi**		
(i)	**IDPL**	Token allocation for minimal regulatory compliances. Actual would depend on the approval by Cabinet for revival of IDPL package	10
(ii)	**HAL**	Minimal Up gradation of facilities	10
(iii)	**BCPL**	Meeting gaps in the revival package	10
(iv)	**Jan Aushadhi**	Continuing scheme to be strengthened in the 12th plan for ensuring access to affordable quality unbranded generic medicines for the poor masses	200
	TOTAL		12922.5

METHODOLOGY

(A) Constitution of Working Group

Planning Commission constituted a working group on Drugs and Pharmaceuticals, vide their letter noI&M-3(25)/2011, dated 10.5.2011.

(a)Terms of Reference (TOR) of the Working Group

The working group was given following Terms of Reference:

i. To articulate the long term goals to be achieved in terms of growth, competitiveness and share in global trade for the domestic Drugs & Pharmaceutical Industries.

ii. To review the current status of domestic Pharmaceuticals Sector highlighting the achievements during the 11th Plan and reasons for major deviation/shortfall, if any, in respect of fulfilment of targets and identifying areas of strength and weakness of the Indian industry vis-à-vis international Drugs and Pharmaceuticals Industry.

iii. To benchmark indigenous drugs & pharmaceuticals industry against international drugs & pharmaceuticals industry and suggest appropriate measures for bridging the gaps where necessary, including the needs for further R&D activities and/or technology collaboration for upgrading technology.

iv. To examine the structure and capability of the domestic drugs & pharmaceutical industry, its export trend & performance and identify emerging areas having specific potential for growth and competitiveness as well as to suggest measures for putting the indigenous industry on sound footing and growth path keeping in view the goals to be articulated under item 1 above.

v. To review the present status of WHO-GMP (World Health Organization – Good Manufacturing Practice) certification and schedule-M compliance and suggest measures for raising the level of compliance by manufacturers of drugs and pharmaceutical products in the country.

vi. To examine the impact of new patent regime on domestic pharmaceutical industry including its implication on drug prices.

vii. To study the efficacy and appropriateness of current drug pricing system as well as its control and enforcement mechanism and suggest measures for further improvement, if applicable.

viii. To assess the present capability for innovation vis-à-vis R&D status of the domestic Drugs & Pharmaceuticals industry and to suggest ways and means to improve the domestic efforts, enhance industry participation and intensify Industry-Institutional/academia linkage to promote domestic R&D for establishment of its international competitiveness and meeting the emerging challenges arising out of the WTO regime.

ix. To study change in structure of domestic pharmaceuticals industry in the light of current trend of merger & acquisitions/takeovers/collaborations and its correlation with related FDI norms and suggest measures to safeguard national interests.

x. To examine the trend of employment growth in the Drugs and Pharmaceuticals industry and project likely requirement of skilled manpower during the Twelfth Plan period as well as to meet the long term goals. To suggest measures for putting in place adequate academic and training infrastructure and facilities to meet the requirements.

xi. To assess the adequacy and relevance of present regulatory mechanism of drug and pharmaceuticals sector and examine need for further strengthening to tackle the menace of spurious drugs etc. and examine need for an apex authority to control price, quality and supply of drugs.

xii. To suggest measures towards improvement of accessibility of essential medicines for common man particularly the poorer sections of the population and to identify steps required for facilitating implementation of the National Health Policy.

xiii. To assess the current status of domestic medical/surgical equipment industry, its export potential and competitiveness and suggest measures for improvement and augmentation of capabilities, where necessary.

xiv. To indicate the milestones to be achieved in the 12th Plan in the context of long term goals as per item-I of the ToR and recommend pogrammes/schemes/measures that are to be initiated, continued or discontinued in the 12th Plan period and estimated fund requirement.

xv. To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

(b) Members of the Working Group

The working group consisted of following members:

1.	Secretary, Department of Pharmaceuticals (DOP)	**Chairman**
2.	Secretary, Department of Scientific & Industrial Research/ DG, Council of Scientific & Industrial Research or his Representative	Member
3.	Principal Adviser/ Adviser (Health), Planning Commission	Member
4.	Secretary, Ministry of Health & Family Welfare or Nominee	Member
5.	Secretary, Department of Science & Technology or Nominee	Member
6.	Secretary, Department of Bio-Technology or Nominee	Member
7.	Secretary, Department of Consumer Affairs or Nominee	Member
8.	Chairman, National Pharmaceutical Pricing Authority	Member
9.	Additional Secretary & Financial Adviser, Department of Pharmaceuticals (DOP)	Member
10.	Adviser (I&VSE), Planning Commission	Member

11.	Joint Secretary (PI), Department of Pharmaceuticals (DOP)	Member
12.	Joint Secretary (Pharma), Department of Pharmaceuticals (DOP)	Member
13.	Director, Central Drugs Research Institute, Lucknow	Member
14.	Director, National Institute of Pharmaceutical Education & Research, Mohali, Punjab	Member
15.	Chairman, Pharmaceuticals Export Promotion Council, Hyderabad	Member
16.	President, Indian Drugs Manufactures Association	Member
17.	Chairman, Confederation of Indian Pharmaceuticals Industry	Member
18.	Secretary General, Indian Pharmaceuticals Alliance	Member
19.	President, Organisation of Pharmaceuticals Producers of India (OPPI)	Member
20.	President, Bulk Drug Manufacturers Association	Member
21.	Chairman, Dr. Reddy's Laboratories Ltd., Hyderabad	Member
22.	Chairman, CIPLA Limited, Mumbai	Member
23.	Chairman, Lupin Limited, Mumbai	Member
24.	Economic Adviser, Department of Pharmaceuticals (DOP)	Member

(B) Constitution of Sub Working Groups

Based on the thrust of the ToRs, Department of Pharmaceuticals constituted four sub working groups. The members and ToRs of the sub working groups are as below:

(a) Sub-Group on Status and Structure of the Pharmaceutical Industry

Composition of the Sub-Group

1. Joint Secretary (AJ), Department of Pharmaceuticals	Chairman
2. Nominee of Secretary, Department of Scientific & Industrial Research	Member
3. Nominee of Secretary, Ministry of Health & Family Welfare	Member
4. Nominee of Secretary, Department of Science & Technology	Member
5. Adviser (I&VSE), Planning Commission	Member
6. Chairman, Pharmaceutical Export Promotion Council, Hyderabad	Member
7. President, Indian Drugs Manufacturers Association	Member
8. Chairman, Confederation of Indian Pharmaceuticals Industry	Member
9. Secretary General, Indian Pharmaceuticals Alliance	Member
10. President, Organisation of Pharmaceuticals Products of India (OPPI)	Member
11. President, Bulk Drug Manufacturers Association	Member
12. Deputy Director General, Department of Pharmaceuticals	Member
13. Director (BKS)	Member Secretary

Terms of Reference (TOR)

(i) To articulate the long term goals to be achieved in terms of growth, competitiveness and share in global trade for the domestic Drugs & Pharmaceutical Industries.

(ii) To review the current status of domestic Pharmaceuticals Sector highlighting the achievements during the 11th Plan and reasons for major deviation/shortfall, if any, in respect of fulfilment of targets and identifying areas of strength and weakness of the Indian industry vis-à-vis international Drugs and Pharmaceuticals Industry.

(iii) To benchmark indigenous drugs & pharmaceuticals industry against international drugs & pharmaceuticals industry and suggest appropriate measures for bridging the gaps where necessary, including the needs for further R&D activities and/or technology collaboration for upgrading technology.

(iv) To examine the structure and capability of the domestic drugs & pharmaceutical industry, its export trend & performance and identify emerging areas having specific potential for growth and competitiveness as well as to suggest measures for putting the indigenous industry on sound footing and growth path keeping in view the goals to be articulated under item 1 above.

(v) To study change in structure of domestic pharmaceuticals industry in the light of current trend of merger & acquisitions/takeovers/collaborations and its correlation with related FDI norms and suggest measures to safeguard national interests.

(vi) To assess the current status of domestic medical/surgical equipment industry, its export potential and competitiveness and suggest measures for improvement and augmentation of capabilities, where necessary.

(vii) To indicate the milestones to be achieved in the 12th Plan in the context of long term goals as per item I of the ToR (By Planning Commission) and recommend pogrammes/schemes/measures that are to be initiated, continued or discontinued in the 12th Plan period and estimated fund requirement.

(viii) To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

(b) Sub-Group on Regulatory Issues in the Pharmaceutical Industry

Composition of the Sub-Group

1. Joint Secretary (DC), Department of Pharmaceuticals	Chairman
2. Nominee of Secretary, Ministry of Health & Family Welfare	Member
3. Nominee of Secretary, Department of Science & Technology	Member
4. Nominee of Secretary, Department of Bio-Technology	Member
5.Principal Advisor/Advisor(Health) or Nominee, Planning Commission	Member
6. Drug Controller general of India/Nominee	Member
7. President , Indian Drug Manufacturers Association	Member
8. Chairman, Confederation of Indian Pharmaceuticals Industry	Member
9. Secretary General, Indian Pharmaceuticals Alliance	Member
10. President, Organisation of Pharmaceuticals Products of India (OPPI)	Member
11. President, Bulk Drug Manufacturers Association	Member
12. Director (MV), Department of Pharmaceuticals	Member Secretary

Terms of Reference (TOR)

i. To review the present status of WHO-GMP (World Health Organization – Good Manufacturing Practice) certification and schedule-M compliance and suggest measures for raising the level of compliance by manufacturers of drugs and pharmaceutical products in the country.

ii. To assess the adequacy and relevance of present regulatory mechanism of drug and pharmaceuticals sector and examine need for further strengthening to tackle the menace of spurious drugs etc. and examine need for an apex authority to control price, quality and supply of drugs.

iii. To indicate the milestones to be achieved in the 12th Plan in the context of long term goals as per item I of the ToR(By Planning Commission) and recommend pogrammes/schemes/measures that are to be initiated, continued or discontinued in the 12th Plan period and estimated fund requirement.

iv. To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

(c) Sub-Group on Pricing and Availability of Drugs

Composition of the Sub-Group

1. Chairman, National Pharmaceutical Pricing Authority	Chairman
2. Nominee of Secretary, Ministry of Health & Family Welfare	Member
3. Nominee of Secretary, Department of Consumer Affairs	Member
4. Adviser (I&VSE), Planning Commission	Member
5. Member Secretary, NPPA	Member
6. Secretary General, Indian Pharmaceuticals Alliance	Member
7. President, Organisation of Pharmaceuticals Products of India (OPPI)	Member
8. President, Indian Drugs Manufacturers Association	Member
9. Chairman, Confederation of Indian Pharmaceuticals Industry	Member
10. President, Bulk Drug Manufacturers Association	Member
11.Director(Monitoring), NPPA	Member Secretary

Terms of Reference (TOR)

i. To examine the impact of new patent regime on domestic pharmaceutical industry including its implication on drug prices.

ii. To study the efficacy and appropriateness of current drug pricing system as well as its control and enforcement mechanism and suggest measures for further improvement, if applicable.

iii. To suggest measures towards improvement of accessibility of essential medicines for common man particularly the poorer sections of the population and to identify steps required for facilitating implementation of the National Health Policy.

iv. To indicate the milestones to be achieved in the 12th Plan in the context of long term goals as per item I of the ToR (By Planning Commission) and recommend pogrammes/schemes/measures that are to be initiated, continued or discontinued in the 12th Plan period and estimated fund requirement.

v. To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

(d)Sub-Group on R&D, Training and Employment Generation in the Pharmaceutical Industry

Composition of the Sub-Group

1. Director, NIPER, Mohali, Punjab	Chairman
2. Nominee of DG, Council of Scientific & Industrial Research	Member
3. Nominee of Secretary, Department of Science & Technology	Member
4. Nominee of Secretary, Department of Bio-Technology	Member

5. Project Director , NIPER , Hyderabad	Member
6. Director, Central Drugs Research Institute, Lucknow	Member
7. Secretary General, Indian Pharmaceuticals Alliance	Member
8. President, Organisation of Pharmaceuticals Products of India (OPPI)	Member
9. Chairman, Dr. Reddy's Laboratories Ltd., Hyderabad	Member
10. Chairman, CIPLA Limited, Mumbai	Member
11. Chairman, Lupin Limited, Mumbai	Member
12.Deputy Director General, Department of Pharmaceuticals.	Member
13.Director(SCS), Department of Pharmaceuticals	Member Secretary

Terms of Reference (TOR)

i. To assess the present capability for innovation vis-à-vis R&D status of the domestic Drugs & Pharmaceuticals industry and to suggest ways and means to improve the domestic efforts, enhance industry participation and intensify Industry-Institutional/academia linkage to promote domestic R&D for establishment of its international competitiveness and meeting the emerging challenges arising out of the WTO regime.

ii. To examine the trend of employment growth in the Drugs and Pharmaceuticals industry and project likely requirement of skilled manpower during the Twelfth Plan period as well as to meet the long term goals. To suggest measures for putting in place adequate academic and training infrastructure and facilities to meet the requirements.

iii. To indicate the milestones to be achieved in the 12th Plan in the context of long term goals as per item-I of the ToR (By Planning Commission) and recommend

pogrammes/schemes/measures that are to be initiated, continued or discontinued in the 12th Plan period and estimated fund requirement.

iv. To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

As the ToRs were having no mention of Central Public Sector Undertakings(CPSUs) in the Department of Pharmaceuticals, it was decided to have a subgroup on CPSUs also.

The sub group consisted of following members

1.	Joint Secretary (DC), Department of Pharmaceuticals	**Chairman**
2.	CMD, IDPL	Member
3.	MD, HAL	Member
4.	MD, KAPL	Member
5.	MD, BCPL	Member
6.	Under Secretary (Shri A.K. Sah)	Member Secretary

The ToRs of the sub group are as below:

i. To articulate the long term goals to be achieved in terms of growth and competitiveness of Pharma PSUs.

ii. To indicate the milestones to be achieved in the 12th Plan in the context of long term goals as per item (i) above and recommend programmes/ schemes/ measures that are to be initiated, continued or discontinued in the 12th Plan period and estimated fund requirement.

iii. To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

The working group on Drugs and Pharmaceuticals first met on 29.06.2011.Thereafter different sub working groups held their meetings separately and finally submitted their reports which was seen and analysed by the working group meeting held on 12.08.2011.

(C) Rearrangement of ToRs

The ToRs have been arranged in various Chapters based on the focus area as below:

Chapter1-Industry Structure &SWOT Analysis consists of following ToRs:

(i) To articulate the long term goals to be achieved in terms of growth, competitiveness and share in global trade for the domestic Drugs & Pharmaceutical Industries.

(ii) To review the current status of domestic Pharmaceuticals Sector highlighting the achievements during the 11th Plan and reasons for major deviation/shortfall, if any, in respect of fulfilment of targets and identifying areas of strength and weakness of the Indian industry vis-à-vis international Drugs and Pharmaceuticals Industry.

(iii) To benchmark indigenous drugs & pharmaceuticals industry against international drugs & pharmaceuticals industry and suggest appropriate measures for bridging the gaps where necessary, including the needs for further R&D activities and/or technology collaboration for upgrading technology.

(iv) To examine the structure and capability of the domestic drugs & pharmaceutical industry, its export trend & performance and identify emerging areas having specific potential for growth and competitiveness as well as to suggest measures for putting the indigenous industry on sound footing and growth path keeping in view the goals to be articulated under item 1 above.

(v) To review the present status of WHO-GMP (World Health Organization – Good Manufacturing Practice) certification and schedule-M compliance and suggest measures for raising the level of compliance by manufacturers of drugs and pharmaceutical products in the country.

(ix) To study change in structure of domestic pharmaceuticals industry in the light of current trend of merger & acquisitions/takeovers/collaborations and its correlation with related FDI norms and suggest measures to safeguard national interests.

(xi) To assess the adequacy and relevance of present regulatory mechanism of drug and pharmaceuticals sector and examine need for further strengthening to tackle the menace of spurious drugs etc. and examine need for an apex authority to control price, quality and supply of drugs.

Chapter 2: Research & Development consists of the ToR(viii) which is as below:

(viii) To assess the present capability for innovation vis-à-vis R&D status of the domestic Drugs & Pharmaceuticals industry and to suggest ways and means to improve the domestic efforts, enhance industry participation and intensify Industry-Institutional/academia linkage to promote domestic R&D for establishment of its international competitiveness and meeting the emerging challenges arising out of the WTO regime.

Chapter 3 : Capacity Building and Employment consists of ToR(x), which is as below:

(x) To examine the trend of employment growth in the Drugs and Pharmaceuticals industry and project likely requirement of skilled manpower during the Twelfth Plan period as well as to meet the long term goals. To suggest measures for putting in place adequate academic and training infrastructure and facilities to meet the requirements.

Chapter 4: Pricing and Availability consists of ToRs (vi), (vii) and (xii) which are as below:

(vi) To examine the impact of new patent regime on domestic pharmaceutical industry including its implication on drug prices.

(vii) To study the efficacy and appropriateness of current drug pricing system as well as its control and enforcement mechanism and suggest measures for further improvement, if applicable.

Chapter 5 Medical Devices consists of ToR(xiii) which is as below:

(xiii) To assess the current status of domestic medical/surgical equipment industry, its export potential and competitiveness and suggest measures for improvement and augmentation of capabilities, where necessary.

Chapter 6 is related to Central Public Sector Undertakings.

Chapter 7 is Resource Requirement in the Department of Pharmaceuticals

Chapter 8 Schemes and Proposals consists of ToRs (xiv) and (xv) which read as below:

(xiv) To indicate the milestones to be achieved in the 12^{th} Plan in the context of long term goals as per item-I of the ToR and recommend pogrammes/schemes/measures that are to be initiated, continued or discontinued in the 12^{th} Plan period and estimated fund requirement.

(xv) To make any other recommendations as may be appropriate for sustained growth and competitiveness of the sector.

Chapter 1

PHARMACEUTICALS INDUSTRY: STRUCTURE & SWOT ANALYSIS

1.1 INTRODUCTION

The Indian pharmaceutical Industry is driven by knowledge, skills, low production costs, quality. Due to this there is demand from both domestic as well as international markets. This has resulted in a robust growth of around 14% since the beginning of the 11th Plan in 2007 from about Rs 71000 crores to over Rs1 lac crores in 2009-10 comprising some Rs 62,055 crores of domestic market and exports of over Rs 42,154 crores (Table-1).

Table-1: Export and Domestic Growth

Year	Exports	Growth	Domestic	Growth%	Total	Growth%
Mar 2006	21230	23.23	39989	17.17	61219	19.21
Mar 2007	25666	20.89	45367	13.45	71033	16.03
Mar 2008	29354	14.37	50946	12.30	80300	13.04
Mar 2009	39821	35.66	55454	8.85	95275	18.65
Mar 2010	42154*	5.86	62055	11.90	104209	9.38

*Provisional

The Industry is ranked 3rd globally in volume and 14th in value, supplying around 10% of total global production[1]. This also amounts to around 20% of total volume of global generics. Thus every 5th Tablet, Capsule and Injectable in generics drugs consumed anywhere in the world is manufactured in India. In fact, India manufactures 30% of the world requirement of Anti-HIV drugs. All of this growth has been with affordable price to the common man – one of the lowest in the world. Going forward, it is expected that the growth will be sustained notwithstanding the recent initial decrease due to global economic slow down as brought out in the decreased growth rate from 18.65% in 2009-10 over 2008-09 to 9.38% in the period 2009-10[2].

1.Cygnus Report- Cygnus Business Consulting and Research is a services organization focusing on analysis and research of Economies, Industries and Companies

2.FICCI-IMS Report

Indian pharmaceutical industry is truly international with leading international manufacturers competing in Indian domestic market and several Indian pharma companies having a significant presence in international market, especially in the generic segment. However, the Industry is quite fragmented and comprises of nearly 10,500 units with majority of them in small sector. Of these, about 300-400 units are categorized as belonging to medium to large organized sector with the top 10 manufacturers accounting for 36.5% of the market share[3].

Medium & Large Domestic Companies: The medium and large domestic companies have been the drivers of growth, contributing 75% of domestic sales and over 90% of exports. The export of top 50 companies for the year 2009-10 reveal that pharmaceutical industry's foray in the global market is driven mainly by the domestic companies as may be seen below. Thus top 50 exporters accounted for 76% of total exports of Rs 36,683cr in 2009-10. It is noteworthy that only two foreign companies feature in this list contributing less than 2% of the total pharmaceutical exports.

Table – 2: International sales on consolidated basis (Rs crore) 2010-11[4]

	Consolidated net sales	International sales	Exports as % of net sales 2010-11
Ranbaxy Labs	8960.77	6771.74	75.6
Dr Reddy's Labs	7236.80	5940.70	82.1
Lupin	5706.82	3983.08	69.8
Cipla	6130.31	3361.49	54.8
Sun Pharma	5721.43	2898.20	50.7
Wockhardt	3751.24	2709.91	72.2
Jubilant Lifescience	3433.40	2369.11	69.0
Cadila Healthcare	4464.70	2288.70	51.3
Biocon	2300.52	1956.79	85.1
Glenmark Pharma	3089.59	1955.83	63.3
Stride Arcolab	1695.84	1637.67	96.6
Plethico Pharma	1535.20	1367.22	89.1
Piramal Healthcare	2509.86	1280.58	51.0
Divi's Labs	1307.11	1204.95	92.2
Aurobindo Pharma	4381.48	1112.06	25.4

[3] Indian Institute of Management, Bangalore – Report on "Viable Strategies to make Pharmaceutical CPSEs Self-Reliant" prepared for DoP in 2009-10
[4] Pharmabiz analysis

Torrent Pharma	2121.97	1101.57	51.9
Ipca Laboratories	1882.54	1025.18	54.5
Dishman Pharma	990.84	911.56	92.0
Orchid Chemicals	1781.79	725.85	40.7
Shasun Chemicals	799.42	676.78	84.7
Panacea Biotec	1143.78	610.44	53.4

1.2 DOMESTIC MARKET

1.2.1 Structure & Geographical Distribution

The Domestic Pharmaceutical Market has reached to over Rs 60,000 crores in 2009-10. Understandably, the market is skewed towards cities with the top 23 cities accounting for almost 25% of pharma sales of which the Tier-I towns account for one third of sales and Tier-II cities (population less than one lac) including the rural market accounting for about 40% of market share. This is for the obvious reasons of better health care accessibility and purchasing power of the resident middle class income group. However, due to shifting rural and semi-urban economic status as well as living life styles, the rural areas are witnessing a market increase growth of more than 30% annually. This increase in the growth is catching attention of the major companies who are now focusing on them for future growth.

State wise distribution is:

Table-3: Geographical Distribution of Pharma Companies

S.No.	State	Number of Manufacturing Units		Total
		Formulation	**Bulk Drugs**	
1.	Maharashtra	1928	1211	3139
2.	Gujarat	1129	397	1526
3.	West Bengal	694	62	756
4.	Andhra Pradesh	528	199	727
5.	Tamil Nadu	472	98	570
6.	Others	3423	422	3845
	Total	**8174**	**2389**	**10563**

1.2.2 Formulations and Therapeutic segments in the domestic market:

Within the Domestic formulations market the major therapeutic categories are - anti-infective, gastrointestinal, cardiac, gynecology and dermatology[5]. The leading drug classes were Cephalosporin, Anti-peptic ulcerants, oral anti-diabetic and Ampicillin / Amoxycillin, etc. The top ten dug classes contributed 35% of total domestic market. As per IMS-Health[6] the major therapeutic segments as per MAT value are:

Table-4: Market Turnover of Major Therapeutic Segments

Major Therapies	MAT DEC'05 (Val in Crs)	% Contribution	MAT DEC'10 (Val in Crs)	% Contribution
Anti-infectives	4,056	17.6	8,060	17.2
Cardiac	2,378	10.3	5,318	11.4
Gastro Intestinal	2,537	11.0	5,099	10.9
Respiratory	2,170	9.4	4,080	8.7
Pain / Analgesics	2,059	8.9	4,038	8.6
Vitamins/ Minerals/ Nutrients	2,105	9.1	3,625	7.7
Anti Diabetic	998	4.3	2,743	5.9
Gynaecology	1,261	5.5	2,658	5.7
Neuro / CNS	1,231	5.3	2,633	5.6
Derma	1,255	5.4	2,554	5.5

Source: IMS Health

India is largely self-sufficient in case of formulations, though some life saving, new-generation-technology-barrier formulations continue to be imported. This is evident from the fact that out of the list of 348 medicines enlisted as "Essential Medicines" in the NLEM 2011 , all are manufactured by domestic pharma industry.

1.2.3 Bulk Drug Industry

[5] IMS-Health
[6] IMS-Health

The Bulk drugs component of the domestic industry is around Rs 42,000 crores giving it a share of around 50% of the total domestic market[7]. This gives the Indian Bulk Drug industry a share of about 9% of the global bulk drugs market of about US$ 102 Bn in 2009[8].

The bulk drugs produced in Indian market fall under 21 major therapeutic classes with Antibiotics constituting more than 50% of the total production. This is because of anti-infectives being the therapeutic segment of highest demand in accordance with the prevailing disease class in India. Analgesics and Anti-pyretics account for 18% and Anti-Dysentery and Vitamin constitute about 8%.

As regards the exports of Bulk drugs it has shown a CAGR of 16.98% in the last 3 years – see Table-5 below:

Table-5: Bulk Industry Growth

(In Rs Crores)

2007-08	2008-09	2009-10	CAGR
12,647.51	16,360.71	17,307.02	16.98%

While the Indian bulk drug industry is catering to around 70% requirement of Indian Pharmaceutical Industry there is growing dependence on China with low import costs. This dependence is particularly more in fermentation base APIs such as Pencillin, Erythromycin, etc where it is almost 100% dependent on China. This issue has been voiced at various fora including by MoH&FW as being of strategic concern.

1.2.4 Biopharma Industry

1.2.4.1 Overview of the Global Biologics Sector

[7] BDMA

[8] Cygnus- Cygnus Business Consulting and Research is a services organisation focusing on analysis and research of Economies, Industries and Companies

With global sales of biologics reaching nearly $137 billion in 2009 and the patents on at least 48 biologics due to expire over the next decade, industry experts predict that the global biosimilars market could be worth more than $43 billion by 2020. But biologics differ from conventional pharmaceuticals in some fundamental ways.

1.2.4.2 Size and Composition of the Global Biologics Market

In 2009, global sales of biologics totalled $136.6 billion (Table-6). Avastin (bevacizumab) headed the list of best sellers , with sales of $5.74 billion, while Rituxan (rituzimab) and Humira (adalimumab) came second and third, respectively as per table below.

Table-6: The Global Market for Biologics in 2009

Country	2009 Sales ($ bn)
US	69.02
Europe	41.68
Japan	10.29
Asia/Africa/Australasia	14.4.0
Latin America	1.20
Total Biologic Drugs Market	**136.59**

Source: Visiongain & Pricewaterhouse Coopers analysis

Table-7: The 10 Top Selling Biologics in 2009

Brand	Drug Name	2009 Sales ($ bn)
Avastin	bevacizumab	5.74
Rituxan	rituximab	5.62
Humira	adalimumab	5.48
Herceptin	trastuzumab	4.86
Lantus	insulin glarine	4.29
Enbrele	tanercept	3.87
Remicade	infliximab	3.51

Neulasta	pegfilgrastim	3.35
Epogen	epoetin alfa	2.56
Avonex	interferon beta-1a	2.32

Source: Evaluate Pharma

1.2.4.3 Size and Composition of the Global Biosimilars Market

Biosimilars accounted for sales of just $1.23 billion – less than 1% of the total biologics market – in 2009 (Table 8). However, there is considerable potential for growth.

Table-8: The Global Market for Biosimilars in 2009

Country	2009 Sales ($ bn)	Market Share of Biosimilars (%)
US	0.06	4.9
Europe	0.14	11.4
Other Countries (incl. China and India)	1.03	83.7
Total Biosimilars Market	1.23	100

Source: IMS Health & visiongain

1.2.5 GROWTH

1.2.5.1 Domestic Industry:

As stated earlier above, the domestic pharmaceutical Industry has grown at around 12% CAGR since the start of the 11th Plan in 2007, from Rs 45,367 crores in 2007 to about Rs 62,055 crores in 2009-10. This is sustained by the following factors-

a) market size increase due to increase in the size of middle level income earning population segment as it grows in size from the current 270 Mn to some 583 Million by 2025[9];
b) Increase in purchasing power of this group;

[9] www.Mckinsey.com/mgi/mginews/bigspenders.asp

c) Aging of the Indian population as life expectancy has increased from about 42 years in 1960s to 66.95 years at the beginning of the 11th plan to now 68.45 years in 2010-11[10] coupled with the purchasing power of this segment. It is to be noted that people of old age spend around 3 to 4 times more on drugs than people in younger age groups for obvious reasons;

d) greater market penetration due to increasing spread of private sector medical insurance cover driven by liberalization of the insurance sector of this burgeoning middle class; and

e) sustained expected growth of the Indian economy in general at a GDP growth rate of some 9% to 9.5 % in the12th Plan period[11]

Going forward, the above factors for sustained growth will be matched by the inherent ability of the Indian manufacturers to scale up production with less costs and time, as witnessed in the over Rs 29,000 crores of investment in setting up of new manufacturing plants in the country in the 11th plan period[12].

The product patent now permitted following the 2005 amendment in the Patent Act 1970 has further encouraged the now reasonably prepared Indian pharmaceutical companies to move from its expertise in process chemistry which has served it well for generics products to more complex skills in drug molecule Research and Development. Thus R&D investments of the top 15 Indian manufacturing companies have increased from 3% of sales in 2000 to some 8.68% of sales in 2010[13]. Based on above facts, the projected growth of the pharmaceutical sector as per present outlook is –

Table-9: Projected Growth

Value in Rs crs / Growth in %

Year	Domestic	Exports	Total

[10] Census Commission
[11] Planning Commission
[12] IPA
[13] IPA

	Value	Growth	Value	Growth	Value	Growth
2016-17	130,000	21%	158,000	16%	288,000	18%
2019-20	233,000	22%	248,000	17%	481,000	19%

1.2.5.2 Bulk Drug Industry Growth component:

In India the bulk drugs industry is a major driver for the overall industry growth being driven by the same 6 reasons as for the pharmaceuticals formulations sector mentioned earlier. As per the estimates of Bulk Drugs Manufacturers Association (BDMA), this high growth will continue and the sector will be of USD 20 billion size by 2015 growing at a CAGR of 20% from 2008-09[14]. With these projections, it is expected to touch US$ 28 billion by end of 12th plan in 2017.

