REPORT OF

THE WORKING GROUP ON

DRUGS AND PHARMACEUTICALS FOR THE ELEVENTH FIVE-YEAR PLAN (2007-2012)

PLANNING COMMISSION OF INDIA

1st December 2006

INDEX

P R E F A C E

In the context of formulation of the Eleventh Five Year Plan (2007-12), the Planning Commission has set up a Working Group on Drugs & Pharmaceuticals vide their letter no. I&M-3(25)/2006 dated the18th May 2006 (Appendix-I). Subsequently, the Department of C&PC vide letter No.12025/21/2006-PI.III dated 27thJune 2006 (Appendix II) constituted three Sub Groups for different Terms of Reference (TOR) of Working Group.

Sub Group I chaired by Shri G.S. Sandhu, Joint Secretary (Pharma Industry) in the Department examined the Regulatory Mechanism in Drugs & Pharma with specific reference to item nos. 3, 9, 10, 11 & 13 of the TOR of the Working Group. The Sub-Group held its meeting on 11th July 2006, where representatives of almost all of its members were present. Subsequently, detailed discussions were held with various members of the Sub-Group on specific issues in the Agenda. The Director, NIPER was also consulted on the issues before the Sub-Group.

Sub Group II chaired by Shri Ashok Kumar, Chairman, NPPA examined the status and structure of the Pharma Industry with specific reference to item nos. 1,2,8,12,13,14 & 15 of the TOR of the Working Group. The Sub Group held its first meeting on 10th July 2006 and it was decided that members of the Sub Group, who represent Industry Associations, Top Indian Pharmaceutical Companies, Pharma Public Sector Undertaking, Pharma Export Promotion Council (Pharmexcil), as well as representatives of Department of C&PC & Planning Commission would provide necessary inputs regarding the status of the industry and for finalization of the report of the Sub Group. The final meeting of the Sub Group was held on 26th July 2006 where in the views; comments and suggestions received were discussed to prepare the report.

Sub Group III chaired by Prof. P. Ram Rao, Director, NIPER looked into the issues concerning R&D, Training and Development, Infrastructure, Employment Generation etc. in the Drugs & Pharma Sector with specific reference to item nos. 4,5,6 & 7 of the TOR of the Working Group. The Sub Group met on 12th July 2006 wherein an action plan was discussed and departments concerned were requested to provide the information. Information was received from DST, DSIR, Pharma companies like M/s Wockhardt and M/s Shasun, M/S Cadila Healthcare and Industry associations namely IDMA & BDMA. Inputs were also obtained from other

specialist stakeholders through various interactions at Bangalore and Chennai and different reports were also sourced.

The Working Group on Drugs & Pharma met on the 18th September 2006 where the members considered the reports of the Sub-Groups. Suggestions of members including the representative from Planning Conmission and the Chairperson were deliberated upon. Based on the additional inputs as also the information recieved subsequently, the Report of the Working Group was amended. The amended draft Report of the Working Group was again considered during its second meeting held on 13th November 2006, wherein some updated information about the contents was decided to be included. The financial requirements under various heads were also critically examined with a view to accelerate the growth of Indian Drugs & Pharma Industry and also for striking a balance between the interests of various stakeholders & vast community of consumers particularly those living below poverty line, the present Report has been finalised.

The Executive Summary and Recommendations of the Working Group and funding required to implement these are brought out in the report at appropriate places. As evident from the report, the Department is already in final stages of bringing out the **National Pharmaceutical Policy-2006** that envisages wide ranging changes in the rules and regulations and measures for sustained development of Indian Drugs & Pharma Industry. Various measures proposed in the Policy have been evaluated and relevant details have been included in this Report. In order to move ahead to implement the recommendations of Working Group and to achieve the goals envisaged in the National Commom Minimum Programme of the Union Government, the Planning Commission is requested to make allocation of funds to the tune of **Rs. 3,560 crores** for the 11th Five Year Plan period.

I would like to place on record the sincere efforts and contributions made by the Chairmen and members of the Sub-Groups for completing the onerous task before them within the time frame. I hope that the recommendations of the Working Group would go a long way in carving the future development of Indian Drugs & Pharma Industry.

(Satwant Reddy)
Secretary, Department of Chemicals & Petrochemicals &
Chairperson, Working Group on Drugs & Pharmaceuticals
For Eleventh Five Year Plan (2007-12)

Appendix I

No. I&M-3(25)./2006
Government of India
Planning Commission
(Industry Division)

Yojana Bhawan, Sansad Marg
New Delhi the 18th May,2006

ORDER

Subject : **Constitution of a Working Group on Drugs & Pharmaceuticals for Eleventh Five Year Plan (2007-12)**

In the context of formulation of the Eleventh Five Year Plan (2007-12), it has been decided to set up a Working Group on Drugs & Pharmaceuticals. The Terms of Reference and Composition of the Working Group are: -

I. Terms of Reference

1. To review the status of the industry Tenth Plan targets, vis-à-vis achievements, in terms of production as well as exports, identify the reasons for major deviations, if any, bring out areas of strength and weakness of the Indian industry vis-à-vis international Drugs and Pharmaceuticals Industry.

2. To assess the structure and capability of the domestic drugs & Pharmaceutical industry in the light of the new IPR regime, identify emerging areas having specific potential for growth and competitiveness and suggest measures for putting the indigenous industry on sound footing.

3. To assess the present status of WHO-GMP (World Health Organisation – Good Manufacturing Practice) certification and suggest measures for Schedule M compliance by manufacturers of drugs and Pharmaceutical products in the country.

4. To assess the present R&D status of the Drugs & Pharmaceuticals Industry and to suggest measures for increasing the role of the industry in R&D effort, Industry-Institutional linkages, investment (including foreign) by Industry to make the drugs and Pharmaceuticals industry internationally competitive and meet the emerging challenges arising out of the WTO regime.

5. To assess the requirements of equipment / machinery and indigenous capability for fabrication of internationally competitive equipment and suggest measures for augmentation of capabilities, where necessary.

6. To assess the present employment and likely employment that will be created in the Drugs & Pharmaceuticals Industry during the Eleventh Plan period and in the perspective of 15 years.

7. To assess the present education and training facilities and infrastructure for human resource development pertaining to Drugs and Pharmaceuticals sector and to suggest measures including institutional mechanisms to strengthen it, where required.

8. To assess the existing infrastructure for Pharmaceutical industry and to suggest measures to strengthen it including investment and source of investment alongwith option of revival of Pharmaceutical Public Sector Undertakings.

9. To assess the present regulatory mechanism and assess need for an apex authority to control price, quality and supply of drugs.

10. To review the present Drugs & Cosmetics Act and to suggest amendments to it including for ensuring GMP.

11. To review the present structure of the Indian Drugs Industry and suggest measures for improving the quality of drugs, particularly for tackling the menace of spurious drugs.

12. To benchmark the Indian Drugs and Pharmaceuticals industry against the international Drugs and Pharmaceutical industry and to suggest appropriate measures for bringing it up to international levels.

13. To make such other recommendations as are considered appropriate to make the drugs and Pharmaceuticals industry internationally competitive at the earliest

14. To suggest measures towards improvement of accessibility of essential medicines for the common man particularly the poorer sections of the population and availability of drugs for BPL families.

15. To identify steps required for facilitating implementation of the National Health Policy.

II. Composition of Working Group

1.	Secretary, Department of Chemicals & Petrochemicals (DCPC)	Chairman
2.	Secretary, Deptt. of Scientific & Industrial Research/DG, Council of Scientific & Industrial Research or his Representative	Member
3.	Principal Adviser (Dev.Policy), Planning Commission	Member
4.	Principal Adviser / Adviser (Health), Planning Commission	Member
5.	Additional Secretary & Financial Adviser, Deptt. of C&PC (DCPC)	Member
6.	Joint Secretary (PI), Deptt. of C&PC	Member – Secretary
7.	Adviser (I&VSE) Planning Commission	Member
8.	Chairman, National Pharmaceutical Pricing Authority	Member
9.	Representative of Ministry of Health & Family Welfare	Member
10.	Representative of Deptt. of Science & Technology	Member
11.	Representative of Department of Bio-Technology	Member
12.	Director, Central Drugs Research Institute, Lucknow	Member
13.	Director, National Institute of Pharmaceutical Education & Research Mohali, Punjab	Member
14.	Representative, Pharmaceuticals Export Promotion Council, 101, Aditya Trade Centre, Ameerpet, Hyderabad – 500 038	Member
15.	Representative, Indian Drugs Manufacturers Association 102B, Poonam Chambers, Dr. A.B. Road, Worli, Mumbai – 400 018	Member

16.	Representative of Confederation of Indian Pharmaceuticals Industry, A-3/314, 1st Floor Paschim Vihar, New Delhi – 110 063	Member
17.	Representative of Indian Pharmaceuticals Alliance, 201, Darvesh Chambers, 743 P.D. Hinduja Road, Khar, Mumbai – 400 052	Member
18.	Representative of Organisation of Pharmaceuticals Producers of India Peninsula Chambers, Ground Floor, Ganpatrao Kadam Mary, Lower Parel, Mumbai – 400 013	Member
19.	Representative of Bulk Drug Manufacturers Association. C-25, Industrial Estate, Sanathnagar, Hyderabad – 500 038	Member
20.	Chairman, Dr. Reddy's Laboratories Ltd. 7-1-27, Ameerpet, Hyderabad – 500 016	Member
21.	Chairman, Ranbaxy Laboratories Limited Plot No.90, Sector 32, Gurgaon – 122011 Haryana.	Member
22.	Chairman, CIPLA Limited Mumbai Central, Mumbai – 400 008	Member
23.	Dr. Jai Prakash Narain, Lok Satta 401-402, Nirmal Tower, Punja Gutta, Hyderabad	Member
24.	Dr. Ahmed Masood, Ex-Adviser (PAMD) C2/994, Scottish Villa, Palam Vihar, Gurgaon – 122 017.	Member

2. The Chairman of the Working Group may include additional Term(s) of Reference in consultation with the Chairman of the Steering Committee.

3. The Chairman of the Working Group may co-opt any other Experts as Members of this Working Group, if considered necessary.

4. The Working Group will submit its report within three months of the date of this order to the Chairman of the Steering Committee on Industry. The Working Group will be serviced by the Department of Chemicals & Petrochemicals.

5. The expenditure on TA/DA of official members in connection with the meetings of the Working Group will be borne by the parent Department / Ministry to which the official belongs as per the rules of entitlement applicable to them. The non-official members of the Working Group will be entitled to TA/DA as permissible to Grade I officers of the Government of India under SR190 (a) and this expenditure will be borne by the Planning Commission.

6. Shri D. Banerjee, Dy. Adviser (CI), Planning Commission (Room No. 319A, Yojana Bhawan, Ph. 23096710) will asct as the Nodal Officer and any further communication in this regard may be made with the Nodal Officer.

Sd/-

(K.K. Chhabra)
Under Secretary to the Govt. of India

To

Chairman and all the Members (including Convenor) of the Working Group.

Copy to

PS to DCH / MOS (Planning)/ Members / Member Secretary, Planning Commission All Principal Advisers / Advisers / HODs in Planning Commission
Prime Minister's Office, South Block, New Delhi
Cabinet Secretariat, Rashtrapati Bhawan, New Delhi
Information Officer, Planning Commission, New Delhi.
Joint Secretary (Administration), Department of Chemicals & Petrochemicals
Controller of Accounts, Department of Chemicals & Petrochemicals

Sd/-
(K.K. Chhabra)
Under Secretary to the Govt. of India

Appendix II

MOST IMMEDIATE
TIME BOUND

No. 12025/21/2006-PI.III
Government of India
Ministry of Chemicals & Fertilizers
Department of Chemicals & Petrochemicals

Shastri Bhavan, New Delhi
Dated 27th June,2005

OFFICE MEMORANDUM

Subject: Working Group on Drugs & Pharmaceuticals for Eleventh Five-Year Plan (2007-12) – Constitution of Sub-Groups.

The undersigned is directed to say that Planning Commission vide order No. I&M-3(25)/2006 dated 18th May, 2006 (copy enclosed) has constituted a Working Group on Drugs & Pharmaceuticals under the Chairmanship of Secretary (Chemicals & Petrochemicals). Since the Working Group has to submit its report within three months of the order issued by Planning Commission i.e. by mid August,2006 to the Chairman of the Steering Committee, the following three Sub Groups have been formed in this Department with the approval of Secretary (Chemicals & Petrochemicals) to facilitate discussions and preparation of report :-

Sub-Group I

Regulatory mechanism (Item number 3,9,10, 11&13) of the terms of reference of the Working Group). Sup-Group-I has been formed as under: -

Joint Secretary (PI),	-	**Chairperson**
Representative of Deptt. of Biotechnology	-	Member
Representative of Deptt. of Indian System of Medicines	-	Member
Representative of Planning Commission (Health Division)	-	Member
DCGI, Ministry of Health and Family Welfare	-	Member
Executive Director, Pharmaceutical Export Promotion Council	-	Member
Managing Director, Rajasthan Drugs and Pharmaceuticals Ltd.	-	Member
Representative of Indian Drug Manufactures Association	-	Member
Representative of Bulk Drug Manufactures Association	-	Member
Representative of Organisation of Pharmaceutical Producers of India	–	Member
Director (PI), Department of Chemicals & Petrochemicals	–	**Convener**

Sub-Group II

Status and structure of the Pharmaceutical Industry (Item no. 1,2,8,12,13,14 & 15 of the terms of reference of the Working Group) Sub Group-II has been formed as under :-

Chairman, National Pharmaceutical Pricing Authority (NPPA)	- **Chairperson**
Member Secretary, NPPA	- Member
Senior Representative of Planning Commission	- Member
Managing Director, Hindustan Antibiotics Ltd. (HAL)	- Member
Representative of Pharmaceutical Export Promotion Council (Pharmexcil)	- Member
Deputy Secretary (PSU), Deptt. of C&PC	- Member
Senior Representative of Dr. Reddy's Lab.	- Member
Senior Representative of Ranbaxy Laboratories	- Member
Senior Representative of Organisation of Pharmaceutical Products of India	- Member
Representative of Indian Drug Manufacturers Association (IDMA)	- Member
Representative of Bulk Drug Manufacturers Association (BDMA)	- Member
Sh. Lalit Mohan Kaushal, Director, NPPA	- **Convener**

Sub-Group III

R&D, Training and Development Infrastructure, Employment generation etc. (Item no. 4,5,6&7 of the terms of reference of the Working Group) Sub Group III has been formed as under: -

Director, National Institute of Pharmaceutical Education & Research	– **Chairperson**
Representative of Department of Scientific & Industrial Research	– Member
Representative of Deptt. of Science & Technology (DST)	– Member
Representative of Deptt. of Biotechnology (DBT)	– Member
Representative of Indian Institute of Chemical Technology, Hyderbad	– Member
Director/Representative of Central Drug Research Institute, Lucknow	– Member
Direcor/Representative of Pharmexcil	– Member
Representative of Indian Drugs Manufactures Associations (IDMA)	– Member
Representative of Bulk Drug Manufactures Association (BDMA)	– Member
Representative of Organisation of Pharmaceutical Products of India(OPPI)	– Member
Representative of Indian Pharmaceuticals Alliance(IPA)	– Member
Shri P.U.M. Rao, Addl Industrial Adviser, (C&PC)	– **Convener**

State Drug Controllers and other experts may, however, be invited as Special Invitees for the meetings of all the above mentioned three Sub-Groups.

Meetings of the sub-groups may be convened immediately to take stock of the issues that have been allocated to each sub-group. **Each sub-group is required to prepare a report on the allocated subject and submit the same by 25th July 2006 positively.** Thereafter these reports would be put up before the Working Group, which would make the final recommendations.

A base Paper for the Working Group has been prepared to facilitate discussions by the Sub-Groups. A copy of the same is being enclosed herewith.

Sd/-

(Ram Chander)

Under Secretary to the Govt. of India

Tel No. 23384086 / Fax No. 23383392

To

Secretary, Department of Bio-Technology
Secretary, Department of Indian System of Medicines
Adviser, Planning Commission (Industry Division)
DCGI, Ministry of Health & Family Welfare
Secretary, Department of Scientific and Industrial Research
Secretary, Department of Science and Technology
Member Secretary, National Pharmaceutical Pricing Authority
Director, National Institute of Pharmaceutical Education & Research (NIPER)
Managing Director, Rajasthan Drug & Pharmaceutical Limited (RDPL)
Managing Director, Hindustan Antibiotics Ltd. (HAL)
Director, Indian Institute of Chemical Technology (IICT), Hyderabad
Director, Central Drugs Research Institute, Lucknow
Executive Director, Pharmaceutical Export Promotion Council, Hyderabad
Dr. Reddy's Lab.
Ranbaxy Laboratories
IDMA/BDMA/OPPI/IPA

Copy to: -

PS to Secretary(C&PC)/JS(PI)/Chairman(NPPA)/MS(NPPA)/Director(NIPER), DS(PI)/DS(PSU)/AIA(R)

Copy also to: Adviser (I&VSE), Shri R.C. Jhamtani,
Planning Commission, Yojana Bhavan, New Delhi

Executive Summary

1. Indian Pharmaceutical Industry has established a strong presence for itself in the global market in the last over two decades. Presently it is valued at US$ 12 billion of which the export turnover is around US$ 4.7 billion (23% increase over previous year). The industry ranks 4th in terms of volume and is 13th in terms of value. Presently Indian pharmaceutical industry is contributing aroung 20% in terms of value towards global generic market. In the years to come Indian Drugs & Pharmaceuticals industry has the potential to grow manifold and contribute more significantly to the global drug requirements, particularly in the generics segment. While the pharma exports are growing at over 20% over the last few years the domestic market is showing a growth of about 15% per annum.

2. With almost U.S. $ 60 billion worth of medicines likely to come off patent in the next few years, India is poised to emerge as a significant player in the area of generics. The biopharmaceuticals market is also evolving very fast. India is likely to emerge as one of the largest producers of vaccines in the world in a few years time.

3. Globalization of international market, product patent expiry and increased use of IT offer excellent opportunities for Pharma companies in India. In particular India has the potential to become the world leader in generics. Some of the measures that need to be taken to facilitate this are as under:
    - Increased focus and incentives for research and innovation;
    - Adoption of international GMP standards for improvements in the quality of drugs manufactured in India.
    - Better collaboration between Government, academia and the industry in emerging technology areas.

4. As per Drugs & Cosmetics Rules 1945, requirements laid down under Schedule 'M' for GMP have become mandatory in the country w.e.f 1.7.2005. The requirements are comparable with WHO GMP norms. It needs to be ensured that more and more companies, particularly the small-scale manufacturers adopt these standards.
    - Many companies have already complied with GMP norms.
    - Several Small Pharma units (total number estimated to be 8000) need financial help for upgrading their infrastructure to meet GMP norms.
    - These units play a vital role in supplying low priced drugs. As per the information from Office of the Development Commissioner (SSI), contribution of SSI in Indian Pharma Market is 50% by volume and 30% by Value. It is therefore, essential to safeguard their interests.

    A scheme of interest subsidy has been proposed for providing interest subsidy @ 5% on the loan taken by the drug manufacturers (SMEs) for implementing Schedule M. The requirement for funds for this purpose is estimated to be **Rs.560 crores** during the 11th Five Year Plan (2007-12).

5. For Ayurvedic, Yoga & Naturopathy, Unani, Sidha Homeopathy (AYUSH) units, Schedule- 'T' requirements are already enforced and one third of 9,000 odd Ayurvedic units have reportedly complied with these norms. Department of AYUSH is providing financial help for Schedule 'T' compliance. Department of AYUSH has also notified the draft guidelines on GMP, which will take care of the GMP aspects pertaining to Ayurvedic, Unani and Homeopathic drugs. Draft rules concerning approval of laboratories for carrying out analysis of Ayurvedic medicines have also been issued. Another set of draft notification has been issued concerning labeling, packaging etc.

6. Comprehensive changes are needed in regulatory system to keep abreast with the changing trends in the industry with the objective of maintaining uniform parameters to produce quality drugs. There is need to set up an **autonomous Drug Regulatory Authority** at the National level for control over manufacture, quality & supply of drugs.

7. There is need for coordination among various regulatory authorities in Ministry of Health, Department of Chemicals & Petrochemicals, Department of Bio-technology and Department of AYUSH. Ministry of

Health should take stock of the various regulatory developments taking place abroad and fine-tune the Drugs & Cosmetics Act & Rules accordingly.

8 (a) Regulatory infrastructure has to be strengthened to ensure good quality of products and check production of spurious drugs.

(b). States need to constitute legal cum intelligence cells for carrying on campaign against spurious drugs for which the Central Government should assist State Governments, by extending funds to them. There should also be separate legal Departments with State Licensing Authorities as well as Central Licensing Authorities to take care of the issue of spurious drugs.

9. Regarding procedures for Government's tenders for medicines, as is the practice in Tamil Nadu, Maharashtra and some other states, it is necessary to specify some minimum turnover as well as upgraded GMP certificate as also some of the pre conditions.

10. Availability of and accessibility to essential drugs to the common man, particularly, the poorer sections of society is an important issue. Price competition between different drugs in the same therapeutic group does help keep the prices of such new entities under control; however, additional measures are needed in this regard.

11. The National Pharmaceutical Pricing Authority (NPPA) is entrusted with the task of regulating prices of drugs in India. In order to enable NPPA discharge its responsibilities more effiectively there is immediate need to bring about some fundamental changes in its working and extensive use of computers. A sum of **Rs. 100 crores** may be provided to set up State level Drug Price Monitoring Cells in each State, AppellateTribunal and public awareness for drug prices, website etc.

12. Provisions of compulsory licensing and parallel imports under the Patent regime will help keep prices of patented medicines within the common man's reach.

13. Better compliance of the existing Intellectual Property Rights (IPRs) provisions should be encouraged in the Pharma sector. The post Patent regime presents new challenges for Indian Pharma industry.

14. In order to encourage exports of Pharmaceuticals, Pharmaceuticals Export Promotion Council has been set up. A **Pharma Export Promotion Cell** is also operating in the Department with only a token budget. There is need to give a major thrust to exports of pharmaceuticals from India .It is felt that Departmant of Chemicals and Petrochemicals should play a more active role in this regard. The budget for the cell is proposed to be raised to **Rs. 2 crore per annum** for sharper focus of the efforts of the Cell. The Cell may also attend to the issue of serious threat on account of dumping of some bulk drugs by some countries adversely affecting Indian Pharma exports. A permanent consultative mechanism to look into specific and general issues and to recommend remedial measures is recommended.

15. There was an adverse impact on the Pharma industry in the country on account of two policy measures: (i) Area based tax exemption since January 2003 for industrial units set up in some states, notably Uttaranchal and Himachal Pradesh; (ii) shifting the base for assessment of excise duty from ex-factory price to MRP with effect from January 2005. In order to address to this, Department of Chemicals & petrochemicals had suggested a two point formula

    i) Reduction in the excise duty on drugs and Pharmaceuticals from 16% to 8%; and

    (ii) Raising the turnover exemption limit for levy of excise duty for SSIs from **Rs.1 crore to Rs.5 crores**. There should be no regional disparity as far as taxation system is concerned.

16. In order to improve infrastructure a special scheme for setting up **Pharma parks** in the country (separate for bulk and for formulations) in the next 5 years is needed. Initially 10 Pharma parks with an investment of **Rs.25 crores** each may be considered. Hence the total requirement of funds would be **Rs.250 crores**. The implementation of the scheme through a Special Purpose Vehicle (SPV) and also with the involvement of Industry Associations need to be worked out on the lines of scheme for Textile Parks.

17. There is a need to conduct regular workshops, technical seminars in collaboration with the Central Drugs Standards & Control Organisation (CDSCO) & State Licensing Authorities (SLAs) on the quality issues to educate the SSI units. There is also an urgent need to set up a technical and trade information centre, which can be a collaborative effort of Government and Industry and can be covered

under this activity. In the 11th Five Year Plan period an amount of **Rs.100 crores** can be earmarked for this purpose.

18. The global industry is looking for cost containment through outsourcing and India offers tremendous opportunity in the area of contract R&D, contract manufacturing, clinical trials, bio-informatics, technical services etc.

19. Tax benefits should be such as to attract FDI in this sector particularly clinical trials and research to be undertaken in India.

20. The implementation of the new Schedule 'M' will prompt international Pharma companies to enter into alliances with domestic companies for generic drugs sourcing to be marketed in overseas markets.

21. International operations of Indian companies, overseas acquisitions and exports will be the major thrust of the industry in the post Product Patent era.

22. For strategic reasons, it is essential that Pharma PSUs continue to play an important role in future. They possess vast assets and manufacturing facilities which, if put to optimum use, can can play an important role in keeping a check on the prices of essential drugs. Under the Product Patent Regime, they can also be used as an arm of the Government in manufacturing certain patented drugs required to meet public health emergencies through the grant of compulsory license for government non-commercial use. Pharma PSUs can provide quality medicines at reasonable prices for various healthcare programmes of the Government. Government has approved the revival package of Hindustan Antibiotics Ltd. Two other important PSUs –Indian Drugs and Pharmaceuticals Limited (IDPL) and Bengal Chemicals and Pharmaceuticals Limited (BCPL) also need to be revived.Capacity and GMP standards of two good performing joint sector companies namely, Karnatka Antibiotics and Pharmaceuticals Limited (KAPL) and Rajasthan Drugs and Pharmaceuticals Limited (RDPL) need to be to be augmented. These public sector units can not only meet the needs of India but can also provide low cost drugs to several other countries

23. In order to reposition the Pharma PSUs to enable them to make optimum use of their assets there is need to set up an Apex Body which should handle this role and assist these PSUs. This Apex

Body can be constituted as a society registered under the Societies Registration Act 1860. Similar Apex bodies are in existence for the State Transport Undertakings and States Industrial Development Corporations. A fund of **Rs. 10 crores** may be set apart for this body. For assisting the Pharma PSUs in Drug Development, Patent filing, WHO pre-qualifications etc a **Critical Assistance Scheme for Pharma PSUs** is proposed by the Department of Chemicals & Petrochemicals with **Rs. 20 crores** per annum i.e Rs. 100 crores for the entire 11th Plan Period.

24. There is a need to have schemes in the Public-Private Partnership mode for making essential drugs accessible to the poor families (BPL persons). Some of the schemes could be in the nature of District Drug Banks, Cancer Mesicines Assistance Fund etc.

25. In order to increase accessability of medicines to the BPL families efforts would be made to have Public-Private Partnership to run **District Drug Banks** in each District. Considering that there are nearly 600 districts in the country, an equal number of Drug Banks may be set up in a phased manner by the State Governments with the help of Industry. These banks could be managed by Red-Cross societies, Medicare Societies or such other charitable bodies having linkage with the District Administration/ district level hospitals. Various manufacturers would be encouraged to donate generously to these Drug Banks. Efforts would be made that they adopt one or more districts for this purpose. Such drug donations would be made eligible for **tax exemptions** under the corporate tax. An annual budget fof **Rs. 100 crores** would be needed for this fund spread over the entire plan period. These funds are proposed to render one time assistance to the infrastructure needed for the purpose.

26. For making available anti-cancer and anti-HIV/AIDS drugs at reasonable prices to larger sections of the population, government would evolve a Public – Private Partnership programme with the concerned manufacturers and cancer hospitals in the country. All medicines pertaining to these categories whether under National List of Essential Medicines, 2003 or outside would be brought under this programme.

27. A Public-Private Partnership programme for Cancer Medicines Assistance may be worked out by involving the major cancer hospitals in the country. Industry would contribute cancer drugs at 50% of the

market price. Funds may be provided by the Government of India to provide these drugs free of cost to BPL families, handicapped persons and senior citizens. All others may be provided these drugs at 50% of the market price. This programme may be started with an annual budget of **Rs. 100 crores** or **Rs. 500 crores** for the Plan Period.

28. Investment in preventive measures would yield better results in the country. The role of civil society bodies and the Pharma industry can be enlarged in this area by greater voluntary affirmative action.

29. Effective procurement systems and greater use of generics need to be promoted. Guidelines for rational use of drugs should be implemented.

30. The Pharma industry is going through a period of very significant change. Pressures from external environment, particularly compulsions of Governments of developed countries to reduce healthcare spending combined with wider use of bioPharmaceuticals tend to change the nature of Pharma R & D. There is a paradigm shift in the R & D through shift from the large scale screening of the molecules randomly to research on specific therapeutic areas. Thus, there may be greater contribution of small firms and higher education institutes in basic research the results of which would then be passed on to the big Pharma companies.

31. New technologies of **drug discovery** and development are very cost prohibitive and require high investment in R & D. There is need to extend the fiscal incentives being given for R&D by another 10 years i.e upto 31st March 2017.

32. There are 10 to12 leading Indian Pharma companies that are into **New Drug Discovery** which itself is an achievement, considering the high cost of drug discovery. They are working in the areas of infections, Diabetes, Obesity, Asthma and Cancer. Some products are also in clinical trials. Opportunities can arise by in-licensing these products to MNC Pharma companies who are under pressure to reduce R&D costs.

33. Apart from the fiscal incentives there is need to leverage the provisions of DSTs Drug and Pharma Research Programme (DPRP) towards creation of National centers for various regulatory aspects of registration of NCEs and by making available soft loans to industry

for drug R & D, positive signals have gone as Government's commitment towards promotion of Pharma R & D. To consolidate this, provisions must be made in the 11th plan for creating a more conducive atmosphere for R&D.

34 In order to disseminate information on IPRs and related issues to the Pharma Industry in an effective manner it is proposed to set up 3 IPR Facilitation Cebtres at 3 offices of Pharmexcil. An outlay of **Rs. 1 crore per annum** is proposed to be made available for the purpose. As such fund for the 11th Plan would be **Rs. 5 crores**

35. Indian Pharma Machinery Industry is estimated to be having a turnover of Rs. 2000 crores with a growth rate of 15%. It is meeting the international standards and exports are being made to both developing and developed countries. The industry has to update its technology to meet the new process technology requirements like Process Analytical Techniques (PAT). Indian companies should concentrate on supply of advanced R & D equipment to be produced domestically. There is need for the Pharmaceutical Engineers who can design and construct the equipments as per international standards.

36. The Pharma R&D Programme (PRDP) under Department of C& PC has provided valuable assistance to some important projects, which NIPER had taken up. These included Impurity Profiling Facilities and preparation of standards of impurities & degradation products besides developing various new processes. The Standing Committee of the Parliament for the Ministry of Chemicals and Fertilizers has recommended an increase in the fund under PRDP. With changed scenario the focus has to shift besides research work, to emerging areas of effluent treatment and studies of Environmental aspects vis-à-vis Pharma units. As such it is proposed to continue the existing PRDP (Expanded role) with an annual fund of **Rs. 5 crores** and the entire Plan fund need to be made **Rs. 25 crores**.

37. With the phenomenal growth of Indian Pharma sector and R & D, the direct and indirect employment has increased in the recent past. Though there are 625 AICTE approved institutes having approximately 53,000 B. Pharm., students in the year 2005–2006, there is a gap between demand and supply of highly skilled manpower for the Pharma Industry.