1.3 EXPORT:

1.3.1 Structure

India is among the top 20 pharmaceutical exporting countries globally and has shown commendable export performance with continuous positive trade of balance. Exports constitute a major part of Indian pharmaceutical Industry and at present it is around 45% of total turnover of the Industry. As per DGCIS, the export during 2010-11 has reached more than Rs 45,000 crores.

Indian drugs are exported to around 200 countries in the world with highly regulated markets of USA, UK etc. The top five exporting destination countries are USA, Russia, Germany, Austria and UK with USA alone accounting for almost 20% of total export. The major therapeutic categories of export are anti infective, anti asthmatic and anti hypertensive. Country-wise, the position is as flows:

1.3.2 Growth

[14] BDMA

Exports have grown very significantly at a CAGR of around 19% in the 11th Plan period, from Rs 25,666 crs in 2007 to over Rs 45,000 crores during 2010-11[15]. The table-10 below gives a picture of growth of export for last 5 years.

Table-10: Export Growth

Year	Exports (Rs.crores)	Growth %
Mar 2007	25666	20.89
Mar 2008	29354	14.37
Mar 2009	39821	35.66
Mar 2010	42154	6.6
Mar 2011	45745	7.7

The sustenance in export growth rates will be driven by three factors –

i. Increased dependence on generics production due to patent expiries by 2015, estimated at some US$ 300 Bn of conventional and biopharmaceuticals[16];
ii. Slow down in discovery / invention of new molecules in developed countries; and
iii. pressure on the developed country governments like US, Germany, Japan, etc to contain their healthcare expenditure;

Consequently, the global MNCs are now increasingly depending on the Indian generics producers, as witnessed in the acquisitions/mergers of six major Indian Pharma companies at a worth of over US$ 10 billions in the 2007-2010 period with an average purchase price of about 7 to 9 times the gross revenues for a given company.

1.3.3 Global Share

[15]DGCIS
[16] McKinsey &Company,"Capturing the India Advantage-page 18

India, at present is recognized as a leading global player and holds 3rd position in terms of volume and 14th the in terms of value of the production. The global market for generic drugs in 2009 was worth US$108 billion (FICCI-IMS report on Global Generic Market) and Indian pharma market, which as pointed out earlier consists of almost generic drugs only, contributed around 20% in terms of value. Globally, in the overall pharmaceuticals space, with a turnover of US$21 billion in 2010, Indian Pharmaceutical Industry has a share of 2.4% in terms of value in global pharmaceutical industry which is having a turnover of US$ 878 billion in 2010[17].

1.3.4 Regulatory

India is signatory to the WHO certification protocol on the quality of pharmaceuticals products and has therefore accepted the WHO-GMP standards as an integral part of the standards for export of pharmaceuticals products. As per arrangement, WHO-GMP certification is granted by the office of the DCGI (CDSCO) and State FDAs. The certification is for two years at a time.

Since export of generics to the high growth emerging markets is to be a key strategy for growth of pharma industry in the country, hence upgradation of SMEs to WHO-GMP standards would enable them to export their products and thereby increase profitability. It is estimated that at present about 800 units are certified by CDSCO for WHO-GMP production. As there are about 10,000 plus Pharma SME Units in the country, therefore, the number of WHO-GMP standard units needs to be raised to at least 2000 by the end of the 12th plan in 2017 to enable the SME sector to increase and sustain its participation in the Pharma Industry growth process. Accordingly given the ambitious target of achieving USD 100 Bn production by 2020, it is estimated that about 1000 - 1200 units will have to be assisted for raising their manufacturing standards to WHO-GMP levels. At an average production contribution of USD 10 Mn per unit, this would mean additional contribution of about Rs.10 Bn from the above target achievement.

[17] April-10,2010. IMS – forecasts for global pharmaceutical market – Market Prognosis : www.imshealth.com

Further, there is need to upgrade at least 250 units to US FDA/EDQM/TGA and other International Standards by 2017 and training of 5000 Working Professionals in WHO-GMP and other International Standards GMP requirements.

1.3.5 Competitiveness and Benchmarking

1.3.5.1 Competitiveness

Global Pharma Market

The global market is characterized by -

- Peak years of patent expiries driving growth toward generics
- Publicly funded markets facing slower growth and added uncertainty
- China on path to becoming world's third-largest market in 2011

As per estimates of IMS Health – a global pharma consulting organization - the size of the global market for pharmaceuticals is expected to grow nearly $300 billion over the next five years, reaching $1.1 trillion in 2014. The 5 - 8 percent compound annual growth rate during this period would reflect the impact of leading products losing patent protection in developed markets, as well as strong overall growth in the world's emerging countries. It is to be stated that global pharmaceutical sales grew at 7.0 percent to $837 billion in 2009, compared with a 4.8 percent growth rate in 2008.

The market will continue to driven by patient demand despite the ongoing effects of the economic downturn. In developed markets with publicly funded healthcare plans, pressure by payers to curb drug spending growth will only intensify, but that will be more than offset by the ongoing, rapid expansion of demand in the pharmerging markets. Net growth over the next five years is expected to be strong — even as the industry faces the peak years of patent expiries for innovative drugs introduced 10 - 15 years ago and subsequent entry of lower-cost generic alternatives.

Going forward, IMS has identified the following key market dynamics:

i. **Geographic balance of the pharmaceutical market will continue to shift toward pharmerging countries.** Pharmerging markets (BRIC, South Korea, Turkey, ASEAN, etc.) are expected to grow at a 14 - 17 percent pace through 2014, while major developed markets (US. West Europe) will grow 3 - 6 percent. As a result, the aggregate growth through 2014 from pharmerging markets will be similar to the growth experienced in developed markets — about $120 - $140 billion. This compares to aggregate growth over the past five years of $69 billion in pharmerging markets and $126 billion in developed markets. The U.S. will remain the single largest market, with 3 - 6 percent growth expected annually in the next five years and reaching $360 - $390 billion in 2014, up from $300 billion in 2009.

ii. **The Therapy area growth dynamics will be driven by innovation cycle and areas of unmet need.** As the pharmaceutical industry's research and development programs adjust to the broad availability of low-cost generic options in many chronic therapy areas, higher growth will occur in those therapy areas where there is significant unmet clinical need, high-cost burden of disease, and innovative science that can bring new treatment options to patients. In the areas of oncology, diabetes, multiple sclerosis and HIV, annual growth is expected to exceed 10 percent through 2014 as new drugs are brought to market, patient access is expanded and funding is redirected from other areas where lower-cost generics will be available.

iii. **Broad cuts in spending will be applied by public payers to reduce growth in drug budgets.** Publicly funded health systems are under increased pressure to reduce growth in drug budgets following the global economic downturn.

Countries including Turkey, Spain, Germany and France already have announced plans to apply across-the-board restrictions on access or reductions in reimbursements to reduce drug spending growth. Governments in other countries seeking to restore fiscal balance may take similar actions, or shift more costs to patients.

iv. **Peak years of patent expiries will shift major therapies to generic dominance.** Over the next five years, products with sales of more than $142 billion are expected to face generic competition in major developed markets. Collectively, the impact of patients shifting to lower-cost generics in major therapy areas such as cholesterol regulators, antipsychotics and anti-ulcerants will reduce total drug spending by about $80 - $100 billion worldwide through 2014. This impact particularly will be felt in the U.S., where nearly two-thirds of the total value of patent expiries will occur. Patent expiries in the U.S. will peak in 2011 and 2012 when six of today's ten largest products are expected to face generic competition.

v. **Closer scrutiny of new products will result in restricted contributes to lower initial spending by payers.** The number of new molecular entities launched annually over the next five years is expected to remain in the range of 30 to 35 products. However, these will be subject to more rigorous and complex assessments by payers before being accepted into clinical practice and reimbursed. In many countries — including China, Spain, Italy and Canada — funding and implementation of healthcare at regional or local levels is becoming more significant. This is expected to extend the time it takes for new medicines to become available to patients, and contribute to lower initial spending by payers.

Further that the expected global economic recovery removes an element of uncertainty for the industry over the next five years, although the way payers address lingering budget deficits will remain an issue in many markets. Health system reforms, such as those to be implemented in the U.S., can spur fundamental change in the market — but the full impact may not be felt until the latter half of this decade. Leading up to 2020, IMS expects to see a continuing shift toward biopharmaceuticals, specialty-driven products, and changes in the mix of disease areas of interest.

1.3.5.2 Benchmarking

i. **Research, development and Innovation**
ii. **Human Resources**
iii. **Technical Capability**
iv. **Infrastructure**
v. **Cold Chain infrastructure**

(i) Research, development and Innovation

Research and Development (R&D) is the backbone of the global leaders in the pharmaceutical industry all over the world. The pharma companies in the developing countries with some sizeable turnover are now increasingly therefore looking at innovation and R&D as key strategies for future growth. The Indian pharmaceutical companies cannot afford to be different. Some leading Indian companies like Sun, Zydus Cadilla, DRL, Lupin, etc are increasingly focused on R&D to tap the upcoming opportunities from expiration of patents of several blockbuster products.

The global average R&D expenditure in 2010 was $68 billion which was around 8% of global Pharmaceutical sales in 2010 i.e. $856 billion[1]. Hence, although in terms of percentage the R&D expenditure of big Pharma companies in India is also comparable to global average , however the total expenditure on R&D by Indian

firms is much less as compared to the global expenditure. More details of this is discussed in Chapter 3 on R&D.

(ii) Human Resources

The subject of Human resources required in detail in the Chapter 3 on Capacity Building and Employment. For sake of a complete discussion briefly it may be mentioned here that the Government and the private sector do offer a useful institutional structure for providing diploma to PhD level knowledge development in the pharmaceuticals sector. The Government of India - through the high end National Institute of Pharmaceutical Education and Research established at Mohali, Chandigarh in 1997 followed by setting up of six National Institutes of Pharmaceuticals Education and Research(NIPER) at RaeBareilly, Hajipur (Patna), Hyderabad, Ahmedabad, Guwahati and Kolkata. These provide post graduate and PhD level education and contribute to some 1800 Masters and PhDs per year. Other central government institutes include – The Indian Institute of Chemical Technology (IICT), Centre for Cellular and Molecular Biology (CCMB), National Institute of Nutrition (NIN), Centre for DNA Fingerprinting and Diagnostics (CDFD), Indian Immunological Ltd (IIL), etc.

A number of State Government Universities and Colleges also offer both graduate and post graduate education in pharmaceutical sciences. The above resources are also supplemented by the institutes and colleges in the private sector. Together both the government and private sector roll out some 51000 graduates and 5200 PGs in pharmaceuticals sciences every year[18].

(iii) Technical Capability

The chemistry skills produced in the country through its colleges and universities supported by their demand in the generics dominated production pattern in Indian pharma has played a key role in building Indian dominance in the global generics sector. That this skill has come at low costs has resulted amongst various

[18] Report by Deloitte 2010 for DoP on setting up of new NIPERs

other factors in enabling Indian pharma to produce one of the cheapest good quality drugs in the world. A comparison of the drug prices in India and Pakistan illustrates this point. With hardly any manufacturing base for drugs, the prices of drugs in Pakistan are much higher than in India (3 to 14 times) even though per capita incomes in both the countries are more or less same. However with China there is a tough competition on this front. Nevertheless, India is amongst the few developing countries to succeed in building strong local capability in the technology-intensive pharmaceutical sector.

However, once again the technology development being limited to generics APIs or formulation has been mostly limited to cost-effective process development. This has resulted in poor development of new products. However it can be argued that since the Indian pharma started development only as from 1960s albeit in a MNC dominated environment, it is a credit to it to be able to develop even to the current skills as compared to rest of the world. Surely high risk and high skill demand for new drug development can possibly not be done in barely 25 years of a high technology industry and the Indian pharma rightly first met the needs of country's drug needs in the much required anti-infectives sector (the molecules in this segment were in early 1940-50s) and is now perhaps well placed to take on the new drug development challenges. Were it not so, India would not have been able to tap the globalization and liberalization opportunity now wide open in the generics sector with its low cost good quality base. This is discussed more in the Section 1.7 on SWOT Analysis. Going forward, Indian pharma industry would need to focus on developing competence in advanced areas of drug manufacture e.g. biopharmaceuticals, DNA based drugs etc.

(iv) Infrastructure

Although Indian pharma has globally recognized capabilities in generics production, China is forging ahead with huge investments in API production which requires inter-alia cheap power and other infrastructure facilities. Israel, Germany, Brazil and Turkey are also building large strengths. In the field of medical devices,

the Indian industry is in nascent stage. So, there is a need of developing common infrastructure in drug discovery and development, manufacturing, distribution, exports, medical devices, etc.

The key areas are:

(a) **GLP Compliant Animal Facilities**: Pre-Clinical testing requires primate based large animal testing. However there are limited primate facilities in the country. While ICMR has proposals for transgenic animal facilities and a National center for non-human primate breeding center there is need to build capacity in this area and to do it fast. This would require licensed breeders meeting and maintain GLP standards.

(b) **Biological Sample Storage Facilities:** Access to storage facilities adhering to appropriate bio-safety levels is required, as India addresses challenges of infectious diseases. Currently, samples used in many of the clinical trials are being stored / archived outside India. Many Indian pharmaceutical companies outsource safety, pharmacology and regulatory toxicity studies to other countries, due to lack of comprehensive facility existing in the country, which could carry out these studies in an integrated manner.

(c) **Shared Infrastructure for Optimal Capacity Utilization:** Every scientist ore R&D institution / Industry facility does not require complete self-sufficiency in terms of in-house infrastructure. Pooling of resources between government and industry as also academia even while secrecy conditions would go a long way in building mutually beneficial partnerships.

(v) Cold Chain Infrastructure

The Pharmaceutical Supply Chain is very complex and highly responsible to ensure that the concerned drug reaches the target people without losing its efficacy wherever the drugs are temperature sensitive where the Cold Chain Infrastructure

is paramount. This is particularly important for Vaccines and related treatments like Polio, etc.

This fact is increasingly of importance now in the Indian market given the growing access along with the large and often poorly connected distant places where treatment medicines are to be carried to. Hence, pharmaceutical companies in India have realized the importance of SCM related Cold Chain Infrastructure and are aggressively looking for ways to improve the costs associated with SCM. Distribution in India is proportionally much more costly than it is in the US or EU due to inherently poor transport structure available for drugs. Upto one-third of the revenues are often spent on SCM. Because of lack of developed SCM infrastructure for drugs, the cost is higher in India as compared to US and EU (2% of sales in US/EU as compared to 4-% in India). (BioPharm International www.biopharminternational.com September 200).

One other reason for the absence of a modern SCM infrastructure is that the medicines supply chain in India is highly fragmented with more than 550,000 retail pharmacies spread across vast distances often poorly connected in the country. This also leads to such problems as concerning recall of drugs. Newer technologies would help in keeping track of products along the entire chain and would limit counterfeit drugs to enter into the system. The problems are obviously compounded when mandated cold chain requirements are to be met. This is one of the major challenges faced by the industry if they are to retain product quality during shipment specially the biotech products. Therefore the organized drug retail faces daunting challenges which would therefore be a key factor to improve affordable and quality health care access to all.

1.4 IPR and International Cooperation Issues

1.4.1 The subject of IPR, TRIPS, Patent Linkage, FTAs, Data Exclusivity, etc. are much debated in the national and international fora. Both large and SME units are finding it difficult to cope up with the increasingly new demands being placed on these

issues by the developed markets. It is also widely believed that this is to build non-tariff barriers against the capabilities of the Indian pharma to garner a larger market share in the developed markets now having increasing need for generics for cost containment in the context of limited government budgets and the continuing slow down of the economies.

Indian Pharma Industry consists of 60% domestic and 40% of export market on account of which the exports would be affected due to such an approach of the developed market regulators. The Standard Operating Procedures (SOPs) of different governments is different internationally. Therefore there is a requirement to educate SME units about country specific SOPs for testing their products.

In this regard, the situation is already pitiable even for testing of products for Indian markets due to lack of availability of reference standard products as per Indian Pharmacopeia (IP). Thus while more than 1000 molecules are being manufactured or marketed in the country, IPC has reference standards for about 200 products only. Thus these batch specific and time limited reference products have to be either imported or got manufactured in-house or through other units which is a very tedious and expensive process. There is a need to launch partnership programmes by DoP in partnership with MoHFW / IPC to make reference standard products available not only for IP but also for other countries where major exports are focused. There is also need for increased training for SMEs regarding the SOPs and ensuring availability of reference standard products for testing and fulfilment of exports requirements.

1.4.2 Non-Tariff Barriers (NTBs): The exporting units both bulk drugs and formulations face three types of non-tariff barriers related to regulatory requirements from high export markets like the EU.

i. There is a requirement to ensure compliance to EDQM standards which is available for only 3 years at a time with such high costs as Euro 15,000 per drug per time.
ii. Then in addition to EDQM there is further need to obtain certification from each importing country.
iii. Further in the case of bulk drugs, a third additional requirement is of a third party audit. This audit compels companies to divulge their intellectual property infringing on their right to protect data guaranteed under TRIPs.
iv. Then, EU is insisting on verification of pedigree of Active Pharmaceutical Ingredients in case of export of formulations.

Clearly, if such NTBs are to be addressed there is a need to create greater synergy among various government departments/ministries viz. Department of Commerce (DoC), Pharmexcil, M/o Health & FW, DoP for formulating an integrated strategy to tackle such barriers and may include taking counter measures.

Additionally there seems to be lack of clarity in the multiple trade agreements viz. Trade Related Intellectual Property Rights (TRIPs) of WTO, Anti Counterfeit Trade Agreement (ACTA), etc due to exporters are facing problems in ensuring their compliance which is affecting their exports. These issues need to be tackled in a comprehensive manner by joint efforts of DoP and DoC .

Another issue concerns a recent step taken by some developed counties in the form of Trans Pacific Partnership Agreement (TPPA), a new regional free trade agreement which include the United States, Australia, Peru, Vietnam and Malaysia, Japan, etc. TPPA has discriminatory arrangements between signatory and non-signatory countries which is a violation of TRIPs.

Additional barriers are also being raised in emerging markets like Argentina wherein there is a discrimination in import regulations between bulk drugs (which are allowed) against formulations which are banned. Herein there is also a trust deficit between the industry and the government especially in the context of government signing Free Trade Agreement(s) with various countries wherein facility of zero duty is being extended there is every likelihood of creation of further problems without proper involvement of the Industry.

In the special context of these regulations impinging on Indian Pharma's leadership in the API sector, there is a need to study the details of APIs production especially in Spain, Italy, Portugal and Eastern Europe and prepare a report on export of Indian APIs/formulation drugs to EU and details of APIs being manufactured in these countries. There is a need to tackle these issues in organized manner wherein representatives of the industry need to be co-opted in the efforts. It is proposed to establish a cell in IPA, to be funded by DoP, on all issues related to IPR, regulatory issues, etc. acting as barriers.

In this connection there is need to tap a new development – The adoption of recommendations of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S). This agreement provides for interalia cooperation between countries and pharmaceutical inspection authorities for enabling international development, implementation and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in pharma products. This is to be achieved by developing and promoting harmonised GMP standards and guidance documents, training competent authorities and regulators in the pharma sector.

1.5 2D Barcoding

2D Barcoding has been made a regulatory requirement for export of medicines by DGFT to prevent fake medicines and mis-representation of Indian exports in the

name of other countries like China etc. The SSI units doing contract manufacture for trading houses and other pharma need to be supported by government schemes for building this competencies both by way of infrastructure and financial support. Further the implementation of 2D Barcoding at tertiary level i.e. at strip level also envisaged by DoC could become very expensive and offset Indian price competitiveness in emerging markets. The MNCs who export high priced patented drugs have no such problem. In the 11th plan recommendation had been made for a Rs. 100 crores assistance for assisting SMEs to build export competitive infrastructure and technology support. However the same could not be implemented. There is need to do it now for the 12th Plan.

1.5.1 Apex Authority to Control Prices, Quality &Supply of Drugs

NPPA is mandated for pricing of drugs and DCGI is the authority for ensuring standards for manufacturing and quality of drugs in addition to the basic element of introducing the drug itself in the country for any therapeutic treatment. A need for a common authority has been felt in the past several years (Pronab Sen Report of 2005[19]) for ensuring supply of sufficient good quality drugs. The view of the DoP is that such an authority like the National Authority on Drugs and Therapeutics (NADT) addressing all these issues in a single window mode if constituted should be part of the Department of Pharmaceuticals with the DoP itself being part of Ministry of Chemicals and Fertilisers or otherwise.

1.6 Environmental issues:

1.6.1 Present Status

The Indian pharma industry has evolved around industrial development clusters set up by various state governments. In earlier years, most of the manufacturing and R&D units could take benefit of the then prevalent lax or otherwise environmental laws. But now international customers from developed nations are becoming more

[19] Dr. Pronab Sen Report Sept.2005

stringent on ensuring local environment standard compliance standards and want companies to adhere to these standards. This has led to a big challenge for the Indian pharma industry, particularly small scale units, which either have investment concerns or limitations of growth beyond their allotted unit areas in the industrial clusters set up earlier with antiquated environment standards compliance potential. DoP is expected to play a vital role by providing financial and technical assistance to improve financial sustainability of SMEs on one hand and also safeguard the environment from the hazards associated with the unplanned growth of the industry. This is particularly challenging for the bulk drug industry already a source of adverse reaction in the public in areas around Hyderabad and also for new possible growth centers for the pharma sector. The mission should be **Clean business = more business = Better Health Care medicines for all.**

1.7 SWOT ANALYSIS

The Indian Pharmaceutical industry has emerged as a leading low cost high quality generic medicines supplier to the world. Its future growth is pebbled with several aspects of its strengths, weaknesses, opportunities and weaknesses.

1.7.1 Strengths

(1) Strong Low cost manufacturing sector

Like the rest of the Indian manufacturing and services economy, as compared to the European and US levels, the pharma sector has the strength of -

i. low wage costs;
ii. low material costs like the bulk drugs and the chemicals intermediates required to manufacture the bulk drugs as well as the excepients which go into formulations manufacture; and
iii. low cost of living.

Thus overall drugs manufacturing in India is up to 50% cheaper than in western industrial countries.

In terms of breadth of the industry, the Indian Pharmaceutical sector is having around 10563 manufacturers in the country[20] comprising some 300 large and medium units and balance in the small scale and unorganized sector. The emphasis on generics and the existence of process patent only regime between 1970 and 2005 helped the SME sector to grow. It enabled India to source more than 85% of its domestic demand for bulk drugs, drug intermediates and is almost self reliant in pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles up from domestic production with 20% in 1950s.

This growth was in a large measure triggered by the government initiatives in the public sector with the setting up of large plants for manufacturing antibiotics – HAL in 1951, IDPL in 1961 KAPL in 1981 etc. This growth shared a synergy with the growth of the chemicals sector and the whole gamut of chemical based industries provided the basic technology and science skill for drugs manufacture.

Following liberalization the contribution of the public sector has expectedly decreased in an increasingly commoditized market. At present, the leading 250 pharmaceutical companies control 70% of the market with market leader holding nearly 7% of the market share.

(2) Competitiveness of Indian Generics

An important characteristic of the Indian pharma industry is its exports as pointed out earlier. This is sustained by the increasing competitiveness of the industry vis-a-vis the developed and regulated markets which is reflected in the large number of Abbreviated New Drug Applications (ANDA) and First to File (FTF) fillings for the formulations sector and Drug Master Files (DMF) filings for the bulk drugs by Indian companies in the USFDA for exports to US market which by itself is valued at US $

[20] DoP survery 2007 done in collaboration with MSME –First Pharmaceutical Census – DoP Annual Report 2010.

300 Bn in 2009[21]. Thus, in 2010, over 30% of DMF approvals by USFDA were from India. This shows the competitiveness of the Indian pharma as compared to the other leading generics producers like China, Israel and Germany. It is noteworthy that this proportion of filings by Indian companies has increased from 14% in 2000[22].

This competitiveness is further extended in the EU markets as witnessed by the fact that India has around 461 Certificate of Suitability i.e.19.78% of the total granted by European Directorate of Quality Medicine (EDQM). Also, the products registered by India vary in complexity and range of therapeutic areas. This ensures that competition for the products offered by Indian companies is restricted ensuring steady demand.

(3) Human Skill

The human resources availability in India is characterized by:

- Significant breadth and depth in engineering and science
- Lower cost of innovation and highly motivated scientists.
- Large pool of English speaking employees, a comfort for international customers and regulatory agencies.
- Low cost scientific pool on shop floor leading to high quality documentation and process understanding
- Outsourcing services culture

There is abundance of low to middle level skills in science and technology in general and as also in the pharmaceutical sciences sector. The table-11 below makes this clear.

Table-11: Human resource position in India

Sl	Item	Total numbers
1	No of Universities	409

[21]IMS Health , Spring 2010
[22] Cygnus Report

2	No of colleges	25990
3	No of science colleges	4696
4	Annual student output at degree level in science	2000374
5	Annual student output at degree level in engineering	1663619
6	Total no of pharmacy colleges	1162
7	Number of B Pharm colleges	848
8	Number of Masters in pharmaceuticals area and PhD offering colleges	191
9	No of B Pharm students in pharma	51716
10	No of Masters and Phd students output in pharma	5648

Suffice it to say that the level of availability of manpower in numbers in a general skill capacity is quite abundant. For domestic pharma industry this is adequate in terms of basic needs. To that extent the situation of demand – supply is similar for the MNCs operating in India. The skill base has so far served well for meeting the needs for chemistry skills, R & D and manufacturing infrastructure with proven track record in advanced chemistry capabilities, design of high tech manufacturing facilities and regulatory compliance. This is evidenced by the fact that the largest number of USFDA approved plants outside US are in India. Still, there is shortage of skill in high-tech area.

Lately, in the last 3 to 5 years, there has been an increasing demand for the contract research and clinical trials industry from the MNC end as well as from domestic entities. This is further catalysed by the availability of abundant drug naïve population and variety of gene pool.

1.7.2 WEAKNESSES:

(1) Low R&D Budget:

Although the Indian pharmaceutical industry is large by Indian standards, on the world market its share is merely 2.4%. The estimated investment in R&D by major Indian Pharma companies is around 8.68% of their sales turnover. As a percentage of

total production this works out to only 4.4.% of the total production. Compared to the R&D investment in the developed markets of some 8%[23] the Indian investment is quite low. One reason for this is the emphasis so far on growth based generics production and the prevalent disease pattern of high need of generic anti-infectives, antihistamines, pain management and other third world vector borne diseases like Malaria, Filariasis, Anti-heleminthic, etc. All the drugs for these treatments have been already in the generic space globally for more than 40 years and hence the growth of generics is not out of context. The picture is complete given the low purchasing power of the middle class and the rural areas upto 1980s.

Thus high end R&D was not a requirement and disease control was more an issue of access to public health infrastructure and low cost medicines. To that extent the Indian manufacturing model has served well from the manufacturing point of view. However now that India is poised for a greater role in the global economy in general and also in the pharma sector for reasons discussed earlier in terms of the growth drivers, the weakness in the system of poor R&D is quite evident. The industry's total R&D budget is comparatively very small as compared to the global competitors. Thus individual R&D budgets of many US companies probably amount to much more than the cumulative R&D budgets of all the companies in India(in 2009 ,Pfizer spent around 18% of its sales turnover of US$9.9 Billion)[24]. This is further manifest in some new areas like pharmaco-genomics leading to personalized medicine as the basis of therapeutic treatment with drug therapy tailored to individuals. The emerging areas of bio-pharmaceuticals with highly capital intensive high failure features further raises the entry barrier to modern day pharma R&D.

The problem of R&D investment is enhanced by Lack of supportive funding from government as has been possible in other competing countries like Israel, Singapore and Malaysia. The R&D is no where near the possible funding in developed countries

[23] Pharma Times, June 11, 2011

[24] www.evaluatepharma.com/Universal/View.aspx?type=Story&id=217946&sectionID=&isEPVantage=yes

like US under the National Institutes of Health funding programs. This has also resulted in poor tapping of opportunity presented by the introduction of product patent regime in 2005.

More details on R&D may please be read in Chapter-2 on R&D.

(2) Inadequate Infrastructure

While there is an established basic weakness in basic infrastructure like power, roads and cold chains the Lack of advanced lab and related infrastructure for drugs testing and developed is acutely perceived in the need of greater emphasis on research and development as well as large capacities required for APIs and formulations on the scale at which competitors like China and Israel operate. This is particularly true for such sectors like antibiotics where the country has migrated from a state of complete independence to total dependence on imports from China for fermentation bulk products due to unmatched costs of power and high capacity build up leading to low costs of production. This in a sense is also a strategic issue and has assumed significance following the HINI Swine Flu epidemic.

The development of infrastructure is a key to success, and the Indian Pharmaceutical Industry and so there is need to take more definitive steps to overcome this weakness.

(3) Diffused Industry structure

Diffused nature of the Indian pharmaceutical industry whereby, only about 20 to 30 companies are large enough to bear the transactions costs associated with sustained production including exports particularly in the light of increasingly stringent compliance entry regulations of the developed and emerging markets. Thus there is Lack of depth and breadth now in the context of the international scenario.

(4) Poor Industry-Academia linkage

There is a conspicuous Lack of strong linkages between industry and academia which are essential for growth of the industry.

(5) Limitations to domestic market size

Limitations in growth of the domestic market size due to constraints of low medical and healthcare expenditure in the rural areas of the country in spite of specific projects like NRHM, DOTS, NSAIDS and Pulse Polio.