38. i) There is need for at least five more NIPER-like institutes in different parts of the country to train the manpower to meet the needs of drug discovery and development. The specializations which need to be pursued at this stage are: *Medicinal Chemistry, Molecular Modeling, cell based assays, Systems Biology, Nanotechnology, Biotechnology, in-vivo Pharmacology, regulatory affairs, regulatory toxicology, IND/ANDA/NDA filing expertise, clinical trials, bioethics, Biostatistics, Pharmacovigilence, Pharmacoeconomics, Drug Delivery research, and IPR management*.

ii) To create five National level Institutes like NIPER in Pharma sciences an amount of **Rs. 250 crores** for each Institute would be required in the next five years. As such a total of Rs. 1,250 crores may be allotted for this purpose.At the same time existing facilities at NIPER, Mohali are also needed to be augmented at an investment of **Rs. 150 crores** for upgrading.

Funds requirement for the proposals in the Working Group Report

S. No	Description	Reference in Executive Summary	Reference Section in the Report	Amount required (Rs. crores)
1	For 5 NIPER like Institutes @Rs 250 crores each	Item 38 (page 19)	7.4 (page 82)	1,250
2	Interest Subsidy Scheme for GMP, under Schedule M	Item 4 (page 12)	3.3 (page 35)	560
3	Pharma Export Promotion Scheme	Item 14 (page 14)	1.12 & 3.1 (page 25 & 33)	10
4	10 Pharma Parks @ Rs. 25 crores each	Item 16 (page 14 & 18)	13.1(11) (page 108-09)	250
5	Public Private Partnership for District Drug Banks @Rs. 100 crores annually	Item 25 (page 16)	15.4 (page 116-117)	500
6	Public Private Partnership for Cancer Medicines Assistance Scheme @Rs. 100 crores annually	Item 27 (page 17)	15.4(IV) (page 116)	500
7	Apex body for repositioning of Pharma PSUs [@Rs. 2 crores per annum]	Item 23 (page 15-16)	13.13. (page 111-113)	10
8	Critical Assistance Scheme for WHO prequalification of Pharma PSUs	Item 23 (page 16)	13.1-12.iii (page 113)	100
9	Strengthening of NPPA, Price monitoring (State Monitoring Cell, Appellate Tribunal public awareness on prices)	Item 11 (page 13)	13.1(9) (page 107-108)	100
10	NIPER, Mohali (Infrastructure strenghthening)	Item 39 (page 19)	7.4 (page 80-81)	150
11	Education on quality issues for SSIs, SMEs and General Public (Workshops, conferences, Seminars in India and abroad)	Item 17 (page 14-15)	13.12 (page 109)	100
12	Pharmaceutical Research & Development Scheme including studies for feasibility, designing of CETPs in Pharma clusters.	Item 36 (page 18)	4.28 (page 70)	25
13	Creation of IPR Facilitation Centres at Pharmexcil	Item 34 (page 18)	4.22 (page 65)	5
	Total			**3,560**

REPORT OF THE WORKING GROUP

1. To review the status of the industry including Tenth Plan targets vis-à-vis achievements, in terms of production as well as exports, identify the reasons for major deviations, if any, bring out areas of strength and weakness of the Indian industry vis-à-vis the international Drugs and Pharmaceutical Industry.

Driven by the knowledge, skills, growing enterprise, low costs, improved quality and demand (domestic as well international) the Pharmaceutical industry in India has witnessed a robust growth over the past few years moving on from a turnover of approx. Rs. 5000 crores in 1990 to over Rs. 55,000 crores (approx US$12 billion) during 2005-06. Exports have also grown very significantly to over Rs. 21500 crores during 2005-06 (US$4.7billion). India is today recognised as one of the leading global players in the manufacture of Pharmaceuticals – it holds 4th position in terms of volume and 13th in terms of value of production. The Indian Pharmaceutical Industry which has established a strong presence in the global market is contributing around 22% in terms of value towards the global generic drugs market. The cost of drugs produced in India is amongst the lowest in the world. It is estimated that by the year 2010 this industry would have the potential to achieve a level of Rs. 100,000 crores in formulations with bulk drug production going up from Rs. 8000 crores to Rs. 25,000 crores. India's rich human capital is believed to be the strongest asset for this knowledge-led industry. Various studies show that the scientific talent pool of 4 million Indians is the second largest English-speaking group worldwide, after the US.

1.1 The availability of medicines in the country has improved tremendously. From the level of being a major importer at the time of Independence the country has become supplier to the World. The domestic availability of the medicines can be gauged in terms of domestic sale in recent years. There has been very significant growth in sales of Pharma products in the domestic market as would be evident from the following :-

Year	*MAT Value (Rs. in Crores)*	*Percentage Growth*
2001-2002	15931.83	-
2002-2003	17674.39	10.94
2003-2004	20368.15	15.24
2004-2005	21273.09	4.44
2005-2006	24439.14	14.88

[Source :- ORG-IMS]

Note-These figures capture only part of the domestic market in India.The total domestic market as estimated by ORG-IMS is about Rs 34,000 crores.

1.2 The industry has shown signs of consolidation as indicated by the positive volume growth. Another feature that has emerged is that the Indian companies dominate the sector with 79% value contribution. The value growth in the performance of top 20 large Pharmaceutical companies in India may be seen at **Annexure I**. As per estimates the top players control nearly 65% of the market. As per ORG-IMS, the rural market has increased its contribution to 19% registering a 23% value growth.

1.3 Similarly the growth trends in the Indian Pharmaceutical Industry indicate that the average annual growth during the last five years has also been substantial as appears from the trend given below :-

GROWTH IN PRODUCTION OF PHARMACEUTICAL INDUSTRY

(Rs. In Crores)

Year	Bulk Drugs	Formulations
2000-01	4533.00	18354.00
2001-02	5439.00	21104.00
2002-03	6529.00	24185.00
2003-04*	7729.00	27692.00
2004-05*	9034.00	31946.00

* Estimated

These figures do not include production from unorganised sector, which is estimated at an additional 35% of the production.

[Source : BDMA ‘ Bulk Drug Industry at a Glance 2006’]

1.4 As per industry estimates (source OPPI) the total Bulk Drug production in India in 2005 was approx. Rs. 113 billion (US $ 2.5 Billion). Over 400 Bulk Drugs (APIs) are manufactured in the country. Around 60,000 formulations packs in 60 therapeutic categories are made in the country. The largest number of US FDA approved manufacturing facilities outside USA are located in India. As per projections by Mckinsey and Co.the retail value pharma sector in India is likely to be US $ 25 billion by 2010.

1.5 According to industry estimates (OPPI) there are in all nearly 10,000 Pharmaceutical units including large and medium sized units. The Sub Group II made an attempt to ascertain the exact number of Pharmaceutical manufacturing units in the country. The Sub Group found that as against the frequently quoted figure of about 20,000 manufacturing units the actual figure may be around 8,000 to 10,000. The Sub Group requested various Pharma associations, the Development Commissioner for Small Scale Industries and others in this regard. According to a report by the Committee headed by Dr. R.A. Mashelkar the actual number of drug manufacturing licenses issued was – bulk drugs (1333), formulations (4534), large volume parenterals (134) and vaccines (56). Thus, the total number of manufacturing units engaged in the production of bulk drugs and formulations comes to 5877. Besides, there are 199 medical devices units, 638 surgical dressings and 272 disinfectant units, 4645 loan licencees and 318 repacking units, 1806 blood banks, 2228 cosmetics units and 287 other units not covered in the above categories.

1.6 **SSI units in the Pharmaceutical Sector:**

1.6.1 As per the third All India Census of Registered SSI unit conducted by Ministry of Small Scale Industries, total SSI working units in 2001-2002 were 6090 and the status of Small Scale GMP compliant units is as under: -

- 1672 units are already GMP compliant.
- 1797 units are in the process of GMP compliance.
- 370 units are not in a position to comply to GMP norms due to non-availability of infrastructure.
- 337 units are closed or have surrendered their licences or may have shifted to some other states.

1.6.2 The State wise details are enclosed as **Annexure II & III.** According to the Office of the Development Commissioner (SSI) the contribution of SSI units in Pharmaceutical production in terms of volume is around 50% while

in terms of value it is around 29% (as in July 2005). The Confederation of Indian Pharmaceutical Industry (Small Scale) has quoted the total number of Pharma SSI units as around 8000 in the country with estimated employment around 10 lakh persons (as in July 2005).

1.7 **Export of Drugs, Pharmaceutical and Fine Chemicals:**

Exports touched a level of over Rs. 21500 crores during 2005-06 and constituted 4.74% of the country's overall exports. Exports constitute a very substantial part of the total production of Pharmaceuticals in India. The trend of exports is as follows: -

Year	**Exports (Rs. in Crores)**
1998-1999	6256.06
1999-2000	7230.16
2000-2001	8757.47
2001-2002	9751.20
2002-2003	12826.10
2003-2004	15213.24
2004-2005	17857.80
2005-2006	21578.96

[Source:-Directorate General of Commercial Intelligence and Statistics (DGCIS), Kolkata]

Formulations contribute 55% while the rest 45% comes from bulk drug exports.

1.8 The regionwise direction of exports and the exports to countries in terms of value may be seen at **Annexures IV & V**. Exports in terms of major segments, exports of some major bulk drugs and of some major formulations are in **Annexures VI, VII and VIII**.

1.9 As per available information from the International Trade Centre (ITC) the total global exports of Pharmaceutical raw materials during 2004 was US $ 59.44 billion and medicaments (formulations) was US $ 184.27 billion. India occupied 18th position in global exports of raw materials with 0.78% share and 15th position in medicaments with a contribution of 0.99% in the global export market.

1.10 Exports demand world-class facilities and practices in all areas. Indian companies are aggressively adopting global standards. The country leads in DMF filing. Indian DMFs were around 35% of total 411 DMFs filed during the first half of 2005. There are over 70 US FDA approved plants in India, i.e. the highest outside the US.

1.11 Another notable feature is that India is becoming a hub for outsourcing of Pharma products mainly because of the cost & quality advantage. Research Contracts & Clinical trials are coming at a fast pace to the country. The total global outsourcing market is estimated to be cross US $ 60 billion by end 2005. Similarly, the current Indian Clinical Research outsourcing market is estimated to be around US $ 100 million and is expected to grow at the rate of 80%. Thus outsourcing and clinical research are two very large international business opportunities which need to be tapped.

1.12 For export promotion number of incentives are available under the Foreign Trade Policy as Market Development Assistance (MDA) and Market Access Initiative (MAI) schemes. **Pharma Export Promotion Cell** (PEPS) is functioning in the Department of C&PC with the objective of boosting Pharma exports and to act as nodal centre for all queries & issues regarding Pharma exports. It can also organize some international events alongwith Industry bodies, Pharmwxcil etc. In order to strengthen and take new initiatives, it is proposed that PEPS may be allotted **Rs. 2 crores** annually (**Rs**. **10 crores** during Plan) to carry out export promotion activities.

1.13 **Import of medicinal and Pharmaceutical Products**

With the growth of the industry and increase in production, this sector has seen an increase in imports of medicinal and Pharma products as is evident from the figures given below :

Year	Import (Rs. in Crores)
1998-1999	1625.19
1999-2000	1616.21
2000-2001	1701.46
2001-2002	2001.10
2002-2003	2865.20
2003-2004	2956.63
2004-2005	3169.35
2005-2006	4515.22

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

1.14 The value of imports of medicinal and Pharmaceutical products from various countries is in **Annexure IX**. Major suppliers include China, Switzerland, USA, Germany, Denmark, Italy, France and U.K.

1.15 In terms of the Exim Policy 2002-07 import of a number of bulk drugs and intermediates became restricted on account of relevance to Narcotics & Psychotropic Substances Act, 1985. Apart from specific entries, residual entries as “others” were also placed under import restrictions. Removal of import restrictions for these 9 residual entries has been notified which will enable easy access to these items by the domestic industry.

2. To assess the structure and capability of the domestic drugs and Pharmaceutical industry in the light of the new IPR regime, identify emerging areas having specific potential for growth and competitiveness and suggest measures for putting the indigenous industry on a sound footing.

Disease Pattern & Top Therapeutic Categories: The Highest reported ailments as per ORG-IMS are as follows:

- Respiratory tract infections,
- Fever,
- Diarrhoea / Gastroenteritis,
- Viral infection,
- Essential(Primary) hypertension,
- Acid peptic disease/Acidity/Hyperacidity,
- Supervision of normal pregnancy,
- Bronchitis,
- Urinary tract infection,
- Dental caries,
- Asthma,
- Gastritis and duodenitis,
- Diabetes mellitus

2.1 According to ORG-IMS data, the top therapeutic categories prescribed in India are:

Top 10 Drug types	% Rx*
Anti-infectives	**37.3**
Anti-rheumatic Nonsteroidal Analgesics.	**24.3**
Anti-pepticulcerants	**14.1**
Non-Narcotics,Antipyeretics.	**10.7**
Antihistamines,Systemic	**10.4**
Vitamin B Complex	**10.2**
Cough Preparations	**8.1**

Top 10 Drug types (Contd.)	% Rx*
Haematinics, Iron +Combinations	**5.1**
Antispasm.Antichol. Combinations.	**4.5**
Antiemetic, Antinausatics	**4.2**

[Source: ORG-IMS, December 2005]

2.2 Despite the impressive growth of the sector and low costs there are several concerns, which need to be addressed. Some of these concerns pertain to accessibility and affordability of medicines by the common man particularly the vast segment of the poor population, instituting standards of quality, particularly for units not conforming to standards of regulated markets, strengthening the fragmented regulatory system, sustaining growth of generics – the main forte of Indian Industry, meeting the challenge of product patent regime and so on. In order to find the right solutions and the right balance between various viewpoints an almost continuous debate goes on regarding some of these issues both within and outside the industry, trade, Government and other stake holders.

2.3 The international Pharma scenario is changing due to cost pressures, leading to consolidation of companies, out sourcing and growth of generics. Other changes taking place internationally are globalization of market product, patent expiry and increased use of IT. These changes offer excellent opportunities for Pharma companies in India. Though it is not possible for India to be a world leader in all aspects of Pharma industry, it is possible for India to become a leader in certain niche areas. Given the variety of strengths and entrepreneurial ability and the emerging trends in the international Pharma scenario, the success of the Indian Pharma Industry will greatly depend upon the speed at which policy changes are initiated and implemented to create an environment for research and innovation in India. This industry could become one of the world leaders in providing cost effective product and services to India and others by leveraging its knowledge capital. Some of the measures that could be considered in this direction are:

(i) Increased research and innovation;

(ii) Improvements in the quality of drugs manufactured in India by adopting international regulatory standards like US FDA/MCA (UK) and enforcing stringent regulatory processes for import of drugs; and

(iii) Better collaboration between Government, academia and the industry in emerging technology areas.

2.4 One of the concerns, expressed in many corners, is that the prices of medicines would rise exorbitantly because of the Product Patent. A patent on a product would connote a monopoly for the patent holder and may allow him to charge a price, which he deems necessary to recoup his expenses connected with the R&D of the said product. However, to say that the market would be totally driven or controlled only by patent products may also not be correct. The following facts elucidate this point:

(a) Globally, on an average, only 15 to 20 drugs enter the market every year and only a few of them are commercial success. At the same time, each year patents expire for earlier products. Hence, at a particular point of time only 5 to 10 percent of the drugs in the market may be under product patent protection and the rest of the market could still be in the generic category;

(b) Over the years, it has been observed worldwide that for any of the new patented medicines, at any point of time, there are more than half a dozen patent expired therapeutic equivalents available. Thus the price competition between different drugs in the same therapeutic group will automatically keep the prices of such new entities under control;

(c) In India, majority of the patients pay out-of pocket for medicines and their limited purchasing power will act as a check on explosive price rise for the patented drugs;

(d) Drug price control measures are WTO compatible and the Government will continue to have powers to regulate the prices of medicines sold in the country;

(e) Provisions of compulsory licensing and parallel imports under the Patent regime will help keep prices of patented medicines within the common man's reach;

(f) None of the drugs, presently in the Indian market or those that have been patented prior to January 1, 1995 any where in the World, can be patented in India;

(g) Grant of patent does not necessarily mean commercial exploitation. Where there is no commercial sale, the question of price rise will not arise. It is understood that even in the US, less than 10 percent of the patented products are commercially exploited;

(h) None of the drugs included in the list of essential drugs published by the Ministry of Health is liable to be covered by patent as they are already in the public domain and these drugs would continue to be abundantly available at prevailing prices.

2.5 However, one of the important features of patents is that it results in market exclusivity for the patent holder while commercially exploiting the intellectual property rights contained in the patent. This essentially means that grant of a product patent will create a monopolistic situation. The Patent holder will try to maximize his profits through the sale of this product, which would result in higher price for the product.

2.6 Some of the likely impact on prices of patented drugs under the new patent regime is being tabulated as under:

S.No.	Type of drugs	Remarks
1.	The drugs, presently in the Indian market or those that have been patented prior to January 1, 1995 anywhere in the World,	Such drugs can not be patented in India. All the drugs in the National list of Essential medicine 2003 will fall in this category. No significant price rise is expected in this category
2.	The drugs, presently being manufactured in India and are discovered/ patented after January 1, 1995 and also granted patent in India.	Such drugs are very small in number. If they are being manufactured in India on the date of grant of patent, they will continue to be produced subject to a payment of reasonable royalty. The price of all such medicines should rise proportionate to the royalty payments. existing price control mechanism can control such cases if the increase is beyond permissible levels.
3.	The new drugs (Post 2005) which get patented in India and they are not being produced in India at present.	If their therapeutic equivalents are available then such drugs will be reasonably priced. However, in the case of a blockbuster drug the prices can go far beyond the reasonable levels. In such a situation price control mechanism can be used to take care of the situation or safeguards provided in the Patents Act, 1970 like compulsory licensing can be used.

2.7 As per estimates there are more than 200 approved in-house R&D units in the Drugs and Pharma sector. Having regard to this fact, Indian companies should be capable of taking advantage of the new IPR regime and at least partially overcome the disadvantages of the new IPR regime.

2.8 Better compliance of the existing IPR provisions should be encouraged in the Pharma sector.

2.9 According to industry sources the R&D expenditure made by the Indian pharma companies is around Rs. 12.2 billion (US$ 270 million) in 2005(nearly 4% of sales). However, some companies are reportedly spending over 6% of sales on R&D. A recent report quoted by OPPI states that the R&D spend of top 12 Pharma companies in 2004-05 has grown by 41.5% and is 7.7% of sales compared to 4% in previous year. Compared to about 1-2% of average annual turnover about a decade back, there are presently more than 75 units spending 5 to 15% of their annual turnover for R&D.

2.10 The post Patent regime opens up vast opportunities for Indian Pharma firms. Large companies like Ranbaxy, Nicholas Piramal, Dr. Reddy's, Wockhardt, Lupin etc. are investing heavily in R&D and in a few years should be able to launch their own-patented molecules all over the world.

2.11 India also has the largest number of US FDA approved manufacturing facilities outside U.S.A. In the year 2003-04, India filed the highest number of DMF (Drug Master File) applications with the U.S. FDA. With almost U.S. $ 60 Bn worth of medicines coming off patents in the next few years, India is poised to emerge as a significant player in the area of generics.

2.12 The bio-pharmaceuticals market is also evolving very fast and the Indian market is flooded with biogenerics like erythropoietin, filgrastim, interferons, human insulins, vaccines, etc. In fact India is likely to emerge as one of the largest producers of vaccines in the world in few years time. The biotech market is estimated to reach US $ 50 billion by 2010 and almost 70% of this will be bioPharmaceuticals, as estimated by the industry.

2.13 Bulk Drug manufactures in anti infectives are facing a serious threat on account of dumping of these drugs by some countries. Since some of these drugs have strategic importance as cost effective and largely needed y the general public, a permanent consultative mechanism to look into specific and general issues in association with industry, trade, consumers and other stake holders to recommend remedial measures is hence recommended.

2.14 Over the last two decades, the Indian Pharma industry has expanded dramatically and there have been substantial investments. The Pharma

industry has witnessed substantial inflow of Foreign Direct Investment (FDI) amounting to US $ 1.00 billion (Rs. 43.13 billion) between August 1991 and April 2006. Drugs & Pharma figured among the top ten sectors receiving FDI inflow during this period (Source: Department of IP&P).

2.15 The leading 10 Pharma companies control 37% of the market, which indicates the consolidation that has taken place. Yet, to a large extent, the industry is fragmented with over 6,000 units leading to intense competition.

2.16 The emerging scenario necessitates regulatory reforms and rationalization of taxes. There is a high transaction cost on account of a multiplicity of taxes and duties. Adoption of a common rate of VAT across the country, reduction of excise duty, etc may be considered. The need is to step up investment by providing good infrastructure, reduced transaction costs, sufficient profitability to generate surpluses to be ploughed back into the industry, induction of better and newer technologies and upgradation of existing technology, which will help reduce costs, improve productivity, upgrade quality and thereby make industry cost efficient & enable it to produce better products.

1. Shared facilities for pipelines, utilities, analytical testing labs, effluent collection and treatment facilities.
2. Development of training centres for skill upgradation and improved human resources, common R&D centres that may act as incubators.
3. Schemes to promote compliance of Schedule M, improvement in quality by adopting international regulatory standards (such as FDA / MCA) and technology upgradation with special focus on the small sector.

3. To assess the present status of WHO GMP (World Health Organisation–Good Manufacturing Practices) certification and suggest measures for Schedule 'M' compliance by manufacturers of Drugs & Pharmaceuticals products in the country.

The scheme of WHO GMP has been available since 1975 as a means of exchanging information between regulatory authorities in importing and exporting countries. Its purposes are:

I. To provide assurance that a given product has been authorised to be placed on the market in the exporting country, and, if not, to explain why authorisation has been withheld, or has not been requested.

II. To provide assurance that the plant in which the product is manufactured is subject to inspections at suitable intervals and conforms to the requirements for good practices in the manufacture and quality control of drugs, as recommended by WHO.

III. To provide for exchange of information on the implementation of inspections and controls by the authorities in the exporting country. In the case of serious quality defects inquiries may also be made.

India is one of the Member signatory countries to WHO certification scheme on the quality of Pharmaceutical products moving in international commerce as resolved by WHA 22.50 (1969). India, being a signatory State, has accepted the GMP text as an integral part of the scheme to cover export of Pharmaceuticals. WHO GMP certificate is granted after officials from CDSCO and State Licensing Authorities (SLAs) carry thorough in-depth inspection. SLAs also carry out periodic inspections to verify compliance of GMP. The Certificate has two years' validity in India. Quality complaints received by DCGI are taken up with CDSCO and SLA.

3.1 **Status of WHO GMP compliant companies in India:** The number of Pharma units actually functioning in the country is about 300 large and about 6000 SMEs. All the big, medium and small units are required to follow upgraded Schedule 'M' which deals with Good Manufacturing Practices (GMP). A large number of these units have adopted the Schedule 'M' GMP standards The present Schedule 'M' provisions which have become mandatory since 1st July, 2005 conform to international standards and have a higher level of GMP that can lead to better quality of products meant for both domestic and international markets.

3.1.1 **As regards WHO- GMP standards** it is estimated that so far about 800 units have obtained this certification.. Many of the countries like China and some of our South East Asian neighbors & Russia have also started implementing WHO GMP in a serious manner. In order to popularize Indian Pharma products as quality drugs there is a need to promote them under "Made in India"/ "Sunrise India" brand.

3.1.2 Another development relating to GMP is that WHO GMP is no longer the only requirement for exports. Many regulators from importing countries visit India to carry out inspections before registering medicines. More and more Indian companies are going for international regulatory approvals from agencies like US FDA, MHRA UK, TGA Australia, MCC South Africa. With nearly 100 US FDA approvals, mainly for APIs, India has largest US FDA approved plants outside USA. Slowly the number of US FDA approvals for dosage form plants is also increasing. Europe is occupying the number one position for Indian Pharma exports. More and more companies are going for European certification for approval of their products. Slowly the scenario is changing and realisation is dawning on the companies to have at least WHO GMP if they want to compete in international markets. In the post 2005 era many of the small units may face problems. However, the competition will be tough and it is expected that more and more companies will upgrade their GMP practices if they have to survive in the business. An important development is that MNC companies are increasingly entering into **contract manufacturing** with Indian companies. Therefore, GMP will be indispensable for Indian Pharma units.

3.2 **Recent developments concerning Schedule 'M':** As stated above, the upgraded Schedule 'M' is mandatory w.e.f 1st July 2005. The correct picture as to how many units have conformed to new Schedule 'M' is not available. Gujarat FDA has cancelled a number of manufacturing licenses of units, which have not met this deadline. At the same time it is felt that there is shortage of qualified manpower trained in GMP affairs. GMP auditing is a challenge. At present there are only 1,100 drug inspectors in the states and augmenting this number is necessary.

3.2.1 There are many difficulties in this regard and the proposed new National Pharmaceuticals Policy includes a proposal for creation of an **Upgradation Fund** to meet these difficulties and financial requirements. Regarding other measures for Schedule 'M' compliance many of the small Pharma units are not in a position to invest money for upgrading the facility. This is more so because there is a shift in the business to tax exempted States and therefore, operation of units in other States like Maharashtra, Gujarat, Andhra Pradesh is becoming unviable.

3.3 **Pharmaceutical Technology Upgradation Fund Scheme (PTUFS):** In view of the relaxation offered about implementation of Schedule M by SSI units, by the Ministry of Health & Family Welfare vide GSR738(E) dated 8th November 2004, Department of C&PC has proposed PTUFS for creating GMP complaint facilities in their manufacturing plants by way of offering an interest subsidy of 5 percentage point on the loans availed by SSI units.

The basic features of the proposed Scheme are as under:

a) Reimbursement of 5 percent point of interest on the loans taken from the scheduled Banks/Financial institution by the small and medium Pharma units.

b) Provision of interest subsidy of SIDBI by the Government, which in turn will distribute the interest subsidy to various banks or disburse them directly in case the loans are taken from SIDBI.

c) The scheme will be operational initially for a period of 2 years and may be extended for one more year at the discretion of the Government.

d) The scheme will allow only the purchase of new machinery. Further, foreign currency loans will also be covered for the purpose of importing the new machinery.

e) Interest reimbursement under the scheme would be available for a period of repayment of loan for a maximum period of 5 years.

f) SIDBI will act as a nodal agency for operation of scheme and reimbursement of interest subsidy.

g) The approximate fund requirement upto financial year 2012-13 will be **Rs.560.00** crores.

h) The Government in association with SIDBI and Pharma Associations will publicize this scheme. This Scheme needs more popularization for benefit of SSI Pharma units.

3.4 **Regulatory Mechanism for AYUSH: For** AYUSH drugs/ companies Schedule T of Drugs & Cosmetics Act is operational since 2002 to help them upgrade themselves to relevant GMP requirements. Out of about 9,000 units in the country under the purview of AYUSH, as many as 3,000 are Schedule T compliant. 20% of the expenditure incurred by these Pharmacies on Schedule T implementation is reimbursed. The number of drug inspectors for AYUSH is also inadequate.

In addition to the herbal drugs, food supplements and neutraceuticals are a grey area where proper control system is lacking as on date. US FDA is reported to have classified herbal drugs & food supplements as Botanical

drug products and Rules & regulations for them have been framed. In India also Ministry of Law & Justice has recently notified(*Notification No 34 dated 24th August 2006*) creation of **Food Safety and Standards Authority** under FSSA Act 2006. The Notification, inter alia, lays down rules and regulations for monitoring, control and regularization all food products including botanicals/ herbals food additives and neutraceuticals.

3.5 **International Committee on Harmonisation (ICH):** The birth of ICH took place at a meeting in April 1990, hosted by the European Federation of Pharma Industry Associations (EFPIA) held at its HQ in Brussels. Regulatory agencies and industry associations of Europe, Japan & USA met, primarily to plan an International Conference but the meeting also discussed the wider implications and terms of reference of ICH. Many amendments and modifications have since taken place about ICH and the **Revised ICH Terms of Reference** for ICH are:

I. To maintain a forum for a constructive dialogue between regulatory authorities and the Pharmaceutical industry on the real and perceived differences in the technical requirements for product registration in the EU, USA and Japan in order to ensure a more timely introduction of new medicinal products, and their availability to patients;
II. To contribute to the protection of public health from an international perspective;
III. To monitor and update harmonised technical requirements leading to a greater mutual acceptance of research and development data;
IV. To avoid divergent future requirements through harmonisation of selected topics needed as a result of therapeutic advances and the development of new technologies for the production of medicinal products;
V. To facilitate the adoption of new or improved technical research and development approaches which update or replace current practices, where these permit a more economical use of human, animal and material resources, without compromising safety;
VI. To facilitate the dissemination and communication of information on harmonised guidelines and their use such as to encourage the implementation and integration of common standards

Indian Pharma Industry would be benefited by the deliberations of ICH and it has to keep abreast of these international developments in order to remain competitive in current global scenario.

4. "To assess the present R&D status of the Drugs & Pharma industry and to suggest measures for increasing the role of the industry in R&D effort, industry Institutional linkages, investment (including foreign) by industry to make the drugs and Pharmaceuticals industry internationally competitive and meet the emerging challenges arising out of the WTO regime."

Between the start of 9th Plan and start of 11th Plan periods (1997 to 2007) the drugs and Pharma industry both in India as well as in other parts of the world has seen dramatic developments in structure as well as discovery of drugs. New tools of discovery have made India a hub for contract drug research, which includes discovery and development. As far as Pharma sector is concerned the coming 5 Year Plan from 2007 is crucial. Consequent upon introduction of Product Patents for Pharma in India, there is a need to review the Global Pharma industry and R&D and its impact on the Indian scenario. This will facilitate to fix the benchmarks for the progress of Indian Pharma Industry and R & D in the coming five years.

4.1 The Pharma industry is one of the most successful industries in the technology sector and its ability to innovate and it has seen launched nearly 1,400 new chemical entities as human therapeutics over the last 30 years. Despite this success, the environment in which the industry operates is becoming more competitive and the R&D process to bring a drug successfully to market remains challenging. Drug development is a risky, unpredictable and expensive process involving combination of scientific excellence & a thorough understanding of the business environment.

4.1.1 It is estimated that each year, nearly six million people in the developing world die of malaria, tuberculosis, and HIV/AIDS. Yet, of the $70 billion spent annually worldwide on Pharma R&D, only about 10 percent is focused on finding vaccines and drug treatments for diseases affecting 90 percent of the global population. The current system of rewarding Pharma innovation through exclusive patents fails to create incentives to produce drugs and vaccines for diseases primarily affecting the poor. Pharma companies must invest heavily into R&D, and will do so only if they expect to recoup expenses and make a profit from sales of the final product.

4.2 GLOBAL PHARMA INDUSTRY - OVERVIEW **:** As per IMS health, in 2005 overall global Pharma drug sales rose by 7% to $602 billion. North America, which accounts for 47 percent of global Pharma sales, grew 5.2

percent, to $265.7 billion, while Europe experienced somewhat higher growth of 7.1 percent, to $169.5 billion. Sales in Latin America grew an exceptional 18.5 percent to $24 billion, while Asia Pacific (outside Japan) and Africa grew 11 percent to $46.4 billion. Japan, the world's second largest market, which has historically posted slower growth rates, performed strongly in 2005, growing 6.8 percent to $60.3 billion. Of the 30 NCE launches in 2005 (including biotech), 22 were in the specialist area and eight in primary care. Over the next five years 50-55 new oncology drugs are expected to be approved, with the oncology market worth $55 billion by 2009. Table 4.1 provide leading global Pharma industry sales, Table 4.2 contains R&D investments by global Pharma units & Table 4.3 reflects some leading blockbuster drugs.

Table 4.1. Leading Global Pharma Industry ($ billions)

2005 Rank	2004 Rank	Company(Country)	2005 global Pharma sales ($bn)
1	1	Pfizer(US)	44.3
2	2	GSK(UK)	34.0
3	3	Sanofi-Aventis(France)	32.3
4	7	Novartis(Swiss)	25.0
5	6	Astra-Zeneca(UK)	24.0
6	4	J&J (US)	22.3
7	5	Merck (US)	22.0
8	N/A	Roche(Swiss+Chugai)	15.7
9	9	Wyeth (US)	15.3
10	8	Bristol-Myers Squibb	15.3
11	11	Eli Lilly (US)	14.7
12	10	Abbott Labs(US)	14.0
13	13	Amgen(US)	12.0
14	14	Boehringer Ingelheim	10.8
15	15	Takeda(Japan)	8.5
16	N/A	Astellas(Japan)	8.0
17	16	Schering Plough(US)	7.6
18	18	Bayer(Germany)	7.6
19	N/A	Daiichi Sankyo	7.3
20	17	Schering AG(Germany)	6.3
21	22	Genentech(US)	5.5
22	25	Novo Nordisk (Denmark)	5.4
23	19	Eisai(Japan)	4.8
24	20	Teva(Israel)	4.7
25	21	Merck KGaA(Germany)	4.6
26	24	Otsuka (Japan)	3.3
27	29	Forest Labs(US)	3.2
28	26	Baxter international (US)	3.0
29	31	Akzo Nobel(Netherlands)	2.9
30	32	Altana(Germany)	2,8

Table 4.2. R & D Investment by Global Pharma Industry

2005 Rank	Company	Pharma R&D Spend ($ Bil)	% of Sales
1	Pfizer	$7.4	16.7
2	Johnson & Johnson	$6.3	28.3
3	GlaxoSmithKline	$5.7	16.8
4	AstraZeneca	$5.4	22.5
5	Sanofi-Aventis	$4.8	14.9
6	Novartis	$4.5	18.0
7	Roche(includes Chugai)	$4.2	26.8
8	Merck	$3.8	17.3
9	Eli Lilly	$3.0	20.4
10	Amgen	$2.3	19.2
11	Schering-Plough	$1.9	25.0
12	Abbott Labs	$1.8	12.9
13	Takeda	$1.3	15.3
14	Wyeth	$1.3	8.5
15	Genentech	$1.3	23.6
16	Astellas	$1.3	16.3
17	Daiichi-Sankyo	$1.3	17.8
18	Schering AG	$1.2	19.0
19	Boehringer Ingelheim	$1.1	10.2
20	Bayer	$1.1	14.5

[*Source- Pharmaceutical Executive May 2006]*

Table 4.3 Leading Block buster Pharmaceutical Drugs

Drug/Company	*Disease*
Lipitor(Pfizer)	Cholesterol
Zocor(Merck)	Cholesterol
Advair Seretide(GSK)	Asthma
Norvasc(Pfizer)	Hypertension
Zyprexa(Eli Lilly)	Schizophrenia
Nexium (Astra Zeneca)	Gastrointestinal disorders
Procid Eprex(J&J)	Anemia
Zoloft (Pfizer)	Depression
Effexor(Wyeth)	Depression
Plavix (Bristol Myers Squibb)	Thrombosis
Celebrex (Pfizer)	Arthritis
Fosamax (Merck)	Osteoprosis
Diovan Co-Diovan(Novartis)	Hypertension
Risperidal (J&J)	Schizophrenia
Cozaar Hyzaar (Merck)	Hypertension
Neurontin(Pfizer)	Seizures
Pravachol (Bristol Myers Squibb)	Cholesterol

Singulair (Merck)	Asthma
Epogen(Amgen)	Anemia
Drug/Company	*Disease*
Prevacid(TAP Pharmaceuticals)	Gastrointestinal disorders
Aranesp(Amgen)	Anemia
Lovenox Clexane (Sanofi Aventis)	Deep vein thromosis
Remicade (J&J)	Arthritis
Plavix/Iscover(Sanofi Aventis)	Thrombosis

4.3 **New Areas of R & D and Products:** Some of the areas where major research is going on are Anti infectives, Anti Cancers, Anti diabetics, CVD, Neurological disorders and Depression, Pain management, Asthma and Respiratory disorders. Novartis's Anti Cancer Gleevac (Imatinib Mesylate) was a break through product. The NDA was filed only 32 months after first dose in mice more than halving typical drug development time of six years. Paromomycin is an off patent medicine in Phase III clinical trials in India for Kala Azar. In the Anti-infective segment there is new class of compounds called Carbapenems covering products like Ritipenem (Pharmacia), Biapenem (Wyeth), Doripenem (Shionogi). There are Oxazolidinones where Linezolid (Pharmacia) has been introduced. Indian company Ranbaxy also came up with a product Ranbezolid. An orphan drug for infection from Romark by name Alinia (nitazoxanide) was approved by USFDA. A novel antibiotic Daptomycin from Cubist Pharma was approved for skin infections. There are new classes of anti-fungals called Echinocandin, Caspofungin. After Vancomycin, products like Oritavancin have come into market.

4.3.1 Quinolines have rosy future with Purifloxacin, Balafloxacin already approved. Other products like Sitafloxacin, Olamufloxacin, Fandofloxacin, Caderofloxacin have been reported. Other new products are Cerivastatin, Fluvastatin, Pitavastatin (Obesity), Donepezil, Galantamine and Rivastigmine (Alzheimers), Nateglinide, Mitiglinide, Rapaglinide (Anti-Diabetics), Ribavarine, Atazanvir, Adefovir, Tenofovir, Oseltamivir, Zanamivir (Anti-virals). Trandolapril, Zofenopril, Telmisartan, Irbessartan, Olmesartan (hypertension) Moexipril, (CVD), Etanercept, Lefluonamide, Adalimumab (Arthritis), Alendronate, Teriparatide, Bisphosphonate, Zolidronic Acid (Osteoporosis), Flutamide, Oxaliplatin,Nelarabine, Zofenopril, Quetiapine, Nefazodone, Mirtazepine, Ziprasidone, Aripiprazole, Risperidone, Memantine, Pulexetine, Lamitrigine (Neurological disorders), Atomoxetine (ADHD) Tamsulosin, Dutasteride (BPH), Naratriptan, Zolmitriptan, Rizatriptan, Almotriptan (Migraine), Miltefosine (Kala Azaar), Miglustat (Gaucher's disease), Pimecrolimus (Dermatitis), Micophenolate

Mofetil (Immuno-suppressant). All these are new drugs. Roche and Trimeris have discovered a novel HIV fusion inhibitor, Fuzeon (Enfuvirtide) launched in US under medical aid programme. Major manufacturers do not bring orphan products, which benefit very small but needy segment of population, to market because financial returns are not there. As a means of addressing this market gap, orphan drugs programme has been introduced in US, EU, Australia, Japan and Singapore. The programme brought incentives to undertake R&D of products for rare diseases. US Orphan Act (ORA 1983) outlines how ORA intended to stimulate orphan drug research and development of drugs for rare diseases.

4.3.2 EMEA introduced orphan drug policy in 1999 for treating rare diseases. The first medicine approved in 2002 was Bosentan (Tracleer) from Swiss Biotech Company Acteion for Arterial hypertension. Another disease is Gaucher's for which Oxford Glico sciences has developed Miglustat (Zavesca).An orphan drug has been developed by orphan Europe by name Carglumic Acid for treating a congenital disorder to eliminate waste nitrogen from body. 4th orphan drug is Pegvisomant (Somatopert) from Pharmacia to treat increase in size of hands, feet and face. Some other new drugs are Adefovir from Gileod Sciences for treatment of Hepatitis and an Anti viral agent Oseltamivir from Roche, Ertapenem from MSD for fighting infection. There is also a drug from Alcon by name Olopatadine for treating Hay fever.

4.4 **Decline in R&D Productivity:** The number of NCEs launched worldwide fell from around 60 a year in late 1980's to a little less than 30 now. However, R&D spending rose in line with sales. The decline in research productivity may be because of several reasons. There is a paradigm shift in the drug discovery and development. Several new technologies have been introduced in the life sciences The genomic revolution epitomized by the sequencing of human genome has given rise to a scenario where individual genes associated with a particular disease are isolated and the proteins they encode, studied as potential drug targets. Compounds are designed to modulate the activities of these proteins. The emergence of genomic and proteomic approach to discovery and validation of novel biochemical targets and meteoric rise of the application of high through put screening (HTS) methodologies in the early phase of drug discovery increased the cost factor and every one predicted the success rate would increase.

4.4.1 Much of the R&D spending goes to clinical trials, the last stage of drug development. A decade ago testing a drug on 1000 patients was enough to

prove its safety and efficacy. Now regulators demand trials on 4000 or more patients and an array of biochemical and clinical tests all of which add to the expense and duration of a trial. As per Cambridge Pharma consultancy, upto 70% of total development cost is taken by drugs that do not even make it to market. For every 10,000 molecules screened in a given programme in the laboratory, only one will make it through to launch.

4.4.2 The concepts of an R&D pipeline was no longer a useful model as products no longer moved down a pipe, but were instead poured into a funnel from which a handful of candidates emerged, as per Dr. Anders Ullman, Chief Scientific Officer at the Swedish firm Biovitrum. In the past, the scarcity of molecules emerging from discovery meant that most entered the formal preclinical, Phase I, II and III pipeline. But such a scarcity is no longer the case. Discovery is now producing an abundance of potential new compounds, which progress together as a group through preclinical and proof of concept trials before selection of a lead compound is made relatively late in the process. It is gathered that the early pipeline is now rich and more failures are happening beyond phase II. The industry should be aiming for drug development times of three to five years by 2010 rather than the current 8-12 years, and in fact many of the techniques that could achieve this have already been developed, as per Dr. John Hall, formerly vice president of global strategic drug development at the CRO Quintiles.

4.4.3 Some companies are restructuring their R&D efforts over the past decade, following growth through a series of mergers. Pfizer reported that research has now been reorganized globally into 11 therapy areas, with single global therapy area leaders, and fully accountable and decision-making project teams within those areas. Centres of excellence in research operations or clinical trials provide their expertise to the project teams, with a clear separation between science and operations. Duplicated efforts have been eradicated with the help of a Microsoft planning and resource management tool, and 24 hour working introduced. Pfizer head of development mentions that cost should not be the only driver for relocating R&D functions to less expensive parts of the world, such as India or China, because in fact costs are rising rapidly in those regions.

4.4.4 GSK was one of the first major Pharma companies to change its R&D organization radically by the creation of Centres of Excellence in Drug Discovery (CEDDs). There were 97 NCEs in development at the end of 2005, compared with 50 in 2001. The new arrangement consists of the CEDDs being set up as small, entrepreneurial units that are individually accountable and incentives, and supported by genetics R&D division on the one side and preclinical development and clinical development on the other.

4.5 **Scenario pertaining to R&D in neglected diseases:** Global forum for health research believes that less than 10% of global spending on health research is devoted to 90% of world's diseases. The changing scenario shows NGO's like MSF, Oxfam becoming very active in health care sector. MSF that won Noble prize sources Anti retrovirals from Pharma companies including those from India and supplies the same to patients in African region. Then there are other international organizations like Global fund to fight AIDS, TB and Malaria set up in 2002 to provide $ 1.5 Billion over 2 years to 93 developing countries.. There is also Global Access for Vaccine Initiative from contribution from leading countries and also sponsored by Bill and Melinda Gates foundation and other similar set ups. One past analysis of drug development outcome over past 25 years showed that only 15 new drugs were indicated for tropical diseases and TB. These diseases primarily affect poor population and account for 12% of Global disease burden. In comparison 179 new drugs were developed for cardiovascular diseases.

4.5.1 In a symposium and workshop organized in conjunction with the official opening of the Novartis institute for Tropical Diseases (NITD) in Singapore sometime back, the presentations concentrated on TB and dengue fever–in line with the institute's research remit- it was also made clear that there are few effective therapies and virtually no new drugs in development for a number of other disorders. Dr. Bernard Pecoul of the non-profit drugs for neglected diseases initiative (DNDi) identified sleeping sickness (trypanosomiasis) and leishmaniasis as particular problems. The DNDi announced a new initiative to register paromonmycin for visceral leishmaniasis in Africa and is looking at new combinations of existing drugs.

4.5.2 While some malaria treatments such as Novartis's Coartem (artemether plus lumefantrine) are being made available at low cost, the infection still causes around a million direct or indirect deaths in African children every year, according to Professor Robert snow of the KEMRI-Wellcome Trust malaria programme in Kenya. The continent accounts for around 90% of fatalities worldwide. Among recent drug related development, clinical trials started in Burkina Faso and Thailand with fixed dose combinations of Artesunate plus either amodiaquine or mefloquine.

4.5.3 One potential novel anti-malarial, Eurartekin (dihydroartemisinin plus piperaquine), from the non profit Medicines for Malaria Venture (MMV) has moved into Phase III trials, and a second, pyronaridine plus artesunate, has entered Phase II, Combining artemisinin or its derivatives with another type of anti-malarial improves its efficacy, and reduces the treatment duration and the likelihood of resistance development.

4.5.4 The institute for One World Help (iOWH) claims to be first non-profit US Pharma company to have licensed a novel class of Azole compounds from Yale University and Washington University for parasitic diseases in developing world. The initial focus will be on Chagas disease. iOWH has also began a 670 patient, phase III trial in India testing Paromomycin in Leishmaniasis (Kala Azar) one of the largest phase III trials ever for a parasitic disease. Subsequently, Drug Controller-General of India has approved the drug Paromomycin Intramuscular (IM) Injection for the treatment of visceral leishmaniasis (VL) or Kala Azar developed and is being manufactured by M/s Gland Pharma Ltd, Hyderabad in India.

Table 4.4. TB Drug Clinical Development Pipeline

Treatment	*Development stage*	*Sponsor / Co-ordinator*
Gatifloxacin	Phase III	European Commission/OFLOTUB consortium, Institute de Recherche pour le Development, WHO TDR , Lupin
Moxifloxacin	Phase II/III	Bayer, Global Alliance for TB drug development, US Centers for Disease Control and Prevention, University College London, Johns Hopkins University
TMC 207 (previously R207910)	Early bacterial activity	J&J (Tibiotec)
OPC-67683	-do-	Otsuka Pharmaceutical
PA-824	Phase I	TB Alliance
LL-3858	Phase I	Lupin

4.5.5 For multinational companies, these projects are definitely non-commercial with expected returns falling well below the benchmark of $500 million per year peak sales. Yet multinationals now account for nearly 50% of these new neglected disease projects, conducting the R&D either alone or, predominantly and increasingly, in public-private partnerships (PPPs). Working in a PPP allows large companies to share the cost of the R&D with their partners. By covering some or all of a company's external project costs, PPP contributions can make neglected disease projects virtually cost neutral to the multinational company.

4.5.6 "Transferable market exclusivity" is an idea the Pharma industry is considering as a solution to the R&D gap in neglected diseases. Pharma R&D is a costly and time consuming process- it is often estimated that it costs $ 1 billion to bring a new product to market. Revenues from products for neglected diseases are always low. Companies therefore, need to be

rewarded to undertake serious research on neglected diseases. Most of the neglected diseases are prevalent in poor countries where the patients cannot pay high prices for the R&D developed products.

4.5.7 Earlier an idea, although a few years old and really only debated in academic circles, was put forward by the International Federation of Pharma Manufacturers Association's 22nd Assembly in Barcelona. This would involve a Pharma company being granted patent extensions to products they market in rich countries, including blockbusters in exchange for conducting R&D on a neglected disease. For e.g. If a company discovered a treatment for leishmaniasis, it would be rewarded by being able to extend marketing exclusivity on any of its other products. To a certain extent, the idea is based on US Orphan Drugs legislation, which gives Pharma companies a marketing exclusivity period for researching treatment for a rare disease. Perhaps it is too radical an idea. At least, there are other options that can be considered as alternatives to the neglected diseases problem including public private partnerships. For e.g. the Medicines for Malaria Venture is working on 20 anti-malarial projects. There are also R&D tax credits, which the UK has brought in, and purchase funds, which help create a market for future medicines.

Table 4.5. List of some Neglected Diseases

Blinding trachoma	Leprosy	Chagas disease
Lymphatic filariasis	Dengue fever	Malaria
Diarrhoreal diseases	Onchocerciasis	Hepatitis E
Schistosomiasis	HIV/AIDS	Hookworm
Trypanosomiasis	Leishmaniasis	TB

4.6 **Mergers & Acquisitions:** In 1990s, in an effort to generate sufficient new products, Pharma companies made some strategic errors through M&A. Under a new report issued by SCRIP regarding relationship between M&A and R&D compares R&D pipelines now and at the time of mergers. Since, 1999 there have been 9 major mergers involving six of the top 10 global Pharma companies.

- Aventis (Rhone Poulenc and Hoechst)
- Pharmacia (Pharmacia and Up John and Monsanto)
- Pfizer / Warner Lambert
- GSK
- Abbott/Knoll
- Johnson & Johnson / ALZA
- BMS & Du Pont

- Roche/Chugai
- Amgen & Immunex

Certainly for the first quarter of 2005, it seems big licensing deals were preserve of Pharma companies calling upon biotech companies, although a few did decide it was more effective to acquire rather than license.

An activity helps to build critical mass, but does not necessarily result in an improvement in market share says a new study. Sanofi-Synthelabo and Aventis, the main protagonists in last year's round of consolidation, secured the number three spot in the Pharma company rankings. But the whole did not prove to be significantly greater than the sum of the individual parts.

4.7 **Cutting down drug discovery costs:** The high cost, high risk and lengthy process of developing new drugs now has to cope with the added twist of information overload. In order to bring a single drug to market anyway between 5000-10000 compounds must be tested in a battery of in-vitro and in-vivo tests to determine their drugability – their viability as a drug from safety and efficacy stand point. Only about 10 of these extensively screened candidates advanced into pre clinical studies per year per company. There is more than 90% failure rate. The entire process takes 10 to 15 years. Considering patent protection for 20 years, a company can expect to enjoy the revenue from a new drug for only 5 to 7 years before loss of patent protection. Revenue from one drug has to support the failure candidates. Over past 10 years R&D productivity has declined.

4.7.1 One of the reasons is FDA has raised the bar for the approval of drugs. This has limited the development of "Me too" drugs, at the same time increasing the amount of efficacy and safety data demanded from companies for novel drugs. The advances in genomics and tools have brought about increase in the number of new genes identified.

4.7.2 The widespread introduction of combinatorial chemistry rapidly led to availability of millions of novel compounds. Now researches have plenty of targets, a huge number of compounds and the ability to screen huge number of drug candidates in HTS assays. However, the success rate of drug discovery has not gone up. Advances in technology and automation combined with this shift in drug discovery are changing the coinage of drug discovery towards assay development, target validation and ADMET (Absorption, Distribution, Metabolism, Excretion and Toxicity) testing. Today's drug discovery labs are using a range of simple to complex assays at varying throughput requirements and for many extremely diverse usages.

4.7.3 The respected Tufts centre for study of drug development indicated that the total cost for approved drug could be slashed by $ 221-242 million if discovery programmes boosted their success rates from the current 1 in 5 agents to 1 in 3. This figure was calculated from cost involved in 68 randomly selected new drugs tested by 10 companies in humans during 1983–1994. Overall cost of R&D increased 2.5 times in the last decade. By adopting following strategies, cost can be reduced.

- Shifting 5% of all clinical failures from Phase III/Regulatory review to Phase I and
- Cutting development and regulatory review time by 25%.

4.7.4 Several factors like increasing complexity of products, increased expectations from regulatory bodies have affected success of clinical programmes. Mergers have not brought the anticipated success. GW and SKB were working on 400 new drug targets now reduced to 100 after merger (GSK). Some of the new companies are opting to buy in products without companies that developed them, licensing in products; especially smaller companies like Shire Pharma is mainly focusing on low risk development such as reformulating drugs and developing new indications for existing products. Big companies like Roche are concentrating on their own specialization like Oncology, anti-viral, transplantation. The R&D Director of Shire claimed that US $ 800 Million estimated by Tufts for drug development is based on R&D cost of $ 150 –200 Million. **The remaining 600 Million is the cost of failure.**

4.7.5 Genomics, proteomics, metabonomics and the like have already provided Pharma with plenty of new biological targets, but scientists currently know very little about which targets are relevant or which diseases they are associated with. The immediate promise of the molecular sciences is not that they will generate a stream of new drugs. Rather, they are changing the way in which scientists look at disease. Several companies-including Amgen, Celltech and Cambridge Antibody Technology – are in fact already using a disease-centric, biological approach to discover drugs for life threatening conditions like cancer, with dramatic results. They are defining different disease states very precisely and using genomics-based techniques to identity novel targets. They are then validating those targets using biological molecules, thus cutting validation cycles to about two years.

4.8 **Drug Delivery:** The drug delivery industry has dramatically changed in the past three years. Nektar, SkyePharma, Eurand and Alkermes are some of the drug delivery companies.

Table 4.6: Drug Delivery Market

Formulation Type	***No. in 1999***	***No. in 2003***
Inhalable	60	99
Modified release	155	209
Optimized	78	110
Oral enhanced	94	134
Parentral	50	76
Transdermal	154	167
Mucosal	64	102
Miscellaneous	189	235

The market may see profitable drug delivery companies using their proven technologies marketing products on their own account.

4.8.1 Of the two Drug delivery Industry leaders - ALZA and ELAN, today ALZA is a division within Johnson. Both moved away from drug delivery. One of the new technologies (NASTECH Pharma) is *transnasal absorption for small molecules* allowing drugs that were injected or in tablet form to be administered nasally. A more new version is used for large molecules like Alpha Interferon, Human Growth Hormone. By attaching PEG strands to a molecule, that molecule is both slowed and protected. The small polymers can help the drug cross the gut bio barriers. Large protein drugs for injection delivery are now modified with long chain PEG to improve their solubility, slowed clearance.

4.8.2 Many novel drug delivery systems are needed so that more percentage of the drug can reach the tumor. There is an ongoing work with Paclitaxel, an anti cancer drug, where existing method allows only 1% of the drug reaching the tumor. The new method will deliver 12 to 15 times more drug to the tumor by binding the drug to a polymer, polyglutemate. Similarly an advanced project is beginning phase I trials involving a novel form of Gabapentin. New methods are being used for protein delivery. As per various developments reported, the future of global health care suggests that drug delivery can play a critical role in the present scenario where R&D pipeline has dried up and patient compliance is becoming a bigger problem.

4.8.3 Driven by the aim for new device features and enhanced performance, pulmonary inhalation devices are becoming complex. There is Direct Haler device for use in children. There is need for efficient means of delivering API to the target and Direct Haler is easy to use. There are dry powder formulation based inhalers as well. In the new developments this technology of dry powders with improved delivery uniformity has been applied to a wide range of compounds from companies like VECTURA. The difficult to promote pre filled syringes (PFS) a decade ago, are now being

marketed widely specially in countries like US & Europe. This is becoming an appropriate way of presenting wide range of injectables. Specially, biotech drugs are being promoted by PFS in US market. The advantages are painless injection at low cost & accurate drug delivery. Nano-edge drug delivery has been introduced to solve the problems of injectable drugs specially drugs like carbamazepine, dexamethasone, Bupivacaine.

4.8.4 The most important factor in drug delivery is that the drug reaches its therapeutic target in vivo. There is another technology – Atrigel Depot technology where the delivery covers various bulk drugs and provides drug delivery over days to months with a single injection. The biotech products present challenging delivery problems and here the drug delivery companies have to take up new technologies to come up with suitable products.

4.9 **Outsourcing:** The year 2005 has been a good year for the contract services industry, and 2006 promises to be nearly as successful, according to the 2005 Pharma Source–Pharma Technology outsourcing survey. Nearly 50% of the 193 Pharmaceutical company survey respondents expect that their 2005 outsourcing spending will increase by 10% or more, compared with 2004 expenditures. Sixteen percent of respondents anticipate their spending will increase by 20% or more. Perhaps the survey's most surprising result is the low expectation for offshore outsourcing. Overall 53% of respondents indicate they have no current interest in outsourcing to India or China.

4.9.1 Pharma companies are under constant pressure to innovate, comply with myriad of regulations, and meet the demands of quality standards- all while delivering as much profitability as possible. Challenges are escalating. Investors are accustomed to double digit growth, which is a goal Pharma company will be hard pressed to achieve as patents expire, blockbuster launches decline, and large customers, especially government, step up pricing pressures on the industry.

4.9.2 At the same time, compliance with stricter regulatory requirements is lengthening the time to launch a drug into the market place. The average number of clinical trials per new drug application has more than doubled in the past 30 years, and the average number of patients participating in clinical trials has increased two and half times during the same period. R&D costs also are rising. In fact, the cost of bringing a new drug to market has more than doubled in the past decade and has now approached US $1 billion. The Pharma industry's general and administrative costs are high as well – at 28% of revenue, based on A.T. Kearney's analysis of the top 10 Pharmaceutical companies 10K submissions. It's inevitable that global outsourcing will become a part of the answer as it has in other industries.

4.9.3 Until recently, however, Pharma companies were reluctant to outsource beyond the US and Europe, in part because of concerns about intellectual property protection, demands for regulatory compliance, worries about political stability and business continuity. Potential benefits of global outsourcing are difficult to be ignored. A.T. Kearney analysis indicates that if growth and pricing pressures maintain their current trajectory, by 2008 the US Pharma industry will face a US $48 billion gap between investor expectations and estimated revenue.

4.9.4 If companies can shorten today's long lead times for drug development by handing off tasks to third parties that can perform them more quickly because of fewer constraints or additional resources, they will find themselves in an advantageous position. For example, companies conducting clinical trials in India and China can take advantage of a large population base and a diverse pool of currently untreated patients, which are two factors that can accelerate clinical trials.

4.9.5 Global outsourcing also can enhance the quality of and access to talent. Many firms are tapping into India's pool of scientists, who have solid capabilities and strong expertise. AstraZeneca, for example built a research facility in Bangalore that focuses on TB. As per CEO of AstraZeneca, Bangalore is definitely not based on cost, because the cost of doing research is mainly a small part of the total global R&D efforts. The only reason for opting for India is the quality of scientists.

4.9.6 Of course, the savings are compelling. The costs of direct and indirect personnel, depreciation costs, and material are roughly 40% lower in countries such as China and India. One example is clinical trial costs. ClinTec International, a privately owned full service contract research organization with headquarters in Germany, for example, reports that recruiting 200 patients in the United States for a one year study would take approximately 30 months. ClinTec claims this time can be cut in half by recruiting patients in India. The time required for data analysis also can be significantly shorter, from 6-10 weeks in India versus nearly four months in the US. According to the company, the estimated cost savings may reach 50%-60% compared with the costs of conducting the trials in the US.

4.9.7 Lower costs are a result of lower wages of key personnel involved in conducting clinical trials and data monitoring (e.g. clinical research assistants, project management, clinical data management and biostatisticians) and lower investigator grants (i.e. payments to physicians for their expertise and time in monitoring clinical trial patients). For instance, by partnering with a local Pharmaceutical company for selected drug

discovery efforts, companies can minimize capital investment associated with setting up their own R&D facilities in offshore locations.

4.9.8 The top 10 Pharma companies are estimated to spend approximately US $127 billion on general and administrative functions, of which about US $50 billion could be targeted for global outsourcing. Assuming one third to one half of this spending is outsourced over the next 5-10 years and conservative savings estimates of 30% this amount translates into US $5-8 billion in annual cost reduction.

4.9.9 Many of the most troublesome issues are beginning to be addressed. New legislation on intellectual property protection in India, for example, brings the country's intellectual property laws in line with those of the international community in accordance with the WTO. In China, for example the intellectual property situation is subject to interpretation.

4.9.10 For instance, one-fifth of Fortune 500 companies already have R&D facilities in India. India is getting the Lion's share of attention as an offshore destination and is at the center of the Pharmaceutical off shoring activity in emerging markets. China is beginning to gain a foothold in the Pharmaceutical space as well.

4.10 **Government Initiatives for Pharma R&D in Developed Countries:** Several countries including Canada, France and the UK have introduced specific tax relief for research-intensive small and medium sized enterprises. For every Euro 100 spent on R&D by a loss making company with an R&D budget of around Euro 1 million a year, there is tax relief worth Euro 30 in Canada, Euro 25 in France and Euro 24 in the UK. There is also tax relief for profitable companies investing around Euro 500,000 in R&D annually. In Canada, these companies get Euro 29 in tax relief for every Euro 100 spent on R&D; Danish companies get Euro 15, French companies Euro 68 and UK companies Euro 9.5. Other countries with R&D tax incentives include Japan, Hungary (100-300% deductions for R&D spending), Australia, Norway and Belgium (tax credits for firms collaborating with universities).

4.10.1 Australia has Pharma Industry Investment Programme (PIIP), which commenced during July 1999. Participating firms are paid subsidies for eligible R&D and production value added that exceeds prescribed base levels – the programme is designed to reward only incremental activity. A fixed base applies to R&D and moving base is used for value added. The subsidy rate is 20% over a three-year period ending 2001-02 the programme had paid subsidy of $ 140 million to participants.

4.11 **SINGAPORE MODEL (BIOPOLIS):** The Economic Development Board (EDB) is Singapore's lead agency responsible for planning and executing strategies to sustain Singapore's position as a compelling global hub for business and investment. Singapore's achievements in the Biomedical Sciences (BMS) industry include being home to six of the world's top 10 Pharmaceutical companies' manufacturing facilities. As one of the key strategic manufacturing sites of the BMS industry, Singapore currently hosts six of the top ten Pharma conglomerates, key industry players and a growing base of medical technology companies within Tuas Biomedical Park, a 183-hectare BMS-dedicated site slated for expansion to double its current capacity due to increasing industry demand.

4.11.1 Singapore also features a dedicated R&D complex, the Biopolis, which is home to five biomedical public research institutions and labs from the Agency of Science Technology and Research. The Biopolis offers a "plug and play" infrastructure for Pharma and biotech companies to share scientific facilities and services, facilitating cross-disciplinary research and public-private collaborations for the advancement of the field. Novartis established a new tropical diseases research center in Singapore involving a SGD 220 million investment through an agreement between Novartis and the Singapore Economic Development Board (EDB). Apart from Novartis John Hopkins, Singapore Institute of Molecular and Self biology, Institute of Bio Engineering and Nanotechnology are part of Biopolis. It is said that Biopolis will create knowledge intensive jobs with some 2000 research scientists both private and public research outfits working there. This will result in skilled jobs and high value economic activity.

4.12 **Indian Pharmaceutical Industry – Overview:** The Indian Pharma Industry today is worth over Rs. 35,000 Crores in retail sales in domestic market. The country ranks 4th worldwide accounting for 8% of world’s production by volume and 1.5% by value. The larger Pharma units number around 300 in addition to 6000 Small & Medium Enterprises (SMEs).

4.12.1. As per McKinsey & Co. by 2010, the Indian market will be US$ 25 billion. Out of this US$ 11 billion could be domestic market. Generic opportunity could be $ 5-6 billion. There will be new horizons like services, R&D for a value of $ 5-7 billions. A historic development indicating global presence of Indian Pharma companies is about former US President Bill Clinton announcing an agreement with world generic drug manufacturers on a major reduction in the price of AIDS medicines. Many Indian companies are part of this agreement where the products Lamivudine, Stavudine, Zidovudine, Nevirapine will be supplied to Mozambique, Rwanda, South

Africa and Tanzania which have about 33% of all people living with AIDS in Africa and in 9 countries and 3 territories that account for over 90% of people with AIDS in Caribbean. Now the US PEPFAR Scheme of President Bush will also be sourcing Anti Retrovirals from Indian companies whose products have already been approved by US FDA.