(6) Decreasing labour arbitrage

Now rapidly increasing costs of skilled manpower such as scientists/ regulatory compliance personnel / pharmaceutical lawyers/ international business development personnel is pushing up the cost of innovation leading to loss of arbitrage of labour as compared to developed and other emerging market countries.

(7) Poor world class project skills

Project management capabilities to evaluate contracts/alliances etc., is available only in top companies.

(8) Non-availability of major intermediates for bulk drugs

(9) Inadequate overseas marketing infrastructure

The Indian companies are severely Lacking in a global marketing work force no doubt constrained by surplus capital and recurring expenditure costs much required for global dominance. This has resulted in a number of marketing tie-ups of Indian companies with MNCs. These tie-ups while being presented as successful partnerships miss the fact that the lucrative emerging markets are lost due to Lack of ability to tap them by indigenous efforts. While the exact terms of deal are not public privy, the win-win situation requires a deeper study to anlayse the loss of opportunity due to the weakness of the marketing force.

(10) Lack of regulatory infrastructure

Due to major understaffing and Lack of resources with the Central Drugs Standards and Control Organisation (CDSCO) under the Ministry of Health there is a major

bottleneck for timely clearances for new drug trials, pharmacovigilance and assistance to the willing industry members to shore up their technical capacities for better regulatory compliances. The Lack of drug inspectors, both at the centre and the state level in the FDAs is a major hindrance in the smooth growth of the industry. No where is this more evident than in the poor pace of clinical trial clearances and the FDCs segment.

(11) Lack of proper Regulatory Framework for biosimilar drugs

Presently, biosimilars are regulated under the provisions of Environment Protection Act of 1970 and the Drugs & Cosmetics Act of 1940. There are no set of specific rules to enable speedier and unambiguous clearance for production of biosimilars. This is important in the context of the fact that biosimilars is a very strong emerging market opportunity for the country.

(12) Regulation of fixed drug combinations.

Another important issue concerns regulation for approval for fixed drug combinations .This needs to be evolved in consultation with the industry. The DTAB under the DCGI should have a representative of DoP so as to ensure that the Pharma Industry concerns are addressed in a speedy and unambiguous manner.

1.7.3 OPPORTUNITES:

(1) Generics

As per McKensey study conducted by DoP[25], US$300 Bn are expected to go off patent by 2015 for conventional molecules and biopharma. Factoring for the reduction in price and the consequent market value from patent to generics this is estimated to be at least 30-35% which translates to some US$100 Bn.

Compulsory licensing provisions negotiated in the Doha Round, allows for countries to import cheaper generic versions of patented drugs in the interests of public

[25] McKinsey &Company,"Capturing the India Advantage-page 18

health. Thailand and South Africa have already started such initiatives from which Indian firms have benefited. This is an opening opportunity albeit not very large for Indian pharma.

(2) Bio-generics & Bio Pharma

Bio-generics are nothing but generic versions of biological products. India's biotechnology sector is growing fast and is in the early stages of development with initial emphasis on vaccines and bio-services. The industry currently has around 340 companies which employ more than 25,000 technologists. The Indian Bio-Pharma industry has already a strong global presence, producing the fourth largest volume of products in the world. India’s vast pool of skilled manpower, huge patient base and relatively low costs drives many global biotech giants to partner, acquire or outsource to Indian companies. Likewise, some of the larger Indian companies have even begun acquiring foreign entities in the Unites States and Europe, to retail their products and expand product offerings.

Internationally speaking, in a study conducted on behalf of Datamonitor by Bornadata Bain, vice-president and global director of research and analysis, healthcare, and John Shortmoor head of company analysis, both at Datamonitor Group, it has been stated that the product mix of pharmaceutical companies' pipelines and commercial drugs is of crucial importance to contract development and manufacturing organizations as they evaluate their service capabilities and tailor them to demand. Market fundamentals are changing. The erosion of the blockbuster-drug model, traditionally supported by small-molecule drugs (i.e., drugs with a molecular weight of < 500 Da), in favour of an increased emphasis on biologic-based development is an important consideration not only for pharmaceutical companies' product strategies, but for contract service providers that offer drug-substance and finished-product manufacturing.

Although small-molecule drugs will continue to dominate the overall pharmaceutical market, market growth in small-molecule drugs will contract in the near term. In biologics, mAbs will drive growth and so enticing a growing number of companies to expand in this field with the hope of ensuring long-term growth. In fact, 36 of the top 50 pharmaceutical companies (excluding generics companies) will have a presence in the mAb, therapeutic protein, or vaccines sector by 2014. Currently, 32 of the top 50 companies are now in those sectors. Vaccines will grow at a 5.5% compound annual growth rate (CAGR) between 2009 and 2014, partly because of the emergence of new technologies and the recent commercial success of several novel products such as Pfizer's pneumococcal vaccine Prevnar and Merck & Co.'s human papillomavirus vaccine Gardasil.

Biotechnology companies have focused primarily on biologics, but from 2008 to 2014, the dominance of therapeutic proteins within the molecular class mix will decline steadily as mAbs gain market share. Nevertheless, therapeutic proteins will remain the dominant molecule type throughout, accounting for 68.0% of 2014 sales. This shift in focus toward mAbs will be spurred by this molecular class's relatively strong growth of $4.4 billion in 2008–2014, which resulted primarily from the launch of Amgen's Prolia and continued sales growth of Merck KGaA's Erbitux. Interestingly, therapeutic proteins will deliver greater sales growth until 2014 (i.e., $5.2 billion) because of Novo Nordisk's insulin-analog portfolio, which includes NovoRapid, NovoMix, and Levemir. Small-molecule growth will total less than half of that delivered by biologics, at $3.1 billion.

Biogen Idec has the biggest mAb focus and also the biggest biologics focus; mAbs and therapeutic proteins accounted for 98.9% of its 2008 sales. Novo Nordisk will account for the majority of the peer set's therapeutic-protein sales growth, with an increase of $4.7 billion forecast between 2008 and 2014, to be supported primarily by Genzyme (Cambridge, MA, $1.3 billion). By contrast, declines of $741 million and $221 million are forecast for Biogen Idec and Amgen's therapeutic-protein portfolios, respectively

Reflecting the pharmaceutical industry's burgeoning interest in high-growth biologic markets, 27% (seven out of 26) of US Food and Drug Administration new drug approvals in 2009 were for biologic license applications (BLAs). This number represents the highest proportion of biologic approvals since 2003 (2). In fact, the growth in approved BLAs offset the decline in approved new molecular entities (NMEs). Furthermore, the number of US orphan-drug designations has more than doubled in the past decade, from 208 (2000–2002) to 425 (2006–2008) (3). The number of orphan drug approvals grew from 32 to 47, an increase of 47%. In 2009, the European Medicines Agency (EMA) granted orphan status to 103 medicines, the highest number since European orphan-medicines legislation was introduced in 2000.

Injectable drugs will drive market growth

Despite the current dominance of oral drugs, which typically are associated with small-molecule drug delivery, injectable drugs enjoyed strong growth between 2002 and 2008 at 20.8% CAGR. Injectables will continue to enjoy the fastest growth rate of all delivery mechanisms (i.e., 4.9% CAGR) until 2014, aided by the development of vaccines and mAb therapies which are typically delivered by this mechanism. The loss of patent protection for blockbuster brands such as Pfizer's Lipitor (atorvastatin) and Effexor (venlafaxine), and AstraZeneca's Seroquel (quetiapine) will trigger strong generic-drug competition and sales erosion for oral drugs.

Secondary-care therapy areas would become a priority

Historically, small-molecule drugs dominated therapeutic areas such as cardiovascular and central nervous system (CNS) conditions and contributed to significant sales growth. However, these markets are not only saturated with me-too drugs, but also suffer from rapid market erosion because of the influx of generic drugs after the patent expirations of key brands. For example, in 2009, sales of cardiovascular drugs totalled $99 billion; they are forecast to decline at 2.8% CAGR (2009–2014). The forecast contraction in this market is likely the reason for Pfizer's announcement in September 2008 that the company was ending its research and development (R&D) investment in this therapy area—a landmark move, given the dominance of cardiovascular drugs in Pfizer's portfolio.

Now pharmaceutical companies are shifting their R&D focus toward developing novel—often biologic—therapies for the treatment of niche indications, which should ensure longer-term growth given biosimilars' minimal impact to date. Examples of target therapy areas are oncology, immunology and inflammation, and endocrine diseases, which are forecast to grow at rates of 5.9%, 4.0%, and 6.3% CAGR, respectively, between 2009 and 2014.

In 2009, several noteworthy therapies were launched, representing truly novel drugs that target unmet needs. Johnson & Johnson's (New Brunswick, NJ) Stelara (ustekinumab) for plaque psoriasis stands out as a first-in-class agent with efficacy superior to that of traditional therapies. Also, Takeda's Uloric (febuxostat) is the first new treatment for gout in 40 years, and Forest's Savella (milnacipran) is the first drug indicated solely for fibromyalgia .

In addition, these target markets—oncology, endocrinology, and immunology and inflammation—will experience the highest sales growth and become the principal growth drivers for the top 50 pharmaceutical companies (excluding generic-drug companies), collectively generating an additional $45 billion by 2014. It is therefore expected that an increasing number of companies will focus on these more profitable markets.

Factors driving the shift away from the primary-care model

The cash-strapped payers now scrutinizing drugs' costs and clinical benefits and so it is not surprising that the pharmaceutical industry is now focused on biologic therapies in secondary care and niche markets. Additional factors that attract pharmaceutical companies toward niche indications include the faster and cheaper R&D process that results from the smaller patient populations and clinical-trial sizes. In addition, several regulatory agencies provide incentives and subsidize R&D in the development of orphan drugs. The agencies offer tax credits, regulatory assistance, and accelerated approval. Also, one of the largest cost-saving factors for companies with a niche product is that large-scale patient and physician marketing through various channels is largely irrelevant. In fact, annual average marketing costs for an orphan drug are seven times lower than those for nonorphan products. Figure 1 summarizes the factors

inspiring the shift away from the primary-care blockbuster model toward niche indications.

Big Pharma will remain dependent on small molecules, but biologics will spur growth

The Big Pharma business model essentially was built on small-molecule products, which are relatively inexpensive to develop and manufacture, thus allowing companies to concentrate on fuelling growth with an assertive sales and marketing strategy. However, once patent protection is lost, small molecules are easy for generic-drug companies to manufacture. Manufacturers of generic drugs do not have to support large R&D teams and they are able to compete aggressively on price. The resulting commoditization of the small-molecule market has forced the Big Pharma players to seek diversification into areas of high unmet need (e.g., oncology) or, in terms of molecule type, into biologics. The Big Pharma shift to biologics will be led by mAbs, which are forecast to grow by $22.1 billion during 2008–2014 at a 9.5% CAGR, thus making them the biggest growth factor for this sector. Therapeutic proteins also will experience strong growth during 2008–2014, contributing an increase in sales of $9.2 billion at a CAGR of 3.6%. By contrast, small molecules—which accounted for 80.4% of Big Pharma's 2007 sales—will decline by $25.6 billion during 2008–2014. Despite these shifts, Big Pharma will remain dependent on small-molecules, which will account for 71.4% of its sales in 2014. Biologics (i.e., mAbs and therapeutic proteins combined) will account for 21.8% of sales, up 6.7% from 2008.

At a company level, a clear correlation can be drawn between small molecules and declining sales versus biologics and sales growth. Of the top 16 Big Pharma companies, only Novartis, Bayer, Merck & Co, and Boehringer Ingelheim will see net positive growth from their small-molecule portfolios. By contrast, the remaining 12 companies are forecast to see a net growth in their biologics portfolios.

Roche - primarily through its acquisition of Genentech contributes about 51.4% of the mAb growth for Big Pharma. Aside from Roche, Abbott Laboratories also will exhibit strong growth in the mAb sector. Its growth is attributable to its acquisition of Knoll and its licensing of international rights to Synagis and Numax from MedImmune.

Johnson & Johnson also will exhibit strong growth, spurred by the growth of Simponi (golimumab), Stelara (ustekinumab), and its share of bapineuzumab sales.

Growth from therapeutic proteins will be spread more evenly across Big Pharma. Sanofi-Aventis, primarily through insulin analog Lantus; Pfizer, through Enbrel; and Bristol-Myers Squibb, through Orencia and belatacept, will make significant contributions. Novartis also will report growth in therapeutic proteins, primarily attributable to its launch of biosimilar drugs through its generic-drug division Sandoz. However, none of these companies will experience biologics growth remotely close to the level of mAb growth forecast for Roche.

Looking forward

For the foreseeable future, blockbuster drugs will provide the bulk of sales for the top 50 pharmaceutical companies (excluding generic-drug companies). These drugs generated $344 billion collectively in 2008, representing 66% of prescription sales. However, the outlook for these drugs is less than stellar; 66 drugs with blockbuster status in 2010 will see a sales decline of more than $200 million by 2014, in response to me-too and direct or indirect generic competition. As a result, total forecast sales for blockbusters will decline by 2.1% CAGR from 2009 to 2014. Pfizer will be the hardest hit, with 2014 blockbuster drugs sales forecast to decline by $8.3 billion versus its 2009 level. The Wyeth merger will soften the blow slightly for Pfizer, but the company will remain the most strongly affected in terms of blockbuster expirations and total sales losses over the 2009–2014 periods. Bristol-Myers Squibb and Sanofi-aventis are also forecast to experience losses of $5.0 billion in blockbuster-drug sales by 2014 versus 2009 because of the generic erosion of blockbuster brands.

As the industry moves away from the old primary-care blockbuster model toward targeting specialty secondary-care indications, several novel drugs launched in 2009 still have the potential for blockbuster status, including sanofi-aventis's antiarrhythmia agent Multaq (dronedarone), Johnson & Johnson's Simponi (golimumab) indicated for rheumatoid arthritis, and Bristol-Myers Squibb and AstraZeneca's Onglyza (saxagliptin) for the treatment of type 2 diabetes. Nevertheless, entering a

multibillion-dollar therapy area cannot guarantee blockbuster status, particularly in today's price-conscious environment.

Key factors that will be important for determining blockbuster success within the biologic markets include the ability to gain first-mover advantage within a given indication, the subsequent horizontal expansion across disease stages and indications, and the creation of high barriers to competition through the accumulation of clinical safety and efficacy data. In addition, with the increasing cost pressures facing payers, manufacturers will need to demonstrate comprehensive pharmacoeconomic data and drug benefits for these therapies in relation to the disease frequency and severity. They may also need to demonstrate an advantage in comparative effectiveness over existing products. This competitive advantage may be achieved best through coupling drugs with companion diagnostics or creating disease-management solutions. Pharmaceutical companies frequently employ risk-sharing agreements as a means of securing a place on reimbursement lists, thus sharing the risk between the payer and the manufacturer. These schemes also encourage responsible prescribing by healthcare professionals and ensure that resources are not wasted on ineffective treatments. By addressing payer concerns regarding both economic and clinical outcomes, risk-sharing schemes have the potential to change the pricing landscape of high-cost drugs.

These very factors have led to the dominance of mAb products such as Roche's Avastin (bevacizumab), Herceptin (trastuzumab), and MabThera (rituximab); Abbott's Humira (adalimumab); and Johnson & Johnson and Merck & Co's Remicade (infliximab), which together accrued a 72% share of mAb sales in 2008. However, the market share of these top five brands will fall to 57% in 2014 because of increasing competition from newly launched mAbs. In fact, from 2008 to 2014, the number of mAbs achieving blockbuster status will increase from five to 15. Nine other mAbs will generate sales of more than $500 million in 2014. Overall, the mAbs market will remain healthy.

Clearly, a paradigm shift is taking place in the pharmaceutical industry, as the small-molecule business model that historically inspired sales growth is replaced by a high-value specialty-biologics model to fend off further sales erosion. As the patent cliff approaches, it will be increasingly important for all pharmaceutical companies to

consider putting a biologics strategy in place, either through organic means or through partnerships, to avoid being left behind in this dynamic, competitive environment.

(3) Attractive destination for Contract Manufacturing & Research:

The global pharmaceutical industry is at the cross roads. With many of the blockbuster drugs getting off-patented and with increasing R&D costs, its hard by the companies to maintain their bottom-line and remain unaffected. They have found recourse to outsourcing some of their research and manufacturing activities and saving cost in the process. This has led to the growth of contract research and manufacturing services or CRAMS making the companies in India to rejoice. Business of CRAMS has come as a boon to the mid-cap pharma companies in India, these companies are merrily embracing CRAMS taking full advantage of the features enjoyed by India as a country of diverse origin and strong manufacturing base in pharma for years. India could potentially capture 10% of the global CRAMS market of almost US$ 200 billion by 2011[26]. Overall, the CRAMS segment is expected to grow 30-35% per annum on top of a growth of 40-50 percent in the last few years. In terms of contract research, some of the known facts in recent drug discovery are:

(4) Drug Discovery

In the drug discovery value chain, there are key blocks like biology, chemistry, drug evaluation, preclinical trials and clinical trials. Building the skill set and investing in the infrastructure to achieve critical mass will help draw the research work into the country perhaps in a piece-meal initially. As the components get built, entrepreneurial initiatives will kick off on a broader scale, establishing the industry.

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.

[26] Cygnus research

India at this point is ahead of China in chemistry but the impression in many countries is that India is weak on biology front. It is found that India's strength in biology sector is very limited especially in genetically modified animals, biochips and basic molecular biology. The biology capabilities are mainly in government institutes with a handful of companies having skills in molecular biology and protein expression. However, only a handful of GLP labs exist and the availability of clinical investigators and clinical pharmacologists are negligible in comparison to other countries in the field.

Through strategic building of infrastructure, such as organizations conducting chemistry research, preclinical trials and clinical trials and later biology research, India can create a strong vendor base allowing various companies in the world to undertake new drug research. Biology research services market and infrastructure should be developed with conscious effort. Such services in all key segments built even in piecemeal will create good vendor base and augurs well in converting the country into an NCE hub. Obviously, such effort will be a successful driver to earn from export of pharmaceutical services.

(5) Clinical trials Industry

The pressures of declining R&D output and increasing costs has resulted in the globalization of clinical research and emerging markets have begun playing a significant role in the drug development value chain. India too has seen a surge in clinical research activity with an evolution over the last decade, from being an industry focused on BA/BE services to increasingly being viewed as service provider of choice by the global pharmaceutical and biotechnology community in the arena of Phase I-IV trials and allied services.

Emerging markets like India are no more an option but a strategic imperative for global clinical research[27].

[27] "The Global Metamorphosis- Compelling reasons for doing clinical research in India – Report by E&Y and FICCI, 2009

The USD 64 Bn global clinical research industry is witnessing a transition as life science companies are turning toward emerging markets in Asia, Latin America and Eastern Europe, to pursue clinical research. Increasing costs, declining productivity and rising drug development timelines, combined with the strategic advantages offered by these emerging markets, is driving research-driven pharmaceutical and biotechnology companies to conduct clinical research beyond established markets. Emerging markets now contribute to ~36% of global patient enrolment as compared to ~20% in 2001.

India is one of the fastest growing clinical research destinations with a growth rate that is two and a half times the overall market growth.

India participated in 7% of global Phase III and 3.2% of Phase II trials with industry-sponsored trials having grown at a spectacular 39% CAGR between 2004 and 2008. The number of investigators in India has also grown the fastest among Asian, Latin American and Eastern European countries with a 42% CAGR between 2002 and 2008. India has one of the latest subject recruitment rates globally (nearly three to five times the global average), with screen failure and dropout rates lower by nearly 40-50%, as compared to global averages. As a result, India contributes 15-30% of global enrolment in multi-centric studies where it is a participant. India is ranked third across all countries after the USA and China in terms of its overall attractiveness as a clinical trial destination according to a recent AT Kearney global survey.

Further, India's clinical research landscape is undergoing a glorious metamorphosis, aided by many uniquely differentiating capabilities, a rapidly transforming healthcare market and an enabling environment that is rapidly adapting itself to global standards. These are –

(i) Scientific feasibility:

India constitutes 16% of the global population with 20% of the global disease burden. With ~32 million patients in urban areas and ~72 million patients in

rural areas at any given point of time, India has a diverse mix of subjects who are relatively treatment naïve as well as subjects with a high standard of care to meet diverse study protocols.

The country's disease burden is also well aligned with the new drug development therapy focus of global pharma and biotech, with a shift toward non-communicable diseases. India has 65 million patients with CNS disorders, 31 million diabetics, 29 million cardiac patients, 41 million COPD and asthma patients, 0.8 million cancer patients, with most of these ailments expected to increase by over 50% in the number of cases by 2015.

All the five major racial types – Australoid Mongoloid, Europoid, Caucasian and Negroid – find representation among the people of India, with Caucasian being the most prevalent.

(ii) Medical Infrastructure:

The urban healthcare infrastructure, in terms of the number of beds/ physicians/nurses per 1000, is comparable with the global average, India has > 8,40,000 urban beds. There are over 6,00,000 English-speaking physicians and nearly 1,00,000 specialists, with many of them having been trained in the best global institutes. There are 41 hospitals accredited under International Society for Quality in Healthcare by National Accreditation Board for Hospital and Healthcare Providers (NABH) and Joint Commission International (JCI), while 84 hospitals are currently in the process of applying for NABH.

(iii) Regulatory reforms: The Clinical establishment (Registration and Regulation) Act, which is being promulgated by the government to regulate private hospitals and laboratories across the country, will play a significant role in devising and implementing uniform standards of facilities/services and further enhance the quality of care provided by the Indian health care delivery system.

Thus it may be seen that India has significant valid population to participate in clinical trials and the country also has proven capabilities in medical skills, hospital beds and IT capability. This offers an opportunity to capture the market share in global clinical R&D market such as clinical trials, data management, testing, etc. By building the above key blocks in the drug discovery value chain, India can reach the status of integrated provider in chemistry and biology services. The country can learn skills while earning, at least in certain parts of drug discovery process. This could enable the country to attract drug discovery firms to conduct research in India with spin-off benefits in making India as an R&D hub in the long term.

Costs of clinical trials in India are around one-tenth of their levels in the U.S. Currently, India is experiencing a growing number of collaborations between Indian and foreign firms in the domestic market, especially involving the biotechnology sector, in a wide variety of areas such as collaborative R&D including drug discovery and clinical trials. However, scarcity of specialist clinical pharmacologists, clinical investigators is most critical issue facing Indian clinical trial industry.

Another important area is the lack of proper regulatory framework. Some of the important points in this connection are[28]:

(i) Single Window Clearance

There are multiple government departments that may have to be addressed during the execution of the clinical trials for permissions and approvals. They are DCGI - Ministry of Health and Family Welfare, Directorate General of Foreign trade – Ministry of Commerce and Industry, Department of Biotechnology – Ministry of Science and Technology, Ministry of Environment and Forest for biotech products. The industry feels the need to have a single window for approvals. Whereas the specific departments can continue to be the decision maker, for the industry all applications to be made for permission should be a single window.

[28] FICCI Report on Clinical Trials Industry, 2009 prepared for DoP

(ii) Harmonization Of Technical Requirements With ICH Requirements

To help India globally compete and get new therapies to patients faster and also build early developmental capabilities and experience.

(iii) Pre-Clinical Requirements

Today, regulatory requirements for *early drug development* in India are seen as being more restrictive than facilitating when compared to other global regulatory bodies. For example the draft ICH guidelines for Non Clinical Evaluation for Anti-Cancer Pharmaceuticals require a 1 month toxicology package in two species (rodent and non-rodent) for the evaluation of new investigational drugs for the treatment of advanced cancer in Phase 1 clinical trials. A 3-month toxicology package is only needed to support Phase 3 registration studies. As per Schedule Y the current toxicology requirement for India is a 6-month toxicology package to initiate the first-in-man trial for all agents including anti cancer compounds. During the process of drug development the above mentioned pre-clinical studies are conducted late, before Phase-III.

In certain areas such as cancer the Indian regulators can easily adopt the universal regulatory guidance (i.e. ICH – International Conference on Harmonization of Technical requirement for Pharmaceuticals for human use) to allow evaluation of treatment options for this debilitating disease. It should be recognized that since the longevity of patients with advanced cancer is limited, the Phase 1 evaluation may provide some newer treatment modalities for such patients. Patients may actually benefit from the newer experimental option.

(iv) Definition of Phase-I Clinical Trials

The Phase-1 studies fall within the realm of experimental science and require a range of skills and expertise of the highest order. Because of the high-risk nature of these studies, the regulatory body is called upon to play a pivotal role. Phase I trials are

allowed only for molecules 'discovered' in India. The safety / tolerability issues at a Phase I stage are relevant and applicable for molecules whether discovered in India or outside of India. US FDA and many western countries allow the evaluation of India discovered molecules in the respective geographies as long as they clear the IND (investigational New Drugs) and/or CTA (Clinical Trial Application) hurdles. It should be noted that the same yardstick and rigor should be followed for the evaluation of India discovered compounds versus compounds discovered elsewhere.

With more and more partnerships and co -development there is need to have a uniform understanding and interpretation of **Indian** versus **Foreign** molecules. It is unclear what constitutes an Indian molecule. There are many variants including Discovered and Developed in India, Discovered outside India but Developed in India, Discovered in India and Developed outside India, Discovered outside India but are partially or completely owned by Indian companies, Discovered outside India but handed over to an Indian company which is charge of development.

The decisions on development strategies for new medicine and the experimental approaches used to assemble information relevant to the safety of first-in-man and Phase-I clinical trials must be science-based.

(v) Capacity Building

(a) Ethics: Registration and Training of Ethics Committees

India has a large number of Research Institutes and Medical Colleges and Hospitals involved in clinical research. During the last few years these institutions have set up ethics committees. Various independent ethics committees have also come into existence. The purpose of ethics committee is to ensure that the research is conducted in an ethical manner, for which enabling ethical guidelines, laws and effective review mechanism should be in place. Today there are ICMR and the CDSCO Guidelines for this purpose.

However, the functioning and operations of these committees is variable despite having the guidelines in place. Currently Ethics Committees across the country do not have a central body that would either register or accredit these committees to ensure effective functioning. The Indian Council of Medical Research had initiated some steps towards registration of Institutional Ethics Committees some time back but nothing concrete has come out so far. The immediate needs are:

- Registration of Ethics Committees by a central body and the details of these committees that oversee the clinical studies of all phases should be available in public domain.
- Accreditation of Ethics Committees –The process followed could be that of FERCAP (Forum for Ethics Review Committees in Asia and Western Pacific Region). Two Ethics Committees in Mumbai - KEM Hospital and Tata Memorial Centre are undergoing this process currently

A Bioethics curriculum has been developed under the ICMR-NIH Programme
In the second phase a distance learning programme is being developed by this project in collaboration with Indira Gandhi Open University.

(b) Investigator Training

Investigators need to be trained to be able to participate in Clinical Research. The training needs are not just confined to GCP. As practicing doctors, the approach to training has to be novel. They have to be trained in evaluating protocol feasibility and its ethical administration.

(c) Nurses Training

Nurses are key element in the overall healthcare delivery mechanism. Specifically in clinical research, most of study coordinators are Nurses. Unfortunately in India, due to lack of trained nurses, the responsibilities of a study coordinator is primarily shouldered by an Investigator. A focused training program for nurses in clinical

research can go a long way in reducing the current burden on investigators, and also offer enhanced opportunities to the nursing profession.

(d) Regulatory Capacity Building for Site Inspections

For the last few years regulatory authorities like the US FDA and EMEA have conducted various investigator site inspections in India. It is in common knowledge that the DCGI office in collaboration with the USFDA is training a fleet of inspectors for conducting regulatory inspections. Though this is a welcome step and it needs to be viewed more broadly. There needs to be an **established process** for these inspections that these investigators are going to undertake. Since these capabilities of inspections are being developed it is important to predefine the capabilities, the qualifications, the methods/ SOPs in a transparent way reflecting and assuring good governance.

It is also important to note that GCP compliance is taken as a responsibility solely of the monitoring organization and sponsor but the investigator sites also should be equally held accountable and responsible as required by various regulatory agency guidelines including the Indian GCP guidelines. There has to be a mechanism for reporting scientific misconduct / fraud.

It may be important to have a basic mandatory training for the investigators/coordinators/nurses that is certified by a body recognized by the competent authority and a list of such GCP trained and certified investigators can be available on the CDSCO website.

The regulatory authorities should make available to the public, in understandable language, negative and positive assessment reports of the inspection only after completing the inspection process

(e) Infrastructure for Clinical Research

There is a need for Clinical Research Centres for high risk trials like Phase I. The availability of suitably trained manpower, and facility for critical care is important. Whereas, facility for critical care will be linked to the hospital, the availability of trained investigators, specialist from numerous disciplines trained nurses and trained study coordinators are key elements of any world class clinical research centre.

(6) IT in Pharma R&D

There is a growing importance of IT in the pharma industry. Thus, even though the pharma industry is a life saving products and health care industry, it has been a slow and late implementer of IT tools. Use of IT can help in –

i. Data analysis for molecular screening
ii. Clinical research data management (CDM)
iii. Animal modeling
iv. Biomarkers for safety and effectiveness
v. Bio-statistics
vi. Bio-informatics
vii. Genome research
viii. Process implementation in terms of ERPs, Regulatory submissions

Development of tools for these and other activities is a continuous and expensive process particularly for the SME sector. At present DIT, DBT, DST, etc do not have any scheme to assist SMEs for capacity building and IT tools deployment for better, newer and cheaper drugs. This is especially important in the bio-pharma industry where Indian pharma industry needs to develop skills as good as in medicinal chemistry to take the next generation drug revolution leadership globally.

In this context it may be useful to consider a scheme to for filling this gap and ensure capacity building and technology enhancement of the pharma industry to make it globally more competitive.

1.7.4 THREATS

(1) Formulations Sector

The generics market in developed countries is being currently affected by a number of factors:

a) Ever-greening strategy of MNCs to protect market loss due to expiry of patents
b) Increased competition to countries like India from emerging manufacturers in China and East Europe not only from the manufacturing point of view but also barriers being raised by them to protect and develop local industry. This is being done by such processes as long approval time and costs for registration of drugs. Insistence on completing long process for registration for drugs registered earlier by way of specific requirements of fresh clinical trials (markets like Russian Federation).
c) Key markets like the United States are entering into a number of FTA's with different countries with intent to contain Indian exports
d) Prevention from bidding for government contracts as US permits bidders only from countries that are signatories to WTO Agreement on Government Procurement.
e) Submission of separate state level applications for marketing drugs in the United States as there is no nation-wide system of application even where FDA approval has been received.

(2) Bulk Drug Industry

Stiff competition from China on cost front has led to the Indian Bulk Drug Industry particularly the Fermentation industry, to a stage of closure due to various factors including subsidized power and finance costs in the computing country. As a result, no company in India is manufacturing antibiotics like Penicillin and Erythromycin etc.

1.8 GOALS AND RECOMMENDATIONS

(1) Growth Rate

The global growth rate projected is 6 % with the expected market size being USD$ 1200 Bn by 2017. The Table-12 below makes it clear[29].

[29]IMS-2009

Table-12: Global Phama market growth rate

Year	Market in Billion US$	%growth rate
2004	620	7.9
2005	664	7.2
2006	710	6.9
2007	756	6.4
2008	801	4.9

To play a role of global leader in Pharmaceuticals Industry, in long run, the department of pharmaceuticals is setting a goal of achieving a production size of US$ 60 billion by end of 12th plan in 2017 with a CAGR of 18 % for the plan period and finally touching US$ 100 Bn by 2020.

As regards bulk drug industry, it will also continue to grow and the sector will contribute an estimated USD 20 billion size by 2015 growing at a CAGR of 20% from 2008-09[30]. With these projections, it is expected to touch US$ 28 billion by end of 12th plan in 2017.

(2) Global Share

The emerging markets are targeted to grow at 14%. In this context, the Indian market is projected to grow at 18%. Accordingly given the current demand and the ability of the Indian pharma manufacturing sector to continue to meet the demand push, it is expected that the Indian pharma sector would be of about US$ 60 billion size in 2017. Hence it is expected that Indian Pharmaceuticals industry will have a share of 5% in global pharmaceutical industry by the end of 12th Five Year Plan.

(3) Exports

The exports which have grown very significantly to over Rs 45,000 crores in 2010-11, is projected to touch around 130,000 crores by the end of 12th five year plan.

[30] BDMA estimates

1.9 INDUSTRY DEVELOPMENT SCHEMES

On the basis of analysis of weaknesses, threats and gap on other international parameters as explained above, following Industry Development Schemes are proposed:

(1) Industry Promotion

i. Pharma Promotion and Development Scheme (PPDS): This is an ongoing scheme for promotion and development of Pharma sector in the country.

ii. The ongoing scheme of Intellectual Property Right centers in Hyderabad and Chandigarh should be continued. New IPRFCs at Mumbai, Chennai and Ahmedabad can be opened for easy access of the centers by the industry.

(2) Industry Upgradation and Capacity Building

iii. A Capital Subsidy of Rs.1200 crores for 1200 units at the rate of Rs.1 crores per unit for upgrading the units to WHO-GMP.

iv. To upgrade at least 250 units to US FDA/EDQM/TGA and other International Standards by 2017

v. To train 5000 Working Professionals in WHO-GMP and other International Standards GMP requirements.

vi. Opening a national "International Manufacturing Standards Training Centre" at NIPER Mohali and five regional centers at Hyderabad, Chennai, Ahmadabad, Mumbai and Kolkata, especially for the industry regulatory skill building.

vii. Opening a National Formulation Development Centre (NFDC) to assist the SMEs for the development of new formulations which are the source of increasing production in the domestic and export market.

viii. Develop a software, under the technical guidance of DCGI, for helping the SMEs in achieving various regulatory compliances which would be distributed by the Department to the industry free of cost.

ix. Establishment and upgradation of 10 Pharma Growth Clusters by 2017.

Other Recommendations:

i. MoHFW/IPC to explore the possibility of putting Pharmacopeia on the internet as is the practice for several international pharmacopeia such as USP and BP.

ii. Increasing the limit of SSI categorization of pharma units from Rs. 5 crores to at least Rs. 8 crores both for DPCO incentivisation and MSME assessment. Similarly in the DPCO, the exemption from price control should be provided to Pharma Units having appropriately certified investment of upto Rs.8 crores in plant and machineries and having WHO-GMP certification.

iii. **Level playing field**: Indian Bulk Drug Industry is mainly compared with that od China. In China, the industry is fully supported by Government, right from providing infrastructure to various benefits in terms of Taxes in case of export. To promote our Bulk Drug Industry, government has to come up with various supportive schemes.

iv. **Anti Dumping**: Immediate action needs to be initiated for imposition of Anti Dumping Duty on Pen-G and 6 APA.

v. **Subsidized Electricity Supply**: Electricity needs to be supplied at subsidized rates of @ Rs. 3.00-3.50 per unit at par of the prevailing rates in China in order to enable Indian fermentation Industry compete at a level playing field. This will lead to reduction of ~ 10% production cost of Pen- G.

vi. **Subsidized Sugar**: Sugar, being an important input constituting around 30 % of the total cost, needs to be supplied to Pen-G manufacturing fermentation units at a subsidized price of Rs. 20 per Kg. This subsidy may result in a reduction of ~ 7% in the production cost of Pen-G.

The details of the scheme and budgetary requirements are mentioned in Chapter-8.

Chapter 2:

RESEARCH & DEVELOPMENT

2.1 Introduction

Indian Pharmaceutical Industry has already been placed among the top four emerging markets in pharma industry by the market research report published by IMS Health Inc. The global pharmaceutical industry, in the last few years, has shown high interest in India pharma industry because of its sustained economic growth, healthcare reforms and patent-related legislation. Indian domestic pharmaceutical market has seen growth at a CAGR of about 12% since the start of 11th Five Year Plan. The positive approach towards product patent product has encouraged the Indian pharmaceutical companies to invest more in Research and Development.

India's traditional strength lies in small molecule APIs and generics. India ranks third in worldwide volume of production and is 14th largest by value. The main reason for this discrepancy has been determined to be the lower cost of such drugs in India, compared not only to the traditional markets but to smaller markets like Zimbabwe and Si Lanka. However, in top ten global generics players, only one Indian company is present.

Table-13: Top Global Generic Players

Rank	Company
1	Teva
2	Sandoz
3	Mylan/Merck GX
4	Watson Andrx
5	Barr
6	Actavis
7	Ratiopharm
8	Stada
9	Ranbaxy
10	Perrigo

(Source: Capital IQ, Evaluate Pharma and Deutsche Bank Report)

2.2 Research and Development expenditure

The private investment on R&D in Pharmaceutical Sector by domestic companies has increased 40-fold over the last 15 years from Rs 80.61cr in 1994-95 to Rs 3,342.32cr in 2009-10 representing 4.5% of domestic sales in 2009-10.

Table 14: Research and Development Expenditure

Year	Growth in R&D Expenditure – Rs Cr		R&D Expenditure As % of Sales	
	Domestic Companies	Foreign Companies	Domestic Companies	Foreign Companies
Mar 1995	80.61	64.13	1.34	0.77
Mar 1996	142.50	83.37	1.71	0.91
Mar 1997	148.12	89.41	1.55	0.95
Mar 1998	154.15	90.65	1.43	0.88
Mar 1999	218.66	79.78	1.56	0.70
Mar 2000	256.80	90.17	1.56	0.66
Mar 2001	435.07	109.81	2.30	0.72
Mar 2002	597.91	110.04	2.64	0.65
Mar 2003	686.74	232.73	2.93	0.71
Mar 2004	1084.26	346.69	3.81	1.10
Mar 2005	1527.24	510.50	4.98	1.63
Mar 2006	1850.97	816.02	5.35	2.39
Mar 2007	2371.79	695.62	5.01	2.67
Mar 2008	2772.63	700.18	4.78	2.86
Mar 2009	3316.14	846.05	4.89	3.84
Mar 2010	3342.32	934.40	4.50	4.01

Source: CMIE

As compared to this as regards global R&D investment, according to Thomson Reuters' 2011 Pharmaceutical R&D Factbook, Global expenditure on R&D has dropped to an estimated $68 billion from the $70 billion spent in each of 2008 and 2009. The three-year low demonstrates the receding trends of drug success, the amount of drugs entering Phase I and II trials and the number of new molecular entities (NMEs) launched in the global market. On the contrary domestic companies have been increasing their research expenditure, and now invest around 4.5% of their sales in pursuing R&D. As against this, global spend is around 8.68% of the sales in innovation. Worldwide, big pharma companies who invest in "research" in pursuit of new chemical entities (NCE), have started cutting back as clinical trials are expensive, and jack up development costs to billions of dollars, which sometimes give disappointing returns. In contrast, domestic companies have been investing in "development" of copies of existing molecules having more than a billion US$ annual sales and rolling out generic drugs version at a fraction of development cost of new medicines. This has led the global MNCs to set up their research facilities in countries like China where besides low cost work force a huge market is also leveraged. These are:[31]:

This has resulted in a number of R&D centers being set up by multinational pharmacos

ILLUSTRATIVE

DRAFT

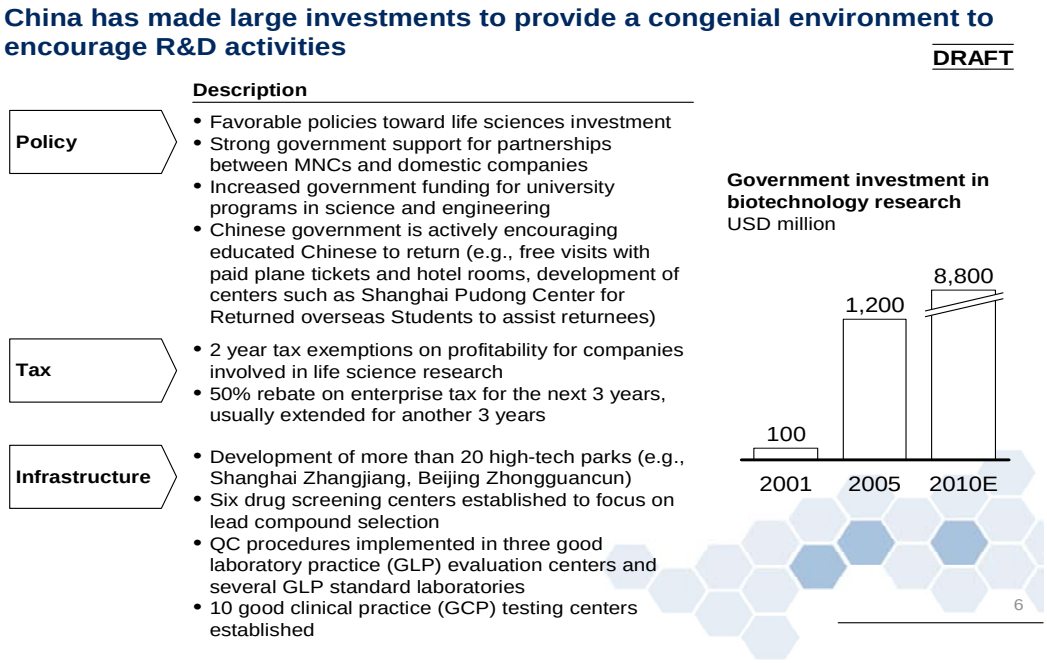
	Location	Business model	Time	Size	Research focus
Roche	Shanghai	Captive	2004	• Initial investment $12mn • ~40 scientists	• Medicinal chemistry for drug discovery programs in antiviral and anticancer areas
	Shanghai, Beijing	Partner with National Genome Centers	2001	• More than $1mn	• Epidemiology projects, focusing on genetic predispositions to diabetes and Alzheimer's disease
Lilly Answers That Matter.	Shanghai	Partner with Chem-Explorer, Synchem	2003	• 100-200 local scientists	• Custom synthesis and other chemistry services
Pfizer	Shanghai	Captive	2004	• Investing $175mn	• New regional headquarter and first clinical trial center in Shanghai, including biometrics capability to support regional and global trials
	Shanghai	Partner with Shanghai Huashan Hospital	2004	• N.A.	• Jointly setting up infectious disease diagnosis and treatment center
AstraZeneca 阿斯利康	Shanghai	Captive	2002	• More than 40 staff members	• Established clinical research unit – East Asia to support regional and global trials
MERCK	Shanghai	Partner with WuXi PharmaTech	2003	• Multiyear, multimillion $ agreement	• Dedicated full-time equivalents (FTEs) to provide discovery chemistry services (e.g., library synthesis)
NOVARTIS	Shanghai	Partner with Shanghai Institute of Meteria Medica (SIMM)	2004	• Multiyear agreement	• Joint program to develop natural compounds in traditional Chinese medicine (TCM)
novo nordisk	Beijing	Captive	2002	• 20, growing to 60 scientists in the next few years	• Center of excellence for molecular biology, protein chemistry, and cell biology

7

Sources: Interviews; literature search; company Web sites; analyst reports

[31] Mckinsey Draft Report for DoP, 2009

This has also been catalysed by massive expenditure support of the government. Thus, if one compares with China the situation is quite challenging as seen below and as brought out by Mckinsey in a Report for the DoP in 2009[32].



As compared with this, the R&D spend scenario is not very encouraging. Thus, the R&D expenses for Indian domestic companies are first of all in the development and filing drug master filings (DMF), and abbreviated new drug applications (ANDA), through conduct of bio-equivalence and bioavailability studies. Even in this space there are selected few big spenders like - Lupin, Dr Reddy's, Ranbaxy and Sun Pharma with roughly 8.5%, 8%, 5.6% & 5.3% of their annual turnovers respectively, for the financial year ended March 2011. If this is compared with the R&D spend of big pharma the situation is quite challenging as may be seen in the table below:

[32] Mckinsey in a Report for the DoP in 2009

Table-15: R&D spending of leading Indian and Global pharmaceutical MNEs, FY 2009[33]

Indian Pharmaceutical Companies			**Global Pharmaceutical Companies**		
Rank in R&D spending	***Company***	***R&D exp. FY 2008/09, million US$***	***Rank in R&D spending***	***Company***	***R&D exp. 2009, million US$***
1	Ranbaxy*	99	1	Roche, CH	8,570
2	Dr. Reddy's	89	5	GlaxoSmithKlin, UK	6,286
3	Sun Pharma	67	10	Elli Lilly, USA	4,300
4	Cipla	51	25	Lundbeck, DNK	615
5	Lupin Labs	50	50	Watson, USA	197

***Ranbaxy was acquired by Daiichi Sankyo from Japan in March 2009.**

2.3 Bio-pharma Convergence

Biotechnology has emerged as one of the key technologies of this century. Biopharmaceuticals have been projected as potential drugs curing many diseases. Many research papers have opined that chemistry based medical innovations of the previous century are becoming to recede in importance, to be replaced by advances in biopharmaceutical research that will boost the growth of revenues and profits in the years to come. Given its potential, most of the global pharmaceutical companies are showing interest in the biopharmaceuticals sector. This trend is likely to

32.Gert Bruche,- 'Emerging challengers in knowledge-based industries? The Case of Indian pharma Multinationals,' Columbia FDI Perspectives, No. 41, July 1, 2011.

continue, as these companies would try to reap the benefit of their sales and marketing capabilities along with technical expertise of biotechnology.

Last year, the pharmaceutical industry spent about $2 billion on assorted R&D activities in India. However, this figure can reach upto $25 billion by 2025 if concerted efforts are made by various stakeholders like the government, academia and industry on developing R&D and innovation in the bio-pharma field. This growth would be driven by tapping the synergy between expanding activities of Indian companies, additional government investment and a growing pool of qualified researchers, according to a new report titled, 'Life Sciences R&D: “Changing the innovation Equation” by the Boston Consulting Group in its position paper.

2.4 Patents Progress

Among other impact of the 2005 amendments, the number of patent filings in India for pharmaceutical products increased steadily. The total number of patents granted in India jumped from 1911 in 2004-05 to 4320 in 2005-06. The current status of pharma R&D in India is best reflected by the growth of domestic pharma industry in last decade in terms of availability of trained manpower, publications and patents, value and volume API finished formulation market, NDDS launched, INDs/NDA filed, Clinical trial permissions obtained, and annual growth in Biopharmaceuticals, Clinical research activity.

As per 2009-2010 annual report of “INTELLECTUAL PROPERTY INDIA”, GOVERNMENT OF INDIA, (MINISTRY OF COMMERCE & INDUSTRY) the major contribution to patents was from CSIR and IIT. The contribution from the Indian universities was extremely poor. NIPER Mohali contributed only 4 patents in 2009-10. This emphasizes the need to develop NIPERs on IIT pattern to boost growth in pharma R&D sector, which also performed poorly in patent filing race.

Top 10 Major Indian Applicants for patents from Pharmaceutical Industry

Sl. No.	Name of Pharmaceutical Industry	Applications filed
1.	RANBAXY LABORATORIES LIMITED	37
2	WOCKHARDT RESEARCH CENTRE	33
3	CIPLA LIMITED	21
4	HETERO RESEARCH FOUNDATION	11
5	SULUR, SUBRAMANIAM VANANGAMUDI	11
6	CONCEPT MEDICAL RESEARCH PRIVATE LIMITED	10
7	RUBICON RESEARCH PVT LTD	08
8	STEMPEUTICS RESEARCH PVT. LTD.	08
9	ENVISION SCIENTIFIC PRIVATE LIMITED	07
10	SUN PHARMA ADVANCED RESEARCH COMPANY LIMITED	07

Top 10 major Indian Applicants for patents from Scientific and Research & Development Organizations.

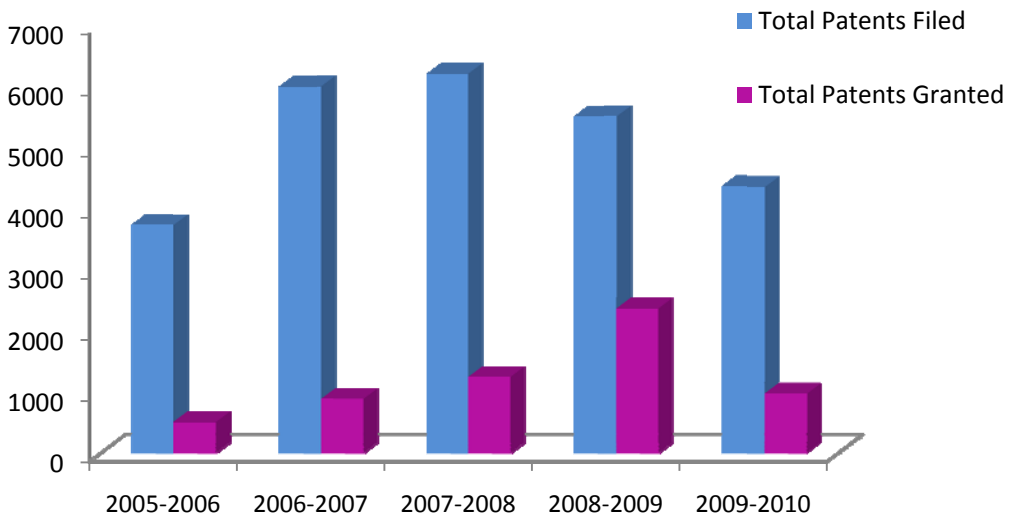
Sl. No.	Name of Scientific and Research & Development Organizations.	Applications filed
1.	COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH (CSIR)	162
2.	DEFENCE RESEARCH & DEVELOPMENT ORGANISATION (DRDO)	80
3.	INDIAN COUNCIL FOR AGRICULTURAL RESEARCH (ICAR)	55
4.	INDIAN SPACE RESEARCH ORGANISATION (ISRO)	17
5.	CENTRAL INSTITUTE OF FISHERIES TECHNOLOGY	13
6.	NATIONAL INSTITUTE OF PHARMACEUTICAL EDUCATION AND RESEARCH (NIPER)	10
7.	CENTRE FOR DEVELOPMENT OF ADVANCED COMPUTING (C-DAC)	07
8.	NATIONAL INSTITUTE OF IMMUNOLOGY	07
9.	INDIAN COUNCIL OF MEDICAL RESEARCH (ICMR)	06
10.	SOCIETY FOR APPLIED MICROWAVE ELECTRONICS ENGINEERING & RESEARCH (SAMEER)	06

Top 10 Indian Applicants for patents from Institutes and Universities

Sl. No.	Name of Institutes/Universities	Applications filed
1.	INDIAN INSTITUTE OF TECHNOLOGY	109
2.	AMITY UNIVERSITY	81
3.	INDIAN INSTITUTE OF SCIENCE	45
4.	SERUM INSTITUTE OF INDIA LIMITED	12
5.	THE ENERGY AND RESOURCES INSTITUTE (TERI)	07
6.	INSTITUTE OF LIFE SCIENCES	06
7.	DALMIA INSTITUTE OF SCIENTIFIC & INDUSTRIAL RESEARCH	04
8.	JADAVPUR UNIVERSITY	04
9.	KRISHNA INSTITUTE OF MEDICAL SCIENCES	04
10.	MANIPAL INSTITUTE Of TECHNOLOGY	04

There has been no growth since 2005 in the number of patents filed onwards by pharma + biotech sectors in India.

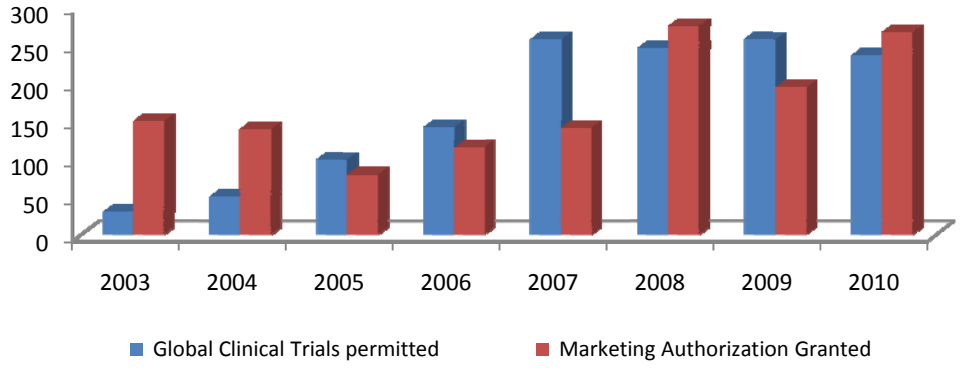
Total (pharma + biotech) Patents Filed / Granted by Indian patent office*



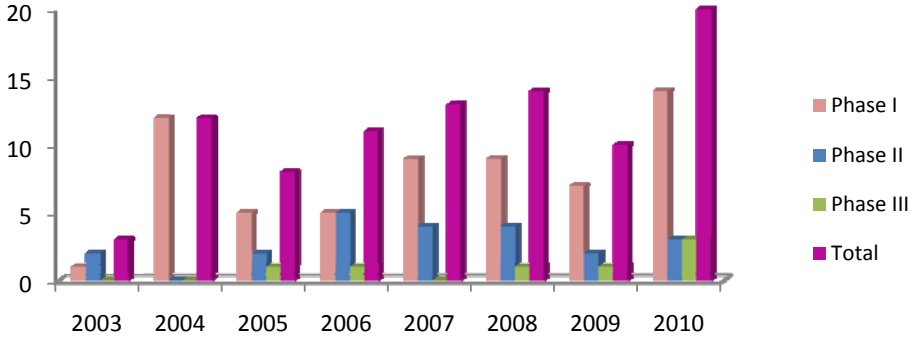
** The total patents filed/granted above include both; the process and product patents filed by Indian as well foreign companies/ intstitutions. Out of total 4373 patents filed in India during 2009-10 by pharma+biotech sector, more than 75% were contributed by non Indian entities.*

The productivity of pharma Industry can be best indicated by the number of marketing authorizations (product launched) and/or clinical trial permissions granted by DCGI. Both the yardsticks in the plots below show steady year wise growth. However these figures are not very impressive if we compare it along with the R&D revenue and manpower deployed since 2003 onwards. There seems to be stagnation in our innovation capability in terms of our R&D productivity.

Clinical Trials from 2003-2010



Phase wise distribution of Clinical Trial Permitted by DCG(I)



2.5 SWOT ANALYSIS

2.5.1 Strengths

i. Cost competitiveness; the cost of developing a new molecule in India is less than 30% of the American cost. Clinical trials cost approximately $300 to $350 million abroad, while it costs only about $ 20 million (Rs 100 crores) in India (Mr. Vijay Moza, Vice-Chairman Institute of Clinical Research, India).
ii. Edge in reverse engineering for generic products and global ANDA filing
iii. Well developed chemistry R&D and manufacturing infrastructure
iv. Low cost English speaking workforce
v. Large, diverse, therapy-naïve pool of patient population in all kind of acute/ chronic disease segments: An ideal for clinical research

2.5.2 Weakness

i. Lack of development skills in complex and difficult to duplicate generic product technologies
ii. Lack of culture for innovation
iii. Poor industry- academia interaction and all around infrastructure, including educational institutions
iv. Low doctor to patient ratio in hospitals, rendering them non-available for clinical research
v. Lack of experience, capability and resources in industry and institutions engaged in new drug discovery
vi. Low capability and motivation for cutting edge research, especially in areas related to understanding of disease, and platform technologies for drug products
vii. Poor infrastructure, training and non availability of trained manpower for clinical research
viii. Low appetite to risk and R&D investment
ix. Ratio of Ph D to Masters degree holders in R&D is low (1:10) against target (1:5)

x. Low level of education & training in the pharmacy institutions and universities

xi. Small, inefficient and in-experienced workforce lacking competency and capacity in our conservative regulatory environment is unable to support innovation & new drug discovery.

2.5.3 Opportunities

i. Development of critical and high-tech manpower (capacity building) for pharma R&D and allied sectors

ii. Converting low cost generic to value added branded generic by SME sector

iii. Develop platform technologies (New drug delivery systems) for improvising conventional generics

iv. Development of new bio- molecules, vaccines and bio-similar

v. Exploitation of clinical research potential of India. According to "Booming Clinical Trials Market in India <http://www.rncos. com/>", a new research report by RNCOS, a number of factors such as low cost, large patient pool, easy recruitment, strong government support and strengthening of its intellectual property environment will enable India to conduct nearly 5% of the global clinical trials by 2012.

vi. India assuming leadership role amongst developing countries for pharma research, manpower development etc.

2.5.4 Threats

China is quite ahead in API, natural remedies and herbals, Clinical research and medical devices.

2.6 RECOMMENDATIONS

India acknowledged the universality of intellectual property rights by embracing the harmonized TRIPS patent regime and enforced it from January 1st, 2005. Since then, a new wave of progress has swept the country. Post 2005, pharmaceutical and medical biotechnology companies experienced some very critical changes, and since then, the only real differentiator has been innovation.

2.6.1 ENHANCED INDUSTRY – ACADEMIA LINKAGES

2.6.1.1 Steps Required from Industry:

i. Indian academia, especially in chemical and life sciences, is equivalent to any world-class faculty. The industry must take advantage of this opportunity and approach them with defined problems.
ii. Industry should provide opportunity to academicians to interact with industry scientists and get exposure to style of functioning of industrial R&D.
iii. Various schemes to promote industrial R&D should be widely circulated to create awareness.
iv. Industries should interact with the academia to become aware of the state-of-the-art facilities available and in use.

2.6.1.2 Steps Required from Academia:

i. Academic institutions should win the confidence of industry with respect to confidentiality and active collaboration which is beneficial to both parties.
ii. The academia need to introduce courses more relevant to the development of the pharma sector. For example, integrated masters' courses in pharmaceutical development with focus on bio-pharmaceuticals and NCEs, intellectual properties issues related to pharmaceuticals, etc. can be developed. These courses should be created after consulting OPPI, IDMA and similar bodies.

iii. The academic Institutions should invite Industry partners to teach parts of these courses so that the industry viewpoint can be conveyed to the next generation workers.

iv. Faculty members of premier institutes can visit industries and spend a short period to apprise themselves of changing industry needs.

2.6.1.3 Steps Required From Government

i. The government needs to create a strong platform for incentivising the innovative approach to produce safe and affordable medicine.

ii. Public-private-partnerships with industry and leading academic partners/ interested stake holders may be arranged to address innovation issues.

iii. The importance of commercially oriented needs should be conveyed to the public institutions. Otherwise these relationships may not survive in the long run.

iv. Programmes like PRDSF need to be encouraged and their scope broadened.

v. Government should give subsidised loans/grants/ funding for New Drug Development.

vi. Start-up companies based on academia generated IP through equity linked funding should be encouraged. This will be a good start to an industry focused approach.

vii. Industry needs to be incentivised through attractive licensing schemes.

Also, it has been found both strategic alternatives which are usually followed – generic medicines and innovative products – as complementary. If one considers the hypothesis that the great expense in R&D is proportional to the cash flow of previous periods, the success domestic firms are getting by selling their generics will make them able to strengthen their financial muscles, adding to their R&D investments. Evidences exist, even if incipient, to confirm preliminarily this assertive. Additionally, as the companies strengthen their links with the innovation systems, they reinforce their qualifications in terms of R&D, opening the possibility of partnerships arrangements with universities, local and foreign companies, and research institutes – both public and private.