4.12.2 Many Indian companies maintain highest standards in Purity, Stability and International SHE requirements namely Safety, Health and Environmental protection in production and supply APIs to MNCs as well as leading generic companies of the world like Teva, Apotex, Ivax, Watson. Keeping in view the highest standards set up by Indian companies like Shasun drugs, the original innovator MNCs like Boots, GSK, Eli Lilly source APIs like Ibuprofen, Ranitidine, Nizatidine and Naproxene from Indian companies.

4.12.3 The country ranks 17th in terms of export value of bulk actives and dosage forms. Indian exports are destined to more than 200 countries around the globe. Excellent performance on the export front with exports touching Rs. 21600 crores (Near to $5 Billion) was observed during 2005–06. The noteworthy feature is, as usual, US being largest importer of Indian Pharmaceuticals amounting to Rs. 30 billion ($ 700 Million). Other major export destinations are Germany, Russia, Canada, UK, China PR, Brazil, Mexico., Spain, Ireland, Netherlands and Japan which are highly regulated markets. More of Indian Companies are now seeking ANDAs (Abbreviated New Drug Approval) in USA in specialized segments like Anti-infectives, Cardio-vasculars, CNS (Central Nervous System) group. Leading Indian Pharma companies derive 50% of their turnover from International business.

4.12.4 In addition to having WHO GMP, more of Indian companies have also been getting international regulatory approvals for their plants from agencies like USFDA, MCA - UK, TGA-Australia and MCC-South Africa. India is second after USA in having more number of USFDA approved plants for generic manufacture. Many Indian companies are acquiring generic companies in USA, UK and Germany and are also tying up with Western companies for marketing of products.

4.13 **Indian R&D Scenario:** While discussing the Indian Pharma Industry and its compulsions to grow to global dimensions and reaching out to global markets, it is often emphasized that it has to move to become an R&D-based industrial segment. The face of the Indian industry needs to change, if it is to survive and grow and that growth has to come not merely by being a

supplier of generic (off-patent) products, but also from new patented products developed through Indian R&D efforts.

4.13.1 At least 10-12 leading Indian Pharma companies are now into new drug discovery and some of them have increased their R&D spending by over 6% of their turnover compared to 2% earlier. Ranbaxy topped in terms of R&D expenditure at Rs. 400 crores. Dr. Reddy's Labs was second with Rs. 300 crores R&D expenditure during 2004-2005. There were 9 Pharma companies whose annual R&D expenditure was more than Rs. 50 crores.

4.13.2 Asthma, Anti infectives, Anti Cancer and Diabetic segments are the areas targetted for discovery of NCEs. Besides NCEs Some Indian companies are also carrying out work on Chiral molecules, new drug delivery Systems, Dosage development, process development etc. With the introduction of product patents for Pharma, Indian companies have to shift the area of focus from process development to developing new products in collaboration with Western Pharma companies to make a beginning.

4.13.3 The country has been able to develop cost effective, non infringing processes for some of the latest patented medicines covering Anti infectives like Moxifloxacin, Gatifloxacin, Imipenam, Cilastatin, Cephalosporins like Ceftriaxone, Cefuroxime Axetil, Cefpodoxime, Ceftibuten, Cefprozil, Cardiovasculars like Quietiapine, Ramipril, Candesartan, Losartan, Irbesartan, Doxazosin, Clopidogrel, Obesity related drugs like Sibutramine, Atorvastatin, Pravastatin, Fluvastatin, Ezetimibe, Anti depressants like Paroxetine, Aripiprazole, Venlafaxin, Mirtazepine, Qutiapine, Risperidone, Sertraline, Zolpidem, Citalopram, Anti Cancers like Paclitaxel, Docetaxel, Irinotecan, Topotecan, Imatinib, Anti fungals like Itraconazole and more important Anti retrovirals like Stavudine, Nevirapine, Nelfinavir, Saquinavir, Efavirenz, Didanosine, Abacavir, Zamvir, Anti diabetics like Glimiperide, Rapaglinide, Nateglinide and many more. These bulk actives are supplied to countries where these are not patented and then to USA for R & D related work. R&D can be carried out in India at a fraction of equivalent cost in Europe or USA. On a Dollar basis, the cost advantage is estimated to be 10-15 times. Many western Contract Research Organizations (CRO) feel that India is important destination for contract research and clinical trials.

4.13.4 At the beginning, the Pharma R&D work pursued by leading companies was mainly focused on development of generics in regulated markets like Europe and USA.The innovative chemistry driven process research leading to non infringing processes for APIs and then identification and characterization of impurity profiling pertaining to APIs are some of the R&D areas. On APIs, the research by the Indian companies relates to non-infringing process, reducing impurity levels and introducing cost effective

routes. The other area of R&D pertains to formulations where Novel Drug Delivery System based products are introduced. Another area pertaining to research is ANDA work prior to registering products in EU, USA and other developing countries.

4.13.5 The Indian new drug discovery started in 1994 with Dr. K. Anji Reddy of DRL, earlier working in IDPL, setting up the first new drug lab at Hyderabad as a distinct facility. At the moment, there are at least 10-12 Indian Pharma companies that are working on developing new drugs. An estimated 60 new compounds are in various phases of development and testing. These are very small compared to world standards where companies like GSK & Pfizer having about 143 and 14 new compounds respectively, under development. Ranbaxy, Glenmark, Wockhardt and Dr. Reddy's Labs are at the forefront having compounds in advanced stages of clinical testing. Ranbaxy is testing its anti malarial, Glenmark has a potential new asthma cure and Wockhardt has a new generation broad-spectrum antibiotic in the works. These developments give a Philip to India as Indian companies were always being projected as mere copycats to original drugs.

4.13.6 DRL's original idea was to take up work on cancer drugs and antibiotics. Keeping in view the work going on at that time on Glitazones for treating diabetes, DRL also took up work in this area. Many of these failed at pre clinical stage and some failed in Phase II of human testing. Then the company adopted out licensing strategy where a promising compound is licensed to MNC to carry rest of the development. DRL worked out a deal with Novo Nordisk but the compounds failed to clear toxicity test. In case of Balaglitazone DRL is collaborating with Denmark's Rheo sciences. The other company Ranbaxy also tried to develop new compounds in the area BPH which failed in early stages Now companies like Torrent, Lupin, Sun Pharma, Zydus Cadila and several others have got into original drug research. The main success in drug delivery happens to be the development of new drug delivery based platform once a day Ciprofloxacin by Ranbaxy for originator company Bayer that has subsequently commercialized it

Table 4.7. Some Promising Candidates

Company	***Molecule***	***Phase***	***Indication***
Ranbaxy	RBX11160	Phase II	Malaria
Dr. Reddy's Labs	DRF 10945	Phase II	Obesity
Dr. Reddy's Labs	DRF 1042	Phase II	Cancer
Glenmark	GRC 8200	Phase I	Diabetes
Wockhardt	WCK 771	Early phase	Infection

4.14 **Strategies adopted by Indian companies:** It is a fact that no Indian company has the resources to pursue the cutting edge research and take a new compound through all stages upto marketing. While costs of conducting research in India are lower compared to West because of low cost scientific manpower, the Western companies always mention that India is weak in early stage of drug discovery. Many Indian companies are pursuing strategies to lower their costs and risk factors. Strategy pursued is to find a new drug within an existing family that has been discovered - finding a compound that is analogous to a discovered compound like DRL where originally Sankyo was doing work on Glitazones. This strategy cuts down on the risk. A company can reduce some of the uncertainties of new drug research though this strategy may not produce a drug as big as a blockbuster. It is also a chance that a 2nd or 3rd drug in this known family may result in a better drug. Japanese drug companies used this strategy successfully in new drug development.

4.14.1 The 2nd strategy is out licensing strategy where the Indian company takes some leads to pre clinical stage. Then it may strike a deal with MNC who will have the right to market the compound in a particular market if all tests are cleared. The Indian company gets Milestone Payments for each stage of clinical trials the compound clears. The interests of MNCs in the out licensing route is because of the high levels of failure in the new drug discovery where to introduce one new drug one needs to start with thousands of compounds.

4.14.2 Indian companies like Ranbaxy, DRL and Glenmark are all following the out licensing route. The case of Glenmark into new drug discovery is unique as it is a medium sized family run Pharma Company. However, new drug research laboratory was commissioned and the company started focusing on a number of targets. A promising molecule from the company from the family of PDE 4 inhibitors code name GRC 3886 (Oglemilast) has shown promising results against Asthma. The company entered into a deal with US based Forest labs for further development on this compound for the North American market. Glenmark licensed the same molecule to Teizen Pharma, a Japanese drug company and in both cases Glenmark received considerable milestone payments. Similarly Indian company Wockhardt has also a promising compound belonging to Fluoroquinolone group used for infections. Ranbaxy is working among other compounds on a synthetic anti malarial compound. Then there is Orchid Pharma, which has also various compounds catering to anti obesity and other areas. Indian company Dabur

Pharma is entirely concentrating on anti cancers. One of their lead molecules which are funded by Government's DPRP programme is moving into Phase III clinical trials for the treatment of cervical cancer.

Table 4.8. Category of diseases Indian Pharma companies are working on.

Company	Categories worked on
Dr. Reddy's Labs	Cardiovascular diseases, Infections, Diabetes and Cancer,
Ranbaxy	Infectious, Respiratory, Urinary diseases and Diabetes.
Orchid	Inflammatory and infectious diseases, Cancer and Diabetes
Glenmark	Respiratory and Inflammatory diseases, Diabetes and Obesity.
Zydus Cadila	Diabetes, Inflammation, Obesity, Novel Drug Delivery
Nicholas Piramal	Inflammation and Diabetes
Dabur	Oncology
Torrent Pharma	Obesity, CVD
Wockhardt	Infections
Sun Pharma	Areas not given

4.14.3 As already stated the new drug discovery is a very costly affair and more so for the Indian Pharma companies. That is why very few companies are able to take up this activity as the funds for the new drug discovery has to come up from the company's sales realization. So some new models are being attempted by the Indian companies to reduce the risks from new drug discovery. One model is taking up new drug R&D set up as a standalone commercial organization freed from the controls of parent company. The R&D set up will raise resources, conduct research and pursue partitions and the parent company reduces its own risks. Sun Pharma is adopting this strategy. To help mitigate the risks faced by companies in research initiatives and in patent litigation unique type of deals between Pharma companies and financial institutions is taking place. DRL has formalized $ 56 million (Rs. 245 crores) agreement with ICICI venture funds management company for the development and commercialization of generic drugs filed in US in 2004-05 and 2005-06. The fund will be towards development, registration and legal costs related to ANDAs.

4.14.4 DRL has formed a separate integrated drug development company, Perlecan Pharma, with equity capital financing from Citigroup Venture Capital international Growth Partnership Mauritius and ICICI Venture Funds Management Company. Perlecan Pharma will be engaged in developing and licensing out new chemical entities.To start with DRL is transferring all rights, including development and commercialization to four NCEs which are in preclinical to late Phase 1 studies, to Perlecan. It will also provide support services, supplying clinical development and commercial quantities to

Perlecan. Perlecan will be managed by an independent board and an executive management team.

4.15 **Contract Research:** There are significant opportunities for India in Pharma research, process development, clinical trials and protein manufacturing. About a third of total R&D investment by the global Pharma industry, estimated at $40-50 billion, could be made in India over the next 10 years, if ambitions are fostered properly, barriers are cleared and Government regulations and the climate are conducive. As per Tufts University studies, globally R&D costs have shot up tremendously without attendant benefits of introduction of more safe drugs in the market. R&D can be carried out in India at a fraction of equivalent cost in Europe or USA.

4.15.1 As per consultancy firm Frost & Sullivan global Pharma R&D outsourcing market is estimated to touch $ 25 billion by 2007. Ever increasing R&D costs are compelling Pharma companies to outsource to regions like India, China. Most Pharma companies are uncomfortable about outsourcing large parts of their R&D, manufacturing and sales to a single provider. There is a paucity of drugs in the industry's late stage pipeline. According to Pharma projects data base, total number in the pipeline is now at an all time high of 6994 but 80% of these potential new products are still in early clinical development. GSK and Novartis have rationalized their manufacturing base by creating global network with small number of external contractors using common standards, management processes and operating procedures.

4.15.2 The advent of targeted treatment will alter the development process itself promising new drugs will ultimately be tested first in man during late stage discovery, tested again in phase II trials and submitted to regulators for conditional approval. CROs can maintain communities of investigators, managing the relationship with patients and collecting genetic data. CROs will be able to provide independent support services for Doctors and patients after launch of a product. Patient monitoring is possible and with mobile communication it is easier to collect clinical data outside the laboratory.

4.15.3 With pressure growing to achieve more demanding development milestones quickly, while controlling R&D expenses and meeting shareholder expectations, biotechs are increasingly finding the capability and expertise of CROs invaluable, not just in conducting their R&D programmes but in designing and managing their compound's drug development. Recent trends towards strategic outsourcing seem to indicate

that entire departments, covering multiple functions are being contracted out to CROs with a view to achieving better efficiency and value overall. Firstly, as the numbers of potential targets for biotech's have proliferated with the advent of genomics and proteomics, CROs can help alleviate the well documented bottlenecks that have arisen in drug discovery, with specialized technology platforms and speedy access to laboratory or clinic space.

4.16 **New Opportunities:** One estimate puts the current R&D expenditure of the Indian Pharmaceutical industry is around $ 74 million (0.003% of global R&D) and the spending by the largest Indian company on R&D is around $ 17 million (0.006% of the largest R&D spending by an MNC). Under such a scenario, Indian companies have to develop their own model for their R&D efforts, India is emerging as the most favored destinations for collaborative R&D bio informatics, contract research and manufacturing and clinical research as a result of growing compliance with internationally harmonized standards such as Good Laboratory Practices (GLP), current Good Manufacturing Practices (cGMP) and Good Clinical Practices (GCP).With the application of product patents in the case of Pharmaceuticals it is imperative for the Indian industry to accelerate its efforts in R&D in this sector. The present level of spend on R&D (about 5% turnover) is much lower compared to most of the developed countries (15 to 20%).

4.16.1 The strategic options available to the Indian Pharma companies are**:**

1. Collaboration with large R&D-based MNCs either for co-development or through the licensing route
2. Work on existing molecules with proven market by developing chiral molecules of racemates currently marketed, or through new formulations of existing drugs with beneficial characteristics of increased efficacy and safety;
3. Identify through clinical trials newer indications for marketed drugs;
4. Develop scientifically validated traditional medicines acceptable to global markets;
5. All these approaches require not only multiple, but special skills on the part of the Indian companies. Among these various approaches the one which holds great promise and potential is the development of chiral molecules of existing racemates.

4.17 **Chiral Molecules-Opportunities for Indian Companies:** India is very strong in Process chemistry and therefore it is not clear as to why we are unable to come up with notable chiral products. In fact here a tie up could be possible with MNC Pharma because the patented molecule is under threat

once patent expires and therefore they are all looking for extension of patents through new variations. It is possible that once a pure chiral form is available, it may have a totally different Pharmacological and therapeutic profile. The highly toxic, banned drug, Thalidomide, which led to several thousand mal-formed babies, bounced back as an anti-cancer drug in a chiral version. Now, we have Esomeprazole, Esloratidine, Escitalopram. Indian companies are also producing these chiral molecules.

4.17.1 Considering the potential for developing new and improved products from existing drugs at much lower costs, compared to discovery and development of new molecular entities, development of chiral molecules is an attractive proposition for Indian companies. While we have, adequate technology strengths in synthesis, clinical trials and drug approvals by regulatory agencies are a crucial factor. Indian Companies have to iget into selves in the development of new chiral products based on existing drugs. The advantage is that developmental proces would be shorter and less expensive. Indian patent laws have to come up with special fast track provisions for chiral drugs for off-patent drugs developed by Indian companies.

4.18 **Contract Discovery Research (CDR):** Globally new drug discovery has become costly affair. Indian outfits like GVK Biosciences, Avra Labs, Sai Life sciences are exploiting outsourcing opportunities in drug discovery services focusing on areas like medicinal chemistry, molecular Biology, Product Chemistry, Regulatory Studies, Chiral Chemistry and their clients include MNC Pharma companies. International drug discovery service companies like Albany Molecular Research Inc. (AMRI) has set up its operations in Hyderabad. Other companies like Evolva and Nectar are also setting up their presence in India. The recent full time equivalent R&D centre deal of GVK Biosciences with Wyeth Pharma is an example where big Pharma in an attempt to reduce R&D costs is an ally of Indian companies. This is an attempt where an economic alternative is being offered to big Pharma companies by Indian set-ups in discovery research. All this is happening because Indian companies have begun to establish their credibility in the area of protecting IPR. By some estimates, global R&D spends may touch $ 100 billion by 2012, which will be around 10% of Pharma market that time. If outsourcing is done from Indian companies, the share can be 1-3% of the figure which could be between $ 1 billion- 3 billion.

4.19 **MNC Collaborations:** MNCs present in India in the earlier 90s like Hoechst (now, Sanofi Aventis) which was wound up.UK based AstraZeneca set up a new R&D centre in Bangalore and conducts work on TB drugs.

German Company Altana Pharma also set up drug discovery lab in Mumbai and will focus on drugs for GI and respiratory diseases. Eisai of Japan and Ethy Pharma of France have put up wholly owned subsidiaries for R&D in India. Eli Lilly's has a tie up with Jubiliant in drug discovery and also DRL has a collaborative discovery set up Aurigene which works with international companies like Denmark's Rheo sciences. MNC Pharma companies are tying up with leading Indian research institutes like IICT, Hyderabad, Indian Institute of Science, Bangalore and National Chemical Laboratory, Pune.

4.19.1 The MNCs are exploiting India's potential drug discovery base through opening independent R&D labs in India or partnering with independent Indian drug discovery services companies and research institutes. Hyderabad based GVK Biosciences started with Bioinformatics and then started providing medicinal chemistry services. They are planning in future to begin collaborative research programme where they can partner with virtual companies not having any fixed assets. Virtual companies work with specialists service providers and sell off the molecule whenever they get optimum price. The following are the discovery services in India:

Table 4.9. Discovery Services in India

Company	Area of work	No. of scientists
Avra Labs, Hyderabad	Product chemistry, Organic synthesis, Chiral synthesis and technology.	220
Bhairavi Labs, Bangalore	Medicinal chemistry services, Custom synthesis and Drug discovery services	10
Bio-arc Research Solutions, Vadodra	Medicinal chemistry, Custom synthesis, Custom research and manufacturing (CRAM).	180
Innovasynth, Mumbai	Medicinal chemistry services, Custom synthesis, CRAM	100
Procitius Research, Chennai	Medicinal chemistry services, Custom synthesis, Biology services, Clinical trials and CRAM	80
Reliance Lifesciences, Mumbai	Molecular biology and Clinical trials	200
Sai Lifesciences, Hyderabad	Medicinal chemistry services, scale up services	100
Shasun Chemicals, Chennai	CRAM organic chemistry, Medicinal chemistry, Custom synthesis	70
Suven lifesciences, Hyderabad	CRAM discovery services, BA/BE studies, Clinical trials and collaborative research	180

4.19.2 There are lesser-known parts of outsourcing R&D services in the process of drug discovery. The lab work in drug discovery takes upto six years involving screening thousands of molecules and putting them through various tests to identify indications upto the time molecule is ready to move into clinical trials. After screening lead identification through combinatorial chemistry, biotechnology, Pharmacology profiling, compounds showing activity are identified. Lead optimization comes with testing compounds for toxicity and their activities in human body and then lead is developed through pre clinical studies– GLP toxicology, safety Pharmacology and screen up chemistry. The animal studies and development of chemistry process comes followed by human trials – phase 1 (20 healthy volunteers), Phase II (500-600 people with that indication) and Phase III (over 5000 volunteers).

4.19.3 India's competitors are China, Brazil and Eastern Europe and next wave of growth for Indian Pharma can come in discovery research outsourcing. With the cost of research going up big Pharma units have to look for cutting down costs. Syngene, Bangalore promoted by Biocon is one of the earlier companies which entered this field of providing services to MNC clients from 1994 offering chemistry `and biology services. They have already completed 300 projects with MNCs. The major areas of work are product chemistry, Organic synthesis, medicinal chemistry services, CRAM, discovery services, BA/BE studies, biology services and clinical trials.

4.19.4 One of the advantages of outsourcing to India is the abundant data management skills available as lot of data is involved in the whole process. Another big difference is unlike generics, in case of discovery services the big Pharma desperate to reduce costs are teaming up with Indian companies. One of the India's strengths is medicinal chemistry. The cost of hiring medicinal chemist in US per year is roughly $ 2.5-3 Lakhs. A company likes Pfizer employees at least 1200 chemists. On a conservative estimate an Indian medicinal chemist can be hired at Rs. 10 Lakhs per annum ($ 20,000). With the product patent in place, now global Pharma companies are willing to share sensitive data with Indian companies which is an encouraging development.

4.20 **Clinical Trials:** Developing a herbal drug for migraine is an example where leading Indian companies by themselves are also conducting clinical trials in India due to availability of upgraded infrastructural facilities. The country becoming a hub for clinical trials is reflected from the fact that MNCs like Pfizer, Johnson & Johnson, GSK, Merck, Eli Lilly, Novartis and Novo Nordisk are using India as a base for running their phase II and Phase III clinical trials. Quintiles, the international CRO has set up its shop to conduct clinical trials, ECG services, data management etc. Icon clinical, Pharma-

olam are other foreign clinical research organizations working in India. CVD and Diabetes gives a good idea of both the need for medical care in India as well as the scope and challenge of running clinical trials.

4.20.1 It was found that approx. 2% of 12,000 people surveyed in Indian villages were diabetic and many of them did not know. This implies that there are at least 20 million diabetics in India which is the highest reported number anywhere in the world. Regarding clinical trials industry, in the medium to long-term strategy no major drug research company can afford to ignore India. The CRO and support industries are also growing. Many of these started running bioequivalence studies for Indian companies and have grown into Phase II- IV market for local and international companies. The ICH guidelines and GCP guidelines are being adopted now.

4.20.2 The ICMR guidelines for bio medical research in humans and the Indian GCP Guide has been released. Most teaching hospitals have ethics committees. However, the MNCs find IPR as a serious issue hindering clinical trials. The advantage of conducting CT in India is its vast and ethnically diverse population. The disadvantages projected are involvement of different bodies, inadequate infrastructure. Ernst and Young estimated that in most cases there is 20-30% time advantage in carrying out phase III study in India compared to US or EU with high number of patients with lifestyle diseases, tropical diseases and those who are treatment naïve, Recruitment rates are made even faster by having many large urban hospitals. In the eagerness to get good quality medical care, there are few drop outs in the patients. Quintiles started operations in India in clinical trial data management. As per them, trials in India are 50-70% less of US costs. The US costs is $ 1-20 million per drug. India can be a leader in clinical data related work. In India 15 companies are conducting about 90 trials on 13000 patients in the areas of CVD, Cancer, Diabetes, psychiatric, infections. US majors are skeptical on the quality and reliability of work done in India.

4.20.3 As per Dr. Arun Bhatt, President, ClinInvent Research Pvt. Ltd., which is part of Chatterjee group indicated that there is shortage of manpower about 500 to 1000 investigators who are medical professionals. There is a shortage of bio analytical scientists, Pharmacokinetic experts. This is also confirmed by Dr. Swati Piramal of Nicholas Piramal which has a CRO by name Wellquest. Estimates from Industry put the Indian CT market at $ 100 million with the prospect of touching $ 300 million by 2010 for which there is a shortage of personal. Maharashtra has started biotech commission at KEM Hospital to train people. There are reputed institutions

for training such as Academy for Excellence and Institute for Clinical research etc.

4.20.4 For India to establish itself as a centre for global clinical research it needs to develop a registry for clinical trials and organize the country's huge patient population base. Indian Society of Clinical Research (ISCR) is a newly formed body to help the clinical research industry in India to grow. It says a registry could serve several purposes, including ICMR helping patient's access investigational products for their ailments.

4.21 **GLP & GCP:** Good Laboratory Practices (GLP), Good Clinical Practices (GCP) are the buzz words now-a-days. India is also not lagging behind in adopting the principles of GLP etc. Already national GLP compliance monitoring authority under Deptt. of Science and Technology has started functioning and approving GLP facilities. India has also notified guidelines for GCP.

4.21.1 Clinical trials are a scientific and regulatory necessity for the evaluation of new drugs and have to be carried out before introducing new products. Since clinical trials have to provide information on efficacy and safety of new drugs there is an urgent need for establishing new centers of clinical Pharmacology. Also urgent action is required on formulating appropriate, comprehensive policy and legislation for implementation of GLP and GCP monitoring authorities for non-clinical safety data and chemical testing results, which have international acceptance.

4.22 **IPR Issues:** It is proposed to create an IPR Facilitation Centres in Pharmexcil for the benefit of Pharma Industry. These Centres are proposed to be set up at Hyderbad, Mumbai and New Delhi. This step would greatly help understand the patents/products patent status of various newly invented drugs/block buster drugs currently in the international market and to develop generic version for avaiing the opportunities in international markets. Approximate budget for this purpose is estimated to cost around **Rs. 5 crores** over the 11th Plan. A note about the Pharmexcil proposal are available vide Annexure XII.

4.23 Government Initiatives in Promoting Pharma R & D: Consequent upon streamlining of Foreign Direct Investment (FDI) procedures where 100% FDI is now permitted in the manufacture of Drugs & Pharmaceuticals, well known Pharma companies from USA, Europe, Japan are setting up R&D bases in India through wholly owned subsidiaries. Due to Government policy initiatives for strengthening R&D Pharma sector by way of fiscal incentives and strengthening of regulatory mechanism through streamlining

of GMP, GCP and GLP, new R&D centres with excellent infrastructure are coming up in various regions of the country.

4.23.1 The New Millennium Indian Technology Leadership Initiative (NMITLI) of CSIR is the largest public-private-partnership effort within the R&D domain in the country. It looks beyond today's technology and thus seeks to build, capture and retain for India a leadership position. The programme synergies best competencies of publicly funded R&D institutions, academia and private industry. The government finances and plays a catalytic role. In the 6 years of its existence, NMITLI programme has evolved 42 R&D projects covering diverse areas and involving 287 partners (222 in the public sector and 65 in the private sector) with an estimated outlay of Rs. 300 Crores. The objective of NMITLI is to catalyze innovation centered scientific and technological developments as a vehicle to attain for Indian industry a global leadership position, in selected niche areas in a true 'Team India' spirit, by synergizing the best competencies of publicly funded R&D institutions, academia and private industry. Some achievements of NMITLI are development of a new TB therapeutic for which IND has been filed, a new nanotech drug delivery system concerning anti TB formulation for which IND filing is in progress. There is another project involving Lupin, CDRI & NIPER concerning development of new single ingredient oral herbal drug for psoriasis, which is under Phase II trial.

4.24 **Current Status Of PRDSF Programme:** Keeping in view Dr. Mashelkar Committee report on promoting Pharma R&D, during January 2004, Govt. of India established Pharma R&D Support Fund (PRDSF) and Drug Development Promotion Board (DDPB) under the administrative control of DST with an initial corpus of Rs. 150 crores.

4.24.1 Later Government of India have decided to dissolve the earlier created Pharmaceuticals Research & Development Support Fund (PRDSF) Corpus of Rs.150.0 crores w.e.f. 24.01.2006. Instead, need based budgetary support would be provided annually for R&D in Drugs & Pharma Sector. There is no change in the objectives, implementation mechanism, composition of Drug Development Promotion Board (DDPB) and the Expert Committee of the programme. This activity is renamed to its original title as Drugs & Pharmaceuticals Research Programme (DPRP). During 2005-06, this programme has utilized Rs.115.0 crores for the above activities (Rs.64.0 crores for Loans and Rs.51.0 crores for Grants-in-Aid).During 2006-07, a total budget provision of Rs.130.0 crores exists (Rs.70.0 crores for Loans and Rs.60.0 crores for Grants-in-aid activities).

4.25 The **DPRP** Programme of DSTcomprises of: -

Collaborative R&D Projects to:

- Supports research both human and veterinary drug development for all systems of medicines including setting of facilities
- Joint research projects of industry and institutions with 50.50 sharing of financial requirements. in possible areas like Cleaner processes, Chiral synthesis, Clinical studies etc.
- Research undertaken by industry to be funded 100% by industry.
- Institution share is supported jointly by govt. and industry.

Soft Loan for Pharma R&D Projects

- Unsecured loan to industry up to 70% of project cost carrying simple interest of 3% on reducing amount
- Repayments in 10 annual equal installments after project period.
- Interest amortized during implementation and will be payable in maximum 5 installments after project period along with installment of principal amount.

Under the DPRP programme, Following National centers were set up:

- Identification of Immuno-modulating potential of products and or extracts of natural origin IICB, Kolkata.
- Strengthening of Pharmacological testing facilities CDRI, Lucknow.
- Facility for the characterization of crystals of biological macromolecules of medicinal and industrial importance. IISc, Bangalore.
- Combinatorial chemistry-cum-medium through puts screening central facility- CDRI, Lucknow.
- National facility on transgenic and Knock-out mice Centre for Cellular and molecular Biology (CCMB), Hyderabad.
- National Bio-availability centre, NIPER. S.A S Nagar.
- National facility on Pharmacokinetic and metabolic studies, CDRI, Lucknow.
- National facility on Genomics Research for Drug Discovery, IGIB, Delhi.
- National Pharmacoinformatics centre at NIPER, S.A S Nagar.
- National Toxicology Centre, NIPER, S.A.S Nagar.

Some completed collaborative projects under DPRP.

- Synthesis and screening of new and Anti-mycotic agents.
- Synthesis of structurally unique Anti cancer agents.

- Rational design and synthesis of novel Anti bacterial agents.
- Development of Drug Delivery System for Anti ulcer drugs.
- Process validation and evaluation of herbal drugs.

4.26 **DSIR IN-HOUSE RECOGNITION:** Department of Scientific & Industrial Research (DSIR) is the nodal department for granting recognition to in-house R&D units in Industry, Scientific and Industrial Research Organizations (SIROs); and registration to Public funded research Institutions, universities, IITs, IISc, Regional Engineering Colleges (RECs), other than hospitals. Secretary, DSIR is the prescribed authority vide Gazette notification No.S.O.85 (E) dated 31st January, 2001 issued by Department of Revenue, Ministry of Finance for granting approval to commercial R&D companies Under Section 80IB (8A) of I.T. Act, 1961; also approval to in-house R&D Centres under Section 35(2AB) of I.T Act 1961 for Weighted Tax Deduction.

4.26.1 In-house R&D units recognized by DSIR in the area of Pharma and bio-tech sectors are eligible for duty free import of specified goods (comprising of analytical and specialty equipment as per list 28) for R&D as per notification No. 26/2003-customs dated 1st March, 2003 (item at Sr. No. 248(1); and duty free import of specified goods (comprising of analytical and specialty equipment as per list 28) for production as per notification No.26/2003-customs dated 1st March, 2003 (item at serial No.248(2); and duty free import of Pharmaceutical reference standards as per notification No.26/2003-Customs dated 1st March, 2003 (item at serial No.138); and also the in-house R&D units engaged in the research and development in the area of Chemicals, Drugs and Pharmaceuticals, (including clinical trials), Bio-technology, etc are eligible for weighted tax deduction of a sum of equal to one and one-half times of any expenditure incurred on scientific research (not being expenditure in the nature of cost of any land, building) as approved by the prescribed authority i.e. Secretary, DSIR.