2.6.2 MAKING THE DOMESTIC R&D INTERNATIONALLY COMPETITIVE

For making domestic R&D internationally competitive and also viable, one has to review not only the current state of industrial R&D going on, but also review the research activities taking place in various centres or institutes. The review could then be further categorized keeping in view the requirement of the vast consumer market, and the time frames for development. Such actions are helpful to curb excess of imports and bringing the pricing of healthcare/ biopharma products in control. We need to focus on following aspects:

2.6.2.1 Regulatory system and funding:

i. The present weighted average tax deduction accorded to R&D should cover international patenting costs, regulatory consultants, outsourced R&D services and patent litigation expenses.

ii. Regulatory reforms are required which can reduce the currently prevalent approval timelines. The cost advantage is negated by the inordinate delays in approval which erode patent life.

iii. A 25% subsidy on salaries of NRI specialists/experts could help companies attract and afford high end talent. Industry should also be prepared to pay competitive salaries to bench-level workers and middle management and not only the high-tier group.

iv. Indian companies spend ~4-5% of their sales on R&D, which is one quarter of the spending by proportion by global pharma companies (Source: IDMA). Government funding and collaboration with academic research institutes is the need of the hour.

v. Reduction in excise and customs duty of chemicals and raw materials that are imported for biotech products is very important to reduce the manufacturing

costs; also tax exemption for export market for a certain period has been suggested.

vi. Skill development is the next big challenge. We have to encourage people abroad to return and set standards in India in some of these areas. As the academia has been able to attract the best of the Indian brains from abroad at much lower salaries, industries need to look at their set-up to identify the lacunae and correct them.

vii. Focus on research capabilities should shift to encompass biopharma development. Since this involves high-end and capital-intensive research, the initial support from government will be welcome.

viii. Another suggestion has been introduction of partnership between pharma giants for each pharmaceutical institute dealing with higher education in this area. The core areas of these institutes need to be strengthened to ensure complementary growth of each. This will also lead to more collaborative research and not competing with each other. Bodies like OPPI, IDMA, etc. can be consulted for this purpose.

2.6.2.2 In-house R&D efforts:

i. A defined mechanism to standardize the domestic R&D efforts against global standards needs to be in place. This could include the process/data/ information standards like ISO/OECD/WHO guidelines. DSIR/NABL certifications are good milestones in this process.
ii. Limited margins, due to low price of products lead to Lack for investing in R&D and needs to be increased by all companies.
iii. Setting up a national Biosimilar Center at Bangalore and three Regional Biosimilar Centers at Chandigarh, Hyderabad and Ahmedabad .
iv. Setting up of a National Pharmaceutical **Nanotechnology** Center at NIPER Kolkota / Mohali.

2.6.2.3 Greater fiscal support and incentives are needed for innovation. Tax incentives for products designed by domestic companies and for application within India e.g. grant-in-aid funding, soft loans, higher weighted average tax deduction for drug innovation, 5 year NPPA exemption for novel drugs, 5 year tax and duty exemption for new drugs, etc.

2.6.2.4 Support for the clinical trials sector:

i. Orientation programmes on Clinical Research organized by industry associations, Medical Schools via conferences, CMEs etc
ii. Regular training of site staff by sponsors/ CRO
iii. Orientation programmes for administrative and legal departments of the hospitals
iv. CRO/ Sponsor to facilitate development of site SOPs
v. Regular Regulatory inspections of sites/ IRBs/ CROs/ Sponsors to ensure quality
vi. Methodology for reporting non-compliant investigators / sites

2.7 NIPER Mohali

In order to strengthen the pharma and health-care sectors, there is a dire need to strengthen NIPERs on the models of newly set-up IISERs and IITs. There is a need to therefore the existing already developed NIPER-SAS Nagar as a Hub to provide full range of services to domestic pharma R&D.

2.7.1 Role of new NIPERs

The newly established NIPERs need to be supported in terms of basic infrastructure and recruitment of faculty. They can work as specialised innovation hubs such as for - thrust on new chemical and biological entities Industry needs to concentrate on biologics as an important therapeutic tool by developing facilities for the same, with the help of academia. NIPERs can play other significant roles, in terms of:

(i) End to end solution to Indian pharma R&D, engaged in discovery and development of NCE and Biologics. This had been a major bottleneck for our industry in taking up molecules all the way to phase III.

(ii) Train & develop manpower in these clinical and non clinical studies with labelled compounds.

(iii) Give a boost to Generics Industry by offering solutions for "difficult" formulations, such as those for drugs with poor solubility, poor bioavailability or other properties that prevent APIs from reaching the market or achieving their full therapeutic potential.

(iv) Support Novel Drug Delivery System (NDDS) groups in NIPER and Industry specially those offering inhalation delivery systems.

2.7.2 Synergism between Academia and industry: A Necessity

In the first year of the 12th five year plan, consolidation of existing data is required. A list of the laboratories under government sector, engaged drug discovery and development related areas is provided in Annexure –A. The lost leads generated in these laboratories need to be resuscitated. This can be done by creating a database of leads with the support of DST, DBT, ICMR, etc. Analysis of the database will allow one to assess the gaps in the existing knowledge base. This will be a good starting point for innovative research, since the leads for drug discovery are already present. Till now, drug discovery in academia has remained a publication tool. The money invested by various funding agencies has resulted in training of human resource and publications in peer-reviewed journals. One major reason could be that the funds invested in extramural research projects are way below those required for serious drug discovery efforts. A clear demarcation of the roles of various laboratories is required. Instead of investing in all facilities in all laboratories, the inherent expertise of each institute needs to be utilized to the fullest. That will result in optimum utilization of funds and skill set available. Thus, the aim of the next five years of XII plan will be to provide value-added return to the pharma sector, by way of product development.

Based on above recommendations, the details of the schemes proposed are in Chapter 8 (Section 8.2).

CHAPTER:3

CAPACITY BUILDING & EMPLOYMENT

3.1 STATUS OF EMPLOYMENT OF TECHNICAL MANPOWER

The employment data for the pharmaceutical sector from the Annual Survey of Industries (ASI) is given below:

Table – 16: Employment Data for Pharmaceutical Sector

Year	No of Employees
Mar 1995	1,81,497
Mar 1996	2,04,609
Mar 1997	2,11,614
Mar 1998	1,89,295
Mar 1999	2,13,999
Mar 2000	2,43,410
Mar 2001	2,33,704
Mar 2002	2,26,416
Mar 2003	2,23,556
Mar 2004	2,40,791
Mar 2005	2,65,396
Mar 2006	2,90,021
Mar2007	3,36,211
Mar 2008	3,53,692

Source: Annual Survey of Industries Ministry of Statistics & Programme Implementation.

According to CMIE data base, the wage bill of the domestic companies reported more than twelve-fold increase over 15-year period from Rs 664cr in 1994-95 to Rs 8,172cr in 2009-10.

3.2 FUNCTIONAL DISTRIBUTION OF HUMAN RESOURCES IN THE PHARMA SEGEMENT*

R&D in the pharma industry is multi-faceted and draws upon the expertise of pharmacists, chemists, biologists, chemical engineers, pharmacologists and medical practitioners to name a few. The different activities include drug development (synthesis and manufacture), formulation, clinical trials and evaluation and finally, launching of the drug.

While the subject of R&D has been discussed in detail in Chapter 3 of this Plan Document, the related subject of Capacity Building and Employment is discussed herein.

In this connection, it is to be stated that closely associated with the R&D and regulatory / quality assurance functions is the need to relate the implementation of these functions/responsibilities with manpower requirements, it will lead to increased demand for pharmacists besides other professionals. Contract manufacturing is estimated to grow US $ 30 Billion, whereas contract research is estimated to reach US $ 6-10 Billion and this is paving way for new job opportunities being created in the Indian Pharmaceutical market. This sector is expected to grow at a rate 17.2% in 2011.

It is estimated that about 20% of the 3.53 lac manpower above is engaged in research and testing as shown below in the table.

Table 17: Percentage distribution of Man-power in Pharma Industry

Function	Distribution
Production & Quality Control 50%	50%
Research/Lab/Testing	20%
Sales, Marketing, Medical assistance	5-10%
Purchase, Logistics, Supply Chain	5-10%
Support functions (HR, Finance, etc.)	10-12%

*NSDC report

Educational qualifications of personnel employed in the Chemicals and Pharmaceuticals Segment in this respect are estimated to be as follows:*

Table 18: Qualifications of personnel employed in the Chemicals and Pharmaceuticals Segment

Qualification	Distribution
Ph. D / MTech / MSc etc.	5-8%
Graduate Engineers	15-25%
Diploma Engineers	10%
ITI and other vocational courses	15-20%
Graduates (BA/BSc/BCom/others)	15-25%
12th standard or below	20-25%

*NSDC report

With the increase in new therapeutic interventions and introduction of genomics/proteomic technologies, an upsurge in demand for skilled manpower to fuel this growing sector has been seen. It has opened different job profiles for aspirants who are looking for a career in this field. Aspirants Interested in R&D sector can work on drug discovery, development of new generic product, analytical R&D, API or bulk drug, and formulation R&D. Drug delivery is also another area where aspirants can look into. Regulation in pharma Industry has been there for a long time now and it is getting stringent day by day. Professionals with expertise in regulatory affairs are growing in demand all over the world. With India's increasing exports and growing domestic industry regulatory affair professional will be a key to any organization's rapid growth. Intellectual property and patent services is another area, which are an integral part of protecting the intellectual pharma research bringing newer therapeutics.

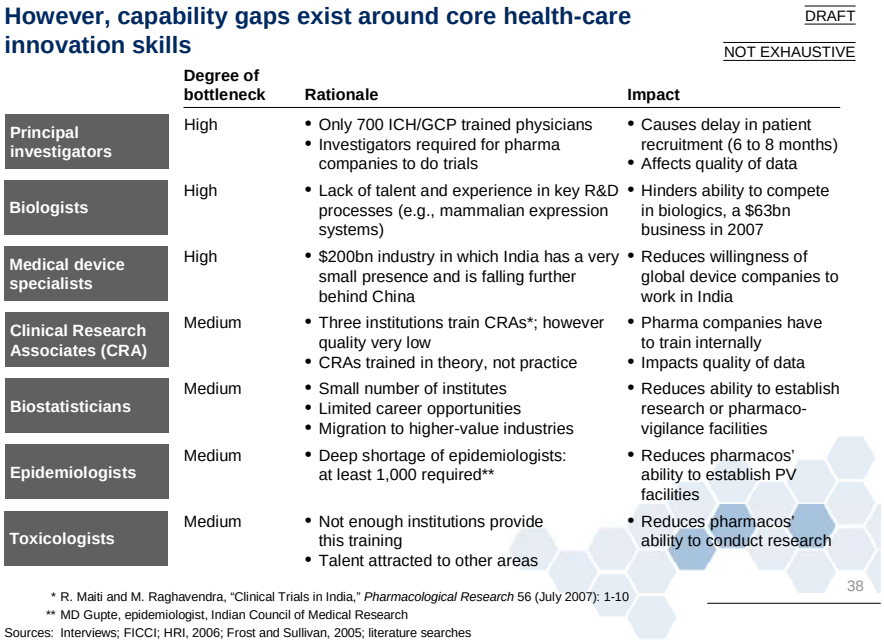
There is an acute need of human resources in the areas of:

i. Pharmaceutical and Biopharma development
ii. Clinical development programs with collaboration with medical institutes.

A Mckinsey Report[34] has brought out this gap as below:

[34] A Mckinsey Report for DoP 2009

Pharma R&D talent gaps assessment in India



However, capability gaps exist around core health-care innovation skills

DRAFT

NOT EXHAUSTIVE

	Degree of bottleneck	Rationale	Impact
Principal investigators	High	• Only 700 ICH/GCP trained physicians • Investigators required for pharma companies to do trials	• Causes delay in patient recruitment (6 to 8 months) • Affects quality of data
Biologists	High	• Lack of talent and experience in key R&D processes (e.g., mammalian expression systems)	• Hinders ability to compete in biologics, a $63bn business in 2007
Medical device specialists	High	• $200bn industry in which India has a very small presence and is falling further behind China	• Reduces willingness of global device companies to work in India
Clinical Research Associates (CRA)	Medium	• Three institutions train CRAs*; however quality very low • CRAs trained in theory, not practice	• Pharma companies have to train internally • Impacts quality of data
Biostatisticians	Medium	• Small number of institutes • Limited career opportunities • Migration to higher-value industries	• Reduces ability to establish research or pharmaco-vigilance facilities
Epidemiologists	Medium	• Deep shortage of epidemiologists: at least 1,000 required**	• Reduces pharmacos' ability to establish PV facilities
Toxicologists	Medium	• Not enough institutions provide this training • Talent attracted to other areas	• Reduces pharmacos' ability to conduct research

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* R. Maiti and M. Raghavendra, "Clinical Trials in India," *Pharmacological Research* 56 (July 2007): 1-10

** MD Gupte, epidemiologist, Indian Council of Medical Research

Sources: Interviews; FICCI; HRI, 2006; Frost and Sullivan, 2005; literature searches

As per the industry, the demand of quality professionals is not been well supported by the supply of quantity manpower and this leads to an employment in equilibrium. There is necessity to expand higher education in pharma and certain areas as per industry need and for this industry participation may be needed.

In the pharmaceutical sector, direct employment has been steadily increasing. In the year 2006 there were 6.9 lacs people engaged, which has risen steadily to 8 lacss in the year 2008.

3.3 GEOGRAPHICAL DISTRIBUTION

Goa, Mumbai, Pune and Hyderabad have been the preferred destinations for formulation players in the past. However, Baddi in Himachal Pradesh and Pantnagar including Haridwar in the state of Uttrakhand are the upcoming formulation clusters, attracting formulation manufacturers from across the country due to fiscal

incentives offered by the government. Traditional bulk drug clusters are located primarily in Gujarat, Maharashtra, Andhra Pradesh, Tamil Nadu, Goa, Pondicherry and Karnataka. Visakhapatnam in Andhra Pradesh is the upcoming bulk drug cluster that has generated significant interest in the API players. The R&D clusters have followed a similar development pattern. Apart from the National capital Region (NCR), other R&D clusters have been limited to the established pharmaceutical regions in the country.

3.4 LIKELY REQUIREMENT OF SKILLED MANPOWER

3.4.1 Requirement by 2015

The projected human resource, keeping in mind the pharmaceutical domestic as well as global market, will be around approx. 15 lacs by 2015 [Source: Human Resource and Skill Requirements for the Chemicals & Pharmaceuticals Sector (2022) - A Report by NSDC]. As the pharma Industry is likely to grow with a rate of around 18% per year and this growth will be further enhanced by the opportunity presented by US$ 300 bn worth of drugs(including Bio-Drugs) set to go off-patent in next five years, the industry will need bulk of quality professionals in various areas, viz. regulatory affairs, QC/QA, production, environment and affluent planning and drug R&D. Industrial growth in this sector is expected to create jobs for people with masters and Ph Ds. Singapor's Biopolis is taking a lead in generating nearly 7500 PhD's for that country. In India, we need to have plans to bring a synergy among the different states engaged in life sciences.

Drug innovation will require a plethora of specialised skills: medicinal chemists, molecular biologists, geneticists, microbiologists, immunologists, bioinformaticians, pharmacologists, clinical researchers, biostatisticians, chemical and biochemical engineers, clinicians, veterinarians, etc. Indian academia and industry would require at least 100,000 professionals by 2015 to pursue meaningful drug innovation of global scale. Some industry experts however anticipate only marginal increase, not enough to absorb large number of pharma graduates coming out of the universities.

3.4.2 Requirement by 2020

It is difficult to predict the requirement at this moment. Future appears to be good provided we are able to contain product costs (through control on inflation and prices, increased productivity, etc.) and produce value added products through continuous innovation and intellectual inputs. By 2020, the requirement for manpower is expected to be around 21.5 lacs [Source: Human Resource and Skill Requirements for the Chemicals & Pharmaceuticals Sector (2022) - A Report by NSDC] keeping in view the already mentioned growth. As the efforts towards making personalized medicine a reality are increasing, in addition to the above mentioned skill set, experts in areas like pharmacogenetics/ pharmacogenomics/toxicogenomics will be needed. As more and more drugs will be manufactured and marketed (off-patents drugs), there will be a need to have a strong vigilance framework and hence hundreds of professionals from pharmacovigilance, PMS (post marketing surveillance), clinical epidemiplogy and population genetics background will need to be made available.

3.5 RECOMMENDATIONS:

i. Greater transparency between industry and academia is a pre-requisite for any successful drug discovery and development effort. Although Indian academia is rated among the best in the world, it has not translated into any noticeable success in terms of product development in the pharma sector. Essentially, a 'culture' needs to be fostered wherein transparency and efficiency are the only operational keywords.

ii. An appropriate climate that is conducive to encourage innovation needs to be created in the country. This could be achieved by building a team of returning Indians, encouraging students' finishing schools abroad, training students to think out of the box and find cost effective solutions suited to the country.

iii. The presence of demographic and geographic diversities as well as the multiplicity of product range allows for the existence of a number of business models and players of different levels. Thus, instead of assuming an 'either-or' attitude between the small-and-medium scale versus multinational entities, a comprehensive study of the market and its requirement needs to be carried out. This will help identify the gaps and allow for the best possible utilization of the available expertise.

iv. It has been projected that India could capture 8-10% of the global outsourcing industry by 2015 (Source: McKinsey & Co.). India has a large pool of highly trained biologists, chemists, trained investigators for clinical trials, biostatisticians and hospitals with state-of-the-art facilities. What is required is the identification of specific areas in which the Indian pharma sector could contribute and make a difference. In order to achieve India's true potential, a visionary outlook backed by strong government policy, will be the need of the hour. However, most of the academic institutes, outside a select few, Lack 'trained trainers'. It is imperative that this middle tier be strengthened. Otherwise, the function of the top research institutes remains limited to bringing them at par and not getting any high-end research done in this sector.

v. As per All India Council for Technical Education (AICTE) web site information of year 2010, more than 75000 students graduate in Pharmacy. This is adequate to cater to the current requirement of the industry. However, there is need to focus on higher skill at the level of MPharma and Ph.D in identified areas of expertise for addressing the need for Research and Development, which is the key to long term growth of Pharma industry.

Based on above recommendations, the details of the schemes proposed are in Chapter 8 (Section 8.2).

Chapter 4
PRICING

4.1 INTRODUCTION

Drug price plays a vital role in access to essential medicines across the world. It is a fact that the drugs manufactured in India are considered to be amongst the lowest priced internationally. Still, a vast section of Indian population is not in a position to access the needed health care as well as the medicines due to various reasons of access and affordability.

Undeniably, universal access of quality medicines at affordable prices is of critical importance. Central Government has been taking various steps in this regard and from time to time, drug policies have been adopted to strike a balance between the often conflicting interests of industry and consumers in moving towards the objective of greater accessibility and affordability of drugs. Unlike in most other developed countries, where public healthcare and other forms of subsidized or prepaid coverage account for a substantial healthcare expenditure, out of pocket expenditures on health are quite high in India. Therefore, any increase in any component of healthcare costs tends to fall across a very wide cross-section of our people, who have no fall-back options. This is one of the principal reasons why international experiences and price control models may not be readily adaptable fully to our situation. But certainly, the relevant parts of those models need to be considered on merit.

It is, therefore, necessary to evolve a strategy which would meet the twin objectives of ensuring that the relative price of drugs does not deviate sharply from the pattern and growth of purchasing power in country, and on the other, the Indian pharmaceutical industry continues to maintain its robust growth path.

4.2 DRUGS UNDER DPCO'95: CURRENT PRICING SYSTEM

The Drugs Prices Control Order, 1995 (DPCO' 95) was promulgated by the Government of India on 6th January; 1995 in exercise of the powers conferred by Section 3 of the Essential Commodities Act. Under DPCO' 95, 76 bulk drugs (now 74 drugs as Amikacin Sulphate and Mefenamic Acid were omitted by S.O. 626(E) dated 2/9/1997), the prices of which are controlled under DPCO 1995, have been enlisted in the First Schedule of this Order. Under para 3 of DPCO'95 Government is empowered to fix the Maximum Sale Prices of Bulk Drugs specified in the First Schedule with a view to regulate the equitable distribution and increasing supply of Bulk Drugs specified in the First Schedule and making it available at a fair price from different manufacturers. The Govt. may after making such enquiry as it deems fit, fix from time to time by notification in the Official Gazette, Maximum Sale Price at which such Bulk Drugs shall be sold.

4.2.1 Schedule Drugs

Para 8 of DPCO, 1995 empowers the Government to fix from time to time retail price of scheduled formulations in accordance with the formula laid down in para 7 of the DPCO. Under para 9 of DPCO, the Government is empowered to fix ceiling prices of scheduled formulations from time to time, in accordance with the formula laid down in para 7 keeping in view the cost for efficiency for both, of major manufacturers of such formulations and such price shall operate as the ceiling sale price for all such packs including those sold under generic name and for every manufacturer of such formulations. These prices are fixed/ revised from time to time and notified in official gazette. The manufacturers and formulators are required to follow the prices fixed/revised by the Government from time to time (both for bulk drugs and formulations including ceiling prices) within 15 days from the issued of such order by the Government. No one can sell any scheduled drug / formulation at a price higher than the price fixed by NPPA / Government.

4.2.2 Non Scheduled Drugs

In respect of drugs, not covered under the Drugs (Prices Control) Order, 1995 i.e. non-scheduled drugs, manufacturers fix the prices by themselves without seeking approval of Government / NPPA. Such prices are normally fixed depending on

various factors like the cost of bulk drugs used in the formulation, cost of excipients, cost of R&D, cost of utilities / packing material, sales promotion costs, trade margins, quality assurance cost, landed cost of imports etc. As a part of price monitoring activity, NPPA regularly examines the movement in prices of non-scheduled formulations on the basis of monthly reports of ORG-IMS (now IMS- Health) and the information furnished by individual manufacturers in following conditions –

(i) Increase in price of more than 10% in one year

(ii) If the annual turnover of the formulation pack exceeds Rs.1 crores.

(iii) The share of formulations in that segment of the formulation is required to be at least 20% of the market or the medicine is one of the top 3 brands of that group.

If a formulation/pack meets the above criteria, then the manufacturer and / or distributor is asked to give justification for price increase of more than 10% per annum. If no information is received after the letter and reminder or the reply of the company is not satisfactory, show cause notice is issued to the manufacturer stating as to why action should not be initiated for price fixation under para 10(b) of DPCO'95 in larger public interest. Although this provision has not really been used, there is evidence that its presence has moderated the pace of price increases in drugs.

4.2.3 Pricing of Imported & Domestic Formulations

In respect of formulations manufactured in the country, ex-factory price worked out by adopting the norms/ guidelines forms the basis whereas in the case of imported formulations, landed cost of import forms the basis of price fixations. Vast difference between imported and indigenously produced medicines containing the same salt is observed in almost all cases wherever equivalent substitutes are available in domestic markets. This is despite the fact that the provision in DPCO was incorporated to consider/ allow lower margin i.e. upto 50% for imported formulations as against the 100% for indigenously produced medicines under para 7 of DPCO 1995. Even in such cases of imported formulations when reduced margin of

35% is allowed by the NPPA, the prices worked out/ approved are still manifold higher and, hence, there is no comparison with those that are manufactured indigenously due to the fact that there is no control/ examination of the Cost, Insurance and Freight(CIF) / landed cost of the imported formulations. There is no system for cross-checking or examination of the C.I.F. /landed price of the imported formulations despite the fact that NPPA has been asking for the same. These formulations are mostly imported by the companies from their parent companies. In the absence of details relating to the cost of production of imported formulations, NPPA is not allowing/ considering price increases based on the increased CIF price claimed by the importing companies.

4.3 PRICING & NEW PATENT REGIME

4.3.1. Impact

The impact of new patent regime on domestic pharma industry is marginal as of now, as most of the drugs patented before 1995 are freely available. However, with the passing of the years, more and more patent protected drugs will be launched in India, being a very large market, at which time the impact on pricing will be severe, unless government/ regulator implements proper checks and balances/ price approval mechanism for patent protected products.

Since 2005 only 11 molecules under product patent have been launched in the Indian market. Thus patented products contribute less than even 0.5% of total pharmaceutical market. These are therapeutic options available at affordable prices for the disease conditions addressed by these patented molecules. This means that lifesaving dugs are available at different price points to meet the needs of different socio-economic groups. One of the other positive outcomes of the new patent regime since 2005 has been the increased collaborative agreements between globalized Indian companies (Sun, Zydus Cadila, Aurobindo, Torrent etc) and MNCs (MSD, Pfizer, GSK, Astra Zeneca etc). This augurs well for collaborative research and partnerships to address affordable new inventions to meet the requirements of the developing world.

In this regard the Task Force under Dr. Pranab Sen, in its report submitted in September, 2005 had maintained that all patented drugs and their formulations should be brought under price negotiation prior to the grant of marketing approval.

4.3.2 Industry Observations

Research based pharmaceutical companies, who are introducing the patented products, have adopted varying models to ensure appropriate access to such medicines by the poor.

- Some companies have adopted differential pricing strategies to extend access to low and middle income group patients. Some have lowered their international prices to make their products affordable to the Indian market.
- As per OPPI the patented drugs are new inventions and result of time-consuming R & D initiatives and, hence, such molecules cannot be compared with existing generic molecules for pricing purpose.

IPA stated that the reintroduction of product patent from 1995 has brought about profound changes in the pharmaceutical sector. The significant among them are two as listed below:

- Transition of the domestic companies from generic to innovative with the ultimate focus on the original research. The domestic companies are conscious that it is a big challenge but have started moving in this direction. The increased spend on R&D is indicative of this transformation.
- The revival of foreign companies' interest in the domestic market, leading to greater push for TRIPs plus Intellectual Property Rights (IPR) regime. This has led to shift in focus from the manufacturing to the marketing and the clinical research (services sector), resulting in slow down in investment in fixed assets, rush for divestment of manufacturing plants, outsourcing of manufacturing and importing of finished formulations.

Both these developments will continue to impact the prices of medicines in the country

BDMA maintained that in the next 3 to 4 years, branded drugs in the USA and Europe worth about $100 Billion are going off patent. Indian producers can seize this opportunity by expanding their capacities in producing generics. However there could be costly patent litigations. The governments should help the small and medium sector units by making provision for free legal consultancy service.

4.3.3 Compulsory License

Although compulsory licensing is a weapon in the hands of the Government to contain price rise in the event of steep increase in the prices of drugs affected by the patent holder but that should not send a wrong signal to the patent applicant or to the prospective inventor. Hence, the Govt. should specify various grounds based on which to channel of compulsory licensing could be applied and stipulations to be laid down for its operation.

The objective of compulsory licensing is to ensure accessibility of people at large to the patented medicines at reasonable price. This measure, in turn, helps in protection of public health and nutrition. The Compulsory Licensing allows third parties (other than the patent holder) to produce and market a patented product without the consent of the patent holder. This system has been made use of in USA, Canada, United Kingdom, Italy, Brazil, South Africa, Kenya and Ecuador. Therefore, recognizing the fact that almost 70% of the population still remains uncovered by modern medicines, it becomes essential to increase the availability of medicines at affordable prices through such a measure. This is expected to improve availability of medicines especially anti-cancer, anti-AIDS, several medical implants, etc.

4.3.4 OTHER PRICING METHODOLOGIES

4.3.4.1 Reference Pricing

The reference prices to be used for negotiations of the prices of patented drugs should be based on the premium enjoyed by the drug in the lowest priced market abroad compared to its closest therapeutic equivalent in the same country. This premium can then be applied to the corresponding price of the same therapeutic

equivalent prevailing in the domestic market to determine the reasonable price in Indian conditions. In other words, the patented drugs should be allowed the premium it commands elsewhere, but applied to the prices prevailing in India.

Even for non patented drugs, as recommended by Pronab Sen Committee, the pricing can be based on reference basis rather than cost basis.

4.3.4.2 Pricing of Patented Medicines in Other Countries

(i) **Canada:** Canada has a public funded Health scheme, known as "Medicare", which provides comprehensive coverage. For the pricing of patented medicine under "Medicare", there is Patented Medicines Price Review Board(PMRB), a quasi-judicial body, which ensures that prices offered by manufacturers of patented medicines are not excessive. The Board compares the proposed Canadian price under "Medicare" either to prices of existing drugs in Canada, or to prices in seven markets designated in the regulation (France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States). It ensures that the price charged by patentees, the factory gate price, for patented drugs sold in Canada to wholesalers, hospitals, pharmacies or other for human and veterinary use are not excessive. If the price exceeds then it conducts an investigation as per the Schedule 5 of the Compendium of Guidelines, Policies and Procedures. This investigation may indicate that either the price is well within the Guidelines or the patentee is required to reduce the price and take measures to comply by a Voluntary Compliance Undertaking or a public hearing is called to determine if price is excessive. Once the introductory price is established, subsequent price increases are limited to changes in the Consumer Price Index.

(ii) **France**: In France, pharmaceutical companies sell their products at any price. If companies want the national health care system to reimburse patients for the cost of the drug, they must agree to a negotiated price. Negotiated prices and reimbursement rates paid by the healthcare system are based on the therapeutic value of the drug and the price of the drug in other countries.

(iv) **Other Countries**: Free pricing is applicable in Germany and U.K only. Price setting is negotiated mainly on the basis of negotiation between authorities and companies in Belgium, France, Italy, Netherlands and Spain. Formulation regulation of premium prices by law is only there in Italy. Therapeutic reference pricing is available in Germany and Netherlands. New drugs are included in positive lists in case of Belgium, France, Italy and Netherlands. Reimbursement is automatically granted once market approval is obtained in Germany, Spain and U.K.

4.4 ACCESS TO ESSENTIAL MEDICINES

4.4.1 Income level and Accessibility

Considering that the income levels are low (particularly in rural areas) and the out of pocket expenses are as much as 80%, the prices of medicines play a vital role in ensuring accessibility of the common people. Insurance cover in India is still at a nascent stage, although private sector has been roped in to play this role. The contribution of the State and Centre also is only about 14%.

It is quite evident that the availability of medicines and health facilities in the hilly, tribal and inaccessible areas are either absent or inadequate. A relatively much lower level of per capita expenditure on hospitalization and medicines in rural areas and by the poorer segment of population supports such a situation. Therefore, such areas need to be given special treatment in a mission-mode approach, through which the health services and medicines are provided at affordable rates/prices. The Jan Aushadhi Scheme needs to be expanded to cover these areas. One of the major components that can help reducing this out of pocket expenses lies in providing better public health infrastructure in general but specifically in ensuring availability of drugs at reasonable prices. The Department of Consumer Affairs stated that an assured supply of medicines in public hospitals and health centres will reduce unaffordable sections of the population in approaching the private sector for treatment.

It is quite encouraging to find that several States have taken the initiative to provide medicines at a much lower price than those in the market. These States include Tamil Nadu, Bihar, Orissa and Rajasthan. For instance, Rajasthan has demonstrated that through tender and negotiations if competition could be activated among different reputed manufacturers, the supplies of medicines could be made available at much more affordable rates and in a viable and sustainable manner.

In this regard, if the tender system is meticulously followed and the prices of required medicines are centrally decided at the state level by a single agency, essential medicines of mass consumption can be made available at about one tenth of the printed price. The model does not require government funding or subsidy, unless these are provided free of cost. But the procedures and systems need to be made more transparent for ensuring smooth supplies. This would also re-assure the manufacturers of a continuous and rising demand which would enable them to plan their production programme in advance.

4.4.2 Promotion of Unbranded Generic

Promotion of unbranded generics through Jan Aushadhi Stores (JAS) needs to be implemented as soon as possible for which the Ministry of Health needs to bring out legislation for prescription of medicines in generics nomenclature by the doctors on a mandatory basis as done even in advanced countries like US. This would help JAS to be developed as a brand. Increasing provision of unbranded generics through JAS and public health programmes can also augment availability.

Affordability does not mean low cost drugs only. Through promotion of the industry including assistance to quality standards, more units would be set up (including SSI units) resulting in higher production of medicines. This will enhance availability.

Access is as important as affordability. Industry associations felt along the following lines:

- IDMA maintained that the Government should increase procurement of medicines and should make them available in Rural Health Care Centres. Since this procurement is done by tender mechanism, it is already at a highly competitive price. As the roads, electricity, communication and other infrastructure improve the accessibility to medicines will improve. For BPL families, medicines should be given free, whereas for APL families; cost should be recovered fully/ partly.

- OPPI observed that the challenge is to change current perceptions through realization that medicines are just a part of much bigger access issue of access to healthcare by the common man. This needs to be addressed jointly by well-structured public-private partnership initiatives. There is a need to strengthen the linkage between pricing and healthcare infrastructure, which a collectively increase access to medicines at affordable prices.

A common ground was that the Government needs to partner with the private sector to address India's acute healthcare challenges through public-private-partnerships (PPPs). Recent examples of successful PPPs in the health sector include outsourcing ambulance services, mobile medical units, diagnostics and urban health centers in several states to private NGOs, hospitals and clinics. PPPs in India should adequately cover primary and specialty healthcare, including clinical and diagnostic services, insurance, telemedicine, hospitals and medical equipment.

Allocating resources from national welfare schemes towards health insurance coverage is a step in the right direction. For example, a portion of the MGNREGS (Mahatma Gandhi National Rural Employment Guarantee Scheme) funds could be spent on health insurance premiums for labourers engaged in such work.

Once the health infrastructure is in place, differential pricing policies complemented by access programmes offered by pharmaceutical companies constitute the best way forward. According to the OPPI market competition, monitoring of prices by NPPA and abundant availability of generics will stabilize drug prices and no price control by the Government would be required.

4.4.4 Dr. Pronab Sen Recommendations

The Task Force under Dr. Pronab Sen (Report dated 20th Sept 2005) made certain important recommendations:

i. In the case of proprietary drugs, particularly anti-HIV/AIDS and Cancer drugs, the Government should actively pursue access programmes in collaboration with drug companies with differential pricing and alternative packaging, if necessary.

ii. Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived where possible and used as key strategic interventions for addressing both price and availability issues. Arrangements may need to be made to ensure their continuing viability.

iii. Availability of essential medicines through public health facilities should be ensured both through bulk purchases by government agencies, cooperatives or consumer bodies, through public-private partnerships if necessary.

iv. Insurance companies should be encouraged to extend health insurance to cover medicines.

v. A process of active promotion of generic drugs should be put in place and all public health facilities should be required to prescribe and dispense generic drugs, except where no generic alternative exists.

vi. All patented drugs and their formulations could be brought under price negotiations prior to the grant of marketing approval. The reference prices to be used for such negotiations could be based on the premium enjoyed by the drug in the lowest priced market abroad compared to its closest therapeutic equivalent in that same country . This premium can then be applied to the corresponding price of the same therapeutic equivalent prevailing in the domestic market to determine the reasonable price in Indian conditions.

vii. A centralized agency can be created for negotiation of prices of patented medicines and to ensure its availability by comparing prices based on (i) same active ingredient; (ii) drugs in a pharmacological class; and, (iii) drugs with similar therapeutic effect.

viii. In the Indian context, it could also be possible to draw from the Canadian model and some of the practices in European countries.

ix. Price controls should be imposed not on the basis of turnover, but on the 'essentiality' of the drug and on strategic considerations regarding the impact of price control on the therapeutic class. This must be a dynamic process.

x. Price controls should be applied only to formulations, i.e. the medicine actually used by the consumer, and not to bulk drugs. Intra-industry transactions should not be controlled unless there are compelling reasons for doing so.

xi. The ceiling prices of controlled drugs should normally not be based on cost of production, but on readily monitorable market-based benchmarks.

xii. All other drugs should be brought under a comprehensive price monitoring system with appropriate market based reference prices and with mandatory price negotiations, if necessary.

xiii. The National List of Essential Medicines (NLEM) should form the basis of drugs to be considered for intensive price monitoring, ceiling prices and for imposition of price controls, if necessary.

xiv. In the case of drugs not contained in the NLEM, intensive monitoring should be carried out of all drugs falling into a pre-specified list of therapeutic categories. Any significant variation in the prices would be identified for negotiation.

xv. Over a period of time more effective price monitoring needs to be adopted. All non-controlled drugs could be brought under a comprehensive price monitoring system with appropriate market based reference price and with mandatory price negotiations, if necessary. The ceiling prices of controlled drugs could be based on readily monitorable market-based benchmarks.

General Recommendations of the Pronab Sen Report

i. There is a need to balance the interests of consumers and pharmaceutical industry. Pricing of drugs should neither affect the pharma industry, nor the patients. Hence, State intervention through schemes like the National Rural Health Mission (NRHM) is important.

ii. India, being a very large market, over the years more and more patent protected drugs will be launched here at which point of time the impact on pricing could be large; hence, the Government/ regulator would have to implement proper checks and balances/ price approval mechanism for patent protected products.

iii. Under the new patent regime, the transition of the domestic companies from generic to innovative with the ultimate focus on the original research is taking places. The Government needs to support the R & D effort on original research.

iv. The greater push for TRIPs plus Intellectual Property Rights (IPR) regime needs to be addressed. India should restrict to existing provisions of TRIPS.

v. The option of using compulsory licensing could be explored in certain cases, thereby allowing third parties (other than the patent holder) to produce and

market a patented product without the consent of the patent holder. This would ensure better availability of the medicine.

vi. The focus could be shifted to an essentiality criterion as suggested by the Ministry of Health & Family Welfare. They suggested that if it is difficult to include the 348 drugs and their formulations under DPCO with the same trade margins; there could be a graded system of trade/ profit margins for different categories.

vii. New drugs developed through indigenous R&D having product patent under the Indian Patent Act 1970 may be exempted from price regulation for a period of ten years. Also products of New Drug Delivery System (NDDS) developed through indigenous R&D may be exempted from price regulation for a period of five years.

viii. Lack of proper infrastructure, particularly health infrastructure; and poor delivery mechanism are major hindrances for distribution. Hence, the key to healthcare is not necessarily pricing control but could be better achieved through an improved delivery mechanism, public funding and promotion of the pharma industry.

ix. Affordability does not mean low cost drugs only. Through promotion of the industry including assistance to quality standards, more units would be set up (including SSI units) resulting in higher production of medicines. This will enhance availability.

x. There is a need to ensure access of common man (poorer section) to medicines through public hospitals etc. The success of distribution/ procurement system of the Tamil Nadu Medical Services Corporation is worth replicating.

xi. The success of PPP models in health sector like outsourcing ambulance services etc. to private NGOs as done in certain States could be studied in

other States also. PPPs in India may help in covering primary and specialty healthcare, including clinical and diagnostic services, insurance, telemedicine, hospitals and medical equipments.

xii. Allocating resources from national welfare schemes towards health coverage could also be considered. For example, from the funds allocated for MNREGS, some portion could be made available for paying for health coverage of the labourers engaged in such works.

xiii. Promotion of unbranded generics through Jan Aushadhi Stores (JAS) needs to be explored. JAS could be developed as a brand. Increasing provision of unbranded generics through JAS and public health programmes can also augment availability.

xiv. The availability of medicines and health facilities in the hilly, tribal and inaccessible areas are either absent or inadequate. Therefore, such areas need to be given special treatment in a mission-mode approach, through which the health services and medicines are provided at affordable rates/prices. The Jan Aushadhi Scheme needs to be expanded to cover these areas.

xv. In the case of proprietary drugs, particularly anti-HIV/AIDS and Cancer drugs, the Government should actively pursue access programmes in collaboration with drug companies with differential pricing and alternative packaging, if necessary.

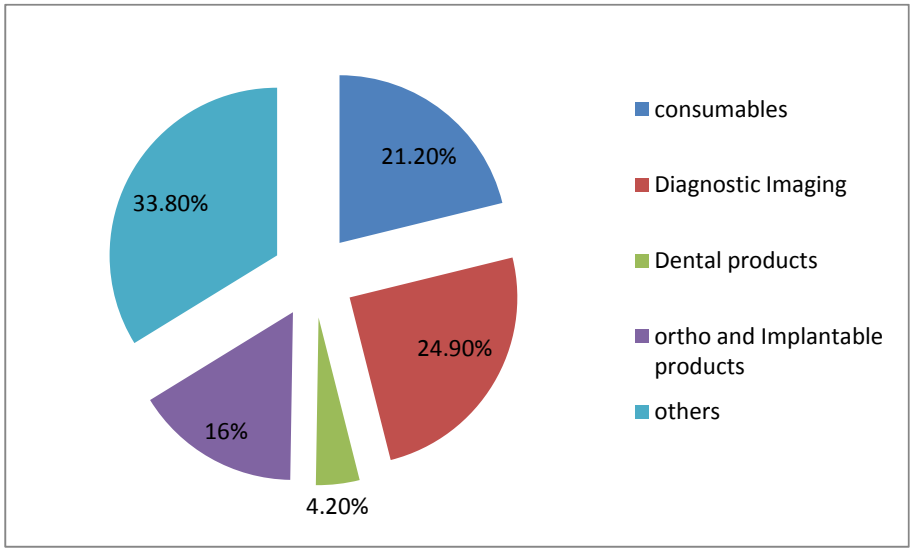
xvi. Public Sector Enterprises (PSEs) involved in the manufacture of drugs should be revived wherever possible and used as key strategic interventions for addressing both price and availability issues. Arrangements need to be made to ensure their continuing viability.

Chapter5

MEDICAL DEVICES

5.1 Status of Domestic Medical/surgical Industry:

As per the estimates of All India Medical equipments and Devices Association, the present market size of Medical Devices and Equipments is around Rs 15,000 crores with break ups as per table below:



As per the estimates of AIMED, there are nearly 750 manufacturing units with distribution of units based on their size as below:

Table-19: Turnover-wise distribution

Turnover	% Distribution
0-10 Cr.	70
10-50 Cr.	20
50-100 Cr.	5
100-500 Cr.	3
500 + Cr.	2

Present Status of Indian medical device Industry:

(i) The medical device Industry in India is very nascent and is largely import dependent. More than 65% of India's requirement of medical devices and equipments are met through imports with domestic production being largely restricted to low technology disposable equipments .

(ii) As shown in above table, the domestic medical device industry is highly unorganized and fragmented in nature. The high tech end of medical devices are dominated by multinationals which are imported in the country.

(iii) Diagnostic imaging , with the market share of 24.9% and Medical consumable , with market share of around 22% dominates the Indian Market.

(iv) The regulatory regime is still developing and DCGI is going to bring detail guidelines on Medical Devices very soon.

5.2 Export & Global Market Potential:

Global market for medical devices is valued at around US$200billion, growing at an average growth rate of around 4.5% compounded annually during last 5 years. Growing awareness about health, new technological innovations in the area of diagnosis and treatment, increasing old age population, changing disease patterns towards long term treatments etc., are some of the factors leading to growth of industry.

The health care industry is showing rapid growth in all economies of the world having population spread across all age groups. In view of this, the growth of medical device industry is unquestionable.

"Convergent Medical Technologies" are now being developed by many companies. These technologies are based on two or more existing technologies platforms. Various medical technology companies as well as growing enhanced medical technology companies in various parts of the world have emerged, where companies and researchers are working together to harness the potential of convergent medical technologies. The key supporting technologies in these efforts include medical

diagnostics, therapeutic and surgical devices, informatics, wireless monitoring devices, nano-technologies, tissue regeneration and specialized materials and quoting. This has opened new area for medical devices.

With the growing income in new world economies such as those of India, Brazil, South Africa, China, Singapore etc., has opened a vast new market for medical devices industry. However, Indian Medical Device Industry, at present is not in a position to reap the benefit of this global market position due to its nascent stage .

5.3 SWOT Analysis

5.3.1 Strengths

i. Well developed Microelectronic, Telecommunication, Software and Precision Engineering Industry, which are supporting industries for medical devices & equipment industry
ii. Ability to attract foreign investments because of strong financial and legal system, rule of law, democratic form of Government, good I.P. laws
iii. Industry's ability to handle low value large volume production as per global quality standards

5.3.2 Weaknesses

i. Low per capita expenditure on health care & low health insurance with an underdeveloped healthcare awareness and infrastructure
ii. Lack of adequate and trained manpower
iii. Lack of incubation and suitable ecosystem encouraging innovation and new products
iv. Absence of linkages between academia and industry
v. Absence of proper governmental promotional policy to encourage exports from the sector
vi. Tariff structure working against local manufacturing in many cases.
vii. Lack of regulation/standards

5.3.3 Opportunities

i. Huge market potential with a growing middle class and rising expenditure on health care
ii. Growing opportunities in export market particularly in EU market where EU's imports from developing countries are increasing at over 25%
iii. Growing demand on account of changing demographic profile, increasing incidences of life style diseases like cancer, CNS and diabetics, etc.
iv. Life cycles of high end medical equipments becoming shorter due to high level of innovation

5.3.4 Threats

i. Growing competition in export markets from countries like Thailand, China, Malaysia, Taiwan etc.
ii. Increasing dependency on imports, which is already 65% of the total demand
iii. Unorganized market for medical disposables
iv. Lack of regulations in medical disposables and surgical items leading to spurious products

5.4 Recommendations:

i. There is a need of independent definition for medical devices and a separate provision for the regulation of these devices. The Ministry of Health and Family Welfare working over these issues.

ii. There is a need for infrastructure creation for setting up **green-field medical devices and equipment parks.** This park may contain facilities like Research and Development Centre focused on Medical Device Industry, Testing Laboratory, Common Sterilization facility, Medical Instruments/Equipment calibration and validation facility, Engineering Services, a training centre to train labours, managers and entrepreneurs etc. The details of the facilities are explained in the ToR related to budget and schemes.

iii. There is also a need for National Center for Medical Devices, which may focus on new product development and assessment for medical device products. This center can complement the green-field medical devices and equipment park as stated above.

The details of the schemes are in Chapter 8.

Chaper-6:

CPSUs

6.1 INTRODUCTION

There are five CPSUs namely, Indian Drugs and Pharmaceuticals Ltd(IDPL), Hindustan Antibiotics Ltd (HAL), Bengal Chemicals and Pharmaceuticals Ltd(BCPL), Karnataka Antibiotics and Pharmaceuticals Ltd(KAPL) and Rajasthan Drugs and Pharmaceuticals Ltd(RDPL). These five Pharma PSUs have a combines business between INR 600 and 700 crores. This works out to be mere 1% of the domestic Pharma Industry turnover. The natural question then will be "what is the relevance of Public Sector units in such a crowded and largely self-sufficient field?" The answer to this lies in the historical development of the drug sector and also current scenario when it comes to making available low value low margin products for public good.

6.2 HISTORICAL BACKGROUND

Historically, it can be seen that when no private player was ready to invest in the capital-intensive drug sector in fifties and sixties, Government of India invested huge capital in infrastructure of this sector establishing public sector units to make life-saving medicines available at affordable prices for government health programs. This also substantially reduced dependence on imports saving the valuable foreign exchange when the country needed it most. Even when in eighties, when private players started entering this field, public sector helped the government to keep the prices of essential medicines under control. Even today the current scenario with respect to poverty and public health in India poses serious problems of affordability and availability of key medicines. Additionally, in cases like epidemics, natural calamities etc where emergency interventions are required, Public sector units are a vital tool in the hands of the government to make desired products available in volumes and at a reasonable price. While it is admitted that the share of Public Sector is minuscule in Pharma sector they can have some strategic importance. It could be useful to make these units competitive and self-sustaining in the long run by providing the necessary fillip at this juncture.

6.3 CURRENT STATUS OF CPSUs:

The Pharma PSUS present a mixed bag with respect to financial performance. While KAPL and RDPL have been declaring profits over the years, the remaining three companies had turned sick and were referred to the Bureau of Industrial and Financial Reconstruction (BIFR). BCPL and HAL are on a path of revival post rehabilitation through infusion of funds and waiver of interest, penalties and renegotiation of terms for financial liabilities, IDPL's case for rehabilitation is pending before the government. Collectively the five pharma PSUs generate revenue of about INR 600 crores to INR 700 crores. Export earnings are currently a small fraction of KAPL and HAL turnover but it is growing.

6.4 Performance of CPSUs:

Table-20: Performance of CPSUs

Parameter	KAPL	RDPL	BCPL	HAL	IDPL	TOTAL
Sales (08-09)	225.01	80.75	77.63	147.39	56.70	594.37
TO/Employees Rs lacs	30	52	10	11	23	19
TO/Sales employees Rs lacs	65	304	134	134	236	106
PAT Rs cr	5.88	0.01	-5.35	-22.08	-37900.9	
Total Employees	739	181	742	1224	243	3129
Sales Strength	345	31	58	105	24	563
Sales (08-09)	225.01	80.75	77.63	147.39	56.70	594.37

6.5 Personnel:

The distribution of personnel across functions reflects the organizational orientation. KAPL and to a lesser extent HAL has a sales and marketing orientation with large sales force while others have traditionally derived almost all of their sales from institutional markets, mainly from the government and manage the business with limited field sales force and several personnel in manufacturing and operations. In

terms of educational profile, the Lack of R&D is underlined by the near absence of PhDs in the talent pool. HAL has a highly qualified workforce with the largest percentage (39%) of employees with postgraduate degree among its peers.

6.6 Source of Revenue

The pharma PSUS have been generating most of their sales through institutional customers, including the Central and State governments. The share of institutional sales of pharma products ranges from about 60 % for KAPL to around 80% for HAL and close to 100% for RDPL, IDPL and BCPL. At the aggregate level, the pharma PSUS generate about 70% of sales of pharma products from the institutional segment. This bias for institutional sales gets reflected in the composition of the sales personnel whereby most people in the sales departments are managing institutional orders and clients. KAPL has the strongest and the youngest field sales force followed by HAL, which has over 100 sales personnel.

KAPL and HAL have been exporting their products primarily to the semi -regulated markets in Asia, Africa and Eastern Europe. KAPL's exports represents less than 5% of its turnover of Rs. 225 crores in 2008-09 while HAL's Rs. 4.73 crores worth of exports represents about 3% of its turnover of Rs.147 crores in 2008-09.

6.7 SWOT Analysis:

Overall, the singular strength of most Pharma PSUs is their manufacturing facilities, many of which are being modernized and upgraded for WHO GMP compliance. Moreover, being part of a government organization, there is a perception of 'good quality' associated with their products, which is an important differentiator in an otherwise commoditized market for generic drugs. Some Pharma PSUs have developed products that enjoy dominance in niche segments (e.g., agro vet products for HAL, OTC and home cleaning products from BCPL) that have potential for scaling up. However, the ability to derive advantage from their good quality manufacturing processes and gain market share is critically dependent on the competencies that Pharma PSUs develop in trade and institutional sales. This is found to be inadequate at present. Most of the Pharma PSUs are dependent on institutional sales that

happen as a result of government's preferential purchase policy (PPP). Even in these cases, Pharma PSUs are feeling the need for developing forecasting techniques and need for having inventory because market pressures are no longer allowing the suppliers to operate on the basis of manufactured-to-order. The biggest inadequacy is however felt in the area of trade sales where, apart from KAPL and HAL, the field personnel for all Pharma PSUs are too low. Most of them have not been able to attract and retain young field sales personnel, as a result of which the existing field sales personnel are aging and about to retire within the next few years, which will result in severe talent crunch. Trade marketing would become Pharma PSUs key source of revenue generation, especially when PPP is withdrawn. This would involve developing sophisticated systems for demand estimation, manufacturing resource planning, inventory management, brand building and sales force management – none of which is visible in most of the Pharma PSUs at present. Pharma PSUs have considerable overlap in products and sometimes compete with one another.

Many of the Pharma PSUs are hamstrung with inadequate working capital finance. This often results in them outsourcing their manufacturing to third party manufacturers. While outsourcing as a short term measure is acceptable, this can harm the reputation of Pharma PSUs in the long run, given the fact that manufacturing of good quality generic drugs is perceived as the "core competence" of these organizations. Most of the Pharma PSUs have plans for exports. However, their strategy or differentiation in exports markets is unclear. While some of them have institutional sales in semi-regulated markets, scaling up exports will need a concerted effort in brand building as well as negotiating the regulatory environment in those markets.

6.8 Goals

The main vision is to make all the CPSUs self-sustaining by year 2020. Towards that end , the road-map for the 12th Five Year Plan includes the actions to be taken in immediate future, the support needed for that, the change of orientation to achieve proper mix of socially relevant business and commercially viable revenue generating business. Moreover there will be some general goals common to all five the

common purpose being the social relevance of , while there will be PSU- specific goals depending on individual PSU's history, strength and present position on market ladder.

It is pertinent to mention here that all the resources required by the CPSUs to become self sustainable, have to be generated by them, may be by selling the surplus land available with them. The government assistance will be limited to the cases of strategic importance.

6.8.1 Short Term Goals:

This will cover first three years of the 12th Five Year Plan.

1) To upgrade the existing manufacturing facilities to WHO-GMP compliance.
2) To identify and introduce the product in key therapeutic segments for mass public use
3) To introduce the products from latest socially relevant diseases like AIDS, Cancer etc.
4) To rationalize human resources for optimal productivity.
5) To engage and expand in the prescription market.

This will provide necessary base and critical mass to launch into more complex areas in the later half of the Five Year Plan and beyond.

6.8.2 Long Term Goals:

This will cover the period of last two years of 12th Five Year Plan and beyond.

1) Bio-pharma drugs with emphasis on Vaccines
2) IV fluids both curative and nutritive.
3) Anti-HIV and Oncology medicines
4) CVD and Non-Communicable diseases medicines.
5) Strategic APIs

6.8.3 Sales Goals for Five CPSUs:

Table-21: Sales Projection of CPSUs

Rs Crores

Year	IDPL	HAL	BCPL	KAPL	RDPL
2012-13	51.7	189	153.37	320	108
2013-14	70	215	176.57	360	122
2014-15	80	264	204.73	425	135
2015-16	92	290	237.6	490	150
2016-17	125.4	319	275.83	560	165

6.9 Recommendations to achieve the goals:

The pharmaceutical industry in the country grew at a CAGR of 14%during 11th Five Year plan. Logically, PSUs should make an attempt to keep pace with the industry. However, the fact that PSUs will have to keep on servicing the low margin socially relevant products and will have significance presence in the institutional market, the CAGR for PSUs needs some tempering. Also the fact three out of five are presently not in the prescription market puts some restriction on the rate at which they can grow in the immediate future. The self-sustaining growth assumes that the profits will be invested in growing the business. At the projected CAGR and ROE levels, the business generates enough resources to fund its growth. The cross-linkages between strategy, operational efficiency and financial leverage generate returns to the shareholders. A change in strategy from 'low cost' to 'differentiation' by changing the product mix in favor of higher margin products in the chronic therapy, improving operational efficiency by generating more sales with the same asset base and a judicious mix of debt and equity can take the firms on an accelerated growth trajectories.

6.9.1. Therapies:

The top 7 therapies in Indian pharma formulations products belong to Alimentary Tract & Metabolism, Systemic Anti-Infectives, Cardiovascular System, Respiratory System, Musculo-Skeletal System, Central Nervous System and Dermatologicals. They have grown at a CAGR of between 12 to 17 % and contribute to over 83% of the industry sales. In each therapy, there is a tremendous amount of concentration of sub-therapies as well as products within each sub-therapy. Therefore, it is relatively easy to identify and select products for driving growth by using the criteria of annual sales and growth. At the same time, the products with large sales and high growth are also the most competitive. Therefore, one must look at other criteria including profitability, capabilities as well as strategic intent to play in certain product – markets to create a portfolio that will drive sustainable growth..

6.9.2. Markets to be concentrated:

UP, Maharashtra and Andhra Pradesh are the largest markets for domestic formulations. If one includes Mumbai, then Maharashtra takes the top spot with a share of 17.5% of the total sales. The regional distribution of sales is useful in identifying and focusing on markets to allocate the field sales force for growing sales through trade. While the large markets seem attractive from the perspective of size, they are also likely to be the most competitive. At the same time, several of the smaller states, in terms of physical size as well as sales of formulations, may be under serviced by leading industry players thus providing the potential for establishing strong brands over a 5-6 year time horizon. Similarly, the metros and large cities are saturated with competitors while the smaller towns and rural areas remain under serviced. An added advantage would be the relatively lower expenses towards sales force compensation and the ability to create force multiplier through partial outsourcing of field sales staff through Business Associates (BA) / Franchisees.

6.9.3. New products and verticals:

PSUs have traditionally remained with mainly the products addressed to the institutional requirements. Most of these products fall under the categories like anti-infectives, pain management medicines, G I tract and gynaecology requirements. Further for reasons of price these are old products. In run up to the self-sustainable

performance, PSUs will identify the new molecules in their areas of competence. At the same times new verticals both socially relevant and commercially attractive will be entered into. Additional therapies will include dermatology products, neutraceuticals, cardio-diabetic medicines and Ayurvedic products.

Two other therapies need a special mention. They are antiretroviral drugs and Vaccines and Sera.

6.9.4 Antiretroviral drugs:

With spread of HIV and social stigma attached to it, Government has taken upon itself to provide the necessary medication for the affected individuals. The purpose is not only to cure the specific individual but also to arrest the spread and provide better quality of life. There are private companies that manufacture these medicines but concentrate on export business for profitability at the cost of domestic patient. There are also the newer medicines that fall under patent regime and therefore not economically available. PSUs can play a major role by offering their facilities for formulation of these medicines. Government support in the form of long-term contract at an assured viable price will be necessary.

6.9.5 Vaccines and Sera:

This is another area identified by PSUs in their long-term strategy. Government of India undertakes vaccination of children for certain specific ailments. The number of such ailments covered is much less as compared to the ones advised by WHO. Further certain epidemics also call for intervention at shorter notice. PSUs would like to enter this area starting with marketing to generate a client base. This will be followed by backward integration into manufacturing. This of course will require establishing a dedicated state of the art facility that is capital-intensive activity and will need budgetary support. The vaccines that could be looked into are influenza vaccine, BCG, Tuberculin, AntiRabies, Hib, TT, Measles, Rubella and Japanese Encephalitis. Similarly Sera for rabies, Snake Venom can be handled in these facilities.

6.9.6 Purchase Preference Policy:

Over last five years, through cabinet approved scheme, Government has provided purchase preference for 102 medicines manufactured by PSUs. This has helped a lot in increasing capacity utilisation, improving top-line, improving bottom-line for profit making PSUs like KAPL and RDPL while helping in reduction of loss for the PSUs in rehabilitation mode. Withdrawal of this preference at this crucial juncture will nullify the benefits of all the efforts made over last 5 years and endanger the benefits of the budgetary support envisaged in the 12th Five Year Plan. Therefore it is absolutely essential to continue this preference for the period of 12th Five Tear Plan. Since Ministry of Health & Family Welfare is already planning to establish a common procurement agency for the medicines required for the governmental use, a long term contract can be signed by Pharma PSUs with MOH & FW under this Purchase Preference Policy *instead of the bidding system followed presently. This contract should be over a period of five years with prices being fixed in consultation with NPPA and the drugs list identification by the MoH&FW as well as other procuring agencies like Railways, ESIC, DGAFMS, etc.*. This will provide assured revenue to PSUs in the early years while the government will be assured of supply of quality medicines.

6.9.7 WHO-GMP :

The long-term sustainability also includes a factor of international presence. This is possible by up-grading the facilities to international standards as per WHO-GMP. While the new project planned in the 12th Plan will factor this at the project stage itself, the existing facilities may need face-lift to achieve those standards. While beyond 3rd year of the plan, internal revenue generation should normally support this, some budgetary support may be required on case-to-case basis.

6.9.8 R & D initiative:

In a dynamic industry like pharmaceuticals, the long-term sustenance can only be ensured with the access to knowledge driven technologies, either in the form of new molecule or new drug delivery system. A robust R & D is necessary for this. To achieve self-reliance by 2020, efforts in this direction have to start in the second half

of the 12 th Plan. A basic infrastructure needs to be put placse as a common facility for all the five PSUs with contribution coming from the PSUs as well as funding from government.

6.10 Janaushadhi:

This is a flagship program of Department of Pharmaceuticals under which commonly required medicines will be made available under generic names and affordable prices through dedicated outlets across the country. Apart from making the medicines accessible to poor sections of the society, this also will provide a platform for PSUs to have foothold in the trade market and in the long run eliminate the need of the crutches of purchase preference. The purpose of making available socially relevant medicines will also be simultaneously served.