4.26.2 A few more incentives introduced by the Government to encourage R&D by industry including writing off of revenue and capital expenditure on R&D, weighted tax deduction on sponsored research programmes of industry with National Laboratories/Universities / IITs; accelerated depreciation allowance on plant and machinery set up by indigenous technology, custom duty exemption on goods imported for use in Government funded R&D projects, excise duty waiver for 3 years on goods produced based on indigenous technologies and duly patented in any two of the countries out of India, European Union(One Country), USA and Japan.

4.26.3 Scientific & Industrial Research Organizations in the area of Medical Agriculture, Natural and Applied Sciences and Social Sciences recognized by DSIR are eligible for notification under Section 35 (1) (ii) (iii) of I.T Act 1961 and also for availing Custom and Excise duty exemption. Commercial R&D companies approved by DSIR before 1st April 2004 are eligible for 10-year tax holidays. Public Funded R&D Institutions registered by DSIR are eligible for availing custom duty exemption on import of equipment, spares and accessories and consumables as per notification No.51/96-Customs dated July, 23, 1996 and also for availing Central Excise Duty Waiver on purchase of indigenously manufactured items as per notification No. 10/97 Central Excise dated March 1, 1997 for scientific research. The broad objectives of above scheme are to:

- Bring in-house R&D into sharper focus;
- Strengthen R&D infrastructure in industry and SIROs;
- Promote R&D initiatives of the industry and SIROs ;
- Ensure that the contributions made by the in-house R&D centres and SIROs dovetail adequately in the overall context of technological & industrial development

4.26.4 Of around 1200 in-house R&D centres recognized by DSIR, 500 belong to chemicals and allied sectors. The major work is involved in drugs and Pharma sector where 200 approved in-house R&D units have been set up. One study shows that at least 75 units are spending a higher amount of +5 % of their annual turnover on R&D compared to 2% average for industry.

4.27 **Public Funded National Laboratories:** Primarily 3 National Laboratories namely CDRI, Lucknow, IICT Hyderabad, NCL, Pune are into drug research related work. Of these CDRI formally inaugurated in 1951 and part of CSIR, is considered to be pioneer organization. It is working in biomedical research area and has developed certain drugs specially process technologies for these drugs. These new drugs include Centchroman, Centbucridine, Arteether, Gugulipid and also a memory enhancer. 70 processes have been released to industry and 13 technologies have been successfully used in industry.CDRI specializes and has modern facilities in areas-molecular and Structural biology, Spectroscopy, Medicinal chemistry, Pharmacology, Toxicology, Analytical technology.

4.27.1 **IICT, Hyderabad** is a premier institute in India carrying out research in the chemical sciences leading to innovative processes. The major areas of research include drugs and intermediates, speciality and fine chemicals and natural products chemistry. More than 150 technologies developed are

in commercial production. They collaborate with Pharma companies from India and other countries.

4.27.2 **NCL, PUNE** is a CSIR lab established in 1950 has 200 PhDs. They collaborate with Pharma industry in different projects, as organic chemistry is their forte. 400 graduate students pursue research towards their Ph.D.

4.27.3 Globally the R&D pipeline is drying up and also the way new drugs are discovered are going to change. The global Pharma companies are looking to new means of cutting down R&D costs. Therefore, the discovery research based Indian Pharma companies will definitely get chance for collaborative R&D work with MNC Pharma companies. Already examples have been given in the report. Coming to making the industry internationally competitive, it is stated that policy initiatives from government like introduction of product patent, up gradation of Schedule M of D&C Act, amendments to Schedule Y of D&C Act to aid parallel phase clinical trials by western Pharma companies, notifying GLP and GCP norms - all these are not only resulting in a confidence building initiatives for promoting Pharma R&D both by Indian and Western Pharma companies, but are also becoming the benchmarks for the Indian industry to stay competitive. Further the government through in-house R&D recognition of R&D centers and also through DPRP and NIMILTI schemes is also opening more avenues for increasing the role of industry in its R&D efforts. The concluding message is that to stay ahead Indian Pharma companies need to develop new products and become internationally competitive to maintain their existing role as supplier of cost effective generic medicines all around the globe.

4.28 **The Pharmaceutical R&D Programme (PRDP)** under the Department of C&PC, with an outlay of Rs. 600 lakhs during 10th Five Year Plan provided financial assistance to some important projects undertaken at NIPER. These projects included ambitious project for acquiring highly sophistivated analytival instrument, namely LC-MS at a cost of nearly Rs. 5 crores. This instrument is vital for Impurity Profiling and preparation of standards of impurities & degradation products besides developing various new processes. A number of other research projects were financed that required only minor balancing equipments, consumables and manpower requirements. These projects have been evaluated and substancial scientific improvements have been demonstrated.

4.28.1 On the recommendation of the Standing Committee of the Parliament for the Ministry of Chemicals and Fertilizers, the Planning Commission agreed to increase the fund under PRDP from Rs. 25 lakhs per annum to Rs

5 crores per annum for the year 2004-05. However, the outlay was again reduced to Rs. 25 lakhs per annum.

4.28.2 In the current scenario a need is felt to modify the objectives & scope of the Scheme. It would now focus on emerging challenges being faced by the Pharma Industry including effluent treatment systems, new technological needs as well as creation of suitable infrastructure to meet the objectives. The new PRDP Scheme(Expended role), besides continuing the existing activities to render financial assistance to smaller research projects, would also address the need for undertaking specific studies through specialised agencies so that results of such studies are available to a large number of Pharma units particularly the SMEs. To start with the Planning Commission may be requested to provide an annual fund of Rs. 5 crores. As such the entire plan fund under PRDP would now be **Rs. 25 crores**.

5. **To assess the requirements of equipment/machinery and indigenous capability for fabrication of internationally competitive equipment and suggest measures for augmentation of capabilities, where necessary.**

Indian Pharma Machinery Industry- Requirements: The word Equipment can be categorized as production equipment and equipment/ instruments related to quality & R&D. Apart from strengths in manufacture of Pharmaceuticals, India also has strengths in the production of Pharma machinery. As per industry association IPMMA, there are 400-500 companies producing Pharma machinery. The production is reported to be of the order of Rs. 2000 Crores growing at 10%. 25% of this production is reportedly being exported to many countries including advanced countries. Only 5% of the domestic turnover is being imported from countries like Germany, Australia and South Korea.

5.1 Pharma machinery covers reactors for APIs, compressors, blenders/mixers, Fluid Bed driers, granulators, washing lines, complete processing lines for formulations- ral/liquid/powders/syrups/ointments and injectables. This in addition to Form, Fill and Seal injection production equipment and then more important all types of packing machinery as well as labeling machinery. Indian companies are in a position to produce all types of machinery including some advanced packing lines. Only sophisticated packing machinery and advanced versions of Form, Fill and Seal machines are being imported. In Indian Pharma plants, it is now a common sight to see most of the machinery of Indian origin, as these are cost competitive. Some of the R & D Equipments available include: -

- High Sheer Mixer (GMP model)
- Fluid Bed Drier
- Fluid Bed Processor
- Ganscoata
- Walk in Stability chambers
- Dissolution Apparatus with intrinsic dissolution assembly
- Bilayer Tablet Compression Machine
- Equipments for liquid orals and semi solid
- Hard gel capsule facility
- Blister packing machine with Alu-Alu facility
- Roll compactor
- Pelletisation facility
- Facility for Effervescent tablets (low RH area)
- Reverse laminar flow.

On the quality and R&D side some of the modern sophisticated instruments such as LC-MS/MS, LCMS, powder XRD, multi nuclei fully automated NMR, DSC, TGA, GC-Head space, several HPLCs, Polarimeter, FT-IR, C,H,N-analyzer,UV-visible Spectrophotometer, Karl Fischer apparatus, Particle size analyzers etc are being used in many Pharma plants but most of them continue to be imported.

5.2 A Good Discovery Research set up needs following main equipments:

- Automated DNA sequencer
- Fluorescence activated cell sorter
- High throughput Screening system
- Laser scanning confocal microscope
- Macromolecular S-Ray crystallography and graphics
- Micro array system
- Scanning electron microscope
- FTIR spectrophotometer
- FT-NMR spectrometer with HR mass
- Multiple organic synthesis equipment
- LCMS
- MALDI TOF mass spectrometer
- NMR for protein structure determination
- Automated haemotology, urine analyzer
- Cryostat microtome
- Random access chemistry analyzer
- Electro cardiograph

5.2.1 The demand for the capital goods for the Pharma sector cannot be accurately calculated, as there is inadequate information. One projection estimates that the total Indian production of Pharma Plant and machinery today stands at around Rs. 2000 crores per annum which matches with the IPMMA projections. The future projections are based on the assumption that the Pharma industry will maintain around 10-20% growth. However, with introduction of product patents the scenario of the Pharma sector in India shall change a lot. Major sector of small-scale Pharma companies will wind up due to various factors in place - compliance with new Schedule M provisions, excise duty related issues. The industry especially dosage form production has to attain sophistication and therefore many of the smaller units may close down more because of extra investment needed for maintaining quality of products. Some sophisticated equipment required by Pharma industry shall have to be imported as Indian Pharma equipment/ machine manufacturing organizations have to gear themselves up at present

to meet the requirements. Also the Pharma packaging machinery of high throughput and other specialized equipment may have to be imported. Significant gap exists in the R&D equipments needed for the industry. There is a very liberal EPCG scheme under Foreign Trade Policy under which machinery as well as instruments can be imported at 5% customs duty subject to export obligation equivalent to 8 times of duty saved on capital goods imported to be fulfilled over a period of 8 years. In case of SSI units the same provisions apply but the export obligation to be fulfilled will be only 6 times the duty saved.

5.2.3 Normally projections are made for planning manufacture of equipment, which will be required in the production of Pharma items in the coming years. Indian companies because of lesser demand and ease of imports cannot produce very sophisticated machinery. Therefore, the sub committee felt that while there is no authentic data on which future projections can be based, there appears to be no need to work out future requirements of machinery in view of position explained above.

5.3 **Suggestions:** 1) Indian manufacturers should tie up with foreign companies to produce some advanced instruments as well as sophisticated machinery for which there is a growing demand.

2) With the chip manufacture and their design for appropriate applications likely to be established, there is a need that CSIR labs, ECIL, BEL etc should set up sub-divisions to carry out developmental work to design and manufacture sophisticated equipment necessary for process control as well as QA / QC.

6 To assess the present employment and likely employment that will be created in the Drugs & Pharmaceuticals Industry during the Eleventh Plan period and in the perspective of 15 years.

6.1 **Employment In Pharma Sector**

The employment in the Pharma industry of India can be classified into two main categories as direct and indirect. As per the statistics provided by one of the industry associations (OPPI), the number of the personnel in the direct category is of the order of 4.6 Lakhs and the number in the indirect category is 24.00 Lakhs in the year 2000.

6.1.1 Pharma industry is a knowledge-based industry and therefore special skills are required. In addition to Pharma manufacturing, the requirement of manpower will be in areas like distribution, marketing, quality control, R&D and other services. Another new area is clinical trial services. It is felt that with the horizon of services expanding, the requirement of manpower will increase in all areas. Only in manufacturing with the cost of wages going up, automation will take place specially the plants, which need to be approved by international regulatory agencies. Therefore, future requirements of manpower will come down.

6.1.2 Another alarming situation is the quality of technical manpower coming from our colleges and universities is very poor. In many cases the reason is due to lack of budgetary support and poor infrastructure. Another crucial factor is while India may be claiming to have large scientific manpower; most of these people will be retiring. The younger generation instead of concentrating on life sciences is going for engineering and medical courses. Therefore the Government needs to address this serious situation. Recently HRD Ministry and UGC have announced setting up of centres of excellence of life sciences but this will be a sort of drop in ocean. UGC and AICTE should join together and develop some benchmark for the hundreds of Pharmacy colleges, which are operating in the country to enable them to produce quality graduates.

6.1.3 India has some 22 million graduates, including 6 million science graduates, 1.2 million with engineering degrees and 600,000 doctors, **according to data compiled by The Economic Times Intelligence Group, the National Association of Software and Service Companies (Nasscom) and other industry sources.** That population is growing rapidly, with nearly 2.5 million graduates added in 2004 alone, including 25,000 doctors and nearly 600,000 science graduates and post-graduates.

By way of comparison, China had more than 2 million students graduating from its universities in 2003. That included 600,000 in engineering, 200,000 in science and 100,000 in medicine.

6.1.4 The 9th Plan Working Group (1997-2002) has gone into detail on the human resources and employment scenario in the Pharma industry. It has come to conclusion that the available information was inadequate. Therefore an assessment was made about direct and indirect employment in that period and also worked out on future projections. One of the points made out was while the production capacities will go up, the additional employment may not be of the same proportionate magnitude because of more automation. Keeping in view, 5% annual growth rate for workers employed in the Pharmaceutical industry the following future projections were given.

Table 6.1. Future Projections

Year	Workers (Projections)
1990	91400
1995	116600
2000	148800
2002	164000
2005	190000
2012	267000

[Source - 9th plan Working Group report.]

6.2 In critical area of R&D India have reasonable human resources in conventional methods of drug discovery. However, the newer tools of drug discovery have to be mastered. This is an area where employment shall be generated. This may need both re-furbishing the skills and knowledge base of some of the existing manpower as also acquiring these skills ab-initio. It has been estimated that a viable drug discovery programme, as envisaged in the Vision by 2007, would need about 2000 highly skilled and trained scientific R&D manpower. With focus on drug discovery and more and more in house Pharma R&D centres coming up, these figures perhaps may need upward revision after 2007.

6.2.1 For the likely employment in 11th Plan period specially in the production part, we have to consider various critical developments effecting Pharma industry. Introduction of product patents leading to decrease in the pace of introduction of new products from now on (under patents) unlike the earlier times, closure of a number of units in SME sector consequent to

implementation of upgraded Schedule M and migration of some manufacturing capacity to excise free zones like Uttranchal etc. are the developments to reckon with. Other factors to be noted are MNC Pharma companies are still not keen to set up manufacturing units in India and more important introduction of automated plants to meet the requirements for international regulatory approvals. All these factors result in a fluid situation which makes it difficult to assess requirement of manpower in XIth Plan period. Perhaps an independent study is needed to be conducted for manpower requirement by Planning Commission (it is understood that DBT is initiating a similar study for Biotech sector).

7 To assess the present education and training facilities and infrastructure for human resource development pertaining to Drugs and Pharmaceuticals sector and to suggest measures including institutional mechanisms to strengthen it, where required.

Human Resource Development in Drugs And Pharma Sector: Highly skilled human resources are "essential for the development and diffusion of knowledge….." and notes that they "constitute the crucial link between technological progress and economic growth, social development and environmental well-being. An important subject of human capital is that which is involved in technological progress or knowledge development, - Organization for Economic Cooperation and Development (OECD). Thus, the role of scientific manpower is critical, and there is a close relationship between human resource in science and technology and economic growth. NCAER's National Science Survey-2004 found that while the number of human resources in S&T by education has grown considerably, the issue that looks worrying is the poor utilization of these persons. One third of such persons were pursuing an occupation that was related to their educational qualifications. Several MNCs are of the opinion that 20-25% of the Science graduates are fit for the deliverables what the industry is looking for. If the country has to make the most of the outsourcing and R&D opportunities coming its way from foreign shores, it will have to look closely at the quality of scientific and technical manpower it is churning out. The All India Council for Technical Education (AICTE), the statutory body that grants accreditation to al professional courses indicates that there were 625 Pharmacy courses with a seat intake of 52,708.

7.1 Going back into the history of Pharma profession in India, three decades ago the awareness about Pharmacy profession among the people in India was not much. There were only around 25 institutions offering degree course and about 15 offering post graduation and doctoral program in Pharmacy. Around 80 per cent of the Pharma companies were multinationals, 10 per cent were Indian-owned private companies and 10 per cent were public sector companies. Those days the job options were very simple and confined to areas like production, quality control in labs and teaching.

7,1.1 During the past three decades, multinationals have introduced globally many patented NCEs. They were reluctant to introduce their original patented NCEs in India due to high import duties and very low pricing structure. During that period, India witnessed an era of reverse engineering pioneered by some of the Indian companies who are the leading ones today. Also the multinationals succeeded in putting pressure on India to sign TRIPS in 1995 thereby making India as a signatory to respect patents from 2005. This has led Indian companies to invest in upgrading their production and QC facilities to International standards, opening up new departments like clinical research, quality assurance, regulatory affairs, R&D (API and formulations), marketing etc. Today there are over 75 Indian companies whose facilities have been approved by US FDA, UK MCA, Australian TGA and Canadian and South African Health Authorities.

7.1.2 The human resource requirements of Pharma industry have changed over the years. Today the Pharma industry needs Pharmacy graduates/post graduates/doctorates who have expertise gained from the educational institution and who can face the global challenges and have the zeal to compete with the multinationals

7.1.3 The new fields of human resources for Pharmacy professionals are clinical research (clinical trials, new molecule research, bioequivalence studies, post-marketing surveillance), herbal drug research, industry regulatory affairs (domestic and international), R&D (formulations and API) metabolism and Pharmacokinetics, Pharmacology, intellectual property, project management and QA & QC, newer drug delivery systems.

7.1.4 There is an immediate need to acquaint the Pharmacy students in GLP, GCP, validations, analytical techniques, innovations in Pharma formulation technology, clinical research, BE studies, Intellectual Property Rights (IPRs), quality management, regulatory management, discovery research, personality development, communication skills and shop floor relations.

7.1.5 Consequent upon implementing these recommendations through the policy of good educational practices it can be assumed that in near future the institutions will rise to the occasion in providing the technical manpower of highest order and become centres for consultancy for the Pharma industry. Sources roughly estimate that a $ 25 billion Indian Pharma industry

may require manpower of at least five times than the current available manpower.

7.1.6 Sources also point out that even though there are provisions to churn out about 40,000 professionals every year, migration of Indian Pharmacists to other countries in search of lucrative jobs is another major factor that cripples the interests of Indian Pharma industry. It is estimated that about 39 per cent of the Pharmacists working in US are of Indian origin and majority of Pharmacists in the Middle East countries are from India.

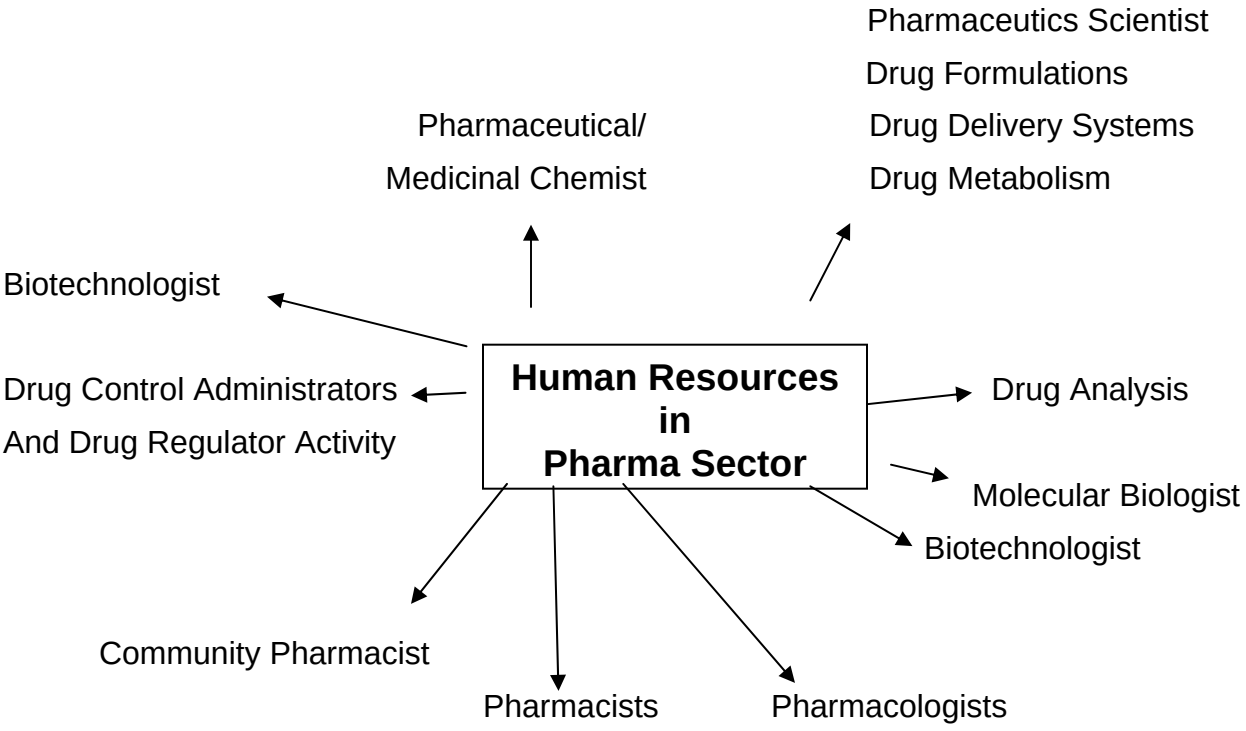
7.1.7 “Soon the Indian industry may have to recruit manpower from abroad, as happened in the case of our aviation sector where many of our new airline companies are forced to massively recruit crew from abroad to operate their flights. Already I have seen many foreigners working in R&D and production lines of many Pharma companies in and around Mumbai. We have to devise long term strategies to meet the future demand” notes Subodh P. Priolkar, President, Indian Pharmaceutical Association (IPA)

7.2 **Need of the Human Resources:** The change in the paradigm in the drug discovery and development has created new avenues and opportunities in the various specializations. India has become a hub of Pharmaceutical R & D. Various Pharma multinational organizations banking on the several advantages offered by India are starting their R & D set ups or planning to outsource their preclinical as well as clinical R & D to India. Hence there is great demand for the highly trained manpower in the areas of Medicinal Chemistry, Pharmaceutics (Formulations), Pharmacology and Toxicology, Drug Metabolism, Pharma Analysis, Pharmaceutical Technology and Pharma Biotechnology. In the recently held meeting of the Pharma subcommittee of National Manufacturing Competitiveness Council (NMCC) (12.05.2005), Indian Pharma Alliance (IPA) presented data regarding the trained manpower requirements. It stated that to double Pharma exports by 2010, Indian Pharma Industry requires 1,000 highly trained manpower per year for the next five years. Its spokesperson requested to set up 10 more NIPER-like Institutes in different regions of the country. An acute shortage of trained manpower was indicated in the areas of medicinal chemistry, Pharma analysis (quality control and assurance), regulatory toxicology, in vivo Pharmacology, Pharmaceutics, clinical trials, Pharmacoeconomics and Pharmacogenomics, clinical trials, drug regulatory affairs and intellectual property rights. Though, the number of Pharmacy degree awarding colleges has steeply increased to around 800, still more than 50% of the posts in these colleges are vacant for want of trained Trainers.

7.3 **Biotechnology/Molecular Biology/ Genomic / Proteomics:** Special attention needs to be given to the above mentioned areas of R&D in view of its strong impact, both to provide new therapeutics and tools for new drug discovery research, viz. increased production of bio-therapeutics, following the generic drugs road map, enhance gene cloning and expression capabilities both for setting up of enzyme and receptor screening systems and increase generic biological industrial production and encourage genome research, with special emphasis on functional genomics and proteomics.

7.4 **HERBAL DRUGS:** With the paradigm shift in the western countries to accept herbal extracts as Pharmacopoeial drugs, provided these are standardized, safe, have reasonable evidence of efficacy. This offers great scope for development of new drugs at much less cost, especially important for therapeutic gap areas and degenerative disorders. There is a need to legislate for change in system of registration of herbal drugs to get better international acceptance. Traditional system of medicines needs to be standardized. There is an urgent need to broaden screening programs, with networking between different centers for generation of new leads.

Fig 7.1 Pharma Sciences to provide the much-needed Human Resource to meet the New Challenges



7.5 **Requirement Of NIPER Like Institutions:** With India joining the World Trade Organization and product patent being in place from January, 2005, the research component in the area of drug discovery and technology development assumes critical importance. Therefore, research and development needs to be given the highest priority to bridge this gap. The Pharmacy services available to the citizens need to be upgraded to the levels provided to the public in other developed countries of the world. This applies specially to community and institutional Pharmacy. These discrepancies are primarily because of the serious deficiencies in the education and training in our country. The kind of manpower which is being produced today in the country may be good enough for meeting a number of Pharmaceutical personnel required for placement to do routine operations. The quality and excellence is by and large lacking, and is actually being felt today and may be more even in coming years when the country will face the global challenges and compete internationally with very best in Pharmaceutical arena.

7.5.1 Therefore, there is dire need to produce human resources of right caliber which can fill this gap and also help Pharma industry and regulatory agencies to meet the global challenges.

7.5.2 The establishment of a National Centre of Excellence in Pharma Sciences and Technology, for which the Pharmacy profession and industry strived for several decades, has now become a reality. The setting-up of the National Institute of Pharmaceutical Education and Research (NIPER) at S.A.S. Nagar has come at the right time when the profession, industry and the country are poised to face the global challenges and meet the national and international needs. The national mindset has to prepare and gear to meet the new reality with vigor and determination. An institution like NIPER is significantly contributing in reaching the goals, which the country has set or may set in future for itself in the Pharma realm. It is providing human resource of the right caliber needed for the industry, the academia, the regulatory bodies and others. Although the institute started its educational activities only a few years ago, it has attracted the attention of both national and international bodies.

7.5.3 However, in a population of over a billion people, one NIPER is not going to completely meet demand of national sector with the growth, which is being envisaged in the near future. The Government recognized the need for the establishment of more higher teaching institutes like NIPER to cater to the need of the country on similar lines, as the Indian Institutes

of Technology (IITs). Looking at the previous growth of this industry and what is envisaged in the next two decades, it is desirable to establish atleast five more centers like NIPER in different regions of the country. The following locations can be tentatively considered for such institutes- Kolkata, Ahmedabad, Hyderabad, Hajipur and Guwahati. The location of these Institutes has been selected because of preponderance of Pharma industries in these regions, except Hajipur and Guwahati. However, in case of Hajipur the need is felt as there are hardly any pharmacy colleges in Bihar .It was informed that the Bihar Government has particularly made efforts for setting up of the institute by offering all possible assistance. Similarly in North- East the need has been recognized because amongst the 8 states of North East and 66 districts, there are only two(2) Institutes imparting Bachelor's programs in the Pharmacy, and hence the need to create an Institute of Excellence in this area is more. All the Institutes may not be started simultaneously but in a phased manner.

7.5.4 It is proposed that these Institutes can be started initially with the external assistance of NIPER (S.A.S. Nagar) for a few years till all infrastructures of these institutes are ready. These will be autonomous institutes headed by a Director, have its Act and function under the Board of Governors. These Institutes should work on similar lines of NIPER and Indian Institutes of Technology (IITs). It is estimated that each institute will cost about **Rs. 250 crores** during a period of 5 years with normal escalation and inflation to be included, and will require about 100 acres land, which should be provided free of cost by the respective State Governments .

7.6 In this regard, therefore, recommendations are being made, as follows:-

India is gradually evolving into an essential element of every global Pharma player's value chain. The R&D out-sourcing is likely to be a $ 600 m market by 2010. While India is going to be a key global player in Clinical Research outsourcing, contract discovery research is also gaining attraction.

7.6.1 Government of India should encourage Pharmaceutical Research and Development by creating a conducive research atmosphere.

7.6.2 **Drug Discovery:** Pharma research can be Contract Discovery Research (CDR) and innovative and integrated drug discovery. Several MNCs are considering that R&D is no longer a core activity and it can be out-sourced to small start up companies. Further, the present Pharma R&D is switching over to specific therapeutic areas, which require basic research and which can be carried out by higher education institutes. In India, traditional knowledge need to be subjected to scientific scrutiny and need to be rationalized**. India is having rich biodiversity, which needs to be exploited, and needs standardization and validations. Government**

needs to encourage the start-up companies, which are involved in CDR and companies/institutes doing innovative research. Furthermore, the Government should also encourage the research in most neglected diseases by establishing Public Private Partnerships.

7.6.3 **Drug Development:** Once the proof of concept of NCE is established, the molecules need to be developed for the purpose of Phase I-IV studies before it is released in market. These activities are cost prohibitive and very few institutions can carry out from beginning to the end. Government of India should set up capacity building with respect to various activities involved in the drug development. Following specific measures are recommended:

1. Creating a helpful Regulatory environment.
2. Competent and time bound regulatory agencies will foster the R&D activities.
3. Unambiguous Rules and regulations with respect to IPR, TRIPS, Data protection etc, need to be promulgated without any further delay.
4. A faster clearance of ethics guidelines with respect to usage of human volunteers as well as animals and biohazardous materials
5. Creation of national facilities which deal with various facets of Drug discovery and development chain. Public, Private Partnership (PPP) need to be encouraged in setting up of these facilities. Encourage a hassle free management of these centers.
6. The number of Pharma parks and higher centers of learning institutes need to be created, as mentioned in the Pharma policy 2006.
7. To handle these technologies and to meet the challenges of Drug discovery and development, highly trained manpower is required. Though there are several Pharmacy colleges throughout India the gap between supply and demand of skilled Pharmaceutical manpower is ever increasing.
8. There is need for creating of five more NIPER like institutes in different regions of the country to meet the demand of highly trained manpower in the area of Pharmaceutical sciences.
9. These new institutes should be complimentary to the existing NIPER and should concentrate on the areas which are in great demand viz., clinical trials training, Drug Regulatory affairs, drug discovery, drug development, newer technologies like nanotechnology etc.

10. R&D in Pharmaceuticals has an important characteristic namely IPR including getting patents for the products. To reap more benefits it is necessary that patents are filed in advanced countries like US, Europe and the like. Apart from high cost of patent filings there are also litigation issues. To meet these costs thee is need for some mechanism of funding. From available information it is felt that DPRP can be an instrument to provide soft loans to mitigate the difficulties faced by Drug Discovery Companies from India in the area of patents.
11. There is inadequate international commitment towards neglected diseases both in terms of work and funding. Some portion of funds under DPRP be earmarked for R& D related to neglected diseases.
12. World class and effective incubation centers where idea can be seeded and nurtured so that private sector gets an opportunity to commercialize them with public private partnerships is the need of the hour. As a Public Private Partnership, time has come to take a cue from Singapore's Biopolis, which is a Biomedical hub where hundreds of Research scientists from government and private labs work and collaborate together to develop new products using common facilities by way of a state of art infrastructure. Scientific equipment is shared in this integrated setup to carry out work in Genomics, Molecular Biology, Bioengineering etc.
13. There is a need to strengthen the areas of Medicinal Chemistry, in vivo Pharmacology, Systems Biology, Pharmacoinformatics, Nanotechnology, Drug metabolism, Pharmacokinetics, regulatory toxicology, Novel/ New Drug delivery systems, regulatory affairs, clinical trials, data reduction, bioequivalency, bioavailability, biostatistics, IVIV correlation, Bio-simulation, project management, Pharmaceutical analysis, QC/QA, PAT, Pharmacovigilance and Pharmacoeconomics.
14. Animal testing is essential in drug discovery. Effective solution needed for undertaking NCE based discovery research to solve the difficulties encountered in conducting toxicity studies in bigger animals (monkeys and dogs). The approval process for animal import, animal experiment protocol improvement needs to be streamlined and expedited.
15. Target validation and identification which forms the basis of drug discovery research is an area where a public sector initiative can be taken who can then sell the targets to industry for drug development.

16. Recognized R&D centers can be given same benefits as units in special economic zones for tax purposes where they can be given exemption on customs, excise duties and similar benefits for promoting R&D.

17. All the fiscal incentives for R&D are at present only available upto 31st March, 2007. Since R&D activity has to be carried over long periods of time, fiscal incentives should be granted over a longer period of time extending upto 10 years i.e. upto 31st March, 2017. Keeping the above approach in view the package of fiscal incentives should be framed on a long term basis. Higher incentives may be considered for R&D intensive companies fulfilling 'Gold Standards' as laid down by Government. A Committee under the chairmanship of Dr R A Mashelkar, Secretary , DSIR is looking into this matter .Based on the recommendations of the Committee suitable provisions would be made regarding fiscal concessions for R&D work

18. It is said that there are many funding agencies in govt. for Pharma R&D. Since different departments have grants for dispersing money towards R&D, there needs to be a National Data Base concerning drug discovery funding so that effective channeling of funds could be there. This is most important.

19. A Committee was set up by the Department of C&PC to examine the possibility of opening more NIPER like institutions in different regions of India. It is estimated that each institute will cost around Rs. 200 Crores spread over a period of five years. In addition, there will be a recurring expenditure of around Rs. 9 crores per annum. Each institute would also require around 70 – 100 acres of land, the cost of which has not been included in the above amount. The Committee has recommended that the land may be provided free of cost by the respective State Governments. These institutes should be set-up as early as possible to bridge the gap between demand and supply of highly skilled personnel required for R&D activities in the Pharma sector. Each of such institutes should be autonomous like IITs and IIMs, specializing in different branches of Pharmaceutical technology.

20. These institutes / centers of excellence must confine to industrially relevant teaching, training and research programmes in Pharma technology, leaving basic research to the existing institutions with a strong science base in the country in the public and private domains, including CSIR labs.

21. <u>To create the national facilities there is need to create a Pharma Technology Fund to the tune of Rs. 1000 crores.</u>

22. Creating of one new NIPER requires Rs. 200 crores for 5 years and 100 acres of land (5 X200= 1000 crores)

23. The existing NIPER, S.A.S. Nagar need to be strengthened further in various disciplines /activities and needs an additional capital budget of Rs. 250 Crores for the next five years. To make India a knowledge base society, a cultural change is required in R&D of Pharma sector.

8. To assess the existing infrastructure for Pharmaceutical industry and to suggest measures to strengthen it including investment and source of investment alongwith option of revival of Pharmaceutical Public Sector Undertakings.

This item has linkage with items no 12 & 13. Measures to strengthen the Indian Pharma Industry for making it internationally competitive include measures to improve infrastructure and providing conducive atmosphere for heavy investment. Revival of Pharma PSUs is also linked with this issue. Revival can make PSUs self sustained only when their role is made complementary to the overall scheme of growth of industry and the goal of making available medicines at reasonable prices to masses. Accordingly, report in respect of this item has been included in the report on items No.12 & 13.

9. To assess the present regulatory mechanism and assess need for an Apex authority to control price, quality and supply of drugs.

Historical Background: In the beginning of the last century, Pharmaceuticals were being imported from abroad. The foundation of the modern Indian Pharma industry came into being with the establishment of Bengal Chemicals & Pharmaceutical Works in 1901 at Calcutta. The country initially was importing Pharmaceuticals from UK, Germany and France. The setting up of the Penicillin unit at Pimpri, Pune in 1950s and IDPL units in 1960s has been important landmarks of the Indian Pharma Industry in the country. The investment in public sector Pharma companies gave a boost to the growth of Pharma sector.

9.1 **Present Status:** In 1948 the sale of Pharma products accounted for hardly Rs.10 crores and in 80's, total turnover of the Industry used to be in four figures in crores. As per ORG reports the market of dosage forms during March 2001 has crossed Rs.15, 000 crores. Initially foreign exchange used to be one of the major constraints as the Industry had to depend on imports of raw materials as well as machinery. Restrictions were placed not only on the importation of items but also on some of the activities, which could be taken up by MNC companies. Today the country is self sufficient in Pharmaceuticals and is an international player. Apart from synthetic drugs tremendous efforts are being made by Ministry of Health & Family Welfare for revival of the Indian Systems of Medicines covering Ayurveda, Unani, Siddha and Homeopathy sector.

9.2 **Drugs & Cosmetics Act 1940:** The Drugs & Cosmetics Act 1940 and Rules 1945 have been amended from time to time so as to effectively monitor quality of medicines manufactured, sold and distributed in India. The Act is a Central Act and implementation is mainly done by the State Governments. The Drugs Controller General(India) is the officer appointed by the Government of India in Central Drugs Standard Control Organization and is mainly responsible for amendments to the Act and Rules. The import, manufacture, distribution and sale and standards of Drugs & Cosmetics are regulated under the Drugs & Cosmetics Act and 1940 and Rules 1945 made there under, in order to ensure their safety, efficacy and quality. The Central Govt. and the State Governments have shared responsibility to achieve these objectives under the Act. The distinct activities undertaken by Central and States are:

9.2.1 **Functions undertaken by CDSCO:** There are following two broad categoriews of the functions performed by the CDSCO:

A. **Statutory Functions:**

- Laying down standards of Drugs (including biotech products), Cosmetics, Diagnostics and Devices.
- Laying down regulatory measures & amendment of Act and Rules.
- To regulate market authorization of new drugs.
- Screening of drug formulations moving in the market.
- To approve licenses to manufacture Large Volume Parenterals (LVPs), blood & blood products, sera & vaccines and medical devices as Central Licensing Authority (CLA).
- To undertake testing of drugs at Central Drugs Laboratories
- Publications of Indian Pharmacopoeia
- Work relating to Drugs Technical Advisory Board and Drugs Consultative Committee
- Investigation & Prosecution of those violating the Drugs & Cosmetics Act.

B. **Other Functions:**

- Coordinating the activities of the State Drug Control Organizations to achieve uniform administration of the Drugs & Cosmetics Act.
- Participating in the WHO GMP Certification scheme.
- Monitoring Adverse Drug Reactions (ADR).
- Conducting training programs for Drug regulatory officials & government lab personnel.
- Assessment of Quota of Narcotic Drugs to be used in medicinal formulations.
- Export permission to New Drugs not approved for marketing in the country/other approved drugs.

9.2.2 Functions undertaken by State Drugs Control Organizations: The main functions of State DCAs are:

- Licensing of drug manufacturing (other than those covered under CLA functions) and sales establishments.

- Licensing of Drugs Testing Laboratories
- Approval of established Drug formulations for manufacture.
- Monitoring the quality of Drugs and Cosmetics including their sampling & analysis.
- Recall of sub standard drugs
- Investigations and Prosecutions

9.2.3 The central authorities do not have the power to supervise or issue directives to State Licensing Authorities (SLAs). Hence the uniformity and the extent of implementation differ from State to State and depend on organizational structure and strength, infrastructure, manpower available in the respective states.

9.2.4 The grant of fixed dose combinations by different State Licensing Authorities has been a very contentious issue. There has been no uniformity as regards to grant of permission to manufacture such combinations. This has led to a situation where another State Licensing Authority grants a product not permitted by one State Licensing Authority. Legally such products can be distributed in a state where the State Licensing Authority has refused to grant permission to such drugs. It has been suggested that existing provisions of Section 33 P may be amended so that the designated officer may be appointed and given powers to revoke the permission to manufacture a particular drug on the basis of Government analyst report.

9.3 **Current Regulatory system of Central & State Drugs Control Organizations (CDSCO/SLA):** Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health & FW, with its headquarter at New Delhi, regulates:

I. Imports of drugs & cosmetics,
II. Coordinates activities of the States/UTs drug control authorities,
III. Approves new drugs (both bulk drugs and formulations) proposed to be imported or manufactured in the country,
IV. Lays down regulatory measures and standards of drugs,
V. Screens formulations moving in the market,
VI. Acts as a Central Licensing & Approving Authority in respect of whole human blood, blood products, and large volume Parenterals, Sera & Vaccines and medical devices,
VII. Inspection of manufacturing units, testing labs, blood banks through its zonal offices.

9.3.1 CDSCO functions from 4 zonal offices and 2 sub-zonal offices to coordinate with the State Drug Control authorities for uniform standard of inspection and enforcement of the drug Rules in the country. Five central Drug Laboratories, situated at Calcutta, Ghaziabad, Mumbai, Chennai & Guwahati carry out tests of specific classes of drugs and also assist various States in analysis of drugs. Other labs like CDL Kasauli, IVRI Izzatnagar etc carry out tests for vaccines on behalf of CDSCO.

9.4 **Constitution of an Autonomous Drug Regulatory Authority at the National level:** As mentioned earlier, the Drug regulatory system has a close bearing on the prices, availability and quality of drugs. Under the Drugs and Cosmetics Act, 1940 there is dual regulatory control over the drugs i.e. by Central and State governments. While regulation of manufacture, sale and distribution of drugs is primarily the responsibility of the State Authorities, the Central Authorities are responsible for approval of new drugs, clinical trials, laying down standards for drugs, control over imported drugs, coordination of the activities of state drug control organizations.

9.4.1 The Expert Committee set up by Government under the chairmanship of Dr R A Mashelkar, Director General, CSIR in its report submitted in 2003 has made comprehensive recommendations for strengthening the drug regulatory system. It has made detailed recommendations to strengthen the existing regulatory organizations both at the Centre and the States.

9.4.2 Subsequently the Task Force set up by Government to **'Explore Options other than Price control for achieving the objective of making available life-saving drugs at reasonable level'** has recommended that in the long run both the functions of drug regulation and price control should be performed by the same agency and there should be an **integrated regulatory system**.

9.4.3 Keeping in view these recommendations it has been decided that:

a) As an immediate step an independent and autonomous body by the name of **National Drug Authority** would be constituted in place of the present Central Drugs Standard Control Organisation (CDSCO).

b) In the long run the proposal of Task Force regarding merger of NPPA and NDA would be considered in the form of National Authority on Drugs and Therapeutics (NADT), which will lead to an integrated regulatory system.

9.5 **Drugs Technical Advisory Board:** A Drugs Technical Advisory Board has been constituted as a statutory body under the provisions of Drugs & Cosmetics Act to advise the Central Govt. and the State Governments on technical matters arising out of the administration of this Act and carry out other functions assigned to it by this Act. The Drugs Technical Advisory Board apart from its other statutory duties examines rationality of drug formulations moving in the market, which are suspected to be lacking in rationality. A sub committee consisting of Medical experts, representatives from Indian Medical Association and State Licensing Authority, examines these formulations. The categories of drug formulations found irrational are recommended to the Ministry of Health & Family Welfare for prohibition of manufacture and sale throughout the country through a gazette notification. So far 71 categories of drug formulations, since 1983, have been prohibited for manufacture and sale.

9.5.1 It is noted that the level of enforcement and quality of inspection vary from State to State depending upon the competence of licensing authority and enforcement staff. The success of Pharma industry in certain States compared to that in the rest of the country is due to the existence of healthy relationship between the industry and Regulatory Authorities. While steps have been taken by DCGI for upgrading Schedule 'M' requirements at par with international standards, there is a big gap between regulation and its implementation. Concern has been expressed that the standards desired from industry by regulatory authorities is at variance from State to State. This scenario is leading to a situation whereby industries which are genuinely introducing regulatory requirements are at disadvantage as far as cost of manufacturing of drugs is concerned which is eventually making them non competitive in the market.

9.6 **Changes in Regulatory Mechanism**: Drastic changes are needed in the regulatory system to keep abreast with the changing trends in the industry with the objective of maintaining uniform parameters to produce quality drugs. Since systems followed in different states are different, a new approach will be needed to bring out uniformity in the procedures to be followed by state licensing authorities. To achieve this, there will be need for proper training facilities for drug regulatory personnel. Since states are looking after health and the licensing of drug manufacturing establishments

along with monitoring of quality of drugs, any change over will have legal implications and needs to be carefully decided.

9.7 Regulatory Procedures for Biotech products: There are separate rules for manufacture, use, import, export and storage of Biotech products in terms of Notification No.GSR 1037(E), dated 5th December 1989. There are following specific Committees to deal with safety, regulations and other issues concerning biotech products:

a) **Recombinant DNA Advisory Committee (RDAC)** to review developments in Biotechnology at national and international levels and recommend suitable and appropriate regulations for India in the field of recombinant research.

b) **Review Committee on Genetic Manipulation (RCGM)** in the Department of Biotechnology monitors the safety related aspect in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms.

c) **Institutional Biosafety Committee (IBSC)** is required to be constituted in the research institutions handling microorganisms/ genetically engineered organisms. The Committee shall comprise the Head of the Institution, scientists engaged in DNA work, a medical expert and a nominee of the Department of Biotechnology.

d) **Genetic Engineering Approval Committee (GEAC)** functions as a body under the Department of Environment, Forests and Wildlife for approval of activities involving large-scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle. The Committee is responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials. Additional Secretary, Department of Environment chairs this Committee.

e) **State Biotechnology Co-ordination Committee (SBCC)** is constituted in the states wherever necessary to inspect, investigate and take punitive action in case of violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services. The Committee periodically reviews the safety and control measurers in the various industries/ institutions handling genetically engineered organisms/Hazardous microorganisms.

f) **District Level Committees (DLCs)** are constituted in the districts wherever necessary under District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment. The representatives of this Committee visit the installations engaged in activity involving genetically engineered organism, hazardous microorganisms to find out hazards and risks associated with each of theses installations and coordinate activities with a view to meeting any emergency. They shall also prepare an offsite emergency plan. The District Level Committee shall regularly submit its report to the State Biotechnology Coordination Committee/ Genetic Engineering Approval Committee.

A note about implementation of the recommendations of Task Force on Recombinant Pharma Sector under the Chairmanship of Dr R A Mashelkar, DG, CSIR, taken from MOEF's website is appended vide **Annexure X.**

9.8 **Regulatory Mechanism for Biotech products abroad:** For nearly a century Biotech Pharmaceuticals have been regulated as a world apart distinct from classically synthesized drugs-as evident in public health law, US FDA Policy and industry practice. This reflects the fact that biological substances are not only complex and difficult to characterize but also their source material is often variable and open to contamination. It has also excluded biotech product from the generic approval process used with the conventional drugs. In the past 15 years, however, international regulatory standards for biologics have become considerably more sophisticated. Recently with some changes internationally like the precedent of DNA derived products, growth hormones and insulin being approved under Section 505 of the US Food Drugs and Cosmetics Act, the classic legal, regulatory and scientific distinctions of drug and biologics are increasingly blurred. As per report in SCRIP Magazine (July/Aug.2000) there are currently two regulatory filing strategies that could lead to approval of a therapeutically equivalent biotech product in the US–505(b)(2) or a biologics license application. A third filing strategy is Marketing Authorization Application (MAA) via a centralized procedure that would be used for European dossier.

9.9 **Quality control of AYUSH Products:** To fill up the gaps in quality control mechanism of AYUSH products a Centrally Sponsored Scheme (CSS) was implemented five years back to provide financial assistance to strengthen drug-testing labs (DTL) and Pharmacies of government sector under this scheme. 21 DTLs were financed till 2004-05. Schedule T under Drugs & Cosmetics Act making provision for GMP of AYUSH drugs was

issued in June 2000 giving 2 years period for existing units to improve their manufacturing facilities. Revised GMP was notified during 2003. Notification to follow GMP was promoted through workshops. In October 2005 Department of AYUSH had issued orders to State Secretaries under Section-33 (P) of Drugs & Cosmetics Act to cancel manufacturing licenses of non-GLP complying units. By and large in cases of 90% AYUSH formations there is a need to develop Standard Operating Procedures(SOPs) for the manufacture.

9.9.1 There is Ayurvedic Pharmacopoeial Committee looking into development of scientific quality standards and shelf life studies. An important step taken for protection of Traditional Knowledge is in the form of Traditional Knowledge Digital Library(TKDL) for Ayurvedic, Sidha, Unani and Yoga System which has compilation of 36,000 Ayurvedic formulations into Patent compatible format in 6 languages and is available to patent examiners for preventing patent claims based on Indian Knowledge.

9.10 Suggestions /recommendations about regulatory mechanisms for drugs & Pharmaceuticals:

1. Grant approvals for novel drug combinations even if they have not been marketed in other nations, provided these are rationale, safe and due trial scrutiny has been done
2. Frame suitable laws and guidelines for approvals for orphan drugs and alternative therapies, including biotech products
3. The fast evolving segment of nutraceuticals has now been recognised as having a distinct status through a Ministry of Health & Family Welfare Notification issued in October 2006.
4. Setting up combined regulatory Apex Authority having control of quality, supply of drugs.

10. To review the present Drugs & Cosmetics Act and to suggest amendments to it including for ensuring GMP.

Background: In 1940, through an Act, a law was framed to control the manufacture, distribution and sale of medicines in the form of Drugs & Cosmetics Act, 1940. Subsequently Drugs & Cosmetics Rules were framed during 1945. the Drugs & Cosmetics Act has been amended many times with latest amendments being in 1995. In addition to the Drugs & Cosmetics Act some other related Acts and Rules are as follows:

1. The Pharmacy Act of 1948.
2. The Drugs & Magic Remedies (Objectionable Advertisement) Act of 1954.
3. The Narcotic Drugs & Psychotropic substances Act, 1985.
4. The Poisons Act of 1919.
5. The Medicinal & Toilet Preparations (Excise Duties) Act of 1956.
6. The Medicinal & Toilet Preparations (Excise Duties) Rules of 1956.
7. The Drugs (Prices Control) Order 1995.
8. Various Drug Policies announced from time to time by Department of Chemicals & Petrochemicals.

10.1 **Drugs & Cosmetics Act of 1940:** In India the quality of drugs manufactured, sold and distributed is regulated by the provisions of Drugs & Cosmetics Act 1940 and Rules 1945. The provisions about compliance of Good Manufacturing Practices(GMP) are stipulated in Schedule 'M' of Drugs & Cosmetics Rules 1945. Under the provisions of this Act Drugs Technical Advisory Board has been appointed by Central Government to advise the Central and State Governments on technical matters related to the administration of the Act. Similarly, the constitution of Drug Consultative Committee is also part of this Act.

10.1.1 The Drugs & Cosmetics Act interalia prohibits import of any drug, which is not of standard quality, any misbranded and any spurious drugs. Punishment is accorded for contravention of the Act. The Central Government is vested with powers to ban import and manufacture for sale or

distribution of such medicines, which are therapeutically irrational or harmful. The Central and State Governments appoint licensing authorities, analysts and inspectors for controlling the implementation of the provisions of the Act. The CDSCO coordinates the various activities required under the Drugs & Cosmetics Act through their Zonal offices. One of the important items is the monitoring of drug quality under which nearly 50,000 samples are analysed per year by various states and central laboratories. Follow up action is taken by concerned state authorities on non-standard quality drugs depending on nature of defect.

10.2 **Schedules to Drugs & Cosmetics Act:** The Drugs & Cosmetics Act has following Schedules**:**

Schedule A - specimen of prescribed forms
Schedule B - fees for tests or analysis by CDL/Government analyst.
Schedule C & C1 - Biological and special products
Schedule D - Deals with exemption in import of drugs.
Schedule E -List of poisonous substances under Indian system of medicines.
Schedule F -Standards of bacterial vaccines, surgical dressings, bandages etc.
Schedule FF -Standards for ophthalmic preparations.
Schedule G - Drugs to be labelled
Schedule H - Drugs to be sold on prescription only.
Schedule J -List of ailments where no drug should claim cure.
Schedule K -Conditions exempted from provisions of Chapter IV of the Act
Schedule M - Good Manufacturing Practices involving premises and plants
Schedule N -Requirements of minimum equipment of a Pharmacy
Schedule O -Provisions for black disinfectant fluid.
Schedule P - Life period of drugs including combinations.
Schedule Q -List of permitted coal tar colours.
Schedule R - Standards for mechanical contraceptives.
Schedule T-Requirements of factory premises and Hygenic conditions for Ayurvedic and Unani drugs.
Schedule U -Regarding manufacturing Records.
Schedule V -Standards for patented and proprietary medicines.
Schedule W -Drugs which shall be marketed under generic names.
Schedule X - Psychotropic drugs requiring licences for manufacture and sale
Schedule Y - Guidelines for clinical trials, import & manufacture of new drugs.

10.3 **Operating part of Schedules:** The Central Drugs Laboratory has to analyze and test such samples as may be sent to them on payment of

prescribed fees. Rules are prescribed for import and distribution of drugs. The drug rules lay down the qualification, functions and powers of Govt. analyst and drug inspectors. There is also provision where no drug can be sold or distributed unless it is labeled according to prescribed rules. A Drug Consultative Committee consisting of all State Drug Controllers functions to provide advise on matters relating to uniform implementation of the Drugs & Cosmetics Act and the Rules throughout the country. For the purpose of Drugs & Cosmetics Act the Indian Pharmacoepia, United States Pharmacoepia, British Pharmacoepia are part of the prescribed Pharmacoepia and drugs whose standards are not covered under these may not be imported. The IP published by Ministry of Health is the main book of standards for Drugs produced in the country, but there are other drugs, not included in IP even then their standards are also approved by the government. The last updated edition of IP was published in 1996.

10.3.1 **Clinical Trials as per Schedule Y:** Under Schedule Y of current Drug Rules any new Pharmaceutical product cannot be approved immediately in India following its introduction in the source country where it is first approved. This is due to a clause, which stipulates that the Pharmaceutical company can only apply for trial, which is one phase behind rest of the world. Therefore, in most cases the innovative company either MNC or Indian, which is ready with new Pharmaceutical product, has to apply for clinical trials only when the drug is approved abroad. This application is for the free marketing clinical trials known as phase III clinical trials. These clinical trials are required for the registration of a new product in India after its introduction abroad. Ministry of Health has revised Schedule Y allowing foreign manufacturers also to conduct parallel phase clinical trials in India. The benefits of the change include approval of a new drug immediately after its approval in the source country, availability of data on Indian patients before approval of each drug in the country. This may be in addition to upgrading facilities of clinical research investigations in India thereby making them acceptable to International Regulatory Authorities.

10.3.2 **Good Clinical Practices (GCP) as per Schedule 'M':** Good Clinical Practice is a set of guidelines for biomedical studies which encompasses the design, conduct, termination, audit, analysis, reporting and documentation of the studies involving human subjects. The fundamental tenet of GCP is that in research on man, the interest of science and society should never take precedence over considerations related to the well being of the study subject. It aims to ensure that the studies are scientifically and ethically sound and that the clinical properties of the Pharmaceutical substances under investigation are properly documented. The guidelines seek to

establish two cardinal principles: protection of the rights of human subjects and authenticity of biomedical data generated.

10.3.3 A need is felt to develop Indian Guidelines to ensure uniform quality of clinical research throughout the country and to generate data for registration for new drugs before use in the Indian population. An Expert Committee set up by CDSCO in consultation with clinical experts, has formulated GCP guidelines for generation of clinical data on drugs. These guidelines have been evolved with consideration of WHO, ICH, USFDA and European GCP guidelines as well as the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research

10.3.4 **The Drug Technical Advisory Board (DTAB**), the highest technical body under Drugs & Cosmetics Act, has endorsed adoption of GCP guidelines for streamlining the clinical studies in India. They should be followed for carrying out all biomedical research in India at all stages of drug development, whether prior or subsequent to product registration in India. There is a proposal to conduct inspections of Clinical Research Organisations by the CDSCO alongwith the experts. Necessary training of the concerned officers in this regard is being planned.

10.4 **Changes in Drugs & Cosmetics Act:** It is a fact that the procedures followed by various state licensing authorities are different. While states like Maharashtra, Gujarat, Andhra Pradesh and Karnataka have stringent regulations; the rules are a bit relaxed in some states. As a result the units in states like Maharashtra, Gujarat, AP etc are finding that their products manufactured under stringent regulations are not in a position to be cost competitive with similar products from units in other states where implementation of Act & Rules is lax. As such it is necessary that uniformity is brought in this regard by all state licensing authorities. There have been suggestions to entralize approvals relating to licensing, GMP and inspection process. Already the procedures have been centralized for blood products, LVPs, Sera and Vaccines. However, Health including drugs are in concurrent list and licensing of drug manufacturers, sale, quality control are to be dealt by state governments.

10.4.1 Formation of Central Drug Authority(CDA) is envisaged which is in line with the recommendations of Dr Mashelkar Committee Report. CDA will take up the issue of grant of license for manufacture of drugs. This will bring in uniformity in implementation of Drugs & Cosmetics Act & Rules in India.

10.5 **International movement of Drugs:** Import of drugs is regulated under the provisions of Chapter III of the Drugs & Cosmetics Act. Any drug of foreign origin can be imported into the country through an Indian agent after

due procedure of registration and issue of import license under Drugs & Cosmetics Act. The export of drugs from India is subjected to various formalities including inspection of Indian manufacturing units by the authorities of the importing country. In India regular inspections could not be taken up due to shortage of manpower.

10.5.1 Under Part IV of the Drugs & Cosmetics Rules registration of the plants of overseas manufacturers as well as their products is now mandatory for last few years, in case of imports of Drugs & Pharmaceuticals. Some of the salient features of registration procedure are as follows:

- The word imports changed to “import and registration” under Drugs & Cosmetics Rules.
- Both the company and products will be registered and prescribed fees is US$ 1500 in respect of site registration and US$ 1000 per drug or equivalent in Indian rupees
- There is procedure for inspection of manufacturers premises. A fee of US$ 5,000 has to be deposited in case a manufacturing site is to be inspected.
- Provides for provisions for import of small quantities of drugs by government hospitals and dispensaries.
- There are rules for import of all drugs under provisions of Drugs & Cosmetics Rules

10.6 **Regulation of medical devices:** The Ministry of Health & Family Welfare has announced guidelines for Import and manufacture of medical devices vide Gazette notification S.O. 1468 (E) dated 6/10/2005 declaring the following sterile devices to be considered as drugs under Section 3 (b) (iv) of the Act.

1. Cardiac Stents.
2. Drug Eluting Stents.
3. Catheters.
4. Intra Ocular Lenses.
5. I.V. Cannulae.
6. Bone Cements.
7. Heart Valves.
8. Scalp Vein Set.
9. Orthopedic Implants.
10 Internal Prosthetic replacements.

10.6.1 It was also notified vide GSR 627 (E) dated 7/10/2005 that control over manufacture of these devices be exercised by CLAA i.e. DCG(I) under

said Rules. The Ministry of Health has now approved detailed procedures for licensing of import as well as manufacture of these Medical Devices in the country. **These guidelines are effective from 1st March 2006.**

10.7 **Regulation of Narcotics & Psychotropic Substances**: In order to effectively control the abuse of narcotic and psychotropic drugs in the country the Narcotics and Psychotropic Substances Act, 1985 was enacted. Schedule X of Drugs & Cosmetics Act deals with the conditions about use of Narcotics & Psychotropic Substances for medicinal applications. It lays down conditions & procedures required to be observed with regard to manufacture and sale of formulations containing prescribed quantities of Narcotic drugs or Psychotropic Substances.

10.7.1 As per present system the formulators or manufacturers of any Narcotics & Psychotropic Substances have to approach drug control authorities of State & Centre, Narcotics Control Bureau or Central Bureau of Narcotics, which are under Ministries of Home & Finance respectively. Some periodic reports are required to be submitted by the Ministry of Health & Family Welfare to Narcotics Control Bureau for onward transmission to the International Narcotics Control Board(INCB), Vienna. With a view to streamline the policies in this regard and finetune them in accordance with international regulations, the Government constituted an Expert Committee to review the Schedules to the Narcotics & Psychotropic Substances Act & Rules. Based on the recommendations of the said Committee several Psychotropic substances are proposed to be shifted to Schedule III so as to allow the manufacture of such Psychotropic substances only for export.

10.7.2 There is need for better clarity about regulating the sale and use of certain medicines, which contain regulated quantities of narcotic substances, as legally permitted under the Act. Through a notification issued on 14th November 1985 such drugs were exempted from the applicability of the NDPS Act. Manufacture of these drugs is regulated under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Several instances of misuse of these habit forming drug formulations containing ingredients of narcotics and psychotropic substances have been noticed in the past. In order to prevent misuse of such drugs the Department of Health and Family Welfare in consultation with Revenue Department and other concerned agencies would evolve an effective mechanism under the provisions of Drugs and Cosmetics Act, 1940.

10.7.3 In view of the multiplicity of authorities involved in the regulatory mechanism applicable to Narcotics & Psychotropic Substances, it is recommended that the proposed Apex Authority for drugs should have all powers with regard to licensing for manufacture, formulate, import or export of products based upon Narcotics & Psychotropic Substances.

10.8 **Regulation of Ayurvedic drugs**: The Objectives of the Department of AYUSH include upgradation of the educational standards in the Indian Systems of Medicines and Homoeopathy colleges in the country, strengthening existing research institutions and ensure a time-bound research programme on identified diseases for which these systems have an effective treatment, drawing up & implementation of schemes for promotion, cultivation and regeneration of medicinal plants used in these systems & to evolve Pharmacopoeial standards for Indian Systems of Medicine and Homoeopathy drugs. Rule 151 under Drugs & Cosmetics Act prescribes the conditions and requirements of manufacture etc of AYUSH drugs. Being a relatively new Department it has done commendable work & succeeded in putting in place various Schemes aimed at development of various aspects of the Indian Systems of Medicine. However, there is a need to provide exposure to personnel of the Department in international marketing of Indian products & popularize these products globally. **Pharmexcil may help the Department in exploring export opportunities for AYUSH products**. The issue of Data Protection under Article 39.3 of TRIPs Agreement should be resolved at earliest for AYUSH products also.

10.9 **Recommendation:** Keeping in view the above developments there is a need for cooperation between various Regulatory Authorities. GMP, which is a part of Drugs & Cosmetics Act, will be a crucial factor. So Ministry of Health should look towards the various regulatory developments taking place abroad and fine tune the Drugs & Cosmetics Act & Rules accordingly. There is an urgent need to set up an Apex Central Regulatory Authority to oversee all aspects of specific therapies in vogue in the country and implement specific Rules & regulations about drugs under various categories including medical devices.

11. To review present structure of Indian drug industry and suggest measures for improving quality of drugs, particularly for tackling the menace of spurious drugs.

Status of Indian Drugs & Pharma Industry: The Indian Drugs & Pharma Industry has made rapid strides over the years and has shown tremendous progress in terms of infrastructure development, technology base and wide range of production. The industry now manufactures practically the entire range of therapeutic products. The Industry is capable of producing raw materials for the manufacture of a vide range of bulk drugs from basic stage. The domestic companies now focus on process development and have attained skills to work out low cost synthesis routes. The strength of the industry is developing cost effective technologies in the shortest possible time for bulk drugs and drug intermediates without compromising on quality. These bulk actives are used by the buyer companies in the Dosage Forms again subject to stringent assessment by various regulatory authorities in importing countries. This speaks of the highest quality standards maintained by large number of Indian companies and this should also counter general perception of the West about Indian medicines being of lower standards.

11.1 As reported in SCRIP World Pharma News UK, the country ranks 4th worldwide accounting for 8% of world's production by volume and about 1.5% by value. Today Indian Pharma Industry has retail sales of over Rs. 32000 crores in addition to Rs. 21000 crores by exports of Drugs, Pharma & Fine Chemicals. The world's largest Pharma market- USA is the number 1 import destination for Indian Pharmaceuticals. 25% of exports of Indian Pharmaceuticals are to European region, which is an achievement. India ranks 17th in terms of export value of bulk actives and Dosage Forms.