6.10.1 The key features of the Jan Aushadhi Scheme are:

i. Making available quality medicines at affordable prices for all, typically the poor and the disadvantaged through specialized outlets called Jan Aushadhi Stores (JAS) to be opened in district hospitals in the first instance as this is the placse where typically the poorer sections of the masses come for treatment.

ii. Provision of built up space for JAS in district hospitals by the State Governments with the operation of JAS by state Government nominated Operating Agencies like NGOs, Charitable Organistions and public societies like Red Cross Society, Rogi Kalyan Samitis typically constituted for the purpose

iii. Operational costs to be met from trade margins admissible for the medicines.

iv. Supply of the generic medicines in the first instance by the Central Pharma PSUs so as to ensure both quality and timely supply. However

wherever there would be need and gap, medicines could be sourced for quality SME units. This would also give support to the Pharma SME sector also as well as promote public-private partnership and avenues for achievement of corporate social responsibilities, goals geared towards affordable medicare for the masses.

v. State Governments to ensure prescription of unbranded generic medicines by the Government doctors. Hence the link of district hospital located JAS to begin with.

6.10.2. Status of JANAUSHADHI Scheme

The central objective of the scheme to begin with was to make medicines available to the poor and disadvantaged sections of the society through the opening of the Jan Aushadhi Stores – one in every district hospital of the country ie a total of 630. This was to be expanded to Sub-division and Block levels later. However, only 102 stores could be set up in 9 states in the last two years which is a cause of concern.

Several reasons have been identified for this poor progress:

i. **Firstly that most States did seem to be sensitive to the issue of availability of quality medicines at affordable prices, especially for BPL families but still advocated free medicine disbursement from the hospital dispensary without admitting to the Lack of medicines availability on time and in required quantities with assured quality to patients visiting these dispensaries in the hospitals at district, subdivision and block levels.** The free supply in any case is a burden which can be reduced if unbranded generic medicines are prescribed and used, but for various reasons the jan aushadhi unbranded generic medicines was perceived to be against the free medicines concept. The feeble attempts by some governments like Bihar, Tamil Nadu, AP and some districts of Rajasthan like Nagaur and Chittorgarh do not lend themselves to sustainable and true unbranded generic medicines support as required which is why they have not been able to make any dent in the problem. The support of the central government in the Ministry of

Health has also not been adequate inasmuch that there is need for supporting opening of jan aushadhi stores in central government hospital premises coupled with monitored prescription of unbranded generic drugs to the out –patients and indoor patients.

ii. Lack of prescription of generic drugs by government doctors was a big hurdle. Few state governments came forward to issue guidelines to government doctors to prescribe generic medicines. Even those that did like Rajasthan, Punjab, Odhisa, Delhi could not enforce it properly. Even the notification dated 19th May 2011 by the Ministry of Health of the Government of India for all central government hospitals and related institutions has not been of much help.

iii. Both the above reasons led to very less number of stores (102 in 9 states) which does not lend itself to viable economic operation both from the production of generic medicines in unbranded generic form and their supply.

6.10.3 Recommendations

i. To overcome the above weakness revised scheme has been prepared. Herein focused efforts would be made in the first instance in scheme friendly states and the Ministry of Health would be encouraged to assist in implementing the scheme in central government hospitals, Ministries like those of Railways, ESIC, Labour etc. A scheme of Rs 200.00 crs is being proposed.

ii. Making the scheme implementation mandatory as part of the health sector funds allocation for supporting the scheme through state government run hospitals. This could be ensured through a mechanism tying up the release of funds from the Central scheme to the state dependant on the progress of the scheme. Appropriate deliverable parameters to be put in place for this in consultation with Department of Pharmaceuticals and the Planning Commission.

iii. Mandatory prescription of unbranded generic medicines by state government and central government institutions doctors and mechanism to ensure its compliance by appropriate audit processes

iv. Involvement of the Department of Consumer Affairs and Information and Broadcasting along with related state government departments for media assisted coverage so as to ensure widespread rural and target group outreach on one hand and to generate demand side supply push so as to make the operations economically viable on the other.

Chapter 7

RESOURCE REQUIREMENT IN THE DEPARTMENT OF PHARMACEUTICALS

7.1 In the Department

The DoP has not been able to take up or launch any new activity in line to its Business Allocation even after three years of its existence. The main reason for this lies in lack of technical capability since its inception.

7.1.1 Existing Technical responsibilities

i. Examination & processing of applications for Import of items restricted for imports.

ii. Examination & processing of applications for DSIR's recognition of in-house R&D units of Pharma Industry.

iii. All technical matters pertaining to NLEM & regulatory systems under Drugs & Cosmetics Act, DPCO, NDPS Act,

iv. All technical matters concerning IPR, WTO, patented drugs & medical devices.

v. Inter-Departmental matters including Free Trade Agreements and Joint Commissions and other bilateral technical matters

vi. Technical issues related to Pharma Policy.

vii. Project plans for setting up National Centre of R&D in Phytopharmaceuticals (NCRDP) to be set up at NIPER, Guwahati.

viii. Examination & processing of applications concerning fixation of Standard Input-Output Norms(SION) for drugs and pharmaceuticals

ix. Examination & processing of applications concerning licensing matters, foreign collaboration etc.

x. Examination & processing of references about development of Infrastructure, manpower and skills for the Pharmaceuticals sector and management of related information.

xi. Education and training including high end research and grant of fellowship in India and abroad, exchange of information and technical guidance on all matters relating to Pharmaceuticals sector.

xii. Promotion of Public – Private – Partnership in Pharmaceuticals related areas.

xiii. Inter-sectoral coordination including coordination between organizations and institutions and institutes under the Central and State Government in areas related to the subject entrusted to the Department.

xiv. Technical support for dealing with national hazards in Pharmaceutical sector.

7.1.2 Difficulties due to Unavailability of Technical Officers

Owing to unavailability of Technical Officers, the Department is facing a lot of problems in consideration of various issues covering developments of the pharma industry. Additionally, it is not able to contribute to inter-departmental issues with DST/DBT, etc. and disposal of various references received from different sources depending upon the nature of above referred activities. In some cases, the schemes cannot be pursued at required pace. The R&D section in the Department is virtually defunct as it is difficult to develop new schemes for much required R&D efforts in drug/pharma department. In some of the high level committees, such as GLP Expert Committee and DPRP Expert Committee, proper representation from the Department could not be made due to lack of senior level Technical Officers. The requirement of technical officers is very crucial in evaluating many proposals received from DGFT in the Department about fixation of SION for bulk drugs, drug intermediates and formulations being exported from India

7.1.3 Action needed

In view of the foregoing it is proposed that action for creating the posts may be taken as proposed below:

(i) Drugs Price Control Division

Table-22

S.No.	Name of post/Pay scale	No. of Posts	Expenditure
1	Joint Director (Cost) (Rs.15600-39100, GP-7600)	1	70762
2	Scientist Gd. C (Rs.15600-39100, GP-6600)	1	68882
3	Deputy Director (Cost) (Rs.15600-39100, GP- 6600)	1	68882
4	Assistant Director (Cost) (Rs.15600-39100, GP- 5400)	2	66626x2=1,33,252
5	Junior Analyst (Rs.9300-34800, GP-4600)	2	52630x2=1,05,260
	Total (for 1 month)		4,47,038
	Total (for 1 year)		53,64,456

(ii) Projects And Trade Regulatory Division

Table-23

S.No.	Name of post/Pay scale	No. of Posts	Expenditure (in `)
1	Deputy Director General (DDG) (Rs. 37400-67000, GP-10000)	1	121992
2	Scientist Gd. C (Rs.15600-39100, GP-6600)	1	68882
3	Deputy Director (Statistical) (Rs.15600-39100, GP-6600)	1	68882
4	Research Officer/Assistant Director (Economic Service) (Rs.15600-39100, GP-5400)	1	66626
5 (a)	Senior Investigator (Statistical Service) (Rs.9300-34800, GP-4800)	2	53006x2=1,06,012
5 (b)	Junior Analyst (Science Cadre) (Rs.9300-34800, GP-4600)	2	52630x2=1,05,260
6 (a)	Junior Investigator (Statistical Service) (Rs.9300-34800, GP-4600)	2	52630x2=1,05,260
6 (b)	Junior Technical Assistant (Science Cadre) (Rs.9300-34800, GP-4200)	2	51878x2=1,03,756
	Total (for 1 month)		7,46,670
	Total (for 1 year)		89,60,040

(iii) Research And Development Division

Table-24

S. No.	Name of post/Pay scale	No. of Posts	Expenditure
1	Scientist Gd. E (Rs.37400-67000, GP-8700)	1	119548
2	Scientist Gd. D (Rs. 15600-39100, GP-7600)	2	70762x2=1,41,524
3	Scientist Gd. C (Rs.15600-39100, GP-6600)	2	68882x2=1,37,764
4	Scientist Gd. B (Rs.15600-39100, GP-5400)	2	66626x2=1,33,252
5	Junior Analyst (Rs.9300-34800, GP-4600)	2	52630x2=1,05,260
6	Junior Technical Assistant (Rs.9300-34800, GP-4200)	2	51878x2=1,03,756
	Total (for 1 month)		7,41,104
	Total (for 1 year)		88,93,248

(iv)Education And Training Division

Table-25

S. No.	Name of post/Pay scale	No. of Posts	Expenditure
1	Scientist Gd. C (Rs.15600-39100, GP-6600)	2	68882x2=1,37,764
2	Scientist Gd. B (Rs.15600-39100, GP-5400)	2	66626x2=1,33,252
3	Junior Analyst (Rs.9300-34800, GP-4600)	2	52630x2=1,05,260
4	Junior Technical Assistant (Rs.9300-34800, GP-4200)	2	51878x2=1,03,756
	Total (for 1 month)		4,80,032
	Total (for 1 year)		57,60,384

The total expenditure on the salary, for implementing above proposal would be approximately Rs 2.9 crores per annum.

7.2 National Pharmaceutical Pricing Authority

7.2.1 Present Status

NPPA since its inception is having total sanctioned strength of 60 regular posts including costing, technical and administrative officials. Since NPPA does not have its own cadre for recruitment of their officials, the required manpower is being provided to NPPA by different cadre controlling authorities such as Indian Costs Accounts Service, Department of Fertilizers, Department of Chemical & Petrochemicals, Indian Economic Service etc.

7.2.2 Studies for Manpower

Staff Inspection Unit (SIU) had conducted a study in 2003 for assessment of work and staff requirement for NPPA. However, no final decision could be taken on this report. Subsequently, a Work Study was conducted by Indian Institute of Public Administrations (IIPA), which submitted a report on 23.11.09. Further, IIPA submitted a supplementary report in January, 2011.

7.2.3 Observations of IIPA Study

As per report of IIPA, the functioning of NPPA is heavily dependent upon the outsourced/contractual staffs i.e. DEOs/YPs as NPPA has hired 40 DEOs/YPs in order to support its 31 regular staffs out of the total 71 working strength of NPPA as on January 2011. As per observation of IIPA, NPPA need additional regular staff for smooth running of following main functions IIPA has reassessed the total staff strength to 132 posts.

7.2.4 NPPA Proposal

NPPA submitted details for creation of 44 additional posts at various levels and simultaneously abolishment of 15, thus increasing the staff strength of NPPA from 60 present sanctioned strength to 89.

Thus the total sanctioned strength of NPPA would be as under:-

Table-26

Sl. No.	Designation of Post	Existing Sanctioned Strength	Concurred by IFD
1	**2**	**3**	**4**
01	Chairman	1	1
02	Member Secretary	1	1
03	Advisors/Directors	5	4
04	Deputy Secretary (Legal)	0	1
05	Under Secretary	0	1
06	Dy. Directors (Cost)	7	5
07	Dy. Directors (Tech.)	3	4
08	Deputy Director (Econ)	0	1
09	Section Officer	3	2
10	Asstt. Director (Tech.)	1	03
11	Asstt. Director (Cost)	2	0
12	Asstt. Director(Stat.)	0	01
13	Private Secretary	1	1
14	Personal Assistant/Steno Grade 'C'	2	5
15	PPS	1	1
16	Senior Investigator	1	2
17	Assistant	1	6
18	Law Officer/Legal Assistant	0	2
19	Technical Assistant	2	8
20	Junior Investigator	1	0
21	Hindi Translator	1	1
22	Steno Grade 'D'	8	1
23	UDC	1	1
24	LDC/Typist	8	16
25	Staff Car Driver	2	2
26	Daftry	2	1
27	Peon/Messenger	5	9

28	Safaiwala	1	2
29	Group 'D'	0	3
30	Database Operator	0	1
31	Sr. Counsel Operator	--	1
32	DEO	0	2
Total		**60**	**89**

Consequent upon implementation of the above re-structuring of NPPA, the net financial implication will be Rs.74.89 lacs per annum

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CHAPTER-8

SCHEME PROPOSALS

8.1 Industry Promotion and Development

8.1.1 Existing Schemes – Continued from 11th Plan

8.1.1.1 Pharma Promotion and Development Scheme (PPDS):

This is a continuing scheme for promotion and development of Pharma sector in the country. Under the scheme, following activities are undertaken:

i. Organizing Seminars, Conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/consultancies for facilitating growth, exports and critical issues affecting Pharma Sector.

ii. Any other activity relating to the promotion of Pharma Sector, export and investment.

A number of studies are proposed to be conducted for proper scheme planning and project development. These could be –

- Census of MSME in collaboration with DCGI, MSME and Ministry of Statistics &PI
- Study on pharmaceutical industry analysis of competing countries – study could be done or available reports procured off-shelf.
- Studies required for the detailed formulation of various schemes given in this Plan Document and further as may be required

It is proposed to continue the scheme for the 12th Plan for the same set of activities which would be required more so now that the department would be able to implement it more effectively based on the experience gained in the last three years following the setting up of the department in July 2008.

Budgetary requirement: Accordingly, the budgetary requirement for the scheme, at the rate of Rs. 2.0 crores per annum will be Rs 10.0 crores.

8.1.1.2 Intellectual Property Rights Facilitation Centers:

This is a continuing scheme and was started in 11th Five Year Plan and two centers one at Pharmexcil Hyderabad and other at NIPER Mohali have been opened. The existing objectives of these IPR Facilitation Centers (IPRFCs) are:

i. Strengthening of interaction between Pharma Industry, Pharma industry support institutions and associations, IP offices and other relevant government organizations with a view to better identifying the needs of Pharma Industry facilitating the implementation of customized targeted activities addressing the specific IP needs of each sector, group or cluster.
ii. Support to national and international efforts for further integration of IP issues in programs and policy initiatives aiming at fostering the technological and innovative capacity and the export potential of Pharma Industry.
iii. Increase awareness and understanding of IP issues within the Pharma business community through awareness raising campaigns and targeted training programs with the optimal use of modern information and communication technologies to maximize their benefits from the use of IP systems.
iv. Advise government to take into account the specific needs of Pharma Industry in their IP Policies.
v. Disseminate information on best practices on the use of IP by Pharma Industry and of their exploitation of technological knowledge.
vi. Make an access to technological knowledge easier and cheaper for the industry.
vii. A detailed study would be got done on the impact of IPR issues on the drug prices and availability in developing countries. For this funding would be done from the budgetary resources of PPDS scheme.

There is a continued need to further strengthen these centers and broaden the scope of work by helping in filing applications related to DMF, ANDA, MHRA, etc given the increasing emphasis on patent issues by the competitive markets and

companies as also the key role which Indian pharma companies can play in bringing out new product patents as well advance their share of the First-to-file applications in the regulated markets like US, Japan and EU. Accordingly, new IPRFCs at Mumbai, Chennai and Ahmedabad can be opened for easy access of the centers by the industry.

Budgetary requirement: The budgetary requirement would be:

- One Time Cost of setting up three Centers Rs. 1.5 crores
  @ Rs 0.50 crs per centre
- Recurring Cost for five centers Rs 5 crores per annum

Total Budget for 12th Five year Plan: Rs 26.5 crores

8.1.2 New Schemes

8.1.2.1 International Pharma Cooperation Initiative (IPCI)

With the increasing influence of India in global pharma production, mutually beneficial international partnerships is a crucial issue with respect to gaining access to emerging markets and sustaining generics capabilities in the developed markets. For this a two fold approach is proposed-

i. Herein the focus would be on BRIC, IBSA, CIS, EE, WA, Africa and ASEAN markets which are growing at 10%+ annually but wherein Indian pharma products are being targeted by competitive MNCs on various grounds including quality and manufacturing standards. The scheme aims to meet this challenge head-on. It is accordingly proposed to have mutually beneficial capital investment projects on a partnership basis to tackle such needs such as –

   - Setting up of Joint testing and lab facilities for certification of Indian pharma products imported into the above identified importing countries – This will enable Indian products to enable faster registration and later continued exports sustainability due to building of mutual trust in respect of quality of drugs imported as certified by the joint facilities

- Development of locally sustainable formulations and drug delivery systems for importing country by joint partnership programs
- Capacity building of regulators of importing country to enable better appreciation of Indian manufacturing standards
- Other mutually beneficial drug development and capacity building projects
- Capital support for export capacity building such as 2D bar coding and such other requirements
- Dossiers preparation support for SMEs for registration of their products in targeted countries
- Studies and reports of competing countries on their pharma industry development and opportunities.
- Joint financing of research and drug development projects of mutual interest

ii. Herein the focus would be on getting a greater share of the generics in the developed markets like the US, EU and Japan which while growing at a comparatively slow pace are nevertheless of high unit value for the products exported. This possible gain is however restrained by the lack of technology for production and filing of such initiatives as – First to File in case of US markets, multiple testing requirements of Testing in EU countries and now increasingly in CIS and West Asian markets. Similarly accessing market share in newly opened generics markets like Japan are of key importance. For meeting these challenges and taking advantage of these new opportunities, it is proposed to launch Joint Partnership Programs such as-

- Development of generics for the concerned markets
- Support for filing of generics drugs in the concerned markets in terms of dossier filing, clinical trials support and other support as required to gain access to the high value market
- Joint funding of schemes for collaboration in pharma sector development as in new drugs or areas of mutual interest

The implementation of these projects would be preceded by MoUs for mutual partnership at Inter-governmental level and appropriate implementation through SPVs as may be required. The projects themselves would require both capital and revenue expenditure.

On the whole there will be an emphasis on the MoU mechanism for bridging partnerships with countries across wherever Indian pharma has key market interests.

It is proposed to allocate Rs 50 crs for this for the 12th Plan.

8.1.2.2 Upgradation of SMEs to WHO-GMP standards

In the 11th Plan upgradation of SMEs to Schedule-M GMP was envisaged. This assistance did not include upgradation to WHO-GMP and higher International standards requirements which are now increasingly required for making the SME Pharma sustainable in an increasingly competitive and demand global manufacturing environment. Accordingly it is proposed to launch a Scheme in the12th Plan for upgradation of 1200 SME pharma units to WHO-GMP and International standards manufacturing standards. For this, as regards, MSME, it would accordingly include the required upgradation list in the list of equipments for financial assistance to SSIs. However this could present difficulties in total project admissible under the on-going scheme of CLCSS of the MSME for technical upgradation of SSIs as it is estimated that upgradation to WHO-GMP standards would require a cost of about Rs.3 crores.

Accordingly, it is proposed that assistance to SSI Pharma Units under the CLCSS may be provided for project cost of upto Rs.3 crores with capital subsidy of Rs.1 crores from the current level of Rs. 25 lakhs capital subsidy on a total project cost of Rs.1 crores. Also, the assistance should be dovetailed to provide soft loan interest rates of 5% by the Banks for this upgradation. Similar assistance would be provided to

the medium scale enterprises who are not WHO-GMP standard but wish to achieve the level for increasing their competitiveness.

On the whole for 1200 units at the rate of Rs.1 crores per unit would require total financial assistance of Rs.1200 crores as subsidy for the period upto 2017. The subsidy is better given as interest-based subsidy which would help stagger the plan allocations on a yearly basis and take care of the wage and means limitations of the budget.

Hence total Budgetary requirement is Rs.1200 crores

8.1.2.3 Training of 5000 Working Professionals in WHO-GMP / International manufacturing standards:

While schemes above would provide manufacturing capability upgradation assistance for capital expenditure, skill development of personnel required for such upgradation and sustenance of supply of skilled personnel would also be required. It is estimated that for this there is a need for training of at least 5000 working professionals in WHO-GMP and other International Standards GMP requirements by 2017. This would entail expenditure of about Rs 50,000 lac per person. Accordingly a sum of Rs 250 crs is proposed for this.

Hence total Budgetary requirement is Rs.250 crores

8.1.2.4 Upgradation of selected Pharma manufacturing facilities including bio-pharma to High Regulated market of US FDA/EDQM/TGA and other International Standards to enable Global Generics and Biosimilars capabilities:

The export of Pharmaceutical products constitutes nearly 45% of total turnover of Indian pharma Industry. In view of the growing importance of generic medicines and the advent of Bio-similars in high regulated world market Indian Pharma

manufacturers need to build capacity for compliance to the stringent standards of high regulated yet high value market countries – US, West EU, Australia and South Africa. Therefore, it is proposed that 250 select units be provided assistance by 2017 to upgrade their facilities as per the requirement of these countries and other international standards. This will be done at the rate of 50 units per year at the cost of Rs. 2 crores per unit and a total cost of Rs. 500 crores. The assistance proposed to be given would be one-time capital assistance to enable quick time bound implementation given the urgency of capacity building in light of the steep patent cliff of small and large molecules valued at US$ 300 Bn by 2015.

The Total Budgetary requirement is Rs.500 crores

8.1.2.5 Setting up of one National and five Regional Formulation Development and Manufacturing standard training Centres (FDC):

Development of generic formulations from patent products for small and big molecules (Biosimilars) is a challenge for the SMEs. For this, it is accordingly, proposed to set up **Formulation Development Centers** which would assist the SME Pharma for development of new formulations with a view to taping the vast opportunity opening up due to off patenting of a number of molecules valued at about US$ 300 Bn. (traditional generics and bio-similars) in the next five to seven years. It is proposed to set up of at least one Regional Formulation Development Centre (RFDC) in each of the identified cluster growth areas of the pharma sector in the country. This may cost Rs. 100 crores.

Consequent to the need of capacity building of the manufacturing personnel required for manufacturing standards upgradation, it is proposed to set up of one National and five Regional manufacturing standards training centres at the total cost of Rs. 60 crores.

Hence total Budgetary requirement is Rs.160 crores

8.1.2.6 Establishment and Upgradation of 10 Pharma Growth Clusters

There is a need of synergy strategies to address infrastructure development issues for promoting integrated growth of the pharma industries. For this, Cluster based approach is an important strategy and is now increasingly being recognized as an effective and sustainable strategy for competitive enhancement of MSMEs. Accordingly, it is proposed to implement a Scheme for Cluster Development of Pharma Companies to provide an integrated set up for enabling Quality, Productivity & Innovative manufacturing by the Pharma SMEs in existing and new clusters. Identified clusters are - Baddi (HP), Hardwar (Uttarakhand) and Gurgaon (Haryana) in the north, Pattancheru, Pashmalyram and Khazipalli (in A.P), Alandur and Ambattur (both in TN) in the South, Thane, Nashik, Aurangabad (all in Maharashtra), Vadodara and Ahmedabad in Gujarat in the West and Goa/Sikkim in other special areas. The proposed central infrastructure which would be developed could include:

- Central facilities for Environment standards compliance
- Central Facilities Centre for Quality Testing and Regulatory compliances.
- Cold Chain facilities
- Formulation and Product Development Facilities.

The assistance would be in the form of a Grant to recognized bodies – association of industries in the concerned clusters with proper safeguard mechanisms and procedures. The assistance would be restricted to assistance for building and machineries. The operational cost of the central facilities so established to the extent of 70% would be met by the industry on a recurring basis.

It is accordingly proposed to establish such facilities at 10 Pharma Clusters by the end of the 12th Plan and such clusters would be labeled as **Pharma Growth**

Clusters. It is estimated that each cluster would require assistance of about Rs.50 crores. Accordingly, the total budgetary requirement would be of Rs. 500 crores.

Hence total Budgetary requirement is Rs.500 crores

8.1.2.7 Infrastructure support for Cold Chain for high end drugs for exports

In order to enhance exports capability for high end drugs requiring exact cold chain standards till the time they are exported from the country in light of stringent developed market requirements, there is a need to establish cold chain facilities. The Department of Pharmaceutical proposes to provide assistance for setting up of such cold chain facilities and a provision of Rs.50 crores is being made in 12th Five Year Plan.

Hence total Budgetary requirement is Rs.50 crores

8.1.2.8 Scheme for environment standards compliance and required infrastructure support including capacity building.

The international customers from developed nations are becoming more stringent on ensuring local environment standard compliance standards and want companies to adhere to these standards. This has led to a big challenge for the Indian pharma industry, particularly small scale units, which either have investment concerns or limitations of growth beyond their allotted unit areas in the industrial clusters set up earlier with antiquated environment standards compliance potential. DoP is expected to play a vital role by providing financial and technical assistance to improve financial sustainability of SMEs on one hand and also safeguard the environment from the hazards associated with the unplanned growth of the industry.

A budgetary provision for Rs 100 crores is proposed in 12th Five year plan

8.2. R&D, Capacity Building and Employment

The following are the Schemes, as per the recommendations made earlier in this Plan Document:

8.2.1 Continuing Schemes

8.2.1.1 NIPER Mohali:

(i) The continuation of the PG and the PhD education at present strength levels would require budgetary support.

For this budgetary allocation of Rs 100 crs would be required for the 12th Plan period.

(ii) Given the huge demand for HR development at Masters and PhD level it is proposed to expand the student output under the existing scheme of NIPER Mohali and it is accordingly envisaged to expand as per below:

Physical target		Budget (Rs crs)
a.	Additional 1000 PGs and PhDs	200
b.	Training Industry and Regulatory personnel	25
c.	Public Health and Pharmacovigilance Trg.	25
d.	Infrastructure Upgradation	250
	Total	**500**

This would involve both capital and revenue expenditure.

8.2.1.2 For HR Development at 6 New NIPERS – Raebareilly, Kolkatta, Guwahati, Hajipur (Patna), Ahmedabad and Hyderabad

The setting up of the 6 new Nipers was started following the approval of the Scheme in the 11th Plan. The Cabinet first approved the setting up of the NIPERs in 2007. Following the progress made, now the Cabinet has approved the permanent establishment of the NIPERs in October, 2011. This would now enable the full scale work for establishment of the NIPERs. As per estimates prepared by the expert

consultants, Deloitte, Touch and Tohamatsu, about Rs 2000 crs would be required both for capital and revenue expenditure.

It is accordingly proposed to allocate Rs 2000 crs for these 6 new NIPERs.

8.2.1.3 Other Schemes

8.2.1.3.1 Setting up of National Centre for Phyto-pharma development

Major capital expenditure of about Rs 100 crores being met from DONER. Present allocation sought for initial years operation as per advice from DONER. A provision of Rs 20 crores is being made in 12th Five year Plan from DoP.

Hence, total budgetary requirement is Rs 20 Crores.

8.2.1.3.2 GLP/GCP/Animal House Lab Schemes:

Under the R&D/ERP Scheme already approved for the 11th Plan the Scheme for setting up of GLP compliant Labs on PPP basis, GCP compliant Lab on PPP basis and a Animal House Lab on PPP basis is under implementation. The selection of Consultants for implementation of the scheme is underway at the Department level. Preparation of report and its subsequent implementation would continue in the 11th Plan. It is proposed to allocate Rs 25 crs for this scheme for the 12th plan period accordingly. As regards the ERP component of the existing approved scheme projects for the same would be finalised in the 12th Plan for the Private sector. Additional allocation of Rs 25 crs is proposed for this component.

Hence total budgetary requirement is Rs 50 Crores in 12th Five year Plan.

8.2.1.3.3 Continuing R&D Schemes for Niper Mohali

Niper Mohali is presently implementing a number of projects in R&D for various pharma areas like neglected diseases, infectious diseases, vector borne diseases, etc. In addition a number of projects are being implemented for Public health, Pharmacovigilance, Regulatory capacity building for academia and industry, etc. NIPER Mohali would a complete assessment regarding the objectives set for these

projects and the achievements so far. Thereafter asses the additional budget requirements for successful completion of such projects would be assessed. After third party assessment the rationale for continuance of such projects in proper scheme format would be considered. Then the concerned projects would be sought to be continued.

Based on this methodology it is proposed to allocate Rs 50 crs for such projects for the 12th Plan.

8.2.1.3.4 Continuing scheme at New Nipers

At present there is only one project under implementation which is for Joint development of Tuberculosis related drugs at Niper Ahmedabad and AIIMS, Delhi. This project would spill over for one year of the 12th Plan. Accordingly a **Budget requirement of Rs 1.00 crs is envisaged.**

8.2.2 New Schemes

8.2.2.1 Setting up of New New NIPERs

As pointed out in the discussion in Chapter 3 of this Plan Document, there is a shortage of 45,000 seats given the 1:10 ratio of PG seats vs Graduate Seats for Pharmacy studies in the country. Accordingly, it is proposed to meet this gap to some extent by setting up of 10 new Nipers which would provide about 5000 more PG seats and also cater to the PhD requirements. This is necessary also as India is targeted to become a global hub for drug discovery and innovation for which a global study by Ernst & Young has already been commissioned. The setting up of these 10 New New Nipers would require a budget allocation of about Rs 3000 crs. These Nipers would follow the same tested model implemented hitherto and the required 100 acres land for each for them would be provided free of cost by the state governments.

Required Budget Allocation: Rs 3000 crs

8.2.2.2 New Schemes at Niper Mohali

It is proposed to launch new schemes as below at Niper Mohali-

Scheme		Budget (Rs crs)
a.	R&D Centre for Biologicals and NCEs	250
b.	R&D Centre for NDDS	250
c.	Setting up 20 New Incubators	100
d.	Incentive Scheme for CROs Devpt for New Drug Discovery	200
e.	Partnership with International Centres of Excellence	25
	Total	**825**

Thus to make India self reliant and globally competitive in niche areas of drugs and pharmaceuticals in HR, R&D and to boost Employment led growth the fund allocation of around Rs 825 crores is projected.