11.2 **Strengths of Indian Pharma Industry:** Many of the original innovator companies source their discovered drugs from Indian companies. India manufacturs and exports medicines from all therapeutic groups. Especially India is a world leader in anti TB segment. The country has been able to develop cost effective processes for some of the latest patented medicines like Glitazones, Rofecoxib, Celecoxib, Statins, Montelukast etc. India also specializes in HIV/AIDS drugs, many of which cost a fraction of MNC prices. These are supplied to many of the African countries, which are poor, but having large number of HIV/AIDS patients. R&D can be carried out in India at a fraction of equivalent cost in Europe or USA; on a dollar basis, the cost advantage is estimated to be 10 to 15 times. Leading Indian companies are setting up satellite research laboratories in USA manned by US personnel and also have set up joint venture units as well as acquired local units to

market generic medicines especially in USA and UK. In the original drug discovery, leading Indian companies have already licensed new molecules to Pharma MNCs for further development and have collected milestone payments. Now a number of companies are not only engaged in the discovery of new drugs but also carry out work on new drug delivery system, dosage forms' development, process development etc.

11.3 **Weaknesses of SSI Pharma Units:** Keeping in view the quality issue, Ministry of Health has already notified and upgraded Schedule 'M'. While larger units numbering 300 have been able to meet the stipulations, it is doubtful whether a major section of SSI units who have a significant contribution in Pharmaceuticals have been able to meet the requirements. There is a greater need to create proper infrastructure including advanced instrumentation for which funds are required. There is a need to assist SSI units for which Planning Commission can provide some sort of funds. For medium companies Government may like to consider sanctioning soft loans through financial institutions to upgrade their infrastructure pertaining to quality. There is also need to make available testing facilities to small units to keep a check on quality. State drug testing labs should be modernized**.**

11.4 **Spurious drugs:** A section of the Industry is doing brisk business at the consumers' cost. Its tentacles are spreading far and wide. Unfortunately, consuming a spurious drug unlike buying a counterfeit designer shoes or apparel has mind-boggling ramifications. Even when spurious drugs do not endanger life, they can leave the patient seriously ill and those with inadequate potency do bigger harm to the society in general. Drug resistance develops when patients consume drugs with inadequate potency forcing them to look for costlier new generation drugs. And these patients could put the entire society at risk by spreading drug resistance. Unlike other cases where the consumer knows his intent, the spurious drug industry thrives on consumers' ignorance, lack of stiff penalty for indulging in such activity and finally on lax regulatory system. Packaging is so nearly perfect that distinguishing a spurious drug from a genuine one is almost impossible.

11.4.1 Re-usage of drugs past their expiry date is yet another menace. The government plans to advocate severe penalties for spurious drug racketing. Plans are also afloat to reward anyone providing evidence of spurious drug manufacturing or selling, and finally to educate the public about the ills of spurious drugs through the electronic media. Brands in antibiotics, analgesics and anti-diarhoeial are the preferred target segments by the fake manufacturers. In fact, authorities and NGOs understood the seriousness of problem only after Pharma companies started raising the issue in various public fora. As the manufacture of spurious drugs is totally an illegal activity,

no convincing estimate of production and availability of these products, is available with governments or any other agencies.

11.4.2 The main reasons for the spread of menace of spurious drugs are:

Infrastructural Problems due to**:**

a) Lack of adequate number of inspectors
b) Lack of adequate laboratory and testing facilities
c) Lack of facilities for speedy communication and mobility
d) Lack of adequate funds
e) Lack of adequate training in investigational skills

Legal Problems:

a) Lack of - summoning powers to the inspectors
b) Special courts for speedy trials - co-ordination with other law enforcing agencies - fear of law.

Other problems:

a) Lack of uniformity in implementation
b) Lack of uniformity of procedures adopted in licensing
c) Variation in size of industry and strength of regulators within States

11.5 **Steps taken by the Government to tackle Spurious drugs:** The Government appointed a high-power committee headed by the eminent scientist, Dr Mashelkar, to study the issue and recommend measures to curb this menace. The Committee submitted its report in 2003. The Committee studied the entire problem in all details and based on its recommendations Ministry of Health & Family Welfare moved a detailed legislation during 2003 for parliamentary approval. However the said bill is no more valid and Ministry of Health & Family welfare has introduced a revised Drugs & Cosmetics Act (Amendment bill) 2005. The salient features of this bill, highlighting its objectives, are contained in **Annexure XI.**

11.6 **Other Suggestions:**

1) Creation of adequate infrastructure
2) Bring restrictions in licensing of retail Pharmacies to avoid agglomeration
3) Limit the restricted licenses to rural areas
4) Creation of Intelligent cum Legal wing in states and zonal office
5) Identifying and notifying nodal officers in each state and zonal office for communications regarding spurious and counterfeit drugs
6) Creating central registry for formulations under the brand names and their compositions.

12. To benchmark the Indian Drugs & Pharmaceuticals Industry against the international Drugs & Pharmaceuticals Industry and to suggest appropriate measures for bringing it up to international levels.

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13. To make such other recommendations as are considered appropriate to make the drugs and Pharmaceutical industry internationally competitive at the earliest.

Pharma Industry - a knowledge-based Industry: Pharma Industry is a knowledge-based Industry. Factors like R&D, infrastructure, qualified manpower, training, technology, modernization have a key role in making the industry internationally competitive. Harmonisation of regulatory procedures, mutual recognition of regulatory procedures plays a crucial role in making the Indian Industry competitive.

The following are some of the additional important recommendations/ suggestions in addition to what has been stated under different heads.

13.1 **Recommendations:**

1. There is a greater need to create proper infrastructure including advanced instrumentation for which funds are required. The larger units can be assisted by way of soft loans from financial institutions. However, there is a greater need to assist SSI units for which Planning Commission can provide some funds to help SSI units in their efforts to improve infrastructure. For medium companies Govt. may like to consider sanctioning soft loans through financial institutions to upgrade their infrastructure pertaining to quality.
2. There is also a need to conduct regular workshops, technical seminars by CDSCO & SLAs on the quality issues to educate the SSI units.
3. Regarding regulatory issues, uniform procedures to be followed by all State Drug Control Authorities.
4. There is a requirement for regular inspections so that quality is maintained. However, there is a lack of infrastructure and, therefore, states should be funded to take care of this aspect of creation of infrastructure by way of recruiting qualified inspectors and also to set up quality testing laboratories with advanced equipment. There is a need to train the staff with advanced techniques for both regulatory personnel at center and the states.

5. States should constitute legal cum intelligence cells for carrying on campaign against spurious drugs. Again in this case, the Central Government should assist State Governments by extending funds to them. Also there should be a separate legal Departments with State Licensing Authorities as well as Central Licensing Authorities to take care of the issue of spurious drugs.
6. Suggestion has come that Central Government should have fully equipped laboratories with all facilities. The small scale firms should be given access to testing facilities available with the State Governments on payment of prescribed fees since many small scale firms find it difficult to get their drugs tested
7. Indian Systems of Medicines & Homeopathy have also notified the draft guidelines on GMP, which will take care of the GMP aspects pertaining to Ayurvedic, Unani and Homeopathic drugs. ISM&H also issued draft rules concerning approval of laboratories for carrying out analysis of Ayurvedic medicines. The issue of rules pertaining to GMP for traditional drugs is an important step. Another set of draft notification has been issued by ISM&H concerning labeling, packaging etc.
8. **Bulk purchases by Government**: Regarding procedures for Government's tenders for medicines, as is the practice in Maharashtra and some other states, it is necessary to specify some minimum turnover as well as upgraded GMP certificate as pre conditions. Following may be adopted as the guiding factors for procurement of bulk purchase of medicines by government agencies:
    I. Procurement preferably in the form of generic drugs.
    II. Technical and price bids to be invited in separate envelopes. Bids /tenders to be invited through press and website of the concerned department.
    III. Procurement only from pre-qualified manufacturers of drugs.
    IV. Schedule M for GMP compliance of the manufacturer to be ensured. In case of Ayurveda , Siddha and Unani drugs Schedule T for GMP compliance of the manufacturer to be ensured . In case of these drugs the quality should be assessed as per guidelines of AYUSH/ Research Councils.
    V. Minimum 3 years of track record in sustained production and marketing of the concerned drug. (at least 10% of the quantity purchased) Balance sheets for the previous three years be

obtained to make an assessment of the manufacturing and financial capacity of the manufacturer.

VI. Post-tender award inspection of manufacturing facilities to be carried out by the purchasing agency.

VII. Batch-wise sample testing of drugs from government run or government approved laboratories before the drugs are put to use. In case of failure of a drug during testing suitable penalties to be imposed on the manufacturer including debarring of the manufacturer from participating in future tenders of the concerned agency for a certain period.

VIII. Packaging specifications may be prescribed for better shelf life.

IX. Minimum shelf life for purchased drugs should be for two years.

X. In case the price quoted by a manufacturer is lower than the price fixed by NPPA by more than 35 percentage points he they may be asked to provide justification for the same. In case they are unable to provide proper justification their bid may be rejected.

XI. Third party quality assurance may be adopted as is being done by Health Department for World Bank funded drugs. It should be the responsibility of this agency to ensure supply of quality drugs.

XII. Where a different criteria and procedure has been prescribed by any lending agency(World Bank, WHO, UNICEF etc) the same may be followed.

XIII. Local purchases of the drugs should be avoided as far as possible.

XIV. Expired drugs must be destroyed by the hospitals as per the norms laid down by Pollution Control Board.

XV. In some of the Central Government Organisations and States, a centralized purchase system for drugs is adopted. It would be in larger public interest that a similar system is adopted in all the Central organizations and the States

9. The general public should be made aware of the precautions to be taken such as not purchasing medicines without cash memo etc. Consumer Awareness Campaigns through print and electronic media on price fixation, revision, use of Generics including Consumer Education and empowerment need to be carried out on a sustained basis for which Government may provide adequate

budgetary resources amounting to **Rs. 100 crores** to National Pharmaceuticals Pricing Authority (NPPA). This amount would be used to set up State level Drug Price Monitoring Cells in each State, AppellateTribunal and for public awareness efforts for drug prices, A dedicated website may also be created which would provide all possible information about drug prices and related matters. In addition to English language, publicity would also be carried out in other Indian languages. State governments would also be involved with this work.

In order to address various grievances and public complaints about overcharging, quality, availability etc the Helpline set up by Consumer Affairs Department would be made use of.

10. **Revision of Indian Pharmacopoeia**: The Indian Pharmacoepia was last revised in the year 1996 and an addendum including anti-retroviral drugs has been released in March 2006. Ministry of Health has initiated the task of revising it. The Scientific Committee of Indian Pharmacoepia has begun the work of revision by forming 20 expert sub-committees, which would provide key inputs. These Committees would focus on areas like clinical medicine and Pharmacology, drug nomenclature, general policies and planning, medicinal chemicals, Parenterals, devices and diagnostics, blood and blood products, biotechnology and recombinant DNA products, vaccines and other biologicals, herbal products etc. Special focus is being given to set standards of medicines for diseases of national importance. In order to keep pace with changing medicinal environment there is a need to revise Indian Pharmacoepia after every 5 years.

11. In order to enable India to achieve a leading position as the **Drug Maker of the World,** it is essential that **a World-class infrastructure** is provided for the accelerated growth of the industry. Added to this are the environmental concerns due to difficulties in hazardous waste disposal by some of the bulk drug units. In order to provide the required infrastructure it is essential to have a scheme where Central Government, State Governments and industry are the partners. A special scheme for setting up **Pharmaceutical parks** in the country (separate for bulk and for formulations) in the next 5 years is needed.

11.1 Presently Pharma parks are being operated by state government like the one in Vishakhapatnam, AP. Considering the environmental issues, the idea of Pharma parks is that the environmental aspects can

be taken care of as similar Pharma manufacturing units in bulk will be located at one place. It is also necessary that all clearances both central as well as state should be through a single window concept. The thrust of Pharma parks is not only to cater to domestic market but more important for the export markets. Here it is also stated that notwithstanding the liberalized procedures, the western Pharma companies instead of setting up manufacturing units will depend more on contract manufacturing. Hence the suggestion on Pharma parks. There could be 10 Pharma parks with an investment of Rs.25 crores each. Hence the total requirement of funds would be **Rs.250 crores**. The implementation of the scheme through SPVs and also with the involvement of industry associations can be worked out after the concept is approved.

12. Based upon the above discussion following additional Schemes are recommended for funding the Indian Drugs & Pharma Industry

i. Pharma industry being Knowledge based Industry; fast developments are taking place not only in the manufacture but also in the R&D. The stakeholders need to keep track of the international developments through conferences, seminars as well as holding up international exhibitions. Certain funding is needed for promotion of Indian Pharma industry in the light of global Pharma development taking place. In the 11th Five Year Plan period an amount of **Rs.100 crores** can be earmarked for this item.

ii. Each manufacturer has to carry out verification of supply chain and file returns with the FDAs at periodical intervals.

v. Creation of advisory bodies at district level with NGOs and Consumer Associations

vi. Preparation of dossiers of suspected dealers and manufacturers

vii. Define exports and apply all the conditions applicable to local manufacturer for exports with proper exemptions in standards and labeling as per import requirements.

13.2 Growth in the industry has generated demand for good infrastructure which should not only be world class but which also addresses the environmental concerns stemming out of the need to provide for efficient disposal of chemical waste and pollutants as well as hazardous waste. A special scheme for Pharma parks / SEZs for Pharma industry is proposed by the Central Government broadly on the lines of the Textile Parks.

13.3 The State Governments have also been implementing schemes relating to setting up of industrial areas and estates. The progress needs to be faster and better infrastructure facilities should be provided, with special focus on infrastructure requirements for the SME sector.

13.4 The industry, Central and State Governments should pool resources for improving infrastructure and special projects can be taken up on public – private partnership model, BOT and BOOT basis and in the private sector as well. It is necessary to increase investment for the purpose.

13.5 Environmental concerns require increased attention to improvement of existing infrastructure and development of new infrastructure facilities for this purpose. The following should be considered while creating new infrastructure, specially for SMEs :-

I. Shared facilities for pipelines, utilities, analytical testing laboratories, effluent collection and treatment facilities.

II. Development of training centres for skill upgradation and improved human resources, common R&D centres, which should also serve as incubators.

III. Schemes to promote compliance of Schedule M, improvement in quality by adopting international regulatory standards (such as FDA / MCA) and technology upgradation with special focus on the small sector.

13.6 The global Pharma Industry is under tremendous pressure to reduce costs. While the drug discovery cost has ballooned to U.S. $ 1 bn per NCE, the R&D productivity is continually declining. The global industry, therefore, is looking for cost containment through outsourcing & India offers tremendous opportunity in the area of contract Research, manufacturing, clinical trails, bio-informatics, custom synthesis, technical services etc.

13.7 A major cost of drug development is in clinical trials. Conducting clinical trials in India will offer three benefits. Firstly, cost of such trials in India is almost half of that of U.S. and other developed countries. Secondly, India has abundance of genetically diverse patient pool that is “drug naïve”(not taken other drugs for their condition in the past). And thirdly, we have many qualified doctors with expertise to conduct and supervise clinical trials according to Good Clinical Practices (GCP), a globally recognized standard. The Ministry of Health has issued revised Schedule ‘Y’ to the Drugs and Cosmetics Act, which gives these Guidelines. Some large companies have started carrying out international clinical trials in India.

13.8 Tax benefits should be such as to attract Multinational companies to get clinical trials and research done through Indian companies.

13.9 The implementation of the new Schedule 'M' for GMP, our manufacturing facilities will conform to international quality standards. This conducive environment will prompt international Pharma companies to enter into alliances with domestic companies for generic drugs sourcing to be marketed in overseas markets. Again the local manufacturing units of MNC subsidiaries can be utilised to manufacture bulk drugs and formulations for global supply to other affiliates. International operations of Indian companies, overseas acquisitions and exports will be the major thrust of the industry in the Post Product Patent era. In the past 2 years, Indian companies have acquired companies overseas to the tune of $ 550 million.

13.10 Keeping in view the limited resources available with SMES and the additional financial burden on account of the mandatory requirement for schedule M compliance, an attractive scheme for assistance for Schedule M compliance is needed with increased spread in the SSI sector. This is specially relevant because as per Annexure III, 370 units have been identified which are not in a position to comply with GMP norms.

13.11 Similarly better access to funds for brand promotion is felt necessary by the domestic companies, specially the small and medium units since they do not have the wherewithal and resources to promote a brand, although their quality and volumes may justify a brand for the product. This deprives the companies of critical value addition.

13.12 Information related to technical aspects as well as on marketing and market access to overseas markets, schemes and incentives available for the industry, and such other information are required to be disseminated and made readily available which can be used by the industry, specially SMEs. Many technical journals, books etc. such as the International Pharmacopeia, Patents, trade journals etc. are not accessible and at times unaffordable for SMEs. There is therefore urgent need to set up a technical and trade information centre for this purpose. This can be a collaborative effort of Government and industry.

13.13 **Revival of Pharma Public Sector Undertakings (PSUs)** - Pharma PSUs are required in the country for strategic reasons. They continue to serve an important social cause even in today's competitive environment. They make available essential drugs at reasonable prices, which help in keeping a check on prices of Pharma items to some extent. HAL introduced Plasma Volume Expander (PVE) in the market. It brought down prices of

PVE from Rs. 156/- to Rs. 75/- per bottle. Also in the event of natural calamities such as floods, earthquakes etc. Pharma PSUs have come forward to meet the need for critical drugs at a short notice, as during floods in July, 2005 in Mumbai, when IDPL supplied six lakhs Doxycycline capsules in bulk for laptospirosis at a short notice of 72 hours, when the medicine was not available in the market. As Pharma PSUs rise to the occasion in emergent situations and serve to keep a check on the prices of some of the critical drugs, it is essential to ensure survival and viability of these not only through financial restructuring but also through policies, which enable them to play an important role in the public health system of the country.

13.13.1 There are 5 central PSUs and 6 joint sector undertakings in the Pharmaceutical Sector under the administrative control of the Department of Chemicals & Petrochemicals. Out of the 5 Central PSUs, Hindustan Antibiotics Limited, Pune (HAL) and Indian Drugs and Pharmaceuticals Limited (IDPL) were set up as Joint Stock Companies by Government of India with the primary objective of creating self-sufficiency in essential life saving drugs. The other 3 PSUs namely, Bengal Chemicals & Pharmaceuticals Limited (BCPL), Bengal Immunity Limited (BIL) and Smith Stanistreet Pharmaceuticals Limited (SSPL) were taken over from the private sector when they became sick. In addition, there are 6 joint sector undertakings promoted by Government of India through HAL and IDPL in collaboration with State Governments. They are Karnataka Antibiotics & Pharmaceuticals Limited (KAPL), Maharashtra Antibiotics & Pharmaceuticals Limited (MAPL), Manipur State Drugs & Pharmaceuticals Limited (MSDPL), Rajasthan Drugs & Pharmaceuticals Limited (RDPL), Uttar Pradesh Drugs & Pharmaceuticals Limited (UPDPL) and Orissa Drugs and Chemicals Limited (ODCL). Besides, there are two wholly owned subsidiaries under IDPL, namely IDPL (Tamil Nadu) Limited, Chennai and Bihar Drugs and Organic Chemicals Limited, Muzaffarpur.

13.13.2 These Pharma PSUs have played an important role by manufacturing for the first time various bulk drugs, especially life saving drugs, in the country and making available such essential drugs at affordable prices. HAL, set up in 1954 was the first company to produce Pencillin, Streptomycin, Gentamycin etc. in the country. Both HAL and IDPL are also instrumental in creating a solid base for the Pharmaceutical industry. However, due to various reasons like making available life saving drugs at low prices, creating infrastructure facilities like township, hospitals, schools, etc. to discharge its social obligation, these Companies could not make sufficient profit to accelerate its future growth. Added to this, non-revision of prices of bulk drugs produced by these units and unhealthy competition have adversely affected the working of these Companies.

13.13.3 From the very inception, the focus of these PSUs was to supply life saving drugs primarily to Government Hospitals and other Government health care programmes. Consequently they could not develop their own base in the Trade Market. With the withdrawal of purchase preference by Government, these PSUs had to face a serious situation whereby they lost their existing market and have to remain helpless, as establishing their own market base is a time consuming process. Eventually, all these Companies became sick, except two joint sector undertakings namely, KAPL and RDPL.

13.13.4 For strategic reasons, it is essential that Pharma PSUs continue to play a pragmatic role in future. These Companies have been at the forefront in times of emergencies arising out of natural calamities like flood, earthquake etc. Their survival and presence are essential in discharging such important social obligations timely and without profiteering. Under the Product Patent Regime, they can also be used as an arm of the Government in manufacturing certain patented drugs required to meet emergencies through the grant of compulsory licenses. The National Common Minimum Programme stipulates that “special attention would be paid to the poor sections in the matter of health care “ and these PSUs can play a vital role in achieving the said objective. Similarly, Government also aims at increasing public spending on primary healthcare over the next 5 years. An important role can be played by these Companies in ensuring quality medicines at reasonable prices for various healthcare programmes.

13.13.5 PSUs may use bulk drug facilities of existing bulk drug manufactures on contract basis, which may be cost effective and also cheaper logisticswise.

13.13.6 Under the Product Patent Regime, PSUs can also be used as an arm of the Government in manufacturing certain patented drugs required to meet emergencies through the grant of compulsory licenses. An important role can be played by Pharma PSUs in ensuring quality medicines at reasonable prices for various health care programmes of the Government. Government has approved the revival package of Hindustan Antibiotic Ltd. Two other important PSUs IDPL, BCPL should also be revived.

13.13.7There is need to reposition the Pharma PSUs to enable them to make optimum use of their assests. An Apex Body may be created to handle this role and assist these PSUs. This Apex body can be constituted as a society registered under the Societies Registration Act 1860. Similar Apex bodies are in existence for the State Transport Undertakings and States Industrial Development Corporations. A fund of **Rs. 10 crores** may be set apart for this Apex Body. For assisting the Pharma PSUs in Drug

Development, Patent filing, WHO pre-qualifications etc a **Critical Assistance Scheme for Pharma PSUs** is proposed with a budget of **Rs. 20 crores** per annum i.e **Rs. 100 crores** for the entire 11th Plan Period.

13.13.8 As these PSUs are arms of the Government for which infrastructure has already been created it is essential that these facilities are adequately utilized. Even if a small portion of the total requirement of medicines required by various Government Departments including Health, Defence and Labour Departments are sourced from the PSUs, the existing facilities available with them can be fully utilized. For this purpose, a list of drugs manufactured by PSUs can be drawn which could be sourced exclusively from them. All Hospitals under the administrative control of various Government Departments can also be required to procure these items from PSUs. This policy will ensure quality drugs at reasonable rates and avoid possibilities like supply of spurious and misbranded drugs.

13.13.9 The supplies of medicines to below poverty line families need to be subsidized to make the medicines affordable to them. To avoid possible misuse of subsidy and anomaly in distribution, PSUs could be entrusted with this task and subsidies could be extended to them based on certified data furnished by them. This will avoid complicated procedure in case such items are to be procured with subsidy from Companies other than PSUs.

14. To suggest measures towards improvement of accessibility of essential medicines for the common man particularly the poorer sections of the population and availability of drugs for BPL families.

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15. To identify steps required for facilitating implementation of the National Health Policy.

15.1 It is a fact that the drugs manufactured in India are considered to be much cheaper than in most of countries. However, a vast section of Indian population is not in a position to access the needed health care as well as the medicines. About 26% of the country's population lives below the poverty line (BPL) and has very limited affordability even for low priced drugs.

15.2 The prices of several categories of medicines are cheapest in India and that has been possible through the competition. While the role of price control can be highlighted for keeping prices under check, it is also necessary that the growth of industry with sufficient profitability is maintained to have sufficient availability of medicines. All this underlines the need for strategic interventions for making drugs affordable and accessible to the poor. As mentioned in the Pranab Sen Committee report this could include:

- Strengthening of public healthcare system including supply of medicines, especially for the poor.
- Bulk procurement and retailing of medicines by public agencies, cooperatives and consumer organizations.
- Encouraging insurance companies to cover cost of medicines.
- Encouraging private hospitals and doctor's groups to provide group health cover including medicines.

15.3 The focus has to be on Healthcare. India's healthcare spend is less than 1% of its GDP. This has to be substantially increased (WHO recommends 6-7%). Investment in preventive measures such as vaccination, immunization, clean drinking water, cessation of harmful habits (such as tobacco, smoking/chewing), better nutrition, sanitation, hygiene, safe sex habits, etc. would yield better results in the country.

15.4 Some of the schemes contemplated in the Draft Pharma Policy include:-

I. National Health Insurance Policy for BPL families to provide health insurance to this target group.

II. National Illness Assistance Fund, State Illness Assistance Funds and District Illness Assistance Funds through which full financial assistance would be provided for medical treatment of people living below poverty line for free treatment through Government hospitals. The modalities of the new scheme would make the funds more “reachable” and would be administered in a decentralized manner.

III. District Drug banks for the poor – Health Department and States would facilitate setting up of such Drug banks at the State / District level in Public Private Partnership mode with assistance of drug manufacturing companies. These could be managed by hospitals or through Red Cross Societies etc. The recoveries made from the Pharma companies on account of overcharged amount can be deposited in the Fund for Drug Banks. Further, budgetary support by Government of India and contributions by industry would be required to maintain the level of Fund to a workable one. Private contributions could be extended relief under income-tax, financial assistance. As part of public-private partnership Drug Banks would be set up at the district level in the states. There would be three partners in this Scheme, **Government of India** - through Health Ministry and Department of Chemicals & Petrochemicals, **State Governments** - by providing budgetary/medical support, **Pharma Industry** - by providing medicines/fund for drug banks. Drug companies would also donate medicines for the drug banks. Medicines would be provided free to families below poverty line (BPL) from these banks. These banks can be operated like such stores being managed in states like Rajasthan through Medicare Society.

IV. For making available anti-cancer and anti-HIV/AIDS drugs at reasonable prices to a much larger sections of the population government would evolve a public – private partnership programme with the concerned manufacturers and cancer hospitals in the country.There could be partnership between government , industry and cancer hospitals A **Cancer Medicine Assistance Scheme** may be be set up in all the major Cancer hospitals of the country. Through this scheme the pharma companies may supply cancer drugs to cancer hospitals at 50% of the MRP. These medicines may be provided (at 50% of the market price) to all the above poverty line cancer patients. BPL families, handicapped persons & old citizens may be provided cancer medicines free of cost under this scheme. All medicines pertaining to these categories whether under National List of Essential Medicines, 2003 or outside would be brought under this programme.

15.5 The role of NGOs and the Pharmaceutical Industry can be enlarged in this area. Greater voluntary affirmative action is possible by the industry. Similarly Pharma PSUs can play an important role in ensuring quality medicines at reasonable prices for various health care programmes of the Government supply of medicines at subsidized prices is also possible through PSUs mainly to minimise possibilities of misuse of subsidy and anomalies in supplies as also avoidance of spurious and misbranded drugs.

15.6 As per an earlier report of the World Bank, other aspects that need attention are the need for effective procurement systems in the States. The procurement should be geared to the population size and the epidemiological profile of each state. Simultaneously, improvements in the management of drug supplies also need to be improved. Storage and distribution of drugs would need to be developed and existing arrangements improved specially in remote areas. Another aspect to be considered is to place emphasis on good quality generic drugs as they are usually more cost effective. Greater use of generics need to be promoted. Guidelines for rational use of drugs be implemented and not to go in for newly introduced drugs unless they have significant therapeutic advantages, and are cost effective. The World Bank report recommends a better purchasing system based on cost effectiveness and other “Pharmaco-economic criteria”.

15.7 The role of Insurance Companies in health coverage needs to be encouraged. A scheme may be considered which can provide assistance to targeted groups (such as BPL families) for specified ailments to begin with. Such ailments could include cancer, HIV etc. which entail higher cost and treatment is out of reach for the poor. This scheme can be administered by the Central and State Governments through the insurance companies and an initial corpus of funds can be made available by Government to the Insurance company.