8.2.2.3 Pharma Venture Capital Fund

The growth of the Indian pharmaceutical industry over the past few decades has predominantly arisen from manufacturing generic drugs for exports and domestic use. R&D in the pharmaceutical industry has witnessed no success in creating a new drug, despite its efforts for the past sixteen years. This is mainly due to lack of venture fund industry in India as compared to developed countries for the pharma sector. It needs to be pointed out that investing in a fledgling start-up firm, aiming for R&D in the pharmaceutical industry, is risky because of the high rate of failure among new firms. Established firms prefer a strategy hinged on steady returns as opposed to the high-risk R&D path to high returns. This liability of newness" (both a new firm and the new uncertain idea) forms the basis for the need for channelling public resources into drug design, discovery and development.

After consultation with the industry, it has been felt that it would be appropriate to harness the venture capital industry technical and financial acumen for the delivery of public resources into drug design, discovery and development. Venture capitalists

(VC) have the expertise in handling all aspects of a high risk undertaking; they raise funds for such investment and are professionals with specific industry experience. They also provide assistance of other kinds that are important for the success of a new venture: key personnel, strategic advice, financial management, and most importantly establish key governance parameters for constant monitoring and evaluation.

The DoP therefore proposes to consider investment of identified funds into a newly created specialised private equity / venture capital fund **(IPIF)** that undertakes R&D investments into companies in the pharmaceutical industry. This investment will be subject to a market test at the level of the private equity / venture capital funds where the fund under question would have raised a large substantive portion of capital venture fund themselves wherein investment decisions are taken by impartial, experienced, and highly competent, motivated and trained fund managers.

At present there are no such existing venture capital funds in India that invest in innovation in the pharmaceutical industry. Accordingly, DoP has decided to work closely with the National Institute of Public Finance and Policy (NIPFP) under the Ministry of Finance for creation of such a fund and the mechanism for its implementation. It is proposed to invest about Rs 500 crs in the fund for the 11th Plan so that the same could be leveraged with the support of the private sector.

A budget allocation of Rs 500 crs is envisaged for this scheme.

8.2.2.4 Pharma Innovation and Infrastructure Development Initiative (PIIDI)

As discussed in Chapter-8, there is need to

- Develop technical and innovation capacity of Indian pharma for manufacturing quality affordable medicines for the common man in India at par with the world
- Develop International competitiveness of the Indian Pharma so as to be the largest producer of generic medicines in the world
- To make India a preferred destination for global initiatives in curing the world's ailments specially the developing world in a value based manner

To achieve these objectives it is proposed to implement a **Pharma Infrastructure and Innovation Development Initiative** with the following basic strategy elements:

a. Multiple partnerships as a key denominator because innovative drug development is no longer a single agency or entity initiative possibility. This is because individual entities (governments, companies, academic bodies, etc) cannot easily perceive the complete or significantly holistic commitments required, the possible gains and their contribution to individual and collective growth in an Internationally Competitive environment. Nor can the individual entrepreneurial companies and initiatives command adequate resources for creating the critical mass for successful closure and execution of large projects in terms of managerial and financial capacity much less the innovation capability required to bring upon a possible successful project. **PIIDI** therefore, intends to establish a mechanism for seeking the involvement of Multiple Stakeholders in such efforts through assistance linked to International Competitiveness performance.

b. Coordinated efforts by the Central and state Governments including the academia and the industry are necessary for development of Pharma in an internationally competitive scenario. In this context it is important to understand that the growth in Indian pharma has been possible largely through diffused and unconnected efforts with some opportunities thrown

up from time to time through policy measures like process patent on one hand followed by product patent on the other later in the day. Along with a general industry, the pharma sector also grew and not specially so as a specific sector. The state and the central governments have taken rather uncoordinated steps to enable the growth which just happened in a growing industrial economy. Now with increasing competition and various countries taking focused steps there is need to put up an integrated effort also from India if it is sustain its leadership and build on it with the new opportunities on offer.

c. The PIIDI strategy would therefore rest on ways to re-structure and synergise several hitherto unconnected governmental and private sector efforts such as for funding of relevant drug discoveries, upgradation to international standards of manufacture, quality and brand promotion for greater access and projects to reduce production and process costs, value based technologies in clinical trials and drug production.

d. <u>There needs to be special dispensation also by the government to enable government related academia to participate in the SPV with appropriate permission from the employee institution.</u> Accordingly projects under PIIDI could form part of the permissible project activities within the employee institution. As required, the Head of the concerned institution would be member of the appropriate monitoring committee for the projects under PIIDI constituted for the purpose. This arrangement is necessary to harness the large latent potential of the Indian scientific group working in government projects in the country and attune them for identified gains with the support of the private entrepreneurship right from the conception stage itself. Appropriate PhD projects being conducted by various Universities would also be harnessed for this purpose. The promoters of the SPV selected

for implementation of the project would be permitted to appropriate sweat and other equity to such persona.

e. In order to kick start this, an inventory would be made of all the current R&D projects underway with various lead institutions of national importance along with resident research capabilities.

A budget allocation of Rs 2000 crs is envisaged for this scheme.

8.2.2.5 Setting up National Center for R&D in Bulk Drugs at NIPER Hyderabad:

Indian Bulk Drug Industry is facing problems of innovation and capacity building in an increasingly competitive environment specially from countries like China, Israel, Brazil, etc. The industry being populated by SMEs is highly fragmented. Hence the industry lacks in its ability to invest in R&D, make processes more cost effective and scale up operations. Therefore a need has been felt to focus on R&D in Bulk Drugs Sector. It is accordingly proposed to establish a R&D center for Bulk Drugs at NIPER Hyderabad as around 30% of bulk drug producers are in Andhra Pradesh.

The center will benefit both, the internal stake holders i.e. students and faculty of NIPER as well as the external stake holders like industry, entrepreneurs and industry associations. The students and faculty will have facilities of academic research, process oriented research, training for industry practices etc. On the other hand industry will get process innovation, product related R&D, Analytical facilities, consultancy services, development of better and greener process etc.

The key objectives of the center would be:

a. To become an innovative R&D provider in the field of bulk drugs and offer solutions for competitive and environmentally friendly technologies.
b. To provide centralized research facilities and equipments, analytical facilities for drug testing and consulting services.

c. To establish a platform for, maintaining industry-academia and academia-academia linkages.
d. To enhance the capacity of students and faculty at NIPER Hyderabad by providing higher academic courses.
e. To translate concepts developed in basic bulk drug research to commercially viable technologies.

The budgetary requirement for setting up this center at NIPER Hyderabad is Rs 56 crores.

8.2.2.6 National Pharmaceutical Nanotechnology Center

'Pharmaceutical nanotechnology' involves use of nanomaterials for emerging industries like medical devices industry and for new innovative drug delivery systems, diagnostic, imaging and biosensor equipments, etc. Medical devices industry is growing at 30% per annum. Accordingly, there is a need to develop indigenous product development capacity in the field of nano-technology. It is accordingly proposed to set up a National Center for Pharmaceutical Nanotechnology at NIPER Kolkata, with following objectives:

(a) Development of Nanomaterials
(b) New Drug Delivery systems based on nanotechnology
(c) Medical devices
(d) Nano-toxicology and Regulatory aspects concerning nano drugs and devices

Budgetary requirement: Rs. 50 crores

8.2.2.7 Setting up National and Regional Bio similar Centers

The first generation of biological drugs, which have introduced many revolutionary treatments to life-threatening and rare illnesses, is currently facing patent expiration. As a result, research-based and generics pharmaceutical companies alike

are pursuing the opportunity to develop “generic” substitutes to original biologics, which are also known as biosimilars.

Yet the field of biosimilars presents several important challenges – safety, regulatory, legal and economic – which are the topic of discussion across the globe. Most of these discussions stem from the idea that, unlike the relatively straightforward process of introducing a generic equivalent to an original drug based on a new chemical entity (NCE), the process of introducing a biosimilar to an original biological drug is far more complex.

The safety and regulatory issues, are also equally important, including the amount of clinical studies that should be required as part of the testing and approval process, as well as whether the biosimilars should be considered “automatically” interchangeable with the original biologic.

The research infrastructure, talent pool and academic network in India are at the nascent stage so far as biosimilars industry is concerned. The regulatory hurdles are both at domestic as well as global level. The costs and technology related challenges for bio similar are also higher.

In view of above facts, to facilitate the growth of biosimilar industry, there is a proposal to open one National Biosimilar Center at Bangalore and three Regional Biosimilar Centers at Chandigarh, Hyderabad and Ahemedabad , where following activities may be undertaken :

(a) Consulting Activity: The issues related to IPR and other regulatory aspects like, regulations of different countries on biosimilars, domestic and international registration requirements etc would be discussed and expert groups would be there to guide the industry. There would be expert groups for guidance related to issues on clinical trials and testing and approval process of bio similar.

(b) Providing common infrastructure: The equipments, which could be used by industry or academia for carrying out basic research work requiring high precision instruments. This will help in reducing the cost of development of biosimilars.

For opening of one national and three regional centers, the budgetary requirements would be:

(a) One time cost Rs 31crores

(b) Recurring cost for 4 centers 1st year RS 01crores

(c) Recurring cost for 4 centers 2nd year Rs 04crores

(d) Recurring cost for 4 centers 3rd year Rs 06crores

(e) Recurring cost for 4 centers 4th year Rs 08crores

(f) Recurring cost for 4 centers 5th year Rs 10crores

Total Budget requirement is Rs 60 crores.

8.2.2.8 Setting up of a Industry focused Animal House

The Animal house will meet the requirement of end to end services from Primates to small animals for pre-clinical drug development.

A budgetary provision of Rs 100 crores is being proposed for this house.

8.2.2.9 Support to Academia, Research Institutions and private sector for Extra Mural Research

The Academia, various R&D institutions in the government as in CSIR, etc and the private sector companies are doing research in drug related areas. However as discussed in Chapter 8 on R&D, an evaluation reveals that – while the government funded research whether by CSIR, Central Labs (CDRI, etc), DST and DBT with a total of some 51 research institutions are doing research in a non-applied manner with clear lack of targeted drug development as in stages of NCE development, pre-clinical studies, etc, the private sector is mostly limited to formulation and drug delivery systems development. Only a few companies are concentrating new drug development and a number of companies like Glenmark, Suven, etc had to outlicense their initial developments to other companies for further development thus not being able to take full advantage of the full drug development cycle. It is accordingly proposed to launch a scheme for funding both academia individually, as

an institution and private companies for targeted drug development including assistance for clinical trials. The detailed scheme would be prepared after a thorough study as to the outputs from the existing funding in this sector by various government bodies and organizations / schemes and to fill the gap as may be required. The individual projects could be implemented by Nipers in collaborative partnership or under their aegis and guidance.

It is proposed to allocate Rs 100 crs for this scheme.

8.2.2.10 Support to Academia, Research Institutions and private sector for Extra Labs upgradation

The scheme will also have provision for funding upgradation of labs in the private and government sector with sharing basis on 50-50 pattern for the lab upgradation for equipments deployed for drug development under specifically identifiable projects. This capacity building as a form of infrastructure support will also be deployed for training in advanced lab techniques of personnel in the industry on a mutual sharing basis. The training part will require 25% funding from the private sector side.

It is proposed to allocate Rs 10 crs for this scheme.

8.2.2.11 International cooperation in R&D

There is a need to promote R&D in CIS and developing countries for mutual advantages.

It is proposed to allocate Rs 25 crs for this scheme.

8.3 Pricing

The role of NPPA would continue under existing and potentially new drugs policy following the order of the Supreme Court in 2003. In this connection, NPPA had already submitted five New Plan schemes for the 11th Five year Plan 2007-08 to 2011-12 to the Planning Commission. These could not be finalised due to delay in finalisation of the

new policy. It is expected that the new policy would be finalised in the12th Plan and the Plan schemes envisaged for the 11th Plan would need to continue for the 12th Plan. Accordingly, following budgetary requirements are envisaged:

Table-27

Sr No	Scheme	Amount (Rs.Crs)
Continuing Scheme		
1	Monitoring and Enforcement Work	2.00
2	Building Consumer Awareness about pricing and availability	20
New Schemes		
1	Creation of NPPA Cells in States	25.00
2	Scheme for interaction with States	2.00
	TOTAL	49.00

Out of the above scheme at Sr. No. 1 titled "Proposal for building robust & responsive statistical system for NPPA" was approved by the Planning Commission and implemented during the 11th five year plan. It has also been implemented with the help of NIC. Towards the end of September 2011, Planning Commission has accorded in-principle approval for the Scheme on Building Awareness. Details of implementation of this scheme are being worked out by NPPA in collaboration with Department of Consumer Affairs as required by the Planning Commission.

Another important need of NPPA is the availability of Primary Data Base on pricing of drugs. Presently it sources them from only one available source – IMS Health – a private sector organization. This lack of independent official data has been adversely remarked in several court judgments under DPCO'95 from time to time. Even otherwise dependant on a private source and that too only one, is a cause of concern for a public/government body charged with the responsibility of fixing of prices for an entire industry. The DPCO provisions themselves have not helped in collection of data as companies do not give data as per prescribed forms on a voluntary basis. Coercion is not the best option. Hence it is proposed to launch a scheme for collection of pricing and related data by NPPA through possible partnerships with data collection agencies and as far as possible with Ministry of Statistics and Program Implementation in the Government of India.

8.4 Development of Medical Devices Sector

8.4.1 Setting up green-field Medical Devices Park:

In order to tap the high growing medical devices manufacturing industry, particularly in the context of India, it is proposed to set up a specialized Park in the green field where integrated set of facilities would be provided for promoting growth of Medical Devices industry. The envisaged Medical Devices Park would focus on:

- Testing Laboratory and Common Sterilization facility for Medical Devices
- Medical Instruments/Equipment calibration and validation facility
- Engineering Services like surface treatment, coating, electrical and mechanical maintenance etc.
- A training centre to train shop-floor, managers and entrepreneurs level skills for Medical Devices Industry
- Facilitation of business development on regulatory certifications, and product developments.

The Govt of Gujarat has already earmarked land for the project and this would help the project to take benefits from the recently announced National Manufacturing Policy 2011.

The budget for the setting up of the Park : Rs 300 crores.

8.4.2 Setting up National Center for R&D in Medical Devices at NIPER Ahmedabad.

As a complimentary facility to the Medical Devices Park, it is proposed to set up a dedicated R&D Centre for Medical Devices Industry. This Centre will provide high end educational facilities for teaching and research with a multi-disciplinary approach towards innovation in medical devices. There will be incubator facilities as well as reference test facilities for standards certification of medical devices. Facilities would also exist for Preclinical testing of medical devices. It is proposed to set up the Centre at NIPER Ahmedabad.

The envisaged budgetary requirement is Rs.50 Crores.

8.5 CPSUs and Jan Aushadhi

8.5.1 CPSUs

For HAL Minimal Up gradation of facilities, for IDPL to meet the regulatory Compliance and for BCPL to meet the gap in revival package, a provision of Rs 10 crores for each item and a total of Rs 30 crores is being made in the 12th Plan.

Hence total budgetary requirement for CPSIUs is Rs 30 crores

8.5.2 Janaushadhi

As discussed earlier, the Campaign to make available affordable drugs with ensured quality at low prices to the masses is a continuing commitment from the 11th Plan. Accordingly, the Jan Aushadi Scheme launched in 11th Plan and further strengthened through the revised Business Plan would be further widened and deepened in its reach both in terms of geography and therapeutic coverage. It is envisaged that for covering the whole country at an effective level, about Rs.200 Crores would be required in the 12th Plan.

Budgetary requirement: Rs.200 Crores

Annexure-I

GOVERNMENT INSTITUTIONS ENGAGED IN PHARMA R&D

A. Under CSIR:

1. Institute of Integrative and Genomic Biology (IIGB), Delhi
2. Institute of Microbial technology (IMTech), Chandigarh
3. Central Drugs Research Institute (CDRI), Lucknow
4. Central Institute of Medicinal and Aromatic Plants (CIMAP), Lucknow
5. Indian Institute of Toxicological Research (IITR), Lucknow
6. Indian Institute of Integrative Medicine (IIIM), Jammu
7. Institute of Himalayan Bioresource Technology (IHBT), Palampur
8. Indian Institute of Chemical Technology (IICT), Hyderabad
9. Centre for Cellular and Molecular Biology (CCMB), Hyderabad
10. Central Salt and Marine Chemicals Research Institute (CSMCRI), Bhavnagar
11. National Chemical Laboratory (NCL), Pune
12. Indian Institute of Chemical Biology (IICB), Kolkata
13. North East Institute of Science and technology (NEIST), Jorhat

B. Under DBT

1. National Institute of Immunology (NII), New Delhi
2. National Institute of Plant Genome Research (NIPGR), New Delhi
3. Indian Vaccines Corporation Limited (IVCOL), Gurgaon
4. National Agri-Food Biotechnology Institute (NABI), SAS Nagar
5. Bharat Immunologicals and Biologicals Corporation Limited (BIBCOL), Bulandshahar
6. National Centre for Cell Sciences (NCCS), Pune
7. Centre for DNA Fingerprinting and Diagnostics (CDFD), Hyderabad
8. Institute of Life Sciences (ILS), Bhubaneswar
9. Rajiv Gandhi Centre for Biotechnology, Thiruvananthapuram
10. Institute of Bioresources and Sustainable Development (IBSD), Imphal
11. Biotech Consortium India Limited (BCIL), Delhi

C. Under Department of Health Research

1. National Institute of Malaria Research (NIMR), Delhi
2. National Institute of Pathology (NIOP), Delhi

3. National Institute of Medical Statistics (NIMS), Delhi
4. Institute of Cytology and Preventive Oncology (ICPO), Noida
5. National JALMA Institute for Leprosy & Other Mycobacterial Diseases (NJILMOD), Agra
6. National Institute for Research in Environmental Health (NIREH), Bhopal
7. Desert Medicine Research Centre, Jodhpur
8. National Institute for Research in Reproductive Health (NIRRH), Mumbai
9. National Institute of Immunohaematology (NIIH), Mumbai
10. Enterovirus Research Centre (ERC), Mumbai
11. National institute of Virology (NIV), Pune
12. National AIDS Research Institute (NARI), Pune
13. Regional Medical Research Centre, Bhuvaneshwar
14. Regional Medical Research Centre, Dibrugarh
15. Regional Medical Research Centre, Jabalpur
16. Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna
17. Regional Medical Research Centre, Belgaum
18. National Institute of Cholera and Enteric Diseases (NICED), Kolkata
19. National Institute of Occupational Health (NIOH), Ahmedabad
20. Tuberculosis Research Centre (TRC), Chennai
21. National Institute of Epidemiology (NIE), Chennai
22. National Institute of Nutrition (NIN), Hyderabad
23. Centre for Research in Medical Entomology (CRME), Madurai
24. Vector Control Research Centre (VCRC), Puducherry
25. Regional Medical Research Centre, Port Blair

Annexure-II

List of Abbreviations

APIs	Active Pharmaceutical Ingredients
CAGR	Compound Annual Growth Rate
CDSCO	Central Drug Standard Control Organisation
CEP	Certificate of Suitability
CMIE	Centre for Monitoring Indian Economy
CROs	Contract Research Organisations
CSIR	Council of Scientific and Industrial Research
DBT	Department of Biotechnology
DCG(I)	Drug controller General (India)
DMFS	Drug Master Files
DoP	Department of Pharmaceuticals
EDQM	European Directorate for the Quality of Medicine & Health Care
EHS	Environment Health and Safety
FICCI	Federation of Indian Chambers of Commerce and Industry
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GXP	Good X Practice
ICMR	Indian Council of Medical Research
IDMA	Indian Drug Manufacturing Association
IMS	Institute of Management Studies
IOMA	Institute of Management and Administration
IPA	Indian Pharmaceutical Association
IRB	Institutional Review Board
MOH	Ministry of Health
NCEs	New Chemical Entities
NDD	New Drug development
NPPA	National Pharmaceutical Pricing Authority
NSDC	National Skill Development Corporation
OPPI	Organisation of Pharmaceutical Producers of India

PPP	Public Private Partnership
PRDSF	Pharmaceutical Research & Development Support Fund
R&D	Research and Development
SME	Small Medium Entrepreneur
SOPs	Standard Operating Procedures
TOR	Term of Reference
WTO	World Trade Organisation

Table-1: Export and Domestic Growth

Year	Exports	Growth	Domestic	Growth%	Total	Growth%
Mar 2006	21230	23.23	39989	17.17	61219	19.21
Mar 2007	25666	20.89	45367	13.45	71033	16.03
Mar 2008	29354	14.37	50946	12.30	80300	13.04
Mar 2009	39821	35.66	55454	8.85	95275	18.65
Mar 2010	42154*	5.86	62055	11.90	104209	9.38

Table – 2: International sales on consolidated basis

	Consolidated net sales	International sales	Exports as % of net sales 2010-11
Ranbaxy Labs	8960.77	6771.74	75.6
Dr Reddy's Labs	7236.80	5940.70	82.1
Lupin	5706.82	3983.08	69.8
Cipla	6130.31	3361.49	54.8
Sun Pharma	5721.43	2898.20	50.7
Wockhardt	3751.24	2709.91	72.2
Jubilant Lifescience	3433.40	2369.11	69.0
Cadila Healthcare	4464.70	2288.70	51.3
Biocon	2300.52	1956.79	85.1
Glenmark Pharma	3089.59	1955.83	63.3
Stride Arcolab	1695.84	1637.67	96.6
Plethico Pharma	1535.20	1367.22	89.1
Piramal Healthcare	2509.86	1280.58	51.0
Divi's Labs	1307.11	1204.95	92.2
Aurobindo Pharma	4381.48	1112.06	25.4
Torrent Pharma	2121.97	1101.57	51.9
Ipca Laboratories	1882.54	1025.18	54.5
Dishman Pharma	990.84	911.56	92.0
Orchid Chemicals	1781.79	725.85	40.7
Shasun Chemicals	799.42	676.78	84.7
Panacea Biotec	1143.78	610.44	53.4

Table-3: Geographical Distribution of Pharma Companies

S.No.	State	Number of Manufacturing Units		Total
		Formulation	**Bulk Drugs**	
1.	Maharashtra	1928	1211	3139
2.	Gujarat	1129	397	1526
3.	West Bengal	694	62	756
4.	Andhra Pradesh	528	199	727
5.	Tamil Nadu	472	98	570
6.	Others	3423	422	3845
	Total	**8174**	**2389**	**10563**

Table-4: Market Turnover of Major Therapeutic Segments

Major Therapies	MAT DEC'05 (Val in Crs)	% Contribution	MAT DEC'10 (Val in Crs)	% Contribution
Anti-infectives	4,056	17.6	8,060	17.2
Cardiac	2,378	10.3	5,318	11.4
Gastro Intestinal	2,537	11.0	5,099	10.9
Respiratory	2,170	9.4	4,080	8.7
Pain / Analgesics	2,059	8.9	4,038	8.6
Vitamins/ Minerals/ Nutrients	2,105	9.1	3,625	7.7
Anti Diabetic	998	4.3	2,743	5.9
Gynaecology	1,261	5.5	2,658	5.7
Neuro / CNS	1,231	5.3	2,633	5.6
Derma	1,255	5.4	2,554	5.5

Table-5: Bulk Industry Growth

(In Rs Crores)

2007-08	2008-09	2009-10	CAGR
12,647.51	16,360.71	17,307.02	16.98%

Table-6: The Global Market for Biologics in 2009

Country	2009 Sales ($ bn)
US	69.02
Europe	41.68
Japan	10.29
Asia/Africa/Australasia	14.4.0
Latin America	1.20
Total Biologic Drugs Market	**136.59**

Table-7: The 10 Top Selling Biologics in 2009

Brand	Drug Name	2009 Sales ($ bn)
Avastin	bevacizumab	5.74
Rituxan	rituximab	5.62
Humira	adalimumab	5.48
Herceptin	trastuzumab	4.86
Lantus	insulin glarine	4.29
Enbrele	tanercept	3.87
Remicade	infliximab	3.51

Table-8: The Global Market for Biosimilars in 2009

Country	2009 Sales ($ bn)	Market Share of Biosimilars (%)
US	0.06	4.9
Europe	0.14	11.4
Other Countries (incl. China and India)	1.03	83.7
Total Biosimilars Market	1.23	100

Table-9: Projected Growth

Value in Rs crs / Growth in %

Year	Domestic		Exports		Total	
	Value	Growth	Value	Growth	Value	Growth
2016-17	130,000	21%	158,000	16%	288,000	18%
2019-20	233,000	22%	248,000	17%	481,000	19%

Table-10: Export Growth

Year	**Exports (Rs.crores)**	**Growth %**
Mar 2007	25666	20.89
Mar 2008	29354	14.37
Mar 2009	39821	35.66
Mar 2010	42154	6.6
Mar 2011	45745	7.7

Table-11: Human resource position in India

Sl	Item	Total numbers
1	No of Universities	409
2	No of colleges	25990
3	No of science colleges	4696
4	Annual student output at degree level in science	2000374
5	Annual student output at degree level in engineering	1663619
6	Total no of pharmacy colleges	1162
7	Number of B Pharm colleges	848
8	Number of Masters in pharmaceuticals area and PhD offering colleges	191
9	No of B Pharm students in pharma	51716
10	No of Masters and Phd students output in pharma	5648

Table-12: Global Phama market growth rate

Year	Market in Billion US$	%growth rate
2004	620	7.9
2005	664	7.2
2006	710	6.9
2007	756	6.4
2008	801	4.9

Table-13: Top Global Generic Players

Rank	**Company**
1	Teva
2	Sandoz
3	Mylan/Merck GX
4	Watson Andrx
5	Barr
6	Actavis
7	Ratiopharm
8	Stada
9	Ranbaxy
10	Perrigo

Table 14: Research and Development Expenditure

Year	Growth in R&D Expenditure – Rs Cr		R&D Expenditure As % of Sales	
	Domestic Companies	Foreign Companies	Domestic Companies	Foreign Companies
Mar 1995	80.61	64.13	1.34	0.77
Mar 1996	142.50	83.37	1.71	0.91
Mar 1997	148.12	89.41	1.55	0.95
Mar 1998	154.15	90.65	1.43	0.88
Mar 1999	218.66	79.78	1.56	0.70
Mar 2000	256.80	90.17	1.56	0.66
Mar 2001	435.07	109.81	2.30	0.72
Mar 2002	597.91	110.04	2.64	0.65
Mar 2003	686.74	232.73	2.93	0.71
Mar 2004	1084.26	346.69	3.81	1.10
Mar 2005	1527.24	510.50	4.98	1.63
Mar 2006	1850.97	816.02	5.35	2.39
Mar 2007	2371.79	695.62	5.01	2.67
Mar 2008	2772.63	700.18	4.78	2.86
Mar 2009	3316.14	846.05	4.89	3.84
Mar 2010	3342.32	934.40	4.50	4.01

Table-15: R&D spending of leading Indian and Global pharmaceutical MNEs, FY 2009

Indian Pharmaceutical Companies			**Global Pharmaceutical Companies**		
Rank in R&D spending	***Company***	***R&D exp. FY 2008/09, million US$***	***Rank in R&D spending***	***Company***	***R&D exp. 2009, million US$***
1	Ranbaxy*	99	1	Roche, CH	8,570
2	Dr. Reddy's	89	5	GlaxoSmithKlin, UK	6,286
3	Sun Pharma	67	10	Elli Lilly, USA	4,300
4	Cipla	51	25	Lundbeck, DNK	615
5	Lupin Labs	50	50	Watson, USA	197

Table – 16: Employment Data for Pharmaceutical Sector

Year	No of Employees
Mar 1995	1,81,497
Mar 1996	2,04,609
Mar 1997	2,11,614
Mar 1998	1,89,295
Mar 1999	2,13,999
Mar 2000	2,43,410
Mar 2001	2,33,704
Mar 2002	2,26,416
Mar 2003	2,23,556
Mar 2004	2,40,791
Mar 2005	2,65,396
Mar 2006	2,90,021
Mar2007	3,36,211
Mar 2008	3,53,692

Table 17: Percentage distribution of Man-power in Pharma Industry

Function	Distribution
Production & Quality Control 50%	50%
Research/Lab/Testing	20%
Sales, Marketing, Medical assistance	5-10%
Purchase, Logistics, Supply Chain	5-10%
Support functions (HR, Finance, etc.)	10-12%

Table 18: Qualifications of personnel employed in the Chemicals and Pharmaceuticals Segment

Qualification	Distribution
Ph. D / MTech / MSc etc.	5-8%
Graduate Engineers	15-25%
Diploma Engineers	10%
ITI and other vocational courses	15-20%
Graduates (BA/BSc/BCom/others)	15-25%
12th standard or below	20-25%

Table-19: Turnover-wise distribution

Turnover	% Distribution
0-10 Cr.	70
10-50 Cr.	20
50-100 Cr.	5
100-500 Cr.	3
500 + Cr.	2

Table-20: Performance of CPSUs

Parameter	KAPL	RDPL	BCPL	HAL	IDPL	TOTAL
Sales (08-09)	225.01	80.75	77.63	147.39	56.70	594.37
TO/Employees	30	52	10	11	23	19

Rs lacs						
TO/Sales employees Rs lacs	65	304	134	134	236	106
PAT Rs cr	5.88	0.01	-5.35	-22.08	-37900.9	
Total Employees	739	181	742	1224	243	3129
Sales Strength	345	31	58	105	24	563
Sales (08-09)	225.01	80.75	77.63	147.39	56.70	594.37

Table-21: Sales Projection of CPSUs

Rs Crores

Year	IDPL	HAL	BCPL	KAPL	RDPL
2012-13	51.7	189	153.37	320	108
2013-14	70	215	176.57	360	122
2014-15	80	264	204.73	425	135
2015-16	92	290	237.6	490	150
2016-17	125.4	319	275.83	560	165