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Annexure-I

The Value Growth of top 20 Large Phama Companies In India

S.No.	Company	MAT Value (Rs. Crs.) 1995	MAT Value (Rs. Crs.) 2005	Units-1995	Unit-2005	Value Growth % (2005 over 1995)
	Indian Phrma Mkt	**6,211.24**	**23,277.77**	**5858350870**	**11,020,740,280**	**274.77**
1	Glaxosmithkline *	562.25	1,340.25	633884930	905,435,439	138.37
2	Cipla	244.90	1,192.63	185368950	539,447,022	386.98
3	Ranbaxy *	284.95	1,153.06	146095690	373,421,419	304.66
4	Nicholas Piramal *	387.79	1,020.58	448790920	599,571,989	163.18
5	Zydus Cadila *	125.71	835.64	87247990	434,593,705	564.75
6	Sun Pharm Industries	-	754.67	-	250,324,297	-
7	Alkem *	-	690.82	-	220,777,872	-
8	Pfizer *	156.55	627.85	176359240	306,175,063	301.05
9	Sanofi Aventis *	217.11	563.54	350752060	436,495,069	159.57
10	Aristo Pharma *	93.81	550.68	58522400	235,645,755	487.01
11	Dr Reddys labs	82.67	537.50	33767880	180,454,877	550.20
12	Lupin Labs	144.37	523.23	93960050	240,195,093	262.43
13	Abbott *	156.35	482.00	225608670	173,346,357	208.28
14	Torrent Pharma	142.42	450.16	92766190	199,030,464	216.08
15	Micro Labs *	-	431.21	-	178,288,569	-
16	Wockhardt –Merind *	147.19	423.49	120629610	230,387,544	187.71
17	Novartis India .*	151.50	411.76	141537790	179,849,239	171.78
18	Alembic	154.54	403.17	84124810	163,224,290	160.88
19	Intas Pharma *	-	382.38	-	152,134,256	-
20	Unichem *	-	377.76	-	180,293,858	-

ANNEXURE II

State - Wise Principal Characteristics of Drugs and Pharmaceuticals As per third All India Census (Registered SSI Units) 2001-02

SL. NO.	Characteristics / State	No. of Working Units	Employment	Gross Output Rs. Lakh	Export Rs. Lakh
1	Jammu & Kashmir	28	219	918.77	0.00
2	Himachal Pradesh	63	837	6751.27	115.92
3	Punjab	184	2432	17307.42	796.74
4	Chandigarh	16	154	4820.82	0.00
5	Uttaranchal	58	1023	2890.56	0.00
6	Haryana	222	2839	26031.86	811.03
7	Delhi	57	2019	14543.19	178.74
8	Rajasthan	203	1971	16082.92	1091.22
9	Uttar Pradesh	751	5599	27977.90	208.54
10	Bihar	206	962	1507.01	46.28
11	Sikkim	1	41	1382.67	0.00
12	Manipur	1	1	0.15	0.00
13	Tripura	4	33	33.64	0.00
14	Meghalaya	4	25	20.72	0.00
15	Assam	67	559	881.41	0.00
16	West Bengal	260	3526	11379.13	0.00
17	Jharkhand	45	194	175.81	0.00
18	Orissa	103	1075	5579.27	0.00
19	Chhattisgarh	16	156	241.37	0.00
20	Madhya Pradesh	251	3689	35079.83	386.31
21	Gujarat	523	6505	13656.69	7.34
22	Daman & Diu	19	632	30499.19	158.88
23	Dadra & Nagar Haveli	16	335	11066.95	0.00
24	Maharashtra	776	12664	124967.90	14537.18

SL. NO.	Characteristics / State	No. of Working Units	Employment	Gross Output Rs. Lakh	Export Rs. Lakh
25	Andhra Pradesh	440	9804	68551.51	2561.24
26	Karnataka	214	3015	13002.58	846.79
27	Goa	25	1986	59463.21	61.39
28	Kerala	1158	7317	22475.34	105.85
29	Tamil Nadu	357	4375	17149.64	724.70
30	Pondicherry	22	732	16386.01	106.16
	TOTAL	6090	74719	550824.75	22744.28

	For all Industries	1374974	6163479	20325462	1230826

Annexure III

State - Wise Status of Small Scale Drug and Pharmaceuticals Units

Sl. No	State / Union Territory	No. Of GMP compliant units	Under process for GMP compliant	Units which are not in a position to comply GMP norms	No. Of units closed or licence suspended
1	J&K	5	1	24	0
2	Haryana	70	71	89	0
3	Uttarnchal	28	17	1	0
4	Maharashtra	358	465	67	107
5	Uttar Pradesh	126	N.A	N.A.	0
6	Gujarat	407	176	0	64
7	Kerala	8	16	20	4
8	Madhya Pradesh	53	40	0	72
9	Orissa	14	15	N.A.	0
10	Tamil Nadu	57	395	0	0
11	Karnataka	100	32	3	0
12	Mizoram	0	0	0	0
13	Andaman & Nicobar	0	0	0	0
14	Delhi	30	42	0	0
15	Daman & Diu	13	1	0	0
16.	Dadar & Nagar Haveli	2	1	0	0
17	Chhatisgarh	0	9	0	0
18	Sikkim	1	3	0	0
19	Tripura	0	0	2	0
20	Andhra Pradesh	146	308	40	29
21	Bihar	6	7	0	0
22	Goa	48	13	5	6
23	Jharkhand	1	22	0	11

Sl. No	State / union territory	No. Of GMP compliant unit	Under process for GMP compliant	Units which are not in a position to comply GMP norms	No. Of units closed or licence suspended
24	Assam	10	6	0	2
25	Himachal Pradesh	83	24	1	0
26	West Bengal	50	50	115	40
27	Rajasthan	56	86	3	2
	TOTAL	**1672**	**1797**	**370**	**337**

ANNEXURE IV

India's Export of Principal Commodities by Regions

DRUGS, PHARMACEUTICALS & FINE CHEMICALS					
S.No	**Region**	**APR-2002-MAR-2003 Rs. Crores**	**APR-2003-MAR-2004 Rs. Crores**	**APR-2004-MAR-2005 Rs. Crores**	**APR-2005-MAR-2006 Rs. Crores**
1	Europe	2858.28	3839.02	4486.79	**5400.47**
2	Asia	3074.51	3434.73	3889.20	**4453.29**
3	North America	2720.12	3027.60	3488.38	**3916.61**
4	Africa	1664.79	1831.44	2174.74	**2970.10**
5	CIS	785.56	970.99	1352.62	**1739.08**
6	Middle East	742.78	986.54	1088.17	**1359.03**
7	LAC	717.78	836.32	1044.78	**1307.28**
8	Oceania	117.93	124.61	165.15	**233.69**
9	The Caribbean	95.34	133.22	142.52	**195.47**
10	Others	49.03	28.78	25.45	**3.96**
	GRAND TOTAL (227 Countries)	**12826.10**	**15213.24**	**17857.80**	**21578.96**

[Source: DGCIS]

ANNEXURE V

India's export of Drugs & Pharmaceuticals to various countries in value terms during 2004-05 & 2005-06

S.No	*Countries*	*April 2004-March 2005 (Values in Rs. crores)*	*April 2005 -March 2006 (Values in Rs. crores)*
1	U S A	2714.67	**3062.24**
2	Germany	928.32	**1062.97**
3	Russia	773.80	**1051.12**
4	U K	586.21	**820.63**
5	China P Rp	544.82	**762.55**
6	Brazil	489.78	**615.21**
7	Nigeria	462.94	**512.17**
8	Canada	495.36	**497.27**
9	South Africa	216.62	**442.18**
10	Turkey	238.81	**426.22**
11	Ukraine	336.68	**421.02**
12	Italy	304.32	**411.98**
13	Vietnam Soc Rep	305.16	**400.69**
14	Netherlands	299.37	**388.18**
15	Singapore	238.79	**378.50**
16	Mexico	278.34	**357.09**
17	Spain	345.30	**341.41**
18	U Arab Emts	277.18	**319.45**
19	Israel	168.52	**310.33**
20	Srilanka DSR	276.34	**308.75**
21	Iran	226.54	**297.23**
22	Japan	288.21	**295.04**
23	Bangladesh	243.40	**284.08**
24	Switzerland	208.41	**272.59**
25	Korea Rp	197.82	**250.35**
26	Hong Kong	229.06	**230.22**
27	Thailand	227.53	**229.77**
28	Kenya	127.71	**227.74**
29	Nepal	214.88	**224.77**

S.No	Countries	April 2004-March 2005 (Values in Rs. crores)	April 2005 -March 2006 (Values in Rs. crores)
30	Pakistan IR	258.70	**200.31**
31	Ireland	325.83	**199.14**
32	Belgium	151.43	**197.73**
33	Australia	123.64	**189.97**
34	Finland	125.50	**171.19**
35	France	183.94	**170.61**
36	Indonesia	186.01	**165.57**
37	Slovenia	129.11	**163.91**
38	Ghana	115.12	**156.98**
39	Colombia	106.70	**153.53**
40	Philippines	103.77	**136.64**
41	Malaysia	133.38	**133.10**
42	Argentina	120.19	**132.12**
43	Tanzania Rep	71.38	**121.20**
44	Myanmar	97.11	**117.44**
45	Uganda	91.46	**115.28**
46	Jordan	84.76	**112.73**
47	Afghanistan	118.82	**108.88**
48	Congo P Rep	120.68	**105.79**
49	Sudan	81.14	**102.51**
50	Kazakhstan	70.22	**99.81**
51	Romania	83.09	**95.31**
52	Taiwan	83.09	**94.77**
53	Syria	86.03	**94.32**
54	Poland	94.09	**91.35**
55	Egypt A Rp	86.60	**91.06**
56	Ethiopia	55.98	**88.49**
57	Zambia	46.50	**85.61**
58	Guinea	70.50	**81.57**
59	Angola	57.57	**72.05**
60	Yemen Republc	68.33	**71.96**
61	Algeria	45.65	**70.93**

S.No	Countries	April 2004-March 2005 (Values in Rs. crores)	April 2005 -March 2006 (Values in Rs. crores)
62	Venezuela	74.66	**70.78**
63	Chile	45.14	**69.83**
64	Hungary	86.59	**66.40**
65	Cameroon	31.90	**63.53**
66	Malawi	30.50	**62.76**
67	Peru	54.10	**62.72**
68	Portugal	39.44	**60.82**
69	Austria	18.99	**58.66**
70	Denmark	61.19	**57.65**
71	Malta	21.20	**53.53**
72	Saudi Arab	53.77	**50.44**
73	Iraq	71.95	**49.00**
74	Cambodia	42.45	**48.18**
75	Uzbekistan	30.05	**46.96**
76	Dominic Rep	29.83	**46.74**
77	Zimbabwe	30.10	**45.50**
78	Czech Rep.	40.77	**44.04**
79	Haiti	20.09	**42.56**
80	Korea Dp Rp	63.09	**40.46**
81	Burundi	22.08	**38.70**
82	Benin	26.92	**38.49**
83	Mauritius	41.10	**38.32**
84	Latvia	26.44	**37.67**
85	Guatemala	19.69	**36.51**
86	Belarus	29.43	**35.12**
87	Mozambique	35.51	**34.16**
88	Uruguay	33.04	**30.99**
89	Azerbaijan	61.04	**30.12**
90	Iceland	17.48	**30.04**
91	Costa Rica	27.48	**29.97**
92	Cyprus	31.60	**29.61**
93	Senegal	13.10	**28.90**

S.No	*Countries*	*April 2004-March 2005 (Values in Rs. crores)*	*April 2005 -March 2006 (Values in Rs. crores)*
94	Cuba	18.30	**28.74**
95	Oman	30.92	**28.57**
96	Honduras	13.03	**28.12**
97	Mali	28.82	**27.54**
98	Namibia	9.65	**26.49**
99	Djibouti	11.89	**26.32**
100	Burkina Faso	19.79	**26.03**
101	Madagascar	24.77	**26.00**
102	Newzealand	27.26	**25.93**
103	Lithuania	31.89	**25.92**
104	Trinidad	17.32	**25.65**
105	Rwanda	18.93	**25.03**
106	Puerto Rico	25.90	**24.58**
107	Cote D' Ivoire	24.17	**23.78**
108	Greece	22.02	**22.22**
109	Croatia	22.30	**20.55**
110	Morocco	39.09	**19.71**
111	Sierra Leone	18.71	**17.21**
112	Maldives	12.41	**16.64**
113	Jamaica	18.08	**16.01**
114	Bulgaria	7.79	**15.60**
115	Moldova	10.81	**15.40**
116	Papua N Gna	14.03	**15.15**
117	Turkmenistan	14.64	**14.03**
118	Slovak Rep	16.82	**13.64**
119	Albania	12.24	**12.79**
120	Guyana	10.89	**12.40**
121	Bolivia	11.29	**12.08**
122	Panama Rep.	6.97	**11.98**
123	El Salvador	4.41	**11.76**
124	Togo	9.71	**11.69**
125	Liberia	8.44	**11.21**

S.No	Countries	April 2004-March 2005 (Values in Rs. crores)	April 2005 -March 2006 (Values in Rs. crores)
126	Somalia	6.74	**10.92**
127	Eritrea	3.44	**10.88**
128	Serbia Montngro	9.24	**10.68**
129	Niger	16.36	**10.67**
130	Nicaragua	12.56	**10.52**
131	Fiji Is	8.73	**10.45**
132	Sweden	9.22	**10.32**
133	Lebanon	4.78	**10.08**
134	Libya	3.34	**9.97**
135	Paraguay	6.08	**9.46**
136	Norway	1.06	**9.26**
137	Mauritania	4.12	**8.85**
138	Tajikistan	3.51	**8.08**
139	Chad	5.81	**7.96**
140	Georgia	7.22	**7.90**
141	Kyrghyzstn	13.44	**7.54**
142	Gabon	4.15	**7.17**
143	Lesotho	2.98	**7.04**
144	Kuwait	7.98	**6.59**
145	Vanuatu Rep	3.11	**6.46**
146	Botswana	7.29	**6.24**
147	Baharain Is	6.04	**5.63**
148	Swaziland	3.02	**5.50**
149	Macedonia	4.07	**5.47**
150	Tunisia	9.11	**5.25**
151	Ecuador	6.84	**4.83**
152	Cafri Rep	1.18	**4.48**
153	Macao	3.23	**3.94**
154	Gambia	2.74	**3.89**
155	Seychelles	3.86	**3.28**
156	Lao Pd Rp	0.82	**2.98**
157	Belize	0.92	**2.92**

S.No	Countries	April 2004-March 2005 (Values in Rs. crores)	April 2005 -March 2006 (Values in Rs. crores)
158	Qatar	1.38	**2.70**
159	Mongolia	2.77	**2.29**
160	Bahamas	1.93	**2.27**
161	Dominica	0.90	**2.20**
162	Armenia	1.78	**1.98**
163	Bhutan	2.94	**1.82**
164	Suriname	0.87	**1.57**
165	St Lucia	0.73	**1.31**
166	Congo D. Rep.	3.24	**1.29**
167	Barbados	0.64	**1.08**
168	Antigua	2.71	**1.07**
169	East Timor	2.79	**0.89**
170	Monaco	1.65	**0.85**
171	Bosnia Hrzgovin	0.61	**0.77**
172	Br Virgn Is	-	**0.76**
173	Estonia	0.27	**0.69**
174	Tuvalu	-	**0.62**
175	Comoros	0.15	**0.56**
176	Equtl Guinea	0.95	**0.56**
177	Montserrat	0.35	**0.54**
178	Tonga	0.42	**0.46**
179	Cayman Is	0.60	**0.43**
180	Brunei	0.59	**0.39**
181	Guinea Bissau	0.45	**0.35**
182	Virgin Is Us	2.12	**0.34**
183	Neutral Zone	-	**0.29**
184	Cook Is	-	**0.27**
185	Cape Verde Is	0.32	**0.27**
186	Guadeloupe	0.07	**0.27**
187	Solomon Is	0.31	**0.25**
188	Netherland	0.80	**0.24**
189	Guam	0.92	**0.22**

S.No	Countries	April 2004-March 2005 (Values in Rs. crores)	April 2005 -March 2006 (Values in Rs. crores)
190	Anguilla	1.17	**0.18**
191	St Kitt N A	0.03	**0.16**
192	St Vincent	0.01	**0.14**
193	Grenada	0.10	**0.13**
194	Palau	0.23	**0.12**
195	Heard Macdonald	0.06	**0.07**
196	Ameri Samoa	1.11	**0.05**
197	Reunion	0.46	**0.04**
198	Micronesia	-	**0.03**
199	Turks C Is	0.01	**0.03**
200	Kiribati Rep	0.80	**0.03**
201	Andorra	0.01	**0.03**
202	Norfolk Is	-	**0.03**
203	Cocos Is	-	**0.03**
204	Luxembourg	0.02	**0.03**
205	Marshall Island	-	**0.02**
206	Aruba	0.16	**0.02**
207	New Caledonia	0.00	**0.01**
208	Tokelau Is	0.05	**0.01**
209	Samoa	0.63	**0.01**
210	Faroe Is	-	**0.01**
211	Pitcairn Is	0.02	**0.00**
212	Sao Tome	0.04	**0.00**
213	Greenland	-	**0.00**
214	Gibraltar	0.48	**0.00**
215	Fr Guiana	0.07	**-**
216	Fr Polynesia	0.03	**-**
217	Liechtenstein	0.14	**-**
218	Martinique	0.66	**-**
219	Nauru Rp	0.01	**-**
220	Niue Is	0.02	**-**
221	Panama C Z	0.04	**-**

S.No	*Countries*	*April 2004-March 2005 (Values in Rs. crores)*	*April 2005 -March 2006 (Values in Rs. crores)*
222	Saharvi A.Dm Rp	0.00	-
223	Wallis F Is	0.01	-
224	unspecified	19.95	1.43
	Total	**17857.80**	**21578.96**

ANNEXURE VI

Pharma Export of Major Segments

Segment	Percentage
Bulk Drugs	35.9%
Formulations	34.5%
Raw Materials / Chemicals / Intmediates.	26.2%
Biotech & BioPharma	1.8%
Medical Devices	1.2%
Ayurvedic & Herbal	0.4%

Total Value of exports: Rs. 290 Billions

[Source: Cygnus Research]

ANNEXURE VII

Some Major Bulk Drugs (its Derivatives) Exported

2004-2005

Bulk Drug	**Rs. crores**
Cefadroxil	207.91
Menthol	187.50
Amoxycillin	126.84
Erthromycin	118.88
Cephalexin	99.49
Sulphame Thoxazole	63.99
Ranitidine	56.19
Ampicillin	55.26
Ibuprofen	48.40
Ciprofloxacin	41.03

ANNEXURE VIII

Some Major Formulations Exported

2004-2005

Formulations	Rs. crores
Antibiotics – Others	377.05
Ayurvedic Medicants	255.75
Amoxycllin in Capsules etc.	154.85
Ibuprofen Paracetamol & Combinations	141.35
Omeprazole & Lansoprazole	120.60
Insulin Injection	89.42
Tranquilizers	82.18
Mixed Vaccines for MMR	75.85
Cimetidine, Rantidine	73.17
Ciprofloxacin	69.17

ANNEXURE IX

IMPORT OF MEDICINAL & PHARMA PRODUCTS

S.No	*Countries*	*Apr 2004- Mar 2005 (Rs. crores)*	*April 2005 - Mar-2006 (Rs. crores)*
1	China P Rp	908.57	**1563.53**
2	Switzerland	375.44	**547.35**
3	U S A	298.11	**425.32**
4	Germany	188.82	**276.33**
5	Denmark	107.48	**174.48**
6	Italy	131.22	**170.89**
7	France	108.88	**158.42**
8	U K	130.64	**132.10**
9	Belgium	106.77	**115.58**
10	Sri Lanka Dsr	3.92	**101.84**
11	Netherlands	121.81	**93.57**
12	Spain	76.19	**82.95**
13	Ireland	36.70	**61.43**
14	Japan	58.80	**61.42**
15	Korea Rp	59.97	**59.46**
16	Austria	49.45	**54.95**
17	Poland	28.42	**50.01**
18	Thailand	17.91	**31.97**
19	Malaysia	16.23	**28.07**
20	Russia	15.36	**23.19**
21	Mexico	82.25	**22.52**
22	Nepal	21.37	**21.49**
23	Hong Kong	32.49	**20.33**
24	Australia	18.78	**19.19**
25	Singapore	10.27	**17.56**
26	Slovak Rep	28.18	**14.25**
27	Vietnam Soc Rep	1.08	**11.81**
28	Israel	15.27	**11.79**
29	Argentina	4.47	**10.46**
30	Hungary	8.49	**10.41**
31	Canada	13.56	**10.28**
32	Sweden	8.64	**10.22**
33	Norway	4.21	**8.76**
34	Slovenia	12.00	**8.69**
35	Taiwan	10.32	**8.50**
36	Czech Republic	10.42	**8.16**
37	South Africa	2.00	**4.51**
38	Panama Republic	0.22	**3.92**

S.No	Countries	Apr 2004- Mar 2005 (Rs. crores)	April 2005 - Mar-2006 (Rs. crores)
39	Philippines	2.67	**3.58**
40	Brazil	1.06	**3.57**
41	Indonesia	13.75	**3.38**
42	Turkey	2.05	**3.32**
43	U Arab Emts	1.69	**3.16**
44	Oman	0.08	**2.97**
45	Korea Dp Rp	0.14	**2.51**
46	Finland	1.17	**1.92**
47	Congo P Rep	3.53	**1.66**
48	Bulgaria	0.60	**1.60**
49	Newseland	0.13	**1.36**
50	Puerto Rico	0.55	**1.09**
51	Egypt A Rp	2.81	**0.99**
52	Ukraine	1.71	**0.81**
53	Croatia	1.08	**0.69**
54	Iceland	0.00	**0.47**
55	Cuba	0.37	**0.28**
56	Kenya	0.06	**0.26**
57	Saudi Arab	-	**0.25**
58	Pakistan IR	0.02	**0.15**
59	Romania	0.36	**0.10**
60	Qatar	-	**0.08**
61	Uganda	0.02	**0.08**
62	Solomon Is	-	**0.08**
63	Cote D' Ivoire	-	**0.07**
64	Guatemala	-	**0.06**
65	Latvia	0.00	**0.05**
66	Bermuda	-	**0.05**
67	Portugal	0.03	**0.04**
68	Chile	0.27	**0.03**
69	Jordan	-	**0.03**
70	Colombia	0.01	**0.03**
71	Liechtenstein	-	**0.03**
72	Greece	0.01	**0.03**
73	Congo D. Rep	-	**0.01**
74	Belarus	-	**0.01**
75	Bosnia-Hrzgovin	-	**0.00**
76	Syria	-	**0.00**
77	Bangladesh P R	0.02	**0.00**
78	Cyprus	-	**0.00**

S.No	*Countries*	*Apr 2004- Mar 2005 (Rs. crores)*	*April 2005 - Mar-2006 (Rs. crores)*
79	Senegal	-	**0.00**
80	Kazakhstan	-	**0.00**
81	Iran	0.03	**0.00**
82	Sudan	-	**0.00**
83	Nigeria	-	**0.00**
84	Morocco	0.00	**-**
85	Kuwait	0.00	**-**
86	Georgia	0.00	**-**
87	Armenia	0.00	**-**
88	Lithuania	0.01	**-**
89	Niger	0.01	**-**
90	Costa Rica	0.01	**-**
91	Guadeloupe	0.02	**-**
92	Baharain Is	0.07	**-**
93	Uzbekistan	0.09	**-**
94	Malta	0.13	**-**
95	Unspecified	10.07	**44.73**
	total	**3169.35**	**4515.22**

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Annexure X

Recommendations of the **Task Force on Recombinant Pharma Sector** under the Chairmanship of Dr R A Mashelkar, DG, CSIR, taken from MOEF's website

The Ministry of Environment & forests (MoEF) under 'Rules for the Manufacture, use, import, and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells, 1989', framed under the provisions of the Environment (Protection) Act, 1986 is concerned with the environmental clearances of genetically modified foods/crops/Pharmaceuticals. To streamline the regulatory process in respect of the r-Pharma sector under the above-mentioned rules, the MoEF had constituted a Task Force on Recombinant Pharma Sector under the Chairmanship of Dr. R.A. Mashelkar, DGCSIR with a vide OM No.12/7/2004-CS dated 20.4.2004. The mandate of the Task Force was to review the current framework and recommend a transparent and streamlined regulatory mechanism and process for the use of living Modified Organisms (LMOs) in the Pharmaceutical industry during the various stages of R&D, testing manufacturing and import of LMOs as drugs.

2.0 The Task Force held five meetings during the period April 2004 to June 2005. The review and recommendations of the task force are based on a consultative approach involving a large number of stakeholders spanning diverse interests. The draft final report was posted on the MoEF website for a period of 6 weeks for further stakeholder consultation. Based on the recommendations and comments received, the report was adopted by the members of the Task Force on 13th June 2005.

3.0 The Chairman of the Task force, Dr. R.A. Mashelkar, DG-CSIR presented this report to Hon'ble Union Minister for environment & Forests, Thiru A Raja on 13.9.2005 for consideration of the Government. The recommendations were subsequently adopted by the Ministry of Environment and Forests, Department of Biotechnology, Drugs Controller General of India and Ministry of Health in the inter-ministerial held on 23rd January 2006.

The recommendations and procedures outlined by the Task Force have been adopted by the Government of India and shall be in force from 1st April 2006**.** Accordingly, the following recommendations and procedures under 'Rules for the Manufacture, Use, Import, and Export and Storage of Hazardous Micro organism generically Engineered Organisms or Cells, 1989' of EPA, 1986 shall be applicable in respect of recombinant Pharma products under Rules 1989. All applicants seeking the approval of

RCGM approval for pre-clinical animal studies:	45 days
DCGI approval for Human clinical trials protocol	45 days
DCGI examination of clinical trial data and response:	90 days
DCGI & GEAC decisions (simultaneous)	45 days

(GEAC clearance to be harmonized with the best practices guidelines for regulatory approvals adopted by MoEF).

D Other Linked recommendations:

The products emanating from monoclonals derived from rDNA technology in the form of therapeutic proteins/drugs would attract the provisions of Rule 1989 of EPA, and can be treated under Protocol I as Risk Category I & II.

If there is a change in the host organism or expression construct, fresh permission will be required to be sought from RCGM for the change by providing adequate data on bio-equivalence. If the data is found to be inadequate then RCGM may prescribe limited pre-clinical and/or clinical studies to be conducted to establish bio-equivalence. This would also be applicable to finished imported products intended for marketing.

No imported recombinant Pharma product should be allowed to be introduced in the Indian market without adequate evaluation of clinical trials data or clinical evaluation in the country. The Task Force recommends that the efficacy and safety of the imported product should be evaluated for its efficacy on the Indian population before issue of market authorization.

For import of GMO/LMO for research/contract manufacturing or similar service, where the product (which is not an LMO) is to be exported out of India, a procedure should be laid down so that the companies can explore opportunities for this business.

Annexure XI

Highlights of the bill about the measures proposed to deal the problem of menace of the Spurious drugs

Government of India constituted a Broad Based Committee of Experts on January 27, 2004 under the Chairmanship of Dr. R.A. Mashelkar, Director General, CSIR to undertake a comprehensive examination of drugs regulatory issues including the problem of spurious drugs in the country and recommend measures required to deal with the problem effectively.

The Committee was asked to make recommendations and suggest road map for implementation of the recommended measures so that this problem could be solved in its entirety. The Committee had eminent scientists, an eminent lawyer, former police commissioners as its members. Officials representing key Ministries/Departments/States/drug manufactures, consumer and professional associations were also included as members. Drugs Controller General (India) (DCGI) acted as Member Secretary.

Dr. R.A. Mashelkar, Chairman of the Expert committee, submitted its report to the Govt. in November 2003. The report of the Committee has been divided into two parts. Part A and Part B covers the problem concerning spurious and sub-standard drugs in the

STEPS INITIATED BY GOVT.

Legislative Measures:

Based on the interim report of the Mashelkar Committee, the Ministry of Health and Family Welfare considered the recommendations of the aforesaid Committee and introduced a Bill (no. 93 of 2003) called “The Drugs and Cosmetics (Amendment) Bill, 2003” in the Lok Sabha on December 22, 2003 for its legislative enactment for the amendment of the said Act. However the said bill is no more valid a Ministry of Health & Family welfare has now introduced a revised “Drugs & Cosmetics Act(Amendment bill) 2005” which is to be considered by Rajya Sabha.

The Bill, in brief, seeks to achieve the following objectives:-

(*i*) The existing provisions contained in section 27 of the aforesaid Act, *interalia,* provide for scale of punishment for the first offence in respect of adulterated or spurious drugs. Clause *(a)* of section 27 of the aforesaid Act, provides for imprisonment for not less than five years which may extend to life and with fine of not less than rupees ten thousand for the manufacture and sale of adulterated or spurious drugs or drugs not of standard quality which are likely to cause death of the patients or harm on the patient’s body

as would amount to grievous hurt. It is proposed to enhance the period of imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine of ten lakh rupees or three times the value of the drugs confiscated, whichever is more;

(*ii*) It is also proposed to insert two provisos in the said clause *(a)* so as to provide that the fine imposed on the convicted person and realised from him under the said clause shall be paid to the person who used such adulterated or spurious drugs and in case of his death, to his relative;

(*iii*) Clause *(b)* of said section 27 provides for punishment of imprisonment for not less than one year which may extend to three years and fine of not less than rupees five thousand for manufacture and sale of any adulterated drug (not being a drug referred to in section 17A) or manufacture and sale of drugs without a valid licence. It is proposed to enhance the said punishment of imprisonment being not less than three years but may extend to five years and with fine which shall not be less than one lakh rupees;

(*iv*) Clause *(c)* of aforesaid section 27 provides for punishment of imprisonment for not less than one year which may extend to three years but which may extend to five years and with fine which shall not be less than rupees five thousand for manufacture and sale of any spurious drug (not being a drug referred to in section 17B). It is proposed to enhance the said punishment of imprisonment being not less than seven years but which may extend to imprisonment for life and with fine which shall be three lakh rupees or three times the value of the drugs seized, whichever is more;

(*v*) Clause *(d)* of aforesaid section 27 provides for punishment of imprisonment for a term which shall not be less than one year but which may extend to two years and with fine. It is proposed to provide that the fine shall not be less than twenty thousand rupees;

(*vi*) It is also proposed to provide for a fine of not less than twenty thousand rupees under section 28 for non-disclosure of the name of the manufacturer and under section 28A for not keeping documents, etc., and for not disclosure of information;

(*vii*) It is also proposed to enhance punishment specified under section 30 for subsequent offences. Clause *(a)* of said section 30 provides for punishment for imprisonment not less than two years which may extend to six years and with fine of not less than rupees ten thousand for manufacture and sale of any adulterated drug or manufacture and sale of drugs without a

valid licence. It is proposed to enhance the said punishment which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees. Clause *(b)* of aforesaid section 30 provides for punishment for imprisonment for not less than six years, which may extend to ten years and with fine of not less than rupees ten thousand for manufacture and sale of a spurious drug. It is proposed to enhance the punishment of imprisonment which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees;

(*viii*) It is also proposed to designate one or more Court of Session as Special Court for trial of offences related to adulterated or spurious drugs;

(*ix*) It is also proposed to make offences relating to adulterated or spurious drugs as cognizable and non-bailable in certain cases;

(*x*) It is also proposed to confer powers upon the police officers not below the rank of sub-inspector of police and other officers of the Central Government or State Government authorised by it to institute the prosecution under the aforesaid Act;

(*xi*) It is also proposed to provide compounding of certain offences not being an offence punishable with imprisonment only or with imprisonment and also with fine.

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Annexure XII

IPR Facilitation Centres at Pharmexcil

Pharmexcil Initiative Aims to:

- Encourage Pharmexcil Industries to more effectively use IP as part of their business strategy;
- Promote a greater use of the intellectual property system by Pharma Industry;
- Strengthen the capacity of Government to develop strategies, policies and programs to meet the intellectual property needs of Pharma Industry;
- Improve the capacity of relevant public, private and civil society institutions, such as business and Industry Associations, to provide IP-related services to Pharma industry;
- Provide comprehensive web-based information and basic advice on IP issues to Pharma Industry support organizations worldwide.

Role of IPR Facilitation Centres

- Strengthening of interaction between Pharma Industry, Pharma Industry support institutions and associations and IP offices, and other relevant government organization 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
- Support of national and international efforts for further integration of IP issues in programs and policy intitiative aiming at fostering the technological and innovative capacity and the export potential of Pharma Industry.
- Increase awareness and understanding of IP issues within the Pharma business community particularly through awareness-raising campaigns and targeted training programs with the optimal use of modern information and communication technologies, so as to enhance the capacity the capacity of Pharma Industry to maximize their benefits from the use of the IP Systems.
- Advice government to take into account the specific needs of Pharma Industry in their IP policies.

- Disesminate information on best practices on the use of IP by Pharma Industry and of their exploitation of technological knowledge through the valorization and commercialization of IP rights.
- Make a access to technological knowledge easier and cheaper for Pharma Industry,

Pharmexcil proposed activities

- Pharmexcil is identifying existing programs and activities designed to enhance Pharma Industry competitiveness at national, regional and international levels to help assess the needs of Pharma Industries, Identify and disseminate information on best practices, and forge partnership with appropriate institutions.Cooperation with these institutions and strengthening their IP component is a key focus of WIPO's Pharma Industry program.

- Pharmexcil plans to outreach activities include distance learning programs, distribution of publications, self-help kits, pilot training workshops web-based dissemination of information, press campaigns, and direct support to business associations in their own outreach activities.
- Information on the role of intellectual property rights in the overall business strategy of an enterprise are presented from managerial perspective, with an emphasis on the role of patent in product development strategy, as well as the use of trademarks, designs and geographical indications as marketing tools.
- Workshops, seminars, and information materials focus on:
- Introduction to IP concepts from a business perspective
- IP management for business success
- Use of patent and trademark data as a source of technological and commercial information
- Exploitation of IP assets through licensing, franchising, technological alliances and joint ventures.

Budget for setting up an IPR facilitation Centre

Particular	Amount
ONE TIME COST	
Infrastructure cost for setting up an IPRFCs Facilitation cell in Hyderabad, Mumbai & Delhi	30,00,000.00

RECURRING COST:

Hiring of IPR and WTO consultants for Technical Technical assistance rendered to Pharma Industry's (per month) @ Rs.50,000 per Consultant per month	
3 consultant X 12 months	18,00,000.00
Publication cost (including E-Publications)	12,00.000.00
Website maintenance cost	5,00,000.00
Cost of Salaries to staff including Professionals on regular duty	20,00,000.00

Total Cost	85,00,000.000

